Biodiversity and the Law

Intellectual Property, Biotechnology and Traditional Knowledge

Edited by Charles R. McManis

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Rabodo Andriantsiferana is a researcher and director at the Centre National d'Applications des Recherches Pharmaceuticque (CNARP) in Madagascar. She is also involved or has been involved in many other organizations and projects, among them: principal investigator in the International Cooperative Biodiversity Group (ICBG) programme in Madagascar: Biodiversity Utilization in Madagascar and Suriname; principal investigator in the project funded by the United Nations Development Programme (UNDP)/ONE: Valorization of Medicinal Plants in Menabe (Morondava) in Madagascar; President of the Interministerial Committee for the Study and Regulation of Traditional Medicine, Madagascar; member of the Regional Committee of Experts for Traditional Medicine in Africa; member of the National Committee *Prunus Africana*; member of the Western Ocean Indian Islands Sustainable Use Specialists Group: Focal Point for Medicinal Plants; member of the Specialists Group of Plants of Madagascar; and member of the Convention on International Trade in Endangered Species (CITES) Committee for Plants.

Alejandro Argumedo, a Quechua agronomist from Peru, is an expert in issues related to human rights and the environment. He is an active member of a network of native peoples working within national, regional and international processes for the recognition of indigenous peoples' cultural, environmental and human rights. He is currently associate director of the Quechua-Aymara Association for Sustainable Livelihoods 'ANDES', a community-based organization of Cusco, Peru; and International Coordinator of the Indigenous Peoples' Biodiversity Network (IPBN). Argumedo is actively involved in the development of local strategies for the protection and promotion of indigenous peoples' knowledge and innovations and in the international debate about the ownership and protection of indigenous knowledge. He has been involved recently in the establishment of the 'Call of the Earth Circle', an indigenous peoples' expert group on intellectual property and indigenous knowledge (www.earthcall.org).

Michael J. Balick studies the relationship between plants and people, working with traditional cultures in tropical, subtropical and desert environments. He is a specialist in the field known as ethnobotany, working with indigenous cultures to document their plant knowledge and local floras, understand the environmental effects of their traditional management systems and develop sustainable utilization systems – while ensuring that the benefits of such work are always shared with local communities. Dr Balick also conducts research in New York City, in a National Institutes of Health (NIH)-funded project to study traditional healing practices of the Dominican community in Washington Heights. In addition to ethnobotany, Dr Balick is an expert on the uses of palms, an economically important family of plants in the tropics. From 1986–1996, working with Drs Douglas Daly, Hans Beck and others, Balick had a major commitment to The New York Botanical Garden contract with the Developmental Therapeutics Program of The National Cancer Institute, collecting bulk samples of higher plants for screening as potential anti-AIDS and anti-cancer therapeutics. His focus in this work was on ethnopharmacological investigations, primarily in the Central American nation of Belize.

Dr Kelly Bannister is an assistant professor in the School of Environmental Studies and a research associate with the POLIS Project on Ecological Governance in the Faculty of Law, University of Victoria (British Columbia, Canada). She holds a post-doctoral fellowship from the Social Sciences and Humanities Research Council of Canada. Dr Bannister has BSc and MSc degrees in biochemistry/microbiology from the University of Victoria. She completed a PhD in ethnobotany/medicinal plant chemistry in 2000 at the University of British Columbia in the Department of Botany and a post-doctorate in law and environmental studies at the University of Victoria. Her doctoral research was in collaboration with the Secwepemc First Nation of British Columbia, and examined antimicrobial properties of Secwepemc food and medicinal plant resources. Dr Bannister also undertook a review and critical analysis of the Canadian intellectual property rights system for its potential use in protecting the Secwepemc plant knowledge shared during her dissertation research.

Dr Bannister works with several First Nations in British Columbia as well as internationally on research-related issues of sharing cultural knowledge, with an emphasis on non-legal mechanisms such as community protocols. Her current research examines ethical and legal issues, as well as policy and practical barriers, in developing ethical and equitable collaborative research between communities and universities. She founded the Community-University Connections initiative at the University of Victoria in 2000 to explore and address these issues (http://web.uvic.ca/~scishops).

Roger Beachy is president of the Donald Danforth Plant Science Center in St Louis, Missouri. He previously held academic positions at Washington University, St Louis and The Scripps Research Institute, LaJolla, California. His work in 1986 to produce virus resistance in tomato and tobacco via genetic engineering has been replicated by other researchers to produce many types of plants with resistance to different virus diseases. Research from his lab is reported in more than 250 journal articles and book chapters and has led to ten pending and issued patents.

Dr Beachy is a member of the National Academy of Sciences, a fellow in the American Association for the Advancement of Science (AAAS), the American Academy of Microbiology and the Academy of Science of St Louis. In 2001 he received the Wolf Prize in Agriculture and an honorary Doctor of Science degree from Michigan State University. Dr Beachy has received the Dennis R. Hoagland Award from the American Society of Plant Physiologists, the Ruth Allen Award from the American Phytopathological Society and the William D. Phillips Technology Advancement Award. Dr. Beachy was named R&D Magazine's Scientist of the Year for 1999. In 1995, the San Diego Press Club recognized him with a Headliner of the Year Award.

Dr Charles Benbrook is the Chief Scientist of The Organic Center, a small non-profit organization working on the consumer health benefits of organic food and farming. He ran Benbrook Consultant Services from 1990 through 2005. He worked in Washington, DC, on agricultural policy, science and regulatory issues from 1979 until 1997. He also served as the agricultural staff expert on the Council for Environmental Quality/The White House at the end of the Carter Administration, during a period of intense focus on soil conservation, farmland preservation and pest management policy. He was also the executive director of the Subcommittee of the House Committee on Agriculture with jurisdiction over pesticide regulation, research, trade and foreign agricultural issues, and oversight of the US Department of Agriculture (USDA). Benbrook was recruited to the job of executive director, Board on Agriculture of the National Academy of Sciences in 1984, and served in that job through 1990.

In 1998, he developed Ag BioTech InfoNet, (www.biotech-info.net) one of the Internet's most extensive independent sources of technical, policy and economic information on biotechnology. Benbrook's technical reports, comments to regulatory agencies, speeches and analyses are posted on the page. Other long-term activities include work on the implementation of the Food Quality Protection Act (FQPA), as a consultant to Consumers Union (CU) (see the CU FQPA website, www.ecologic-ipm.com) and participation in the University of Wisconsin-World Wild Wide Fund for Nature (WWF)-Wisconsin Potato and Vegetable Association potato integrated pest management project.

Sara Boettiger is the programme director for the Public Intellectual Property Resource for Agriculture (PIPRA). Her doctoral studies at the University of California at Berkeley focus on intellectual property law and economics, developing countries, access to agricultural technology, and the economics of open source software production.

Stephen Brush was trained as an anthropologist and is professor in the Department of Human and Community Development at the University of California, Davis. At Davis, he serves as the chair of the Community Studies and Development unit within that department and the master adviser for International Agricultural Development. He was senior scientist at the International Plant Genetic Resources Institute in Rome, 1994–1995, where he designed a global programme for on-farm conservation of crop genetic resources. He was on the faculty of College of William and Mary, 1973–1984 and served as staff associate and then director of the anthropology programme at the National Science Foundation, 1980–1983. His research concerns agricultural ecology and the conservation of crop genetic resources. Brush has done fieldwork on these topics in Peru (1970–1986), Turkey (1990–1994) and Mexico (1995–). He has been a consultant to the World Bank, the Office of Technology Assessment, the UNDP, the Food and Agricultural Organization of the United Nations (UN) and the United Nations Educational, Scientific and Cultural Organization (UNESCO).

Dr Lawrence Busch is University Distinguished Professor of Sociology and director of the Institute for Food and Agricultural Standards at Michigan State University. He is co-author or co-editor of a number of books, including *Plants, Power, and Profit: Social, Economic, and Ethical Consequences of the New Biotechnologies* (Blackwell, 1991); *From Columbus to Conagra: The Globalization of Agriculture* (Kansas, 1994); *Making Nature, Shaping Culture: Plant Biodiversity in Global Context* (Nebraska, 1995); and most recently, *Agricultural Standards: The Shape Of The Global Food And Fiber System* (Springer, 2006), as well as more than 100 other publications.

Nuno Pires de Carvalho has served in the Secretariat of the World Intellectual Property Organization (WIPO) in Geneva since 1999. He is currently the acting director of the Division of Legislation for Public Policy and Development. Prior to this, he served as the head of Genetic Resources, Biotechnology and Associated Traditional Knowledge Section in the Traditional Knowledge Division: and as counsellor, Intellectual Property Division, World Trade Organization (WTO), Geneva (between 1996 and 1999); and was a visiting adjunct professor at the School of Law at Washington University.

His most recent publications include: *The TRIPS Regime of Patent Rights*, a book with comments on those provisions of the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement with a direct impact on patent protection, including a general introduction on the primary function of patents and comments on the protection of pharmaceutical test data, published by Kluwer Law International in November 2002; and several articles on industrial property law, such as: 'From the shaman's hut to the patent office: How long and winding is the road?', *Revista da ABPI*, no 41 (Jul/Aug 1999); 'Requiring disclosure of the origin of genetic resources and prior informed consent without infringing the TRIPS Agreement: The problem and the solution', *Washington University Journal of Law and Policy*, no 371 (2000); and 'The primary function of patents', *University of Illinois Journal of Law, Technology and Policy*, no 25 (2001).

Jim Chen has been a member of the University of Minnesota Law School faculty since 1993. Professor Chen teaches and writes in the areas of administrative law, agricultural law, constitutional law, economic regulation, environmental law, industrial policy and legislation. He received his BA degree, *summa cum laude*, and his MA degree from Emory University. After studying as a Fulbright Scholar at the University of Iceland, he earned his JD degree, *magna cum laude*, from Harvard Law School, where he served as an Executive Editor of the *Harvard Law Review*. Professor Chen's lectures have spanned ten countries, four continents and three languages. In 1995, he held a *chaire départementale* in the Faculté de Droit et des Sciences Politiques of the

Université de Nantes. In 1999, he became the first American to teach law as a visiting professor at Heinrich-Heine-Universtität in Düsseldorf. He taught in 2000 at Slovenska Pol'nohospodarska Univerzita v Nitre (the Slovak Agricultural University in Nitra).

Roger Chennells is a South African attorney practising in the firm Chennells Albertyn, in Stellenbosch. He has an LLM degree from the London School of Economics, and has been practising in South Africa since 1980. The firm specializes in various branches of human rights law, focusing on issues of land, environment, development, labour and indigenous peoples' rights. Over the past ten years Chennells has acted on behalf of the San peoples of Southern Africa, acting as legal counsel for the Working Group of Indigenous Minorities in Southern Africa (WIMSA) the South African San Institute (SASI) and the Indigenous Peoples of Africa Coordinating Committee (IPACC).

Initial work for the San peoples included land claims, but has over the past few years begun to encompass protection of identity, culture and intellectual property. He is currently finalizing an intellectual property claim involving the San traditional knowledge relating to the appetite suppressant properties of the Hoodia succulent, which was patented by the CSIR (Council for Scientific and Industrial Research) and licensed to Pfizer Inc in the US.

David Corley, a Nestle corporate executive who is currently director of Intermarket Regulatory Affairs, was formerly employed at G. D. Searle, where, as team leader and research fellow in Natural Products Discovery, he was responsible for Searle's participation in the ICGB-Peru Project, the Principal Investigator of which was Dr Walter Lewis, Professor of Biology at Washington University in St Louis.

Kate Davis is the Convention on Biological Diversity (CBD) implementation officer at the Royal Botanic Gardens (RBG), Kew. She works with botanists and horticulturalists at Kew and other botanical institutions on access and benefit sharing (ABS) policy and practical implementation. She also provides advice to the UK government and other policy makers, sometimes as a member of the UK delegation to CBD meetings, on the implications of ABS developments for non-commercial biodiversity research.

As part of her work to raise awareness of the CBD in botanical research sectors, her published works include: C. Williams, K. Davis and P. Cheyne (2003) *The CBD for Botanists: An Introduction to the Convention on Biological Diversity for People Working with Botanical Collections*, Royal Botanic Gardens, Kew (a plain language slide pack guide in English/French/Spanish); V. Savolainen, M. P. Powell, K. Davis, G. Reeves and A. Corthals (eds) (2006) *DNA and Tissue Banking for Biodiversity and Conservation: Theory, Practice and Uses*, Royal Botanic Gardens, Kew.

Rodrigo Gámez is general director and president of INBio, Costa Rica's National Biodiversity Institute, positions he has held since the institution's foundation in 1989. As biodiversity advisor to President Oscar Arias (1986–1990), he ran the process that led to the establishment of the National System of Conservation Areas within the first Ministry of Natural Resources (presently the Ministry of the Environment), and to the creation of INBio, as a private, non-profit, public interest organization.

Dr Gámez has been also associated with numerous national and international initiatives in biodiversity conservation. As a Costa Rican government delegate, he was active in the formulation of the UN Convention for Biological Diversity and served on a number of United Nations Environmental Programme (UNEP) biodiversity-related advisory committees. During the last two decades, Gámez has written and lectured extensively on Costa Rica's pioneering efforts in biodiversity conservation and sustainable development. During the course of his scientific career, he worked and published extensively on viruses of basic food crops in Central America, insect transmission of plant viruses and the molecular characterization of those viruses. He received numerous awards and recognition for his scientific work, including the 1983 Organization of American States Bernardo Houssei Prize in Science. Dr Gámez was also active on numerous national and international boards and institutional committees of organizations such as Costa Rica's National Research Council, the Organization for Tropical Studies and the American Phytopathological Society-Caribbean Division. He is currently a member of the Costa Rican National Academy of Sciences and is also associated with several local educational and sustainable development foundations.

Michael Gollin, a registered patent attorney, prosecutes patents and trademarks, negotiates intellectual property agreements, and litigates patent, trademark, copyright and trades secret cases. Mr Gollin oversees the intellectual property portfolios for a pharmaceutical company, a medical device company and a biotechnology instrumentation company, involving several hundred patents and trademarks worldwide. He provided dozens of formal opinions regarding patent infringement and validity, and conducted the first intellectual property audits of five International Agricultural Research Centres on five continents.

In addition, Gollin negotiated many complex technology transfer agreements, including patent licences, a bioinformatics subscription by Novartis, a biochip licence from Affymetrix, a domain name purchase, and biodiversity access for biotechnology research based on plants obtained from Panama, Fiji and Central Africa. Gollin is an adjunct professor at Georgetown University's McDonough School of Business where he teaches Strategic Management of Intellectual Property. He has served on the boards of technology and environmental organizations, such as the Rene Dubos Center for Human Environments, Inc. Gollin is launching Public Interest Intellectual Property Advocates, a *pro bono* referral service for developing country clients, with Venable support. He is a prolific writer and lecturer; he co-authored the books *Innovations in Ground Water and Soil Cleanup: From Concept to Commercialization* (1997) and *Biodiversity Prospecting* (1993). He has published and presented over 40 papers around the world and has been interviewed on National Public Radio and by several newspapers.

When **Ursula Goodenough** enrolled at Barnard College, her intention was to major in English and French literature. But her first class in zoology changed all that; it instilled in her a passion for life sciences, and she has never looked back.

Goodenough is the author of the textbook *Genetics*, which she wrote as a post-doc and which is recognized as a classic in the field. The book has been through three editions and translated into five languages. She teaches Introduction to Cell Biology for junior and senior biology majors and was awarded a Faculty Teaching Award in 1986. She also directs graduate seminar courses on topics in cell biology. Goodenough currently serves on the American Society for Cell Biology (ASCB) Public Policy Committee, is chair of Women in Cell Biology (WICB), and recently completed a three-year term on Council. Goodenough is also particularly active in ASCB's public policy efforts and last year accepted ASCB Public Policy Chair Marc Kirschner's invitation to represent the ASCB membership's interest in the National Science Foundation (NSF). She often reminds colleagues that the NSF strongly supports basic science in all disciplines and is frequently the only source of funding for some ASCB members. For these reasons, Goodenough believes that advocacy of the NSF is critical. Goodenough's public policy interests go beyond the NSF; she recently published an op-ed on the importance of biomedical research in the St Louis Post-Dispatch.

Anil Gupta helped establish NIF (National Innovation Foundation) India, with a view to helping India become an inventive and creative society and a global leader in sustainable technologies; was National Project Director for a GEF (Global Environment Facility) and UNDP-supported PDF B project on Conservation of Biodiversity in Dry Lands in North Gujarat sanctioned by the Ministry of Environment and Forestry, and designed and implemented by SRISTI (Society for Research and Initiatives for Sustainable Technologies and Institutions) to develop a larger project for conservation of faunal and floral biodiversity in two sanctuaries and agro-biodiversity in farms within and outside protected areas; President, SRISTI and editor, *Honey Bee* (a newsletter on indigenous innovations); and professor, Centre for Management in Agriculture, Indian Institute of management, Ahmedabad, 1981 to present. He has received many honours and awards and has been widely published.

Gupta is currently a professor in the Centre for Management in Agriculture. His unique work analysing indigenous knowledge of farmers and pastoralists and building bridges to science-based knowledge led to the honour of being elected at a young age to India's National Academy of Agricultural Sciences and recognition through Pew Conservation Scholar Award from the University of Michigan. Biodiversity conservation through documentation, value addition and dissemination of local peoples' innovative resource conservation practices is the thrust in future work. His desire to develop a platform to recognize, respect and reward local innovators was the stimulus behind the creation of the *Honey Bee* network. The name *Honey Bee* was chosen to reflect how innovations are collected without making the innovators poorer and how connections are created between innovators.

Brian Halweil, a research associate, joined Worldwatch in 1997 as the John Gardner Public Service Fellow from Stanford University. At Worldwatch, Halweil writes on the social and ecological impacts of how we grow food, focusing recently on organic farming, biotechnology, hunger and rural communities.

Halweil's work has been featured in the international press, and he recently testified before the US Senate Committee on Foreign Relations on the role of biotechnology in combating poverty and hunger in the developing world. Halweil has travelled extensively in Mexico, Central America and the Caribbean, and East Africa learning indigenous farming techniques and promoting sustainable food production. Before coming to Worldwatch, Brian worked with California farmers interested in reducing their pesticide use, and set up a two-acre student-run organic farm on Stanford campus.

Neil Hamilton is the Distinguished Professor of Law and director of the Agricultural Law Center at Drake University. One of Hamilton's goals is to help students appreciate the empowering nature of drafting legislation to shape public policy. The Agricultural Law Center is directly involved in helping citizens and law students recognize the choices available to our nation and how we can best use the law to achieve the future we desire.

John Hunter is with the Warawawa Indigenous Studies Department at Macquarie University in Australia. He describes himself as 'a Gamilaraay Murri, Australian Aboriginal man of the Gamilaraay tribe from north western NSW (New South Wales, Australia)'. He is a member of the Mt. Druitt Aboriginal community, the largest Aboriginal community in Australia, situated in western Sydney. He is primarily involved in cultural revival and the retention/protection of Aboriginal cultural heritage.

Hunter is also a guest lecturer in Aboriginal studies presenting seminars and workshops; Aboriginal Heritage Consultant, providing information in various settings, including archeological excavation and survey for the Derubin Local Aboriginal Land Council; and an artist.

Peter Jaszi is professor of law and director of the Glushko-Samuelson Intellectual Property Clinic and Program on Intellectual Property and the Public Interest. He is on the Editorial Board of the *Journal of the Copyright Society of the USA*; has held many memberships, including American Association of Law Schools, Educators' Ad Hoc Committee on Copyright Law, and Librarian of Congress's Advisory Committee on Copyright Registration and Deposit. Jaszi has been widely published: *Copyright Law, Legal Issues in Addict Diversion, Protection of Intellectual Property in the Digital Technology Environment*, and *Beyond Authorship: Refiguring Rights in Traditional Culture and Bioknowlege*, just to name a few.

Jaszi has participated in the development of several academic innovations at Washington College of Law: student exchanges with the University of Paris X – Nanterre and the City University of Hong Kong and a Supervised Externship

Program, which gives students working for credit in legal workplaces around Washington an opportunity to reflect on the meaning of their field experiences in a classroom setting. Currently, he is working on a new initiative to create a specialized programme in my own field of specialization: intellectual property.

Chris Jones is a Bioprospecting and Indigenous Knowledge Research Fellow in the Warawara Department of Indigenous Studies; a casual lecturer at the Centre for Environmental Law; and a course designer of two post-graduate courses on bioprospecting law and indigenous knowledge at Macquarie University.

Research and publication areas include: environmental philosophy (intrinsic value theory), bioprospecting related law and indigenous knowledge, interdependence of cultural and biological diversity, dependency of human civilization on indigenous diversity, Baha'i environmental theology, historical and philosophical criticism of enlightenment, indigenous cultural knowledge, cross-cultural dialogue, relationship between inter-religious dialogue and international peace, and facilitation of indigenous self-determination contexts in higher education.

Gurdev Khush joined the International Rice Research Institute (IRRI) in the Philippines as a Plant Breeder, and was appointed Head of the Plant Breeding Department in 1972. He retired in February 2002 as Principal Plant Breeder and Head of the Division of Plant Breeding, Genetics and Biochemistry. During his 35-year career at IRRI, he spearheaded the programme for developing high yielding and disease- and insect-resistant varieties of rice, which ushered in the Green Revolution in rice farming.

Dr Cantrell, Director General of IRRI summed up Khush's contributions by saying 'while his name may have passed the lips of many, his life's work passed the lips of almost half the mankind'. He has written three books and numerous papers in scientific journals. He has trained numerous plant breeders and served as consultant to several national rice improvement programmes.

For his contribution to food security Dr Khush received Japan Prize in 1987, World Food Prize in 1996, Rank Prize in 1998 and Wolf Prize in Agriculture in 2000. He received honorary degrees from seven universities, the latest being from the University of Cambridge in England. Khush was elected to the Indian National Science Academy, Third World Academy of Sciences, US National Academy of Sciences and the Royal Society of London.

Steven King joined Napo Pharmaceuticals Inc. as Vice President of Ethnobotany and Conservation in 2002. Prior thereto, he was the Chief Operating Officer and Vice President of Ethnobotany and Conservation at Shaman Pharmaceuticals in charge of international relations, field research, conservation and the long-term supply of plant material for all of Shaman's research and development activities. Prior to joining Shaman, King worked as the Chief Botanist for Latin America for the Nature Conservancy in Washington, DC. Before joining the Nature Conservancy he worked at the National Academy of Sciences as part of the Committee on Managing Global

Genetic Resources where he focused on managing the genetic resources of tree species. He earned his PhD in biology as the first doctoral fellow of the Institute of Economic Botany of the New York Botanical Garden.

King has created and manages an extensive global network of government, academic and community-based plant supply collaborators. He and his colleagues have worked closely with the international natural products and conservation community to create and disseminate research on the long-term sustainable harvest and management *Croton lechleri*, the widespread and abundant source of SP303, an anti-diarrhoea compound discovered through collaboration with indigenous people. King has conducted ethnobotanical and ethnomedical field research in 15 countries in Latin America, Africa and South East Asia. He has published 54 scientific papers and presented 75 invited lectures on ethnobotanical research focusing on food and medicinal plants. He has been actively involved in international debates and discussions focusing on collaboration with indigenous peoples, the conservation of biological diversity and global human health care needs.

Meto Leach is of Maori descent (indigenous to New Zealand) and belongs to the tribal groups in the Tairawhiti region (Ngati Konohi, Te Aitanga-a-Mahaki, Rongowhakaata). Dr Leach has recently relocated from Waikato University, where he lectured in chemistry, to Crop and Food Research, where he now leads the Institute's Maori Research. Leach is a natural products chemist specializing in the isolation and identification of bioactive compounds using commercially available biological assays. He is director of the government-funded programme Te Kete a Tini Rauhanga, a programme that aims to document the selection, preparation and medicinal uses of native plants by Ngai Tuhoe, and identify the bioactive compounds responsible for the medicinal properties observed.

Walter Lewis is a Professor of Biology at Washington University. He is known worldwide as an ethnobotanist and is an expert on airborne and allergenic pollen and famous for targeting medicinal plants in the tropical rain forest. Lewis did his post-doctoral work at Kew Gardens in London and at the Swedish Academy of Sciences in Stockholm. His wife Memory Elvin-Lewis is a Professor of Biomedicine at Washington University. The Lewises have travelled to the Peruvian jungle in search of new plants that might yield new drugs. They credit many of their discoveries to the way they work as a team. Both are ethnobotanists and specialize in communicating with native peoples around the world to learn about their traditional medicines.

Mercedes Manriques-Roque is a lawyer from Peru, who represented the Confederation of Amazonian Nationalities of Peru (CONAP) in negotiating a know-how licence with G.D. Searle, as a part of the ICBG-Peru Project.

Charles R. McManis, Thomas and Karole Green Professor of Law, and Director of the Intellectual Property and Technology Law Program at Washington University, is active nationally and internationally in the area of intellectual property law. Professor

McManis has been a frequent visiting lecturer and paper presenter at universities and academic conferences throughout the US, Asia, Europe and in South America. Professor McManis' book, *Intellectual Property & Unfair Competition in a Nutshell*, is now in its fifth edition. He is also co-author of *Licensing Intellectual Property in the Information Age*, the second edition of which was published in 2005 by Carolina Academic Press. In 2001, McManis was awarded the Washington University School of Law Alumni Association Distinguished Teaching Award and the law students also named him Teacher of the Year. In 2004, McManis became the Director of the law school's new Center for Research on Innovation and Entrepreneurship, and helped establish a new Intellectual Property and Business Formation Legal Clinic at Washington University.

Margaret Mellon came to the Union of Concerned Scientists (UCS) in 1993 to direct a new programme on agriculture. The programme promotes a transition to sustainable agriculture and currently has two main focuses: critically evaluating the use of biotechnology in plant and animal agriculture and assessing animal agriculture's contribution to the rise of antibiotic-resistant diseases in people. Prior to joining UCS, Mellon was the Director of the Biotechnology Policy Center at the National Wildlife Federation. Trained as a scientist and lawyer, Dr Mellon received both her PhD and JD degrees from the University of Virginia. Before joining the National Wildlife Federation, she worked at Beveridge & Diamond, PC, and the Environmental Law Institute in Washington, DC. Mellon is a visiting professor at the Vermont Law School, where she teaches a popular summer course in biotechnology and the law.

Dr Mellon lectures widely on sustainable agriculture, biotechnology and antibiotic issues and has been a frequent guest on television and radio shows, including *The Today Show*, *Good Morning America* and National Public Radio's *All Things Considered* and *Talk of the Nation*. Among her recent publications is *The Ecological Risks of Engineered Crops* co-authored with Dr Rissler and published in 1996 by MIT Press. In 2000, Mellon was appointed to the United States Department of Agriculture's Advisory Committee on Agricultural Biotechnology.

James Miller is the William L. Brown Curator of Economic Botany at the Missouri Botanical Garden as well as an adjunct assistant professor at the University of Missouri – St Louis. As curator and head of the Applied Research Department, he coordinates the Garden's programmes in economic botany. These include programmes aiming to discover new pharmaceutical, agricultural, or nutritional products; a project with the National Cancer Institute that searches for new anticancer drugs in Madagascar; the NIH-funded International Cooperative Biodiversity group that look for new medicines and agricultural products from plants in Suriname and Madagascar in partnership with six other institutions; programmes with Monsanto, Novartis and Sequoia Sciences that look for new applications of plants to human health in a variety of countries; and a new collaborative programme with the University of Missouri-Columbia that will establish a Center for Phytonutrient and Phytochemical Studies with funding from NIH.

He also continues his interest in the floristics of Madagascar and is completing a botanical inventory in collaboration with P.-J. Rakotomalaza and J. Raharilala of the Reserve Naturelle de Marojejy, a 50,000-hectare protected area in northeastern Madagascar, a project that has been supported by the National Geographic Society and the WWF. He also studies systematics of tropical Boraginaceae and continues to describe new species from both the old and new world tropics. His current research interests include generic delimitation in the subfamilies Cordioideae and Ehretioideae and the preparation of floristic treatments for Madagascar and several regions of the Neotropics.

Since 1982 he has continued to broaden his tropical field experience in such locations as Mexico, Venezuela, Ecuador, Madagascar, Ghana, Peru, Suriname and Gabon, just to name a few. Miller holds many memberships, including Association for the Taxonomic Study of the Flora of Africa, American Society of Plant Taxonomists, and the Botanical Society of America. He is a prolific author of over 80 publications, nine papers in press, several book reviews, 14 published abstracts, and articles in various publications, including the *World Book Encyclopedia*. He has given numerous presentations all over the world.

Adrian Otten is director of the Intellectual Property Division of the Secretariat of the World Trade Organization (WTO), the responsibilities of which include intellectual property, competition policy and government procurement. Otten is a graduate of the University of Cambridge, England. After posts with the Commonwealth Secretariat in London, working on international trade questions, and with the Swaziland government in Brussels, assisting them in their negotiations with the European Economic Community (EEC) in the context of the first Lomé Convention. He joined the General Agreement on Tariffs and Trade (GATT) Secretariat in 1975, holding a variety of posts: between 1986 and 1993, he was Secretary of the Uruguay Round Negotiating Group on Trade-Related Aspects of Intellectual Property Rights.

Ana Maria Pacon is a professor of Law at the Pontificia Universidad Catolica del Peru. She has been an international consultant on numerous projects, including: a member of the research project sponsored by the Universities of Valencia, Castellon and Castilla-La Manch, *The collective industrial design and its effects in small and medium companies*, Spain, since 2002; a member of several International Chamber of Commerce (ICC) Commissions on Intellectual Property (Commission on Intellectual Property, Task force on TRIPS, Task force on Access and Benefit Sharing, Task force on IP Roadmap), with the objective of elaborating documents on intellectual property, Paris, France, since 2002; a member of the Group of Experts in Biodiversity, German Ministry of the Environment (Bundesamt für Naturschutz, BfN), Germany, since 2002; a member of the project 'WBCSD [World Business Council for Sustainable Development] Project on Innovation, Technology, Society, and Sustainability: Intellectual Property Rights in Biotechnology', Berlin, Germany, since 2001; Arbitrator of the Chamber of Commerce of Lima, since 2001; and consultant to the Peruvian interim government for the Committee for the Intellectual Property and

Competition, Peru, since 2001. Pacon is also a lecturer, moderator and commentator in different international symposiums and seminaries on industrial property as well as a prolific author.

Ralph S. Quatrano, Spencer T. Olin Professor and Chairman, Department of Biology, is interested in the mechanisms underlying how cells become polar and how tissue-specific factors and hormones regulate gene expression in plants. Zygotes of the brown alga (Fucus) and protonemal cells of moss (Physcomitrella) are being used as models to study intracellular polarity. Arabidopsis is the plant for analysing tissue-specific gene expression via the phytohormone abscisic acid (ABA) and for understanding the evolution of the maturation programme of seed development. Complementing moss polarity mutants and generating insertion and activation tagged moss lines to identify genes that play a role in polarity are in progress. These genomic sequences as well as other candidates from our Expressed Sequence Tag (EST) project will be used in targeted gene disruption and gene replacement studies using homologous recombination in moss. Projects on gene regulation during seed maturation are focused on the regulatory protein VP1/ABI3 from maize and Arabidopsis and one of its target genes, Em. The studies are designed to determine the spectrum of embryonic genes expressed during seed maturation and whether any can be activated by VP1 in non-embryonic cells/tissues. VP1 is also being used to study the evolution of the maturation pathway of embryos from seed plants.

Veena Ramani is a graduate law student, who is studying for her JSD degree at Washington University School of Law. She is also currently employed in Washington, DC, with the consulting firm of Camp, Dresser and McKee, where she works on sustainable development, corporate social responsibility and environmental issues.

Peter H. Raven is president of the Missouri Botanical Garden and George Engelmann Professor of Botany at Washington University in St. Louis. He is also Chairman of the National Geographic Society's Committee for Research and Exploration, and chair of the Division of Earth and Life Studies of the National Research Council, which includes biology, chemistry and geology.

Described by TIME magazine as a 'Hero for the Planet', Raven champions research around the world to preserve endangered plants and animals and is a leading advocate for conservation and a sustainable environment. In recognition of his work in science and conservation, Dr Raven has been the recipient of numerous other prizes and awards, including the prestigious International Prize for Biology from the government of Japan. He has held Guggenheim and John D. and Catherine T. MacArthur Foundation Fellowships. In 2001, he received the National Medal of Science, the highest award for scientific accomplishment in the US. Dr Raven served for 12 years as Home Secretary of the National Academy of Sciences, and is a member of the academies of science in Argentina, Brazil, China, Denmark, India, Italy, Mexico, Russia, Sweden, the UK and several other countries and the Pontifical Academy of Sciences.

Raven is co-editor of the *Flora of China*, a joint Chinese-American international project that is leading to a contemporary account on all the plants of China. He has written numerous books and publications, both popular and scientific, including *Biology of Plants* (co-authored with Ray Evert and Susan Eichhorn, Worth Publishers, Inc., New York), the internationally best-selling textbook in botany, now in its seventh edition, and *Environment* (Saunders College Publishing, Pennsylvania), a leading textbook on the environment.

Jo Render is the Associate Director of First Peoples Worldwide, the international department of First Nations Development Institute (FNDI) in Virginia, US. First Nations Development Institute is an indigenous-led organization founded in 1980 with the mission to assist native communities in controlling their assets and in building capacity to direct their economic future. Its programmes and strategies focus on assisting tribes and native communities so they control, create, leverage, utilize and retain their assets.

First Peoples Worldwide focuses the majority of its attention outside the US in promoting the rights of indigenous peoples for self-determination and control over their social and economic future. Recently, Jo has focused her attention on programmes that meet the challenges presented by the intersection between the private sector and indigenous community concerns. She engages with and advises companies on both policy and practice, informs socially responsible investors on key issues and cases of concern to indigenous communities, and works with indigenous organizations to devise strategies and develop skills to maximize community capacity for direct negotiation with companies. She has also participated in broader global efforts to improve private sector practice, such as the Global Reporting Initiative.

Prior to joining FNDI, Jo was part of the founding staff of CIVICUS: World Alliance for Citizen Participation, serving most recently as senior program manager. She played the lead staff role in initiating CIVICUS' corporate engagement programme area, which included participating as part of the early leadership team of the Knowledge Resource Group for Business Partners for Development. Jo has degrees in political science, economics and international studies.

Joshua Rosenthal is Deputy Director of the Division of International Training and Research of the Fogarty International Center of the National Institutes of Health. The Fogarty International Center provides grant support for a wide variety of scientific research and capacity-building programmes related to global health.

Dr Rosenthal directs two interagency research and capacity-building programmes at the interface of health and the environment. The first, the International Cooperative Biodiversity Groups, supports cooperative agreements that conduct interdisciplinary research and development projects in natural products drug discovery, economic development and biodiversity conservation in 12 countries around the world. The second, the Ecology of Infectious Diseases programme, supports research to develop integrated methods for the prediction of infectious disease dynamics in relation to ecosystem disruption. Previously, Rosenthal was a Science Policy Fellow of the AAAS and a USDA funded research specialist on physiological plant responses to insect damage at the Department of Environmental Policy, Science and Management at the University of California at Berkeley. He has authored a variety of technical, policy and popular publications, including research reports, research topic reviews, magazine articles, opinion pieces and one edited book on Biodiversity and Human Health. He received the NIH Director's award in 2001 for leadership in pursuit of the protection of global biodiversity and the advancement of human health. Rosenthal serves on a variety of advisory panels for various US Government, United Nations and World Health Organization programmes related to conservation of biodiversity, informatics, disease ecology, genetic resources and biomedicine.

Michael Roth received his BS degree in 1973 and his JD degree in 1978, both from Case Western Reserve University. He has been at Monsanto since 1996 and is currently Associate General Counsel, Europe/Africa. Mr Roth served on the US delegation to the 1991 Diplomatic Conference on the Union for the Protection of New Varieties of Plants (UPOV) Convention on plant variety protection and was the lead US attorney on the Drafting Committee for that treaty. He has also represented agricultural and biotechnology companies in the UPOV Administrative and Legal Committee, the UPOV-World Intellectual Property Organization Joint Committee of Experts, the WIPO Committee of Experts on Protection of Biotechnological Inventions and the UN Food and Agriculture Organization (UN-FAO) Commission on Plant Genetic Resources, and advised the Mexican and Chinese governments on plant breeders' rights legislation. Roth represents Monsanto on committees of the American Seed Trade Association and the International Seed Federation.

Manuel Ruiz is a Peruvian lawyer and the Director of the International Affairs and Biodiversity Program at the Peruvian Society for Environmental Law. Dr Ruiz has been actively involved in the ICBG-Peru Project. Ruiz has worked over the years on issues related to the CBD, especially access to genetic resources, intellectual property, indigenous peoples' rights, biosafety and agro-biodiversity among others. He was also involved in the development of a new *sui generis* Peruvian law protecting traditional knowledge. He regularly advises national, regional and international institutions on these issues and has published extensively.

Barbara Anna Schaal is a Professor of Biology in Arts and Sciences and Professor of Genetics at the Washington University School of Medicine. Professor Schaal's research investigates the evolutionary process within plant populations using a wide variety of techniques, from field observations to quantitative genetics and molecular biology. Schaal has studied hosts of plant species ranging from oak trees to Mead's milkweed, a midwestern prairie plant. Her recent work has turned to wild relatives of crop species, such as cassava, a major subsistence crop of the tropics. She is known for applying molecular genetic techniques to the study of plant evolution. Current research projects in her lab, many in collaboration with students from the Missouri

Botanical Garden, span the range from molecular evolution of specific DNA sequences to higher-level systematics and analysis of developmental patterns.

She is a much sought-after speaker at symposia throughout the country. Her expertise has made her a popular mentor of doctoral candidates. Professor Schaal is an elected fellow of the AAAS, the American Academy of Arts and Sciences, and the National Academy of Sciences. In addition, she serves on the board of trustees of the St. Louis Academy of Sciences. She has served as an associate editor of *Molecular Biology and Evolution*, *The American Journal of Botany, Molecular Ecology* and *Conservation Genetics*.

Along with her notable research, Schaal has taught courses in population biology and genetics, as well as participating on an interdisciplinary team teaching a freshman seminar, 'Lewis and Clark and the American Experience'.

Karel R. Schubert is Vice President for Technology Management and Science Administration at the Donald Danforth Plant Science Center. He previously was a professor of botany and microbiology at the University of Oklahoma and taught biochemistry at Michigan State University. He served as a research manager for Monsanto, as well as liaison with the company's soybean and wheat seed companies. He founded the biotechnology company, ProTech, Inc. He also served as the co-director of the Oklahoma University Bioengineering Center and served on the Oklahoma Technology Transfer Center Advisory Board, the Oklahoma Science and Technology Committee, the NSF Experimental Program to Stimulate Competitive Research (EPSCoR) Biotechnology Network Board, and the International Center for Biological Control. Professor Schubert received a BS in chemistry (*magna cum laude*), from West Virginia University, and an MS and PhD in biochemistry from the University of Illinois.

Ana Sittenfeld, is the Director of the Office of International Affairs and External Cooperation (OAICE) of the University of Costa Rica (UCR). Dr Sittenfeld, a Professor of Microbiology at the Center for Research in Cellular and Molecular Biology (CIBCM) of the University of Costa Rica, obtained a Professional Doctorate in Microbiology in 1978, and an MSc in Microbiology in 1985 at UCR. As a faculty member of CIBCM, she participates in research and teaching in the areas of cellular and molecular biology, biotechnology, microbial ecology and microbial gene prospecting. Her research activities includes the characterization of microbial communities living in extreme environments and, as part of the Rice Biotechnology Group at CIBCM, she leads efforts related to intellectual property, freedom to operate and public perception.

From 1991 to May 1996, she joined the National Institute of Biodiversity (INBio) as its Director of Bioprospecting, with direct responsibility for facilitating the sustainable economic use of biodiversity and biotechnology. She has served in several national and international committees dealing with biodiversity and biotechnology including the National Biotechnology Committee, the Inter-American Commission on Biodiversity and Sustainable Development and the National Advisory Committee for Biodiversity (COABIO). From 1997 to 2003 she joined the Board of Trustees of the International Livestock Research Institute (ILRI) (CGIAR), with headquarters in Kenya and Ethiopia. More recently she became a member of the Board of Trustees for the International Plant Genetic Resources Institute (IPGRI) (CGIAR). Dr Sittenfeld is author or co-author of more than 200 papers and presentations in scientific meetings.

Maui Solomon (Moriori, Kai Tahu and Pakeha) – is a Barrister with 18 years legal experience specialising in commercial and company law, resource management, intellectual property and Treaty/Indigenous Peoples Rights issues. He has been actively involved in Maori fisheries issues for the past 15 years and is currently a Commissioner on the Treaty of Waitangi Fisheries Commission.

Solomon is currently representing three of the six tribes in the Waitangi Tribunal claim (Wai 262) concerning indigenous flora and fauna and cultural/intellectual heritage rights of Maori in New Zealand. He maintains an active interest in international indigenous peoples issues with particular emphasis on the CBD and the work of WIPO. He was a member of the Advisory Group on establishing a Court of Final Appeal for New Zealand (2002).

Solomon was also a member of a negotiating group who negotiated a framework for the development of customary fisheries regulations in New Zealand. He has also been a key advocate for the recognition of the rights and identity of his own Moriori people of Rekohu (Chatham Islands).

Glenn Davis Stone is an ecological anthropologist who has studied indigenous agricultural systems for the past 20 years. His principal focus has been on sustainable farming systems in West Africa, with a secondary focus on the American southwest.

Stone has written extensively on intensification, labour organization, the sexual division of labour, ethnicity and production, spatial organization and especially relationships between population, conflict and agricultural change. His current research concerns ecological, social and political aspects of crop biotechnology for developing countries, and in 2000 he took an NSF-sponsored leave to participate in research on genetic modification of cassava at the Danforth Plant Science Center. He has recently begun research among cotton farmers in Andhra Pradesh, India, where GM crops are being introduced.

He has taught at Columbia University in New York and Washington University in St Louis, where he is currently Associate Professor of Anthropology and Environmental Studies. For his work he has been awarded an NEH Fellowship, a Weatherhead Fellowship and a Gordon Willey Prize.

Brendan Tobin, barrister at law (Honorable Society of the King's Inns, Dublin), holds dual Irish and Peruvian citizenship. He served as Coordinator of the Access and Benefit Sharing Programme of the United Nations University, Institute of Advanced Studies in Tokyo, where he was a visiting research fellow. This programme is designed to assist, facilitate and provide input for negotiations of an international regime on benefit sharing as called for by the World Summit on Sustainable Development (WSSD) Plan of Implementation.

Since 1993 he has been actively involved in national and international debates on access and benefit sharing (ABS). This has involved participation in the development of national and regional ABS legislation for Peru and the Andean Community, acting on behalf of indigenous people in the negotiation of the Peruvian ICBG agreements, and promotion of participatory processes for development of *sui generis* legislation to protect indigenous rights over traditional knowledge. At the international level he was a member of the First Expert Panel on Access to Genetic Resources and Benefit Sharing and has frequently represented Peru at CBD negotiations. In this role he co-chaired the renegotiation of the Bonn Guidelines during COP VI, in The Hague.

In 1997 he received an Ashoka Fellowship for social entrepreneurs for his work with indigenous peoples. He is a co-founder and board member of the Lima-based non-governmental organization (NGO) the Asociacion Para la Defense de los Derechos Naturales (ADN), which is dedicated to the practice of environmental law and indigenous rights. He has written extensively on the issues of ABS and the protection of traditional knowledge.

Jennifer Urban is assistant clinical professor of law and director of Intellectual Property Clinic, University of Southern California Law School. She received her BA from Cornell University in 1997, and her JD from the University of California, Berkeley (Boalt Hall), in 2000. She is a member of the California Bar, and is admitted to practise before the California Supreme Court, the US District Court for the Northern District of California, the US Court of Appeals for the Ninth Circuit, and the US Court of Appeals for the Eleventh Circuit. Prior to joining the law faculty at USC, she was an attorney in the IP Group of Venture Law Group, 2000–2001; Fellow and Lecturer, Samuelson Law, Technology, and Public Policy Clinic, Boalt Hall School of Law, 2002; and Visiting Acting Clinical Professor of Law, Samuelson Law, Technology, and Public Policy Clinic, Boalt Hall School of Law, 2003–2004. She teaches Intellectual Property and Technology Law and Policy; Licensing; and Clinical Teaching.

Geertrui Van Overwalle is senior researcher at the Centre for Intellectual Property Rights of the University of Leuven (Belgium). She is Professor of Intellectual Property Law at the University of Leuven, where she teaches patent law and IP law in the biosciences. She is also professor at the University of Brussels where she teaches plant breeder's rights law. Furthermore, she is professor at the University of Liège (Lüttich) where she teaches on the TRIPS Agreement. She has been visiting professor at the United Nations University (2000–2003) and Monash University, Melbourne (2003).

She is author of numerous articles and monographs in the field of patent law in a national and international context. Her main fields of research are patent law, plant breeders' rights law, patents and biotechnology, IP and biodiversity, IP and ethics. At present she is heading a research project on 'Gene Patents and Public Health', funded by the Fund for Scientific Research (FWO-Flanders) and the Sixth Framework Programme of the European Union (Eurogentest).

Van Overwalle is a member of the Belgian Federal High Council for Intellectual Property, the Belgian Federal Council for Plant Breeder's Rights and the Belgian Federal Council for Bioethics. She is a member of the European Commission's Expert Group on Biotechnological Inventions, and has been appointed as a member of the Board of Appeal of the Community Plant Variety Office at Angers.

Joseph Vogel is the Director of the Research Unit in the Department of Economics at the University of Puerto Rico-Rio Piedras. He specializes in the economics of biodiversity and has done extensive consultancy work with multilateral agencies and non-governmental organizations. Prior to arriving in Puerto Rico in 2003, Vogel had been Professor of Economics at FLACSO-Ecuador and earlier a Fulbright Scholar in Brazil and a Research Fellow in Australia.

Vogel is a prolific author, his publications include: *Genes for Sale* (Oxford University Press, 1994), *The Biodiversity Cartel* (CARE, 2000) and dozens of refereed articles. His most recent work focuses on ecocriticism as an economic school of thought (*Ometeca*). With Camilo Gomides, Vogel has drafted a textbook, entitled *Amazonia in the Arts: Ecocriticism vs. the Economics of Deforestation*, which examines, *inter alia*, 'geopiracy' (their neologism) in the visual media. An invited speaker at over 200 venues worldwide, Vogel bridges economics with law, biology and the humanities.

Florence Wambugu is founder and director of A Harvest Biotech Foundation International in Kenya. She owes her career as a scientist to the wisdom of her mother, who sold the family's only cow to raise the cash to send her to secondary school, a far-sighted action in those days, when women were considered unworthy of education. From school, Florence gained a place at the University of Nairobi, where she read zoology and botany. On leaving university, she got a job at the Muguga research station of the Kenya Agricultural Research Institute (KARI). Here she came into contact with scientists from the Centro Internacional de la Papa (CIP), who gave her an opportunity to work on the crop she remembers as the mainstay of her mother's farm, the sweet potato. During this period she also learned about tissue culture and became interested in its potential to improve the supply of high-quality planting materials to farmers.

Under a scholarship from the United States Agency for International Development (USAID), she became the first African scientist to take up a fellowship in biotechnology at Monsanto's Life Sciences Research Centre, in Missouri, US. Here she worked with Kenyan colleagues and Monsanto counterparts to develop Kenya's first ever genetically modified sweet potato plants. The plants are now being field tested in Kenya. In 1994 Dr Wambugu returned to Kenya to take up the post of director of the African Centre of the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

A prominent scientist in her own home country and region, Wambugu has also become well-known internationally for her expertise and advocacy in the field of biotechnology. She has combined her career with a family life, raising three children at her home in Nairobi. One of the major and leading authorities on the biographies of distinguished individuals worldwide, The American Biographical Institute, US, proclaimed Dr Florence M. Wambugu Woman of the Year 2001 based on her outstanding accomplishments and the noble example she has set for her peers and entire community.

Egleé L. Zent is the mother of two sons and has an eclectic academic background (art history, anthropology, botany, conservation biology). She holds a PhD from the University of Georgia (1999), an MA degree from the University of California, Berkeley (1995) and a Magíster Scientiarium degree from the Instituto Venezolano de Investigaciones Científicas, IVIC (1991). She has carried out ethnoecological, ecocosmological and ethnocartographic research (including ethnobotany, ethnomycology, behavioural ecology, self-demarcation of Indian territories) in the high Venezuelan Andes among Paramero people as well as in the lowland Amazon among the Hotï, an Amerindian group. Her research embraces transdisciplinary epistemologies and approaches, drawing in material and ideological, quantitative and qualitative, aspects. Since 2000 she has held the position of Associate Researcher in the Anthropology Center at IVIC.

Stanford Zent has a PhD degree in Anthropology from Columbia University in the City of New York and for the last ten years has worked as a researcher in the Anthropology Department of the Venezuelan Institute for Scientific Research, Caracas, Venezuela. His research interests include ecological anthropology, ethnobiology, development studies, biocultural conservation, non-timber forest products, and native cultures of lowland South America. He has conducted long-term fieldwork among the Piaroa and Hotï ethnic groups of the Venezuelan tropical forest.

His current research projects include: an applied study of Hotï and Eñepa ethnocartography and land demarcation; an inventory of wild plant products traded in the markets and streets of the Caracas metropolitan area; and the persistence, loss and change of ethnobotanical knowledge and practices among indigenous and rural communities in Venezuela.

He presently serves as scientific advisor for the Venezuelan Bureau of Indian Affairs (DGAI), the Foundation for Science and Technology of the Biodiversity of the Guayana Region (BioGuayana), the Amazonian Center for the Research and Control of Tropical Diseases (CAICET), and the Scientific Monograph Series *Scientia Guaianae*. He is the author or co-author of approximately 30 scientific papers published or in press as journal articles or book chapters and in 2000 won the national prize for the best scientific work in the Social Sciences awarded by the Venezuelan National Council for Science and Technology (CONICIT).

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List of Acronyms and Abbreviations

AAAS	American Association for the Advancement of Science
AATF	African Agricultural Technology Foundation
ABA	abscisic acid
ABRAE	Areas bajo Administración Especial (Areas under Special Administration)
ABS	access and benefit sharing
ABSP	Agricultural Biotechnology Support Program
ACCT	Agence de Coopération Culturelle et Technique de la Francophonie
ACG	Area de Conservación Guanacaste (Costa Rica)
ADN	Asociacion Para la Defense de los Derechos Naturales
AGERI	Agricultural Genetic Engineering Institute
AIPPI	International Association for the Protection of Intellectual Property
AMM	authorization to market medicines
'ANDES'	Quechua-Aymara Association for Sustainable Livelihoods
ARIPO	African Regional Intellectual Property Organization
ASCB	American Society for Cell Biology
BfN	Bundesamt für Naturschutz (Germany)
BGI	Beijing Genomics Institute
BioGuayana	Foundation for Science and Technology of the Biodiversity of the Guayana Region
Bt	*Bacillus thuringiensis*
CAH	Consejo Aguaruna y Huambisa
CAICET	Amazonian Center for the Research and Control of Tropical Diseases
CAMES	Conseil Africain et Malgache de l'Enseignement Supérieur
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
CIBCM	Center for Research in Cellular and Molecular Biology
CIMMYT	International Maize and Wheat Improvement Center
CIP	Centro Internacional de la Papa
CITES	Convention on International Trade in Endangered Species
CIVICUS	World Alliance for Citizen Participation
CNARP	Centre National d'Applications des Recherches Pharmaceuticque
COICA	Coordinating Body for the Indigenous Organizations of the Amazon Basin
COM	College of Micronesia
COMPITCH	Consejo de Medicos y Parteras Indigenas Traditionales de Chiapas
CONAP	Confederation of Amazonian Nationalities of Peru

CONICIT	Venezuelan National Council for Science and Technology
COP6	VI Conference of the Parties
CRIFC	Central Research Institute for Food Crops
cry proteins	crystalline proteins
CSIR	Council for Scientific and Industrial Research (South Africa)
CU	Consumers Union
DGAI	Venezuelan Bureau of Indian Affairs
ECOSUR	El Colegio de La Frontera Sur
EEC	European Economic Community
EEEPGA	Ecological Equilibrium and Environmental Protection General Act
EPO	European Patent Office
ESA	Endangered Species Act (US)
ESPH	Empresa de Servicios Públicos de Heredia
EST	Expressed Sequence Tag
ETC Group	Action Group on Erosion, Technology and Concentration
EU	European Union
FAO	Food and Agriculture Organization (of the United Nations)
FDA	US Food and Drug Administration
FLACSO	Facultad Latinoamericana de Ciencias Sociales
FLPMA	Federal Land Policy and Management Act
FNDI	First Nations Development Institute
FQPA	Food Quality Protection Act
FTO	freedom to operate
FUDECI	Foundation for the Development of the Physical and Mathematical Sciences (Venezuela)
GATT	General Agreement on Tariffs and Trade
GEAC	Genetic Engineering Approvals Committee
GEF	Global Environment Facility
GIAN	Grassroots Innovation Augmentation Network
GM	genetically modified
GMOs	genetically modified organisms
GR	Green Revolution
GRRF	Genetic Resources Recognition Fund
GSPC	Global Strategy on Plant Conservation
GTI	Global Taxonomy Initiative
HCP	habitat conservation plan
HIPPO	Habitat destruction, Invasive species, Pollution, Population and Over-harvesting
HT	herbicide tolerant
IARCs	International Agricultural Research Centres
ICBG	International Cooperative Biodiversity Group
ICC	International Chamber of Commerce
IDB	Interamerican Development Bank
IGC	(WIPO) Intergovernmental Committee (on Intellectual Property and

	Genetic Resources, Traditional Knowledge and Folklore)
IIMA	Indian Institute of Management, Ahmedabad
IKS	indigenous knowledge systems
ILO	International Labour Organization
ILRI	International Livestock Research Institute
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
INPI	Brazilian National Institute of Industrial Property
INSTAR	International Network for Sustainable Technology Applications and Registration
IP	intellectual property
IPACC	Indigenous Peoples of Africa Coordinating Committee
IPBN	Indigenous Peoples' Biodiversity Network
IPC	International Patent Classification
IPCC	Intergovernmental Panel on Climate Change
IPEN	International Plant Exchange Network
IPGRI	International Plant Genetic Resources Institute
IPM	integrated pest management
IPR	Intellectual property rights
IRGSP	international rice genome sequencing project
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agri-Biotech Applications
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	World Conservation Union
IVIC	Instituto Venezolano de Investigaciones Científicas
KARI	Kenya Agricultural Research Institute
KWS	Kenyan Wildlife Service
LHS	left-hand side
LOC	Letter of Collection
LOI	Letter of Intent
MARNR	Ministry of Environment and Natural and Renewable Resources
MBG	Missouri Botanical Garden
MC	marginal cost
MEA	Millennium Ecosystem Assessment
MIHR	Centre for the Management of Intellectual Property in Health Research and Development
MINAE	Ministry of the Environment and Energy
MNL	Molecular Nature Ltd
MRS	marginal rate of substitution
MRT	marginal rate of transformation
MS	multilateral system
MST	Ministry of Science and Technology
MTA	material transfer agreement
NARS	national agricultural research systems

NBC	National Biosafety Committee (Costa Rica)
NCI	National Cancer Institute
NEPA	National Environmental Policy Act
NGO	non-governmental organization
NIF	National Innovation Foundation (India)
NIH	National Institutes of Health
NSF	National Science Foundation
NSW	New South Wales, Australia
NYBG	New York Botanical Garden
OAAM	Organización Aguaruna del Alto Mayo
OAMPI	Office Africain et Malgache de la Propriété Intellectuelle
OAPI	Organisation Africaine de la Propriété Intellectuelle
OAU	Organization of African Unity
OAU/STRC	Scientific and Technical Research Committee of the Organization of African Unity
OCCAAM	Organización Central de Comunidades Aguarunas del Alto Marañón
OCEI	Oficina Central de Estadística e Información (Central Office for Statistics and Information)
PBZT	Parc Botanique et Zoologique de Tsimbazaza
PCT	Patent Cooperation Treaty
PDT	photodynamic therapy
PIA	prior informed approval
PIC	prior informed consent
PIIPA	Public Interest Intellectual Property Advisers
PIPRA	Public Intellectual Property Resource for Agriculture
PLT	Patent Law Treaty
PPT	ammonium glufosinate
PRSV	papaya ringspot virus
R&D	research and development
RAFI	Rural Advancement Foundation International
RBG	Royal Botanic Gardens
RBP	Rice Biotechnology Program (Costa Rica)
RBP-CIBCM	Rice Biotechnology Program of the Centro de Investigación en Biología Celular y Molecular
RCA	Research Collaborative Agreement
REC/TRM	Regional Expert Committee on Traditional Medicine
RGRP	Rice Genome Research Programme
RHBV	rice hoja blanca virus (disease)
RHS	right-hand side
RMPs	resistance management plans
RR	Roundup Ready
SAR	systemic acquired resistance
SASI	South African San Institute
SPDA	Peruvian Society for Environmental Law

SPFMV	sweet potato feathery mottle virus
SPLT	Standard Patent Law Treaty
SRISTI	Society for Research and Initiatives for Sustainable Technologies and Institutions
TAK	traditional agricultural knowledge
TC	transaction costs
TCK	traditional cultural knowledge
TEK	traditional ecological knowledge
T.E.K*P.A.D	Traditional Ecological Knowledge Prior Art Database
TEV	total economic value
TK	traditional knowledge
TKDL	Traditional Knowledge Database Law (India)
TMK	traditional medicinal knowledge
TRIPS	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UCR	Universidad de Costa Rica
UCS	Union of Concerned Scientists
UGA	University of Georgia
UN	United Nations
UNCCD	United Nations Convention to Combat Desertification
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UN-FAO	United Nations Food and Agriculture Organization
UNIDO	United Nations Industrial Development Organization
UPCH	Universidad Peruana Cayetano Heredia
UPOV	International Convention for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
USDA	US Department of Agriculture
USM	Universidad Nacional Mayor de San Marcos, Museo de Historia Natural
USPTO	United States Patent Office
VLAA	St Louis Volunteer Lawyers and Accountants for the Arts
WBCSD	World Business Council for Sustainable Development
WCT	WIPO Copyright Treaty
WHO	World Health Organization
WHO/AFRO	World Health Organization Regional Office for Africa
WICB	Women in Cell Biology
WIMSA	Working Group for Indigenous Minorities in Southern Africa
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization
WWF	World Wide Fund for Nature

Chapter 1

Biodiversity, Biotechnology and Traditional Knowledge Protection: Law, Science and Practice

Charles R. McManis

This volume addresses one of the great questions of our times – namely how to promote global economic development, while simultaneously preserving the local biological and cultural diversity of 'this fragile earth, our island home'.[1] The international debate over how to reconcile these two seemingly conflicting goals has increasingly focused on the interplay among three international agreements that have entered into force during the past 15 years.

The Convention on Biological Diversity (CBD 1992), which was opened for signature at the Earth Summit in Rio de Janeiro in 1992, seeks to promote the conservation, sustainable use, facilitated access to, and an equitable sharing of the benefits arising out the utilization of genetic resources.[2] As a part of this larger objective, Article 8(j) of the CBD specifically calls upon its members to 'respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, and to promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the sharing of benefits arising from the utilization of such knowledge, innovations and practices'.[3] To date, over 187 countries (with the notable exception of the US) have ratified the CBD.[4]

The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement 1994) is one of a bundle of agreements embodied in the larger 1994 Agreement Establishing the World Trade Organization (WTO), which currently has 149 members.[5] The TRIPS Agreement seeks to stimulate international trade and economic development by setting international minimum standards for the protection and enforcement of intellectual property rights.[6] As of 1 January, 2005, all but the least-developed members of the WTO were obligated to be in full compliance with TRIPS, including its controversial requirements governing patent and plant variety protection.[7] Disputes over compliance with TRIPS obligations are subject to resolution through the larger WTO dispute settlement process, and multilateral trade sanctions may be authorized to enforce compliance.[8]

Finally, in 2001, the Conference of the Food and Agricultural Organization (FAO), adopted the new International Treaty on Plant Genetic Resources for Food and Agriculture (FAO International Treaty 2001),[9] which was negotiated with the understanding that it would be in harmony with the Convention on Biological Diversity, and is similar to the CBD in its overall objectives to promote the conservation, sustainable use and equitable sharing of benefits arising out of the use of plant genetic resources for food and agriculture, as well as associated traditional agricultural knowledge, for sustainable use and food security. However, the FAO International Treaty also goes well beyond the CBD, in that it builds on an existing national and international system of *ex situ* germplasm collections of genetic resources for food and agriculture, namely the Consultative Group on International Agricultural Research (CGIAR),[10] and creates a formal 'Multilateral System' – that is, a system of 'common-pool goods' – in 36 genera of crops and 29 genera of forages, guaranteeing both 'facilitated' (i.e. free or low-cost) access to these genetic resources, and a system for equitable sharing of the benefits derived from any commercialized product that incorporates materials from the Multilateral System.[11] Having obtained the required number of adoptions, approvals and ratifications, the International Treaty entered into force on 29 June, 2004 and currently has 98 members, including the US.[12]

The often fractious but nevertheless productive international debate leading up to and generated by the adoption of these three treaties has produced a cascade of 'thinking globally and acting locally' to reconcile the goals of global economic development and the conservation, sustainable use, access to and an equitable sharing of the benefits arising from the use of biodiversity and associated traditional knowledge. In order to critically evaluate the best of this global thinking and its most important local instantiations to date, the Center for Interdisciplinary Studies and the Whitney R. Harris Institute for Global Legal Studies at Washington University School of Law in St Louis, in collaboration with the Washington University Department of Biology, the Donald Danforth Plant Sciences Center and the Missouri Botanical Garden, co-sponsored an international interdisciplinary academic conference on 4–6April 2003, on the general topic, 'Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge'. The chapters of this volume are based on the key-note speeches, papers and written commentary presented at that conference. The oral presentations from that conference may be accessed at: http://law.wustl.edu/centeris/pastevents/biodivagendasp03video.html.

Five of the conference papers, including more extensive versions of four chapters appearing in this volume (namely Chapters 4, 18, 20 and 28), were published as a symposium volume of the *Washington University Journal of Law and Policy*, entitled 'Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge', and can be accessed at: http://law.wustl.edu/Journal/17/index.html. As the title of this volume indicates, the chapters contained herein represent an interdisciplinary effort to address the law, science and practice of biodiversity, biotechnology and traditional knowledge protection. The format of the conference that produced these chapters was designed to promote 'trialogue' – a discussion or conversation in which three persons or groups participate. Specifically, as an academic exercise, the conference was designed to produce an interdisciplinary trialogue among experts representing the life sciences, the social sciences and the humanities (including, prominently, law). Equally important, however, the conference also produced a broader trialogue among academics, government policy makers and representatives from the private sector and various civil society organizations. Finally, and perhaps most importantly, the conference produced an international trialogue among spokespersons from biodiversity-rich developing countries and communities (including indigenous communities), non-profit research organizations involved in international botanical research collaborations in those countries and communities, and two of the international agencies most involved in the debate over how to protect traditional knowledge – namely, the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).

Like the conference that gave rise to it, the volume is divided into four parts. Part I addresses the question: 'Biodiversity: What are we losing and why – and what is to be done?' Part II addresses the question: 'Biotechnology: Part of the solution or part of the problem – or both?' Part III, in turn, addresses the question: 'Traditional knowledge: What is it and how, if at all, should it be protected?' Part IV, entitled 'Ethnobotany and bioprospecting: Thinking globally, acting locally', explores a number of concrete efforts to provide legal protection for traditional knowledge through existing intellectual property mechanisms.

Before introducing the specific chapters contained in this volume, it is important to note some fundamental concepts and distinctions that are essential for understanding these chapters. First, biodiversity loss is to be understood broadly to include biocultural loss, as well as genetic resource loss as such. Social scientists warn that the same forces driving biological extinctions are also producing rampant cultural homogenization,[13] a phenomenon that has been called an 'extinction of experience' – a 'radical loss of direct contact and hands-on interaction with the surrounding environment that traditionally comes through subsistence and other daily life activities'.[14] In a very real sense, the mounting protests over 'biopiracy',[15] and globalization more generally, represent a visceral reaction to this systematic biocultural devaluation.

Second, biotechnology should likewise be understood broadly to include both medical and agricultural biotechnology, although, as we will see, the potential impact of these two fields of biotechnology on biodiversity loss, preservation and sustainable use are quite distinct. Medical researchers are generally more concerned with the loss of non-domesticated *in situ* biodiversity and related traditional medicinal knowledge, as both contribute starting points for further medical research.[16] Agricultural researchers, by contrast, are more concerned with the loss of domesticated (i.e. agricultural) biodiversity, which is frequently preserved *ex situ* in national and international germplasm collections.[17] Moreover, the overall impact of medical research and the resulting biotechnology on the preservation and sustainable use of biodiversity is more likely to be positive, as it tends to enhance the value of *in situ* biodiversity, while the overall impact of agricultural biotechnology is likely to be far more mixed, as agriculture itself is one of the most significant contributing causes of biodiversity loss.[18]

Third, it is important to note that traditional knowledge may likewise be divided into traditional medicinal knowledge and traditional agricultural knowledge, and that the law, science and practices necessary to preserve, sustainably use and promote the equitable sharing of benefits arising from these two different types of traditional knowledge may be quite different.[19] Moreover, for the purposes of determining what forms of existing intellectual property protection might apply, traditional knowledge must also be divided into that which is widely (i.e. publicly) known, that which is collectively known by a particular community but not widely known by society as a whole, and that which is known only by selected members of a particular community, culture or society.[20] Traditional medicinal knowledge, in particular, may be closely held by selected members of a community, rather than being collectively known and held by the community as a whole.[21] Even collectively known traditional knowledge – such as collectively practised agricultural knowledge – may or may not be sufficiently widely known by, or readily accessible to, the rest of humanity to constitute a part of the public domain.[22]

To be sure, some traditional medicinal knowledge, such as traditional Ayurvedic and Chinese medicine, and much traditional agricultural knowledge, such as that embodied in the international germplasm collections of the CGIAR, which were placed under the auspices of the FAO in 1994 to be held in trust for the benefit of humanity,[23] are so widely known and documented as to present distinctive (though not insurmountable) problems for the development of an international system of equitable benefit sharing.[24] On the other hand, some collective community knowledge corresponds more closely to what in western cultural and legal terms might be called proprietary, or closely held know-how, and could thus be protected as collective proprietary know-how or shared with the rest of humanity, depending on the consensus (and cohesion) of the community that possesses it.[25]

Finally, it is important to understand the international legal and public policy mechanisms governing biodiversity, biotechnology and traditional knowledge protection, as well as the political dynamics that gave rise to them. For these mechanisms to be effective and widely viewed as legitimate, they must grow out of an international negotiating process in which all relevant stakeholders are represented, the bargaining power of the various stakeholders is perceived as more or less symmetrical, and the legal mechanisms themselves must be based on theoretically sound foundations and be capable of relatively low-cost implementation and administration as a practical matter.[26]

Fortunately, a growing international awareness of the link between the development of biotechnology and the preservation of genetic resources is creating precisely the necessary window of opportunity for such negotiations, as technology-rich industrialized countries, which are spearheading the development of biotechnology and international trade more generally, are conversely discovering that they are relatively biodiversity-poor, while developing countries, although technology-poor, are beginning to realize that they are the stewards of the bulk of the Earth's biodiversity. It is thus no coincidence that during the last 15 years international negotiations have yielded the triad of multilateral agreements that will be of concern in this volume – namely the CBD, the TRIPS Agreement and the FAO International Treaty – in order to bolster the respective positions of the biodiversity-rich developing world and the technology-rich industrialized world, thus setting the stage for further international negotiations to hammer out a more comprehensive global bargain.

At first blush, these three international agreements hardly seem to offer a particularly apt example of symmetry in the bargaining power of the developing and industrialized worlds. In contrast to the binding and enforceable provisions of the TRIPS Agreement, the provisions of the CBD and the more recently adopted FAO International Treaty essentially amount to toothless declarations of good intentions, as no effective enforcement mechanism is specified in either of the latter two treaties,[27] and much of the treaty language in the CBD, including that recognizing the need to protect traditional knowledge, is hortatory rather than mandatory.[28] Toothless though the latter two treaties may be, however, the CBD has nevertheless stimulated a wave of national legislation having the effect (whether intended or unintended) of restricting, rather than facilitating, access to genetic resources in the developing world, pending the industrialized world's adoption of meaningful benefit-sharing measures. One also senses that the negotiating strength of the developing and industrialized worlds is growing more symmetrical, rather than less, as north and south alike confront the unruly phenomenon of globalization and its discontents.

Following the currency crisis of 1997 and the subsequent teargas-beclouded collapse of the Third WTO Ministerial Conference in Seattle in 1999 amidst violent anti-globalization protests, the Doha WTO Ministerial Declaration of 2001 specifically sought to place the needs and interests of developing countries at the heart of the Work Programme adopted in that Declaration.[29] Specifically, the Doha Declaration noted that the TRIPS Agreement does not and should not prevent members from taking various enumerated measures to protect the public health, and stressed the importance of implementing and interpreting the TRIPS Agreement in a manner supportive of public health, by promoting access to existing medicines and research and development into new medicines, as spelled out in a separate declaration acknowledging the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[30] In addition, the Doha Declaration specifically directed the TRIPS Council to examine the relationship between the TRIPS Agreement and the CBD, as well as the protection of traditional knowledge and folklore.[31]

An equally important development in 2001 was the adoption of the new FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which will govern access to most materials in national and international germplasm collections (more than 6 million accessions in some 1300 collections around the world) as well as to *in situ* and on-farm sources.[32] A critical feature of the 'facilitated access' that the FAO Treaty seeks to promote is that recipients of genetic plant genetic resources covered by the Multilateral System are not to 'claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts, or components, in the form received from the Multilateral System'.[33] Unspecified in the Treaty is how this provision, together with the lip-service the Treaty pays to the concept of 'Farmers' Rights',[34] and a corresponding farmers' privilege to save and sell farm-propagated seeds,[35] is to be reconciled with the TRIPS requirement that all WTO members provide 'for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'.[36] However, the FAO Treaty does specify that germplasm from the Multilateral System is to be available under the terms of a standard material transfer agreement (MTA), which is to include provisions for monetary and other forms of benefit sharing in the event of commercialization of products developed using genetic resources received from the Multilateral System.[37] The stronger the intellectual property protection provided for plant varieties (including those varieties developed by innovative farmers), the more economic benefits in the form of a percentage of royalties there will be to share. Conversely, the broader the scope of any legally recognized 'Farmers' Right' or farmers' privilege, the more likely it is that the benefits emanating from the Multilateral System will consist primarily of the free or low-cost distribution of publicly improved plant varieties as such. In any event, the ultimate success or failure of the FAO International Treaty will depend in significant part on the ability (and willingness) of participating germplasm collections to enforce benefit-sharing terms in applicable MTAs and the ability of the Governing Body responsible for administering the Treaty to reach a consensus as to the level, form and manner of payment of an 'equitable' sharing of monetary benefits.[38]

In September 2003, the Fifth WTO Ministerial Conference was convened in Cancun, Mexico, to take up, *inter alia*, the vexed questions of reducing agricultural subsidies in the developed world as a means of raising prices and improving market access in the developed world for developing world agricultural products.[39] Improved market access for developing country agricultural and textile products was supposed to be the benefit developing countries were to receive in return for strengthening intellectual property protection. However, the Cancun Ministerial only succeeded in producing a deadlock,[40] followed two years later by the exceedingly modest accomplishments of the Sixth WTO Ministerial in Hong Kong, in December 2005, with respect to agricultural subsidies and market access.[41] Notwithstanding the continuing threat of international deadlock on these two highly controversial questions, however, the WTO nevertheless continues to offer the most promising forum for the developing world to negotiate stronger forms of legal protection for biodiversity and traditional knowledge, given the symmetrical advantages to be gained by developing and industrialized countries in that forum. In return for the commitment undertaken by developing countries to conserve, sustainably use and ensure facilitated access to their genetic resources, to strengthen intellectual property protection and enforcement, and to provide greater access to developing country markets, industrialized countries may find it both necessary and expedient – particularly in the absence of significant reductions in agricultural subsidies and increases in market access for developing country agricultural products – to adopt binding legal measures to ensure that developing countries and indigenous or local communities located therein will equitably share in the benefits arising out of the use of those genetic resources and associated traditional knowledge. In other words, to preserve the gains the industrialized world has already achieved in the TRIPS Agreement with respect to enhanced intellectual property protection in the developing world, the industrialized world must demonstrate that it is willing to give something in return – and that 'something' may turn out to be enhanced legal protection for traditional medicinal and agricultural knowledge.

For the developing world and its indigenous and local communities to take advantage of this unique window of opportunity, however, they must develop a coherent strategy for ensuring that the intellectual property regime mandated by the TRIPS Agreement, as well as any *sui generis* systems adopted for the protection of traditional knowledge, are based on theoretically sound foundations and are also capable of relatively low-cost implementation and administration. To that end, the developing world will do well to continue actively pursuing negotiations in another international forum – namely the World Intellectual Property Organization (WIPO), which is the specialized UN agency responsible for developing intellectual property policy worldwide. In the fall of 2000, even before the WTO Doha Declaration of 2001, the WIPO established the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter 'Intergovernmental Committee' or IGC).[42] The mandate of the IGC is to facilitate discussion of intellectual property issues that arise in the context of: (1) access to genetic resources and benefit sharing; (2) protection of traditional knowledge, innovations and creativity; and (3) protection of expressions of folklore, including handicrafts.[43]

Over the past six years, the IGC has produced a considerable amount of 'global thinking' about the protection of traditional knowledge. At the same time, many other government agencies, non-profit research organizations, and private companies have focused on 'acting locally' to demonstrate how intellectual property mechanisms can be utilized to protect traditional knowledge, thereby enhancing the value of biodiversity in the developing world. This volume seeks to critically evaluate this global thinking and its most important local instantiations to date. The four parts of this volume and the contents of the various chapters contained therein are as follows:

PART I BIODIVERSITY: WHAT ARE WE LOSING AND WHY – AND WHAT IS TO BE DONE?

In Chapter 2, 'The Epic of Evolution and the Problem of Biodiversity Loss', Dr Peter Raven, Director of the Missouri Botanical Garden and a renowned plant biologist and ecologist, provides a succinct summary of the 'epic of evolution', and discusses the problem of biodiversity loss. Specifically, he discusses the multiple causes of (and our profound ignorance concerning) the looming 'sixth great extinction' – an extinction being brought about, not by the impact of a meteor or any other natural calamities, as with earlier epic extinctions, but rather from the impact of humankind itself.

Chapter 3, 'Naturalizing Morality', in turn, offers a moral (and quasi-religious) response to the question, 'What is to be done?' Specifically, Dr Ursula Goodenough, a Washington University biology professor and author of *The Sacred Depths of Nature* (1998), introduces what she calls 'religious naturalism', wherein scientific understandings of who we are and how we got here – the Epic of Evolution – provides humanity with a unifying (rather than sectarian) story or myth, from which can be extrapolated six moral capacities – namely: strategic reciprocity, humaneness, fair-mindedness, courage, reverence and mindfulness – that Goodenough argues have arisen during our evolutionary history and undergird our ability to flourish in community. These capacities stand in tension with our moral susceptibilities to greed, hubris, self-absorption, fearfulness, xenophobia and prejudice. Goodenough suggests ways we might go about stacking the decks of our psyches, and our children's psyches, so that mindfulness trumps fearfulness, humaneness trumps hubris and xenophobia, fair-mindedness trumps greed, and mindful reverence trumps self-absorption.

In Chapter 4, 'Across the Apocalypse on Horseback: Biodiversity Loss and the Law', Professor Jim Chen, who is on the law faculty at the University of Minnesota, notes that although biodiversity loss has reached apocalyptic proportions, neither legal responses to the crisis nor the accompanying legal scholarship address the distinct sources of human influence on evolutionary change. Chen notes that the engines of extinction can be described in equine terms, either as the four horsemen of the ecological apocalypse – habitat destruction, overkill, introduced species and secondary extinctions – or in terms of Edward O. Wilson's acronym, HIPPO, derived from the Greek word for horse: Habitat destruction, Invasive species, Pollution, Population and Over harvesting.[44] According to Professor Chen, the problem with current national and international environmental efforts is that they address the causes of biodiversity loss in precisely the reverse order of their current relative significance, focusing more attention on the primary cause of diversity loss in Paleolithic times – namely over-harvesting of large and endangered mammalian and avian life – than on wide-scale habitat destruction, which was first set in motion by the rise of Neolithic agriculture and the spread of sedentary human settlements across much of the globe, and that is now the leading cause of biodiversity loss. For example, he points out that the Convention on International Trade in Endangered Species, or

CITES, imposes severe sanctions for over-harvesting where the human drivers of extinction are politically weakest, but fails to respond adequately to the deadliest horseman (habitat destruction). Having explained how national and international law has failed to keep pace with the scientific understanding of biodiversity loss, Chen suggests a modest agenda for meaningful legal reform. Chen concludes by reminding us that *in situ* preservation of ecosystems remains the only effective way to save biodiversity, and that the academic community has a singularly immense responsibility to educate the public on the importance of realigning environmental law with the scientific understanding of biodiversity loss – a task, he notes, that promises its own epiphany: a more spiritually satisfying understanding of the biosphere at its fullest and most diverse.

In Chapter 5, 'Impact of the Convention on Biological Diversity: The Lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits', Dr James Miller, Director and Curator of the William L. Brown Center for Plant Genetic Resources at the Missouri Botanical Garden, offers a further critique of existing legal responses to the biodiversity crisis, focusing on the impact that the CBD has had on basic and applied botanical research in the developing world. Noting that the stated objective of the CBD is to promote the preservation, sustainable use and equitable sharing of benefits arising out of biodiversity, Dr Miller identifies the kinds of benefits that may be expected to result from natural products discovery programmes; evaluates the extent to which the CBD has helped achieve more equitable distribution of benefits; and describes the impact of the CBD on international botanical research. His conclusions are (1) that developing countries would do well to focus more on relatively certain short-term monetary and non-monetary benefits accruing from actual implementation of research programmes than on less certain long-term monetary benefits; (2) that the CBD has stimulated a variety of benefit-sharing mechanisms, and various US government sponsored research programmes have generated substantial short-term benefits for developing countries, although the public benefits are yet to be demonstrated, as none of these plant screening activities has yet yielded a new drug; and (3) that the principal problem in CBD implementation is the absence of transparent systems for obtaining the prior informed consent of government agencies, and specifically that regulatory systems have not accommodated the differences between commercial and basic or academic research. Appended to this chapter is a short 'History of a landmark collecting agreement: the origin of the National Cancer Institute's Letter of Intent, precursor to modern bioprospecting agreements'.

In Chapter 6, 'Biodiversity, Botanical Institutions and Benefit sharing: Comments on the Impact of the Convention on Biological Diversity', Kate Davis, representing the Royal Botanic Garden, Kew, in the UK, supplements the observations of Dr Miller with respect to the impact of the CBD on botanical research, but focuses more on benefits arising from basic non-commercial botanical research, rather than on those benefits arising out of natural products discovery programmes. She also discusses the role that the Royal Botanic Garden, Kew, has played in developing codes of conduct best practices for botanic gardens and in shaping specific programmes pursuant to the CBD, such as the Global Strategy on Plant Conservation and the Global Taxonomy Initiative.

In further response to the question, 'What is to be done?', Chapter 7, entitled 'The Link Between Biodiversity and Sustainable Development: Lessons from INBio's Bioprospecting Program in Costa Rica', describes the extraordinary efforts that have been made in Costa Rica to preserve and make sustainable use of that country's biodiversity, with particular emphasis on the role of the Instituto Nacional de Biodiversidad (INBio). Dr Rodrigo Gámez, who is Executive Director of INBio, explains how, over the past 20 years, Costa Rica has transformed itself from a country making non-sustainable agricultural use of its resource base, to one making a concentrated effort to 'save, know and use' its biodiversity, an effort that has succeeded to the point that, today, eco-tourism is generating more income than other forms of direct exploitation of natural resources, such as timber and cattle. He also notes that Costa Rica has pioneered the payment to forest owners for environmental services, such as watershed protection, provided by ecosystems. Finally, he explains how bioprospecting can function to support sustainable utilization and conservation of biodiversity, and details the bioprospecting experience of INBio over the past 15 years. Specifically, he describes the criteria and terms of the Research Collaborative Agreement (RCA) used by INBio, the development of INBio's institutional capacities through strategic alliances with the government, and academic and private sectors (including some 20 RCAs to date with industry and academic institutions), as well as a more recent type of partnership with local enterprises, with a view to developing simpler products in a shorter period of time than is required for the development of agricultural, biotechnological or pharmaceutical products. Dr Gámez concludes by summarizing the (modest) monetary and (more substantial) non-monetary benefits derived from INBio's bioprospecting activities, and notes that the Costa Rican government has now launched an effort to develop a local biotechnology industry, and that INBio itself foresees more value-added agreements with academic and international biotech partners, due to the acquisition of several automated fractionators, which allow the isolation of compounds in a high-throughput fashion.

Chapter 8, 'On Biocultural Diversity from a Venezuelan Perspective: Tracing the Interrelationships among Biodiversity, Culture Change and Legal Reforms', by Drs Stanford and Egleé Zent, a husband and wife team of anthropologists from Venezuela, argues that it is no longer possible to separate discussions of biodiversity loss and preservation from the matter of local cultural knowledge protection, and that the very concept of biodiversity is being supplanted by a more complex paradigm of biocultural diversity. Thus, from a biocultural perspective, the question of what biodiversity we are losing and why, and what is to be done about it, must be answered by focusing on the cultural-historical processes affecting it. This chapter describes the pertinent processes taking place in Venezuela, focusing on two ethnographic case studies conducted by the authors with the Piaroa and Jotï indigenous communities, as well as the impact of the CBD, Decision 391 of the Andean Community, and Venezuelan law on basic and applied research in Venezuela, particularly the devastating impact that Venezuelan law has had on the ambitious, but controversial

BIOZULUA database project, which was originally aimed at the salvage recording of fast-disappearing traditional knowledge among various ethnic groups of the Venezuelan Amazon.

In Chapter 9, ‘From the “Tragedy of the Commons” to the “Tragedy of the Commonplace”: Analysis and Synthesis through the Lens of Economic Theory’, Dr Joseph Vogel, an economist on the faculty of the University of Puerto Rico, argues that (1) the mainstream economic approach to determining the optimal provision of reserves sufficiently extensive to allow the continued evolution of species is hopelessly wrong on both theoretical and practical levels, and should more aptly be called ‘the economics of extinction’; (2) while economists have cast doubt that rainforests can generate significant revenues as warehouses for potential pharmaceuticals to finance conservation, economic criticisms of the value of bioprospecting are likewise problematic; and (3) what is needed, if the purposes of the CBD are to be achieved, is an international biodiversity cartel among the megabiodiverse countries of the world, as a true ‘economics of biodiversity’ would begin with a precise limit – that is no deforestation – and ask how we can get people to respect that simple limit (having to pay cartel royalties being one such incentive). Dr Vogel concludes his chapter by offering critical commentary on the chapters by Chen (Chapter 4), Gámez (Chapter 7), Schaal (Chapter 10) and Sittenfeld and Espinoza (Chapter 12).

PART II BIOTECHNOLOGY: PART OF THE SOLUTION OR PART OF THE PROBLEM – OR BOTH?

In Chapter 10, ‘Biodiversity, Biotechnology and the Environment’, Professor Barbara Schaal, who is a Washington University biologist, evaluates the various effects, both positive and negative, that agricultural biotechnology could have on the environment and biodiversity, concluding that these potential effects are highly location and crop specific and that the wealth of biodiversity in tropical regions poses a particular challenge to agricultural biotechnology, as many species are cultivated in close proximity with their wild ancestors. Thus, a careful assessment of the environmental consequences of agricultural biotechnology, particularly in tropical regions of the developing world, is essential.

Chapter 11, ‘Principles Governing the Long-run Risks, Benefits and Costs of Agricultural Biotechnology’, authored by Dr Charles Benbrook, an independent agricultural consultant, describes a set of ‘first principles’ against which agricultural biotechnology can and should be appraised, explains why such principles are needed, applies these principles to selected agricultural biotechnologies, such as herbicide-tolerant crops and vitamin-enhanced crops, and concludes that, instead of trying to find ways to shift developed-world applications of biotechnology with respect to commodity crops (corn, soybeans, cotton, and wheat) to the developing world, a sounder strategy may be to focus on nutrient dense crops that are currently used for food in developing countries – for example cassava, millet, pulses, bananas, beans and squashes – and integrated pest and disease management strategies that will minimize the risk of generating resistance.

In Chapter 12, Ana Sittenfeld and Ana Espinoza, both biologists on the faculty of the University of Costa Rica, in effect respond to the concerns voiced by Professor Schaal, describing how Costa Rica has coordinated its development of rice biotechnology, as well as other aspects of its nascent biotechnology industry, with its ongoing efforts to preserve and make sustainable use of its biodiversity. Specifically, they summarize the recent activities of the Rice Biotechnology Program (RBP) of the Centro de Investigacion en Biologia Celular y Molecular of the Universidad de Costa Rica, which is seeking to deal with various phytosanitary constraints involved in conventional rice production (e.g. viral disease and weeds), by (1) developing transgenic rice that will confer resistance to the virus and tolerance to relatively eco-friendly herbicides; (2) conducting a biodiversity inventory of wild rice relatives and weedy rice biotypes within the country; and (3) assessing and monitoring any potential environmental impacts before any commercial release of the transgenic rice. Preliminary research indicates that the chance of gene flow from transgenic rice to wild and weedy relatives is low. The RBP has also explored the environmental impact of the use of *Bacillus thuringiensis* (*Bt*) as a pesticide by examining the presence of *Bt* in the wildlands of Costa Rica. That research, focusing on *Bt* isolates in host plant leaves, caterpillar guts and caterpillar fecal pellets, appears to have demonstrated that caterpillars (the major herbivores in tropical forests) serve as natural dispersers of *Bt* in their natural ecosystems and that the *Bt* thus dispersed may play a role in limiting forest defoliation.That research, in turn, has identified bacteria in caterpillar guts (a kind of micro-ecosystem) as an interesting source of new enzymes with potential biotechnology applications. Sittenfeld concludes that lessons from the RBP indicate that it is possible to implement sound science practices in agreement with biodiversity concerns.

In Chapter 13, 'Biotechnology for Sustainable Development in Africa: Opportunities and Challenges', Dr Florence Wambugu, a noted biotechnologist from Kenya, proposes an African strategy and agenda for stimulating a 'biotech agricultural revolution' in Africa, somewhat analogous to the Asian 'Green Revolution', which was made possible by the use of conventional plant breeding techniques by public-sector research institutions, such as the International Maize and Wheat Improvement Center (the Spanish acronym for which is CIMMYT) and the International Rice Research Institute (both of which are members of CGIAR) to develop high yielding varieties of wheat and rice that were both pest and disease resistant. Dr Wambugu notes that Africa's current socio-economic status is similar to that of Asia 50 years ago, and that cycles of hunger, malnutrition and poverty, as well as a growing population, are putting enormous pressure on the environment, causing environmental degradation, deforestation and serious loss of biological diversity, even in centres of genetic origin. Africa is also caught in the middle of the conflict of views in the developed world as to the relative benefits and risks of agricultural biotechnology. While many in Africa recognize biotech crops as a potential means to achieve food security and improve income generation in their own domestic markets, some African countries are unwilling to risk future trade problems with the European Union by meddling with genetically modified (GM) agricultural products. African policy makers are also concerned that agricultural biotechnology could give a few big companies control of the seed market. One important element in her proposed comprehensive strategy for biotechnology in Africa includes developing collaborations between public institutions and the private sector, to focus on food security and indigenous African crops, such as cassava, yams, bananas, maize and sweet potatoes. A more extensive discussion of the potential for such collaborative public–private partnerships is offered in the next chapter of this volume.

Chapter 14, 'Biotechnology: Public–Private Partnerships and Intellectual Property Rights in the Context of Developing Countries', is authored by Dr Gurdev Khush, formerly of the International Rice Research Institute, whose research is widely recognized as having contributed to the 'Green Revolution' in developing country agriculture. Dr Khush emphasizes that both public sector and private organizations have an important role to play in harnessing the benefits of biotechnology and the emerging field of genomics, and that collaboration between the two sectors is crucial in addressing the problems of food security and poverty alleviation in developing countries. The status of biotechnology research in developing countries is reviewed and opportunities for public–private partnerships are identified. Dr Khush concludes by commenting favourably on the topic of Chapter 15, namely the Public Intellectual Property Resource for Agriculture (PIPRA), which is being developed by a consortium of non-profit agricultural research centres, including the Donald Danforth Plant Sciences Center in St Louis.

In Chapter 15, 'Agricultural Biotechnology and Developing Countries: The Public Intellectual Property Resource for Agriculture (PIPRA)', Sara Boettiger, Program Director of the PIPRA, and Dr Karel Schubert, Vice President of the Donald Danforth Plant Sciences Center, provide an overview of some of the complex issues that arise in the intersection between intellectual property rights in agricultural biotechnology and developing countries and describe how PIPRA is working to address intellectual property issues in developing country research. PIPRA was founded by a consortium of public sector agricultural research institutions (including the Donald Danforth Plant Sciences Center) and is committed to addressing intellectual property rights issues in the research, development, and distribution of subsistence crops in the developing world and specialty crops in the developed world. Specifically, PIPRA seeks to facilitate access to agricultural technologies used by public sector researchers and to provide a common resource to address intellectual property management issues for crops developed in the public sector. To accomplish these objectives, PIPRA has developed a database of more that 6,600 public sector agricultural patents and patent applications, as well as information on public domain technologies, including expired and abandoned patents. It also engages in a wide variety of research activities, including responding to requests for patent landscapes regarding various technologies and developing a plant transformation vector that has been designed with attention to legal, technical, regulatory, and public acceptance considerations. PIPRA has also organized a large network of IP attorneys who work *pro bono* for the organization, including the Public Interest Intellectual Property Advisors and the Washington University Intellectual Property and Business Formation Legal Clinic, which are described in Chapters 28 and 29, respectively.

In Chapter 16, 'Commentary on Agricultural Biotechnology', Dr Lawrence Busch, who is University Distinguished Professor of Sociology and Director of the Institute for Food and Agricultural Standards at Michigan State University, offers a critique of the chapters by Gurdev Khush (Chapter 14) and Charles Benbrook (Chapter 11), and also takes issue with some of the points made by Professor Neil Hamilton in a conference paper, entitled 'Forced feeding: New legal issues in the biotechnology policy debate', which was published in 2005 as a part of the symposium volume of the *Washington University Journal of Law and Policy* cited at the outset of this chapter.[45] Dr Busch points out that the world is currently awash in cereals, and prices are quite depressed, in part due to the continuing agricultural subsidies in the US and EU that the WTO is finding so difficult to eliminate. He also notes that while there is little doubt that biotechnology could enhance crop production in developing countries, the results to date are disappointing. Moreover, he is sceptical of the potential for partnerships between the private sector and the International Agricultural Research Centres (IARCs) that collectively constitute the CGIAR. In response to Professor Hamilton, Dr Busch argues that the failure of African countries to accept US grain that was genetically modified simply illustrates the lengths to which the biotechnology industry will go to promote their products in the developing world, and the degree to which the US government is willing to provide support. He also echoes the concerns of Schaal (Chapter 10) and Benbrook (Chapter 11) over the environmental consequences of making commercial use of GM crops, and supports Benbrook's points that one cannot treat all biotechnologies in the same way and that greater attention must be given to local knowlege. But while Benbrook frames the issue largely in terms of costs or risks vs. benefits, Busch argues that the new agricultural biotechnology also poses more fundamental questions with respect to the right to know, the right to refuse and the right to participate in determining the future. Thus, Busch offers a friendly amendment to Benbrook's 12 principles, insisting that policy decisions concerning agricultural biotechnology be made in a democratic way.

In Chapter 17, 'The Birth and Death of Traditional Knowledge: Paradoxical Effects of Biotechnology in India', Dr Glenn Stone, an anthropology professor at Washington University, discusses how GM crops might affect the ongoing process of agricultural change – or more precisely, the process of acquiring information and adapting management practices based on that information, a process the author calls 'skilling'. The chapter summarizes the results of the author's anthropological field research investigating the impact of the introduction of transgenic cotton on smallholder farmers in two locales in India. The first case study, set in Andhra Pradesh, is a study in the disruption of indigenous agricultural knowledge. In that study Dr Stone concludes (1) that the introduction of hybrid cotton varieties and the use of conventional pesticides in the 1970s and 1980s had already resulted in the 'deskilling' of smallholder cotton farmers by the time *Bt* cotton was introduced; and (2) while these conventional cultivation practices are manifestly unsustainable, due to the development of pesticide resistance in the rapidly evolving American bollworm, it is overly simplistic to presume that *Bt* cotton is a 'solution' to the problem and will be adopted if farmers find that it benefits them, as the technology may not be entirely compatible with the process of skilling, and may even exacerbate the process of 'deskilling'. The second case study, set in Gujarat, while it lacks the empirical rigour of the first, nevertheless offers an intriguing (yet equally troubling) contrast. Here, the spread of GM cotton has been dominated by illicit seeds, leading to a widespread flouting of seed laws aimed at protecting both the environment and the farmer; but there are likewise signs of success, both in cotton production and in the 'reskilling' of farmers, as Gujarati farmers have begun to produce their own hybrid varieties of GM cotton, some of which appear to outperform approved varieties.

PART III TRADITIONAL KNOWLEDGE: WHAT IS IT AND HOW, IF AT ALL, SHOULD IT BE PROTECTED?

In Chapter 18, 'From the Shaman's Hut to the Patent Office: A Road Under Construction', Dr Nuno Pires de Carvalho, who is currently Acting Director of the Division of Legislation for Public Policy and Development of the WIPO, offers the latest global thinking on the protection of traditional knowledge. In this chapter, Dr Carvalho builds on an earlier article, 'From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?',[46] in which he argued that the road is not so tortuous or obstacle strewn as is commonly believed, that various other elements of indigenous knowledge might be protected by resorting to the traditional mechanisms of intellectual property, such as copyright and related rights, patents, trademarks, geographical indications and trade secrets, but that it also might be possible to develop a *sui generis* regime of protection of the contents of indigenous knowledge databases, which would provide effective protection of indigenous knowledge and yet would permit their holders to describe and register their knowledge in its entirety, without the need to disaggregate it. The purpose of the present chapter is to take stock of what has been done since 1999 to build the road that the shaman will walk from his hut to the patent office, examining the evolution of legal concepts and strategies providing for effective protection of traditional knowledge, with particular reference to the work of the WIPO IGC.

Chapter 19, 'Traditional Knowledge: Lessons from the Past, Lessons for the Future', by Dr Michael Balick, the Director of the Institute of Economic Botany at the New York Botanical Garden (NYBG), discusses the continually changing nature of traditional knowledge, its devolution (i.e. decrease) in the face of modernization, and the factors contributing to that devolution, utilizing case studies such as the Micronesia Ethnobotany Project, the NYBG's work with traditional healers and conservationists in Belize, and others. Dr Balick concludes this chapter by suggesting some parameters for deciding what skills and data should be preserved and what allowed to go extinct, and offering some strategies for rethinking how to protect traditional knowledge. The chapter concludes by describing how traditional knowledge is being saved by being exported to other regions, people immigrate to new islands, countries and continents, and offers a particularly striking example from the NYBG's urban ethnobotany project, involving the expatriate Dominican community living in the Washington Heights area of New York City.

In Chapter 20, 'The Demise of "Common Heritage" and Protection for Traditional Agricultural Knowledge', Professor Stephen Brush, who is on the faculty of the Department of Human and Community Development at the University of California-Davis, considers whether the protection of traditional agricultural knowledge, particularly in cradle areas of crop domestication, evolution and diversity (Vavilov Centers), where plant genetic resources have customarily been treated as common pool resources, according to a set of practices loosely labelled as 'common heritage', will in fact be better accomplished by replacing common pool management with a system of private ownership that is in line with the principle of national sovereignty over genetic resources enunciated in the CBD. Professor Brush notes that until recently, 'common heritage' has been the implicit system for managing the diffusion of crop genetic resources, from the informal movement of crops in prehistoric times to the formal national and international framework of crop exploration and conservation agencies exemplified in the international network of agricultural research organizations organized as the CGIAR, and was explicitly recognized by the FAO, in its now superseded 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture. He also notes the role of traditional agricultural knowledge and innovation in the common heritage regime and in the promotion of *in situ* conservation of crop genetic resources. However, he points out that the promulgation of the CBD in 1992, followed by the establishment of the WTO, which was given authority to implement and enforce the TRIPS Agreement, may have marked a closing of the genetic commons. Although he notes the recent resurgence of common heritage as the underlying principle of a new international framework for managing access to crop genetic resources, with the adoption of the new FAO International Treaty for Plant Genetic Resources for Food and Agriculture, he points out that the Treaty moves away from an earlier strategy for creating a binding international obligation to create a system of 'farmers' rights'. Brush concludes by examining two models for creating farmers' rights at the national level, including the Organization of African Unity's Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (OAU Model Law), discussed in more detail in Chapter 21 of this volume, and expresses concern that the prescribed plant variety protection will provide meagre resources to finance Farmers' Rights. He also identifies weaknesses in the FAO Treaty itself in failing to set out the obligation of industrialized and developing countries alike to support conservation of crop resources beyond contributing funds raised in connection with commercializing improved crop varieties.

Chapter 21, 'Traditional Knowledge Protection in the African Region', by Dr Rabodo Andriantsiferana, a botanist from Madagascar, reviews the development of intellectual property tools in Africa, as well as methods for protecting genetic resources and traditional knowledge, since the early 1960s. In particular, she focuses on recent scientific and legal initiatives of the Organization of African Unity (OAU) and other international and regional organizations, including the development of the OAU Model Law, also discussed in Chapter 20, above, and an OAU Declaration, designating the period 2001–2010 as the Decade for Traditional Medicines.

In Chapter 22, 'The Conundrum of Creativity, Compensation and Conservation in India: How Can Intellectual Property Rights Help Grassroots Innovators and Traditional Knowledge Holders?' Professor Anil K. Gupta, who is a professor at the Indian Institute of Management in Ahmedabad, India, examines the various incentive systems that can be utilized to promote conservation of biodiversity, preservation of traditional knowledge and grassroots innovation generally. In the first part of the chapter, Gupta looks at different kinds of creativity for conserving biodiversity or solving problems of everyday life. In the second part of the chapter, he describes the different ways of conceptualizing incentives, identifies the interplay of natural, social, ethical and intellectual capital (including intellectual property rights) and discusses the different kinds of knowledge systems that contribute to grassroots innovation. In the final part of the chapter, Gupta discusses the implications for the development of intellectual property policy at the national and international levels.

In Chapter 23, 'Holder and User Perspectives in the Traditional Knowledge Debate: A European View', Professor Doctor Geertrui Van Overwalle, who is on the Faculty of Law of the Catholic University Leuven, Belgium, offers an overview of the conceptual issues and pertinent intellectual property problems in the traditional (medicinal) knowledge debate, and in so doing, reviews and comments upon a number of other chapters in Parts III and IV of this volume. From this review and commentary, the author develops a conceptual framework for comparing knowledge-holder and user perspectives on the legal protection of traditional knowledge. She also discusses the 'implementation' of the disclosure of origin requirement in Recital 27 of the European Union Biotechnology Directive, as well as national legislative initiatives in Belgium and Denmark, the only two member states that have taken Recital 27 seriously.

PART IV ETHNOBOTANY AND BIOPROSPECTING: THINKING GLOBALLY, ACTING LOCALLY

In Chapter 24, 'Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities', Dr Joshua Rosenthal, who is the US National Institutes of Health (NIH) official responsible for the NIH's International Cooperative Biodiversity Group (ICBG) projects, compares the efforts in two ICBG Projects – the Maya ICBG in Mexico, and the

ICBG-Peru Project – to develop prior informed consent and fair and equitable benefit-sharing arrangements among indigenous communities. The chapter summarizes how the ICBG-Peru Project succeeded in developing credible, working partnerships among the Aguaruna communities of Peru, while the Maya ICBG Project did not meet with similar success in Mexico, despite enjoying a number of significant initial advantages. From this comparison, Dr Rosenthal draws a number of conclusions about the role of culture, politics and local governance that influenced the differing outcomes in these two ICBG projects.

In Chapter 25, Dr Walter Lewis, an emeritus professor of biology at Washington University in St Louis and the Principal Investigator in the NIH-funded ICBG-Peru project, together with Ms Veena Ramani, a graduate law student at Washington University, details the various ways in which traditional knowledge can be protected under existing legal systems, considers whether and to what extent these modes of protection are adequate, and then describes in detail the combination of contractual and other legal tools utilized in the ICBG-Peru Project to (1) protect the traditional knowledge of a confederation of Aguaruna Indian communities participating in the project; (2) ensure the prior informed consent of participating individuals and communities; and (3) provide for an equitable sharing of benefits growing out of the ICBG-Peru Project.

In Chapter 26, 'Ethics and Practice in Ethnobiology: The Experience of the San Peoples of Southern Africa', Roger Chennells, a South African human rights lawyer, describes the experience of representing the San peoples as they formed their own networking and umbrella organization, called the Working Group of Indigenous Minorities in Southern Africa (WIMSA), to protect both their rights to land and resources, and their traditional knowledge. Specifically, Chennells examines the controversial case of the patenting and licensing of an extract of the Hoodia succulent, which is traditionally used by the San as a thirst and appetite suppressant, and discusses issues of prior informed consent and benefit sharing, particularly as they relate to a benefit-sharing agreement between the patent holder and WIMSA, which was concluded on 24 March 2003.

In Chapter 27, 'Commentary on Biodiversity, Biotechnology and Traditional Knowledge Protection: A Private-Sector Perspective', Dr Steven R. King, Vice President of Ethnobotany and Conservation of PS Pharmaceuticals, Inc. and former Chief Operating Officer and Vice President of Shaman Pharmaceuticals, offers a summary of the process of 'trialogue' taking place in the chapters of this volume on the interrelated topics of biodiversity, biotechnology and traditional knowledge protection, and adds his own private-sector perspective. Specifically, he notes that the spiritual foundation of traditional knowledge forms a circle around the trialogue and that disclosure of origin of genetic resources and associated traditional knowledge and evidence of prior informed consent of the providers of same is the starting point for trialogue. He also summarizes the various defensive and affirmative means for legally protecting traditional knowledge and explains how companies can play a role in the trialogue. He also explains how traditional medicine, biodiversity, patents and public health are linked in the ongoing trialogue, emphasizes how maintaining symmetry in the trialogue is imperative for its utility, and discusses the ongoing 'trialogue on the ground', as illustrated in such research activities as those described by Rosenthal (Chapter 24) and Lewis and Ramani (Chapter 25).

The last two chapters in this volume discuss how developing countries and traditional knowledge holders are to obtain competent legal representation in intellectual property matters on a case-by-case basis, such as the negotiation of benefit-sharing agreements of the sorts described by Walter Lewis, Veena Ramani and Roger Chennells. In Chapter 28, 'Answering the Call: Public Interest Intellectual Property Advisers (PIIPA)', Michael Gollin, a Washington DC patent lawyer discusses how PIIPA, a public interest organization established as an independent international service and referral organization, can help fill this need by making the know-how of intellectual property professionals available in developing countries. Specifically, Gollin describes the increasing global need for intellectual property legal services, traces the genesis and development of PIIPA as a practical response to that need, identifies the logistical, legal, ethical and political hurdles that public interest organizations working in the area of intellectual property must overcome, and concludes by describing the work of PIIPA, including illustrative cases, its plans for growth, and future directions.

In Chapter 29, 'Answering the Call: The Intellectual Property and Business Formation Legal Clinic at Washington University', I describe a recently developed educational programme at Washington University in St Louis, which is designed, in part, to support and complement the work of PIIPA. A primary objective of the Intellectual Property and Business Formation Legal Clinic is to develop expertise in the overlapping fields of biodiversity, biotechnology and traditional knowledge protection, and to make that expertise available, both to prospective developing country clients and to local IP professionals who wish to participate in the *pro bono* activities of PIIPA. In addition, the Legal Clinic is collaborating with the Missouri Botanical Garden, the Donald Danforth Plant Science Center, and a variety of other organizations, including the Public Intellectual Property Resource for Agriculture, described in Chapter 15. The goal of the Intellectual Property and Business Formation Legal Clinic in all of its activities, will be to highlight, for law students, clients and the legal profession as a whole, that the purpose of intellectual property law is a public one – namely to 'promote the Progress of Science and the Useful Arts'[47] – and that the protection and enforcement of intellectual property rights 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.[48]

NOTES

1 *Book of Common Prayer* 370 (1977).
2 Convention on Biological Diversity (hereinafter CBD), available at www.biodiv.org/convention/articles.asp.
3 Available at www.biodiv.org/convention/articles.asp?lg=0&a=cbd-08.
4 Available at www.biodiv.org/world/parties.asp.
5 For the Agreement Establishing the World Trade Organization and related agreements to be administered by the WTO, see www.wto.org/english/docs_e/legal_e/legal_e.htm. This agreement, together with the TRIPS Agreement and other results of the Uruguay Round of Multilateral Trade Negotiations, are included as annexes attached to the Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations (hereinafter Final Act). For the complete bundle of agreements, see www.wto.org/english/docs_e/legal_e/03-fa_e.htm. For the current membership of the WTO, see www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.
6 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (hereinafter TRIPS Agreement), available at www.wto.org/english/docs_e/legal_e/legal_e.htm.
7 For the transitional provisions of TRIPS, see TRIPS Agreement, supra note 6, Articles 65 and 66. For the international minimum standards for patent protection, see ibid., Articles 27–34. For the international standard for plant variety protection, see ibid., Article 27.3(b).
8 For the dispute settlement and enforcement provisions of the TRIPS Agreement, see TRIPS Agreement, supra note 6, Article 64, and the Final Act, supra note 5, Annex 2, Dispute Settlement Understanding, available at www.wto.org/english/docs_e/legal_e/28-dsu_e.htm.
9 International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter FAO International Treaty), available at www.fao.org/ag/cgrfa/itpgr.htm.
10 See www.cgiar.org.
11 See Stephen B. Brush, infra Chapter 20. For a longer version of this article, see Stephen B. Brush (2005) ‘Protecting traditional agricultural knowledge’, *Washington University Journal of Law and Policy*, vol 17, p59, available at http://law.wustl.edu/centeris/Confpapers/index.html.
12 See FAO International Treaty, supra note 9.
13 See David Harmon (2005) ‘On the meaning and moral imperative of diversity’, in Luisa Maffi (ed) *On Biocultural Diversity: Linking Language, Knowledge, and the Environment*, Smithsonian Institute Press, Washington, DC, p61. See also Stanford Zent and Egleé Zent, infra Chapter 8.
14 See Maffi, supra note 13. See also Luisa Maffi, ‘Linguistic and biological diversity: The inextricable link’, available at www.terralingua.org/DiscPapers/DiscPaper3.html.
15 Biopiracy has been defined as ‘appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (patents or intellectual property) over these resources and knowledge’. This is the definition of the ETC Group (formerly known as RAFI – the Rural Advancement Foundation International), an advocacy organization that believes that ‘intellectual property is predatory on the rights and knowledge of farming communities and indigenous peoples’. See www.etcgroup.org/text/txt_key_defs.asp.

16 See Joshua Rosenthal, infra Chapter 24; Walter Lewis and Veena Ramani, infra Chapter 25.
17 See Stephen B. Brush, infra Chapter 20.
18 See Jim Chen, infra Chapter 4.
19 Compare Stephen B. Brush, infra Chapter 20, with Joshua Rosenthal, infra Chapter 24, and Walter Lewis and Veena Ramani, infra Chapter 25.
20 See generally Stephen A. Hansen and Justin W. VanFleet (2003)*Traditional Knowledge and Intellectual Property: A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity*, American Association for the Advancement of Science, Washington, DC.
21 Ibid. See also Stanford Zent and Elgee Zent, infra Chapter 8.
22 Ibid.
23 See www.cgiar.org/index.html.
24 For an example of how an 'open-source' system, such as that established by the FAO International Treaty, supra note 9, can generate in-kind or financial benefits for those contributing to the system, see Stephen B. Brush, infra Chapter 20.
25 See generally Nuno Pires de Carvalho, infra Chapter 18.
26 See generally Charles R. McManis (2004) 'Fitting traditional knowledge protection and biopiracy claims into the existing intellectual property and unfair competition framework', in Burton Ong (ed) *Intellectual Property and Biological Resources*, Marshall Cavendish, Tarrytown, NY, p425.
27 The dispute settlement provisions of the CBD and FAO International Treaty are virtually identical. See CBD, supra note 2, Article 27; FAO International Treaty, supra note 9, Article 22. These articles specify that disputes are to be settled by negotiation and that members may jointly seek mediation. Members may, but are not required, to agree to submit disputes to arbitration to the International Court of Justice.
28 See, e.g. CBD, supra note 2, Article 8, specifying that members are 'as far as possible and as appropriate' to promote *in situ* conservation. This language qualifies the obligation in Article 8(j) to respect, preserve and maintain traditional knowledge relevant to the conservation and sustainable use of biodiversity.
29 Doha Ministerial 2001: Ministerial Declaration, available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.
30 Ibid.
31 Ibid.
32 Cary Fowler (2004) 'Accessing genetic resources: International law establishes multilateral system', *Genetic Resources and Crop Evolution*, vol 51, p609. See also Stephen B. Brush, infra Chapter 20.
33 FAO International Treaty, supra note 9, Article 12.3(d).
34 Article 9 of the FAO International Treaty, supra note 9, purports to recognize the 'enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources', but goes on to state that 'the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments'.
35 Article 9.3 of the FAO International Treaty, supra note 9, states that 'Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.'

36 Article 27.3(b) of the TRIPS Agreement, supra note 6, requires WTO members to 'provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'. Although this provision does not obligate WTO members to join the International Convention for the Protection of New Varieties of Plants (UPOV), available at www.upov.int/en/publications/conventions/index.html, Article 15 of the 1991 version of UPOV specifies that the farmers' privilege to use a protected variety is to be optional with Contracting Parties and, in any event, is to be limited to permitting farmers to use the protected variety 'for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or [essentially derived varieties of the protected variety]'.

37 FAO International Treaty, supra note 9, Articles 12.4 and 13.2(d)(ii).

38 Article 13.2(d)(iii) of the FAO International Treaty, supra note 9, specifies that the Governing Body 'shall, at its first meeting, determine the level, form and manner of payment [of monetary benefits of commercialization] in line with commercial practice'. As of June 2006, this meeting had not yet taken place.

39 See www.wto.org/english/thewto_e/minist_e/min03_e/min03_e.htm. See also Laurence Tubiana (2003) 'Post Cancun WTO: Focus on the objectives, not the means', *Bridges* Sept.–Oct.; Eric Hazard (2003) 'The cotton thread: Was Cancun a failure of regulation or a success for deregulation?, *Bridges* Sept.–Oct.; 'Regional integration spurred and complicated by Cancun', *Bridges* Sept.–Oct.

40 See www.wto.org/english/thewto_e/minist_e/min03_e/min03_14sept_e.htm.

41 See www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm.

42 See www.wipo.int/tk/en/igc/index.html (last visited April 3, 2004). ('The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the WIPO General Assembly in October 2000 (document WO/GA/26/6) as an international forum for debate and dialogue concerning the interplay between intellectual property (IP), and traditional knowledge, genetic resources, and traditional cultural expressions (folklore).')

43 WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore – An Overview, WIPO/GRTKF/IC/1/3 (Mar. 16, 2001).

44 See Edward O. Wilson (2002) *The Future of Life*, Knopf, New York, pp50–51.

45 Neil D. Hamilton (2005) 'Forced feeding: New legal issues in the biotechnology policy debate, *Washington University Journal of Law and Policy*, vol 17, p37, available at http://law.wustl.edu/Journal/17/p%2037%20Hamilton%20book%20pages.pdf.

46 Nuno Pires de Carvalho (1999) 'From the Shaman's hut to the Patent Office: How long and winding is the road?', *Rev. ABPI* (Brazilian Association of Intellectual Property), vol 41, p3.

47 US Constitution, Article I, § 8, cl. 8.

48 TRIPS Agreement, supra note 6, Article 7.

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PART 1

Biodiversity: What Are We Losing and Why – And What Is to Be Done?

Chapter 2

The Epic of Evolution and the Problem of Biodiversity Loss

Peter Raven

This volume is indeed a very interesting one, combining as it does the major themes of biodiversity, biotechnology and traditional knowledge in a way that has rarely been done, but I think in a way that must become more characteristic in the future, if we are going to succeed in finding, saving, commercializing and dealing with biodiversity in a sustainable way that will leave a rich supply of biodiversity, one filled with choices for the people who come after us.

I probably should begin by defining biodiversity. The standard definition is that biodiversity is the sum total of all the plants, animals, fungi and microorganisms on Earth, all of their genetic variations and their phenotypic variation, and all of the communities and ecosystems that they comprise. When we held our conference in Washington in 1986[1] on what was then called biological diversity, which later was shortened into biodiversity in the book that resulted from that conference,[2] we would have defined the term more as the inventory of all the kinds of living organisms on Earth and the threats to their survival, which is what we had in mind then, but it has since been amplified in this elided form into the kind of meaning that I have just given you.[3]

THE EPIC OF EVOLUTION

Now, if we look at the long picture, the history of biodiversity began within a billion years of the origin of our planet Earth 4.5 billion years ago. At a time 3.8 billion years ago there were fossils in rocks, evidences of biological activity, and the evolution of bacteria, and forms such as bacteria and procaryotic organisms, began. One of these groups of bacteria, the cyanobacteria – which used to be called blue-green algae – evolved very early in the process and evidently evolved the process of photosynthesis. As the masses of cyanobacteria floating in those early oceans photosynthesized, they changed the atmosphere of the Earth from a reducing atmosphere, very poor in oxygen, rich in hydrogen, to an oxidizing atmosphere that was rich in oxygen, having about the 20 per cent oxygen that we have now, and in equilibrium with an ozone layer on the top of the stratosphere; O^2 in equilibrium with O^3 that actually defines the ability of organisms to live on the land. The way the ozone layer does that is to protect us from ultraviolet B radiation, which continually bombards the Earth, and is very damaging to biological molecules. It was not until the photosynthetic activities of these early greenish, blue-greenish bacteria operated for long enough that we had an oxygen-rich atmosphere in which living things could evolve on the Earth. The other consequence of the activities and the growth of these masses of bacteria settling down into the world's oceans for 2 billion years was the formation of the deposits that were converted through geological processes, and over time, into the petroleum and natural gas deposits that we human beings have exploited extensively over the past 200 to 250 years, in driving the Industrial Revolution and its modern equivalent.

Multicellular organisms appeared about 80 per cent of the way through the history of the Earth, 700–800 million years ago, the first organisms large enough to see with the naked eye. And, until the invasions of the land occurred about 440 million years ago there were no land living organisms on Earth through 90 per cent of the history of the planet. By about 440 million years ago, and within a relatively short space of time geologically, there began to occur on land the ancestors of the arthropods, insects and their relatives, of terrestrial plants, of vertebrate animals; fishes changing into amphibians, and fungi which began to form the species-rich accumulations that we have at the present time. By about 300 million years ago, there were forests and great masses of vegetation that, when they were pasted into geological strata, became the coal deposits that were the third major source of energy in the industrial age that we are living in at the present time.

The number of species of organisms on land began to multiply rapidly and indeed it is estimated today that the numbers on land are about 85 per cent of all the species on Earth, with only about 15 per cent occurring in the oceans, even though the oceans obviously occupy a much greater proportion of the Earth's surface. Sixty-five million years ago the collision of a giant meteorite or asteroid with the Earth threw up a semi-opaque cloud that was worldwide and obviously interrupted the evolution of species on land and changed the character of life on earth permanently; it drove the last of the dinosaurs into extinction and set forth bursts of evolution in all the major remaining groups of land organisms: mammals, birds and modern reptiles. Even though they existed before the end of the Mesozoic era or the cretaceous period, which is the third and last part of the Mesozoic era, their diversification has taken place over the past 65 million years. So, for example, 65 million years ago the largest mammal on earth was about the size of a house cat, and all of the other lines of mammals, including primates, giraffes, hippopotamuses, bats, whales, seals and everything else that we think of as being characteristic of the world, have evolved subsequently.

About two-thirds of all the species that existed 65 million years ago are estimated to have gone extinct at that time. So, at that point, the Cenozoic era began with roughly one-third of the number of species on land that had existed previously. The number of species has increased significantly over the years. Species evolved and became more diverse as climates became more differentiated, that is, as the pole to equator gradient in climates became sharper, which is something that really followed the accumulation and development of worldwide ice sheets over the last 17 million years, starting in the south and eventually getting to the north. This created more and more distinct kinds of habitats on the land, leading to greater and greater numbers of species on land.

One of the most important characteristics of the biodiversity that we have now is that it is very difficult to estimate the exact numbers of species that exist. And, that is obviously part of the basis for estimating rates of extinction on land, which I will come to shortly. The best estimates available are those developed by Bob May, of Oxford, in a symposium in Washington at the end of the 1990s.[4] May went over the statistical basis for all of the estimates of species of individual groups, such as Terry Erwin's estimate of 30 million species of arboreal insects in the deserts, in the tree tops of the moist forest of South America, and David Hawksworth's estimate of 1.5 million species of fungi based on their relationship to land plants. With only 70 thousand described species of fungi, you can see that is quite an extrapolation. Bob May estimated that the number of species of organisms existing lies somewhere between 7 and 15 million species, which is a wide range, with something like 10 (7 being conservative) million perhaps, being a median estimate. But, we have only named roughly 1.6 million kinds of organisms. Which means that although we know quite a lot about a few groups of organisms such as plants, vertebrates, butterflies and some insects of economic importance (e.g. mosquitoes and ticks), for many groups of organisms (such as mites, nematodes little round worms or fungi and, above all, procaryotic organisms, bacteria) we have only named a very, very tiny fraction of the total number that exists. A couple of points should be made at this stage: whenever we talk about extinction or even geographical patterns of variation on Earth, we are basing our comments on the very small sample of the Earth's species that we really know in detail, and assuming that the patterns in all the groups that we know only poorly will be like those that we know very well.

THE PROBLEM OF BIODIVERSITY LOSS

We can look at the extinction rates in vertebrates, plants, butterflies and a few other groups over the past 300 years or so, and see what they are like because, during that period of time, people were recording extinctions as they occurred. We can look at some other extinction rates, for example, by means of fossil records on islands in the Pacific Ocean as the ancestors of the Polynesians reached those islands. We can study this sub-fossil and fossil record, found during the time of Polynesian occupation – roughly the last 1000 years – tracking the disappearance of birds species that were there before the Polynesians arrived and began clearing those lands for cultivation. We can see that about 1000 species of birds have gone extinct in the Pacific Ocean area alone over the past 1500 years or so. Considering that there are only about 9000 species of birds in existence at the present time, that is a very huge loss proportionately and one that we can demonstrate directly and empirically.

However, for four of the groups that are written up in the literature, we can calculate a rate of extinction roughly 10 to 100 times greater than the historical rate, and, by looking at the fossil record, we can define that as the loss of 0.1 to 1 species per million, per year. Whereas, over the past 65 billion years between 1 and 10 species a year would be a reasonable record of extinction, we are now looking at hundreds or low thousands of species per year as rates of extinction. It is important to remember, when we talk about burning down, ploughing up or chopping down tropical moist forests, that about 19 out of 20 of the species that are consequently destroyed have never been seen or named by anyone. They are completely unknown. As they go, they go without leaving a trace. And even for the 1.6 million that we have catalogued, there is often little more than one cadaver of the animal, let us say, lying in the bottom of a bottle full of alcohol on the shelves in the Natural History Museum in London, with one general locality note from some place in Central Brazil from 1870, which clearly does not tell us very much about the biology of the organism.

Thus, we have a profound ignorance of the biodiversity of life on Earth. And, if you think this applies only to well-known groups, estimates of the described, not the estimated, but the described species of vascular plants range from 250,000 to 420,000 at the present time, using different methods of estimation, which clearly indicates that biologists have not made sufficiently integrated catalogues to really know. And then, how many more are to be discovered? Estimates range from 50,000 to 100,000. So, there is obviously a great deal of work to be done.

Now, the major reason that organisms become extinct is through loss of habitat. The tropical moist forests of the world in Latin America, Africa and South East Asia combined have been reduced from an aggregate area of about the size of the continental United States, to an area of about one-third that size. Think of the US east of the Mississippi River, either clear-cut or disturbed to the point where it is completely changed to a new form, with an area about the size of the state of Indiana being removed with every passing year. Tropical moist forests are being logged for about the same reason that the forests in the northwestern US are logged. Namely, because people want the money. They want to convert them into short-term value, which is more impressive to them than the long-term value that might be gained by leaving them longer. The claim that there are hordes of hungry people cutting down forests because they do not have an alternative – even though that is certainly true in some parts of the developing world – is increasingly being recognized to be a myth. More commonly, most people in the developing world prefer to live in the growing cities, sitting at cybercafes and sending email messages to their friends around the world, in the same was as people do in the developed world. It has been said, for example, that if you took away the boundaries of the National Forest in Costa Rica the change in the distribution of forest would be very slow now, whereas 30 years ago it would have been very fast.

The reason is, basically, that very few people in Costa Rica even know what a donkey looks like anymore and certainly do not want to go into the forest with all its mosquitoes and diseases and make a livelihood clearing patches of forest and growing some kind of crops. They prefer to move into the cities and live a similar life to people in the industrialized world. But, there are still many threats to those forests, partially industrial, and it is estimated that tropical moist forests, which are home to about half of all the species or organisms in the world, are likely to have been reduced to 5 per cent of their original extent by the year 2050.

A human population that consisted of no more than a few million people 10,500 years ago, when people first learned to cultivate crops, grew at first slowly and then more rapidly to 2.5 billion people in 1950, and has shot upwards to 6.5 billion people today. In addition, what people want to consume has increased, as their level of affluence has increased in the same period. In the US, we consume at about 30 to 40 times the level of rural people in Indonesia, many rural people in India and rural people in Brazil. This means that each additional person in the US has 30 to 40 times the impact on the Earth's sustainability as a person living in the rural parts of developing countries. That is why it is a complete fallacy to place the whole problem of the population growth on developing countries. It is our affluence, our incessant desire to raise our standards of living, and our use of inappropriate technology, not only at home but around the world, that is really reducing biodiversity and threatening world sustainability.

While the population of the world has been experiencing this enormous boost upward, there have been a number of results on theoretically renewable world systems, which are proving not to be renewable under the onslaught that accompanies these changes. About 20 per cent of the topsoil in the world has been wasted over the last 50 years. About 20 per cent of the agricultural lands in the world have been lost as a result of salinization because of over-fertilization, desertification, aridity, loss of water or simply urban sprawl, growing out of settlement around all the cities of the world. Certainly in St Louis we have nothing to be proud of, with 2.35 million people in 1950 to 2.6 million people now and yet we found it necessary to grow 45 miles out into the countryside in every direction to accommodate what was really only a small percentage increase in the population. Between 1945 and 1973, the US paved over an area the size of the state of Ohio. The central valley of California, which is one of the richest agricultural pieces of land in the US, is becoming a sprawling megalopolis that goes all the way from Chico to Bakersfield. And that land will soon be lost to agriculture as the population of California zooms on towards 60 million people over the next few decades. In addition to these changes, the last 50 years have seen a one-sixth increase in the amount of carbon dioxide, the main greenhouse gas produced by human beings, thus pushing global warming at a rapid rate; depletion of the stratospheric ozone layer, that I spoke about above, by about 7–8 per cent, which increases the incidence of malignant skin cancer in a latitude such as the continental US by 20–25 per cent; cutting down without replacing them, approximately one-third of all the forests on Earth, and at the same time driving the rate of the extinction of biodiversity up, in the way that I have described. It is for these reasons that George Schaller, the great conservationist at the Wild Life Conservation Society in New York, said at the end of the 20th century that we cannot afford another century like this one.[5] In other words, we cannot afford it for the same reasons that a family that has just inherited 1 million dollars cannot afford to spend 250 thousand dollars a year – they would not feel rich for very long, if they did.

Consider for a minute the human condition on Earth: of the 6.1 billion of us, approximately one-quarter live on less than a dollar a day, in what the World Bank defines as absolute poverty. About one out of every two people on earth is malnourished. Roughly one out of every six receives so few calories that their bodies are literally wasting away; their brains cannot develop properly when they are children. In India, for example, which is a country of over 1 billion people now, growing at one million people every 12 days, 70 per cent of the mothers who give birth are anaemic and about 70 per cent of the children born are of low birth weight. This is among those whom we characterize as the poor. But the same thing, by the way, is happening in the poorest parts of St Louis, which is something we do not give enough attention to. A very unfortunate result of this deprivation is that women and children in the poorest quarter of the world have no ability to gain an education for themselves. Women and children spend their entire lives bringing water back to the places where they live or gathering firewood to cook with. And disenfranchising such a major part of world is highly destabilizing, completely immoral and positively stupid in the face of the fact that we need everything we can to work together to address these problems.

As for prospects for the future, the 20 per cent of the people in the world who control 80 per cent of the world economy have not shown many signs of giving it up. The 80 per cent of the people in the world who live on 20 per cent of the world economy, in what are sometimes, I think, euphemistically called developing nations, have approximately 10 per cent of the world's scientists and engineers living in their areas. As a result – and especially considering that most of them are concentrated in places such as Brazil, Mexico, India and China – there are about 150 countries in the world that completely lack an adequate scientific basis. This is not only in terms of their scientific needs for appropriating advances made by other people for their own use, but they also lack the ability to feed into their own governments' decisions about how they should manage their own natural resources sustainably.

The US, which has had roughly 4.5 per cent of the world's population since the 1870s, and has been growing at the same speed as the rest of the world, uses about 25 per cent of the world's economy to support its standard of living, and emits possibly in excess of 25–30 per cent of most pollutants in the world, and causes about that degree of ecological damage. In other words, American lives, like those of the Europeans and the Japanese, are based on the productive lives of people all over the world and Americans must pay attention to worldwide sustainability, if they expect a relatively secure future. It is paradoxical that the US, which is the richest nation that has ever existed on the surface of the Earth, and the most dependent on other people elsewhere, is also the least generous when it comes to foreign assistance of any kind on a per capita basis. Places such as Finland, Norway, Belgium, Germany and Italy, are so much more generous than US citizens, although this could only be called generosity in a very limited way when American futures really depend on it. We do not really seem to be acting in our own interest. We can, however, do a great deal if we work together, come to respect one another better and decide that we want to build a sustainable world.

The image that I want to leave you with, in conclusion, is this: the world is not going to come to an end, we are not all going to become extinct. We are going to reach sustainability by moving along towards the vector, towards sustainability through time. What we are defining, though, by our actions at the end of an incredibly greedy destructive and wasteful 200 years, is what kind of a world we want to leave for our grandchildren and their grandchildren – what we want the world to look like in 50 years or 100 years. This will not be a general phenomenon, although we can be sure that the world will be impoverished in a variety of productive ways, it will have many fewer species of organisms just at the time when we are beginning to learn about those organisms and can put them to work for ourselves. And by driving so many of these resources down to lower and lower levels, we are leaving behind many fewer options for those who come after us; and many fewer than we really should leave in view of all the good things that we are enjoying now. In short, I would say that, by and large, we do not live lives worthy of the benefits that we enjoy. What we need to do is to figure out a worldwide system by which we are bound together, and law will play a major role in that international understanding – although love and respect of one another around the world has the most fundamental role to play. The world is not going to be deflated completely, but it is going to be a patchwork of richer, healthier, more prosperous places and poorer, sicker, duller places with fewer options. The way in which that plays out will depend on each and everyone of us and it is in our own hearts and in our own brains that we have to find the inspiration to act, with respect to this marvellous planet that we have, in a word, borrowed from our children. And we have to decide what we are going to do and what we are willing to do about it. We are certainly not on short trip, we are not on a trip that will end, but we are on a trip together that will result in what the world is like in the future. And it is up to us as individuals to devise ways to make it better, sounder and more healthy and to that end this conference is poised to make a very valuable contribution.

NOTES

1. Symposium on Life and the Universe, held at the National Academy of Sciences, Washington, DC, 30 April, 1986.
2 Donald E. Ostenbrock and Peter Raven (eds) (1988) 'Origins and Extinctions', based on a Symposium on Life and the Universe, held at the National Academy of Science, Washington, DC, 30 April, 1986.
3 See Peter H. Raven (ed) and Tania Williams (assoc. ed) (2000) *Nature and Society: Proceedings of the 1997 Forum on Biodiversity*, National Academy Press, Washington, DC.

4 See Robert May (1994) *Large Scale Ecology and Conservation Biology*, Blackwell, Oxford; Robert May (1995) *Extinction Rates*, Oxford University Press, Oxford; and Robert May (1999) *Evolution of Biological Diversity*, Oxford University Press, Oxford.

5 See generally George B. Schaller (1993) *The Last Panda*, University of Chicago Press, Chicago.

Chapter 3

Naturalizing Morality

Ursula Goodenough

Religions can be said to have three strands: a theological strand, concerned with such matters as Meaning and Purpose and often including god(s); a spiritual strand, entailing subjective experiences of the sacred; and a moral strand, dealing with how best to be good. A mature religious tradition interweaves these in the context of a unifying story or Myth, but each can nonetheless be teased out and analysed separately.

There is growing interest in an orientation that I will call here religious naturalism, wherein our scientific understandings of who we are and how we got here – the Epic of Evolution – serves as the unifying story or Myth. In my book *The Sacred Depths of Nature*, I suggest ways that this story can elicit such spiritual sensibilities as belonging, communion, gratitude, humility, assent and awe.

My current work considers how morality might be considered in the context of religious naturalism. A recent book by Larry Arnhart, *Darwinian Natural Right* (1998), gives a thorough and thoughtful account of the intellectual history of ethical naturalism, and Terrence Deacon and I are developing a perspective on this question in the context of emergentism (Goodenough and Deacon, 2003). Here I offer an overview of the project and its trajectory, adapting material in part from previous writings (Goodenough and Woodruff, 2001; Goodenough, 2003).

MORALITY IN RELIGIOUS NATURALISM

Any religious orientation worth talking about is also concerned with morality. As theologian John Haught (2001) recently remarked: ‘I would say that in this recent flurry of news about brain and religion, what is often left out is that religion means much more than a state of mind or an ecstatic or mystical mood. It’s a commitment over a lifetime to what a person considers to be good.’ So how do we talk about moral thought and moral action as religious naturalists? What do we say to our children about how best to be good, and on what basis do we ground what we say?

My starting premise, working with understandings developed by Foot (2001), Hursthouse (1999) and Woodruff (2001), and their school of contemporary ethicists, is that morality describes that which allows humans to flourish in community. And given the relentlessly social context of our lineage, it is vital that we generate flourishing communities.

Most organisms have no mandate to flourish in community. For most organisms, their purpose can be said to survive to produce offspring. To say that the purpose of life is to survive to produce offspring is, for some, an uninspiring and perhaps even bleak and depressing notion. For others of us, however, it is freighted with wonder and meaning. That there is life at all, that it is so poignantly purposive, is foundational to the matrix of my own religious life.

That being said, we in fact need not use such a minimalist word as 'survive'. For the mandate is not so much to survive as to flourish. An organism that manages to eke out survival and reproduction in a given ecosystem is far less likely to be the ancestor of a large lineage than an organism that flourishes and produces flourishing progeny in that ecosystem. 'Flourishing' is not a synonym for that old misunderstanding of 'fittest'. To flourish is to be well adapted to the particular environmental circumstance in which one finds oneself, to be healthy and resilient and resourceful. We can also introduce here the word 'good'. A flourishing bacterium or tree or mouse can be said to be a good bacterium or tree or mouse. A good willow maximizes the potential for willowness in all its manifestations: bark quality, disease resistance, pollen production, and so on.

So to return to morality. Most organisms, like bacteria and willows and mice, carry out their purpose – to flourish – with adaptive traits and behaviours, but their biological mandate is carried out in the context of self-interest. The project is an individual project or, in the case of sexual organisms, individuals and their genetic offspring who require some sort of nurture (seed coats, egg shells, nests, milk).

Social animals like ourselves (and unlike the social insects[1]) remain self-interested, but we also cooperate in various vital activities such as food acquisition or protection from predators. Therefore, the mandate is both to flourish as an individual and to flourish in community. A good wolf is a flourishing animal and a member of a flourishing pack; he is genetically scripted both to take care of his own needs and to cooperate with others in the hunt. A good schooling fish participates in schooling; a good bird joins others in chasing off the circling hawk. In flourishing social lineages, adaptive genetic scripts navigate the tensions between self-interest and group cooperation.

Genetic scripts can specify 'instinctive' behaviours, such as schooling, but they can also specify the capacity to *learn* adaptive behaviours. That is, the evolutionary process does not 'care' whether behaviour is hardwired or learned; it only 'cares' about an adaptive outcome. For primates, whose brains undergo profound transitions from immaturity to maturity, much of what is inherited is in the form of capacities. Of interest to us here are capacities for morality, capacities that, when cultivated, allow the individual to flourish in community. These capacities are cultivated in the context of learning, that is, in the context of culture, and religious traditions have served as important cultural venues for moral education throughout human history.

The human who cultivates his or her moral capacities can be said to be a good human. But it is of course not that simple. Always lurking in the wings of our nature are what we can call moral susceptibilities, susceptibilities that emanate from the robust self-interest that we also bring to the project of being alive.

Here I will briefly consider six moral capacities that undergird our ability to flourish in human community, namely: strategic reciprocity, humaneness, fair-mindedness, courage, reverence and mindfulness. I will argue that these have arisen during our evolutionary history and have acquired vast additional import and complexity in the context of our human mentality, a mentality that allows us to engage in symbolic language and hence to formulate abstractions. These moral capacities stand in tension with our susceptibilities to greed, hubris, self-absorption, fearfulness, xenophobia, and prejudice, behaviours that overwhelm us in the face of prolonged stress when we hunker down and engage not in community but in self-interested survival patterns, the default behaviour of all creatures.

STRATEGIC RECIPROCITY

We can begin with the capacity for strategic reciprocity, which is a salient behaviour in social primates and also, curiously, in vampire bats, but undescribed in other social animals. Strategic reciprocity, also known as reciprocal altruism, refers to behaviour that we can summarize as ‘I’ll scratch your back if you scratch mine’. Self-interest remains paramount – my back will be scratched, my coat will be groomed, my status in the social hierarchy will be protected – and in exchange I will groom you and form an alliance to protect your social status. The cultivation of strategic reciprocity entails elaborate acts of cognition – I must remember who reciprocates and who cheats or defects, I must burnish my reputation for being a cooperator, and so on – and humans are astoundingly good at it. Our economic, political and legal systems are heavily grounded in strategic reciprocity, and it is of vast importance in structuring communities that flourish. But in the end, strategic reciprocity is a game, a calculus, and indeed computers can be programmed to be astoundingly good at it as well. After we finish teaching our children that they should be good at strategic reciprocity if they are to flourish in community, it feels like we still have much left to say to them about morality.

THE VIRTUES

So we can next turn to four moral capacities which, when cultivated, acquire the status we often call virtues. Two of these we can designate as pro-social or valenced virtues in the sense that their cultivation assures the flourishing of community. The first is humaneness, which generates such responses as compassion, agape, benevolence and charity, and the second is fair-mindedness, which generates such responses as justice, honesty and trustworthiness. Primatologists have documented manifestations of these traits in non-human primates, who are observed to engage in consolation, in reconciliation, and in affection for one another and for one another's offspring. I also find most attractive the thesis, argued by Geoffrey Miller in his book *The Mating Mind* (2000) that just as we favour humaneness and fair-mindedness in our choice of mates, so did both capacities come to be reinforced by sexual selection during the 5 million years of hominid evolution. Importantly, our ability to form abstract concepts, which develops with maturation and education, allows us to enlarge these capacities such that we come to extend humaneness and fair-mindedness to other human groups, thereby tempering our susceptibility to xenophobia, and then as well to other species, to ecosystems, to the planet itself. We come to care about suffering and injustice in all its manifestations. There are no more promising antidotes than these for our susceptibilities to greed and hubris.

The other two cardinal virtues – courage and reverence – are more complicated. First let's consider what they are.

When we speak of courage, as opposed to reflexive acts of self-defence or defence of kin, we are speaking of the capacity to hold a large idea, a large passion, as being more important than one's own safety. So – the mountain climber is courageous because conquering the mountain trumps her fear of falling; Martin Luther was courageous because his religious conviction trumped his fear of papal authority. Courage, I believe, is essential to human creativity: the passion to break new ground, solve a problem, write a poem, is fuelled by courage and defeated by fearfulness.

When we speak of reverence, which is celebrated in a new book of that title by philosopher Paul Woodruff (2001), we are speaking of the capacity to carry the sense that there are entities larger than the human being, and hence larger than the self, to which one accords awe and gratitude and to which one develops obligation and commitment. Theistic persons traditionally offer reverence towards a supernatural deity or deities, whereas the non-theistic religious naturalist locates reverence in the natural world, the material world, in all its wondrous manifestations and evolutionary history. We speak of reverent family life, reverent leadership, reverent community. Reverence, in whatever context, endows us with humility and hence defeats our susceptibility to self-absorption.

The reason that courage and reverence are complicated virtues is that they are inherently neutral, inherently unvalenced. Courage can be displayed in the name of any ideal, and reverence can be held for any ideal, as we so tragically witnessed on 11 September, 2001. Courage and reverence can make bounteous contributions to the flourishing of community, but they can also sabotage community and hijack the good.

This dilemma brings me to the final moral capacity on my list, the capacity for mindfulness.

MINDFULNESS

Mindfulness represents the human capacity to take in understandings of reality without the distortions introduced by need, bias and prejudice. Rigidity, dogmatism and fundamentalism are antonyms to mindfulness – mindfulness is constantly evolving, ready for surprise.

Wisdom and knowledge are entailed by mindfulness, but mindfulness demands more of us. It is knowledge or wisdom that pulls the mind-and-heart of the knower towards a connection with the way things are in all their exciting particularity. You cannot be mindful and know things in a purely academic way; as you become mindful of something, your feelings and your behaviour towards it are transformed.

Mindfulness is a central concept in Buddhism, where it is lifted up both as a mental state and as a practice. The mindful person, Buddhism tells us, assumes the attitude of pure observation, freed from all false views, and apprehends a reality that is not only objective but also becomes subjective. The mindful person really, really sees.

Mindfulness is also described as a path, a work in progress, rather than an endpoint or achievement. This is because the mindful person is prepared to perceive each particular situation in its uniqueness and respond to it appropriately.

In the broadest and deepest sense, the 'naturalism' part of religious naturalism is all about mindfulness. Scientists, trained in a particular kind of 'pure observation', have provisioned us with stunning understandings of the natural world, and these understandings then provision the religious naturalist with countless substrates for mindful apprehension. So, for example, mindfulness of the body is no longer just about breathing and walking as in the original Buddhist practice; we are now able to contemplate as well the molecular and genetic underpinnings of the body and its evolution from simpler forms.

The religious naturalist is called to be mindful of the following understandings from biology:

- mindful of our place in the scheme of things;
- mindful that life evolved, that humans are primates;
- mindful of the dynamics of molecular life and its emergent properties;
- mindful of the fragility of life and its ecosystems;
- mindful that life and the planet are wildly improbable;
- mindful that all of life is interconnected;
- mindful of the uniqueness of each creature;
- mindful of future generations.

And from psychology and anthropology:

- mindful that our thoughts and feelings are neural;
- mindful of the evolutionary continuity between our minds and other animals' minds;

- mindful of human diversity, including diversity of temperament;
- mindful of human creativity and its wondrous manifestations;
- mindful of the influence of ethnic and family roots and tribal connection;
- mindful that children best flourish when loved and nurtured;
- mindful of the human need for personal wholeness and social coherence.

Similar lists can be drawn from the physical sciences and the earth sciences, from cultural history and imaginative literature, and so on. All such lists are expected to be incomplete and open-ended. They are offered to remind us of what is at stake.

And now, a central claim. I would suggest that virtues, and particularly the neutral virtues, will generate flourishing communities only to the extent that they are mindful virtues. Mindfulness is a precondition for virtue and hence for morality, or, rather, the cultivation of mindfulness and the cultivation of virtue must go together as an essential collaboration if we are to attain moral maturity. The attacks of 11 September 2001 may have been executed in the name of reverence and courage, but it was neither mindful reverence nor mindful courage.

MORAL SUSCEPTIBILITIES

We can conclude by circling back to our moral susceptibilities. How do we go about stacking the decks of our psyches, and our children's psyches, so that mindfulness trumps fundamentalism, mindful courage trumps fearfulness, humaneness trumps hubris and xenophobia, fair-mindedness trumps greed, and mindful reverence trumps self-absorption?

One way to stack the deck is through mindful moral education. From my perspective, this is robustly feasible in the context of religious naturalism. Nor is the project defeated by the naturalistic fallacy: our 'Is' is that we are social animals; our 'Ought' is that we be good social animals. Importantly, religious naturalists are not constrained to describing and celebrating moral concepts in the context of evolutionary biology alone. The moral capacities and susceptibilities of which I speak are, needless to say, embedded in the stories and rituals of all the major traditions – indeed, their universality is yet another testimonial to their centrality to human nature – and there are many ways to convey the rich meanings of these traditions to ourselves and our children in naturalistic contexts.

A second way to stack the deck, obviously, is to ameliorate the conditions wherein humans are physically or emotionally impoverished, threatened, defeated, abused, humiliated, lonely and insecure. Such conditions of prolonged stress induce us to hunker down and render us vulnerable to fundamentalisms that promise deliverance.

HOPE

Hope is another one of those complicated human capacities, complicated in that it can so often be elicited by false promise. But mindful hope, if we can speak of such a thing, is perhaps what we most need in these times of ours.

NOTES

1 The wasps and ants are an informative exception. An ant colony can be analogized to a multicellular organism, such as a human, where individual worker ants are, to a first approximation, the equivalent of individual somatic cells. The ants, and the cells, are genetically identical and individually sterile; their mandate is to cooperate in ensuring the viability and reproductive success of the queen/germ line. A self-interested cell in a human, focused only on its own replication, might generate a malignancy, but not another human. A human has far more tenuous obligations to cooperate with other humans in her/his community than a cell (or ant) to cooperate with other cells (ants): human self-interest has not been discarded in the name of sociality.

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Chapter 4

Across the Apocalypse on Horseback: Biodiversity Loss and the Law

Jim Chen

I looked, and there was a pale green horse. Its rider was named Death, and Hades accompanied him. They were given authority over a quarter of the earth, to kill with sword, famine, and plague, and by means of the beasts of the earth.

Revelations 6:8 (New American Bible)

HEARING THE HOOVES OF THE ECOLOGICAL APOCALYPSE

Life on Earth overcomes mass extinction events on a temporal scale spanning millions of years. By this measure, 'the loss of genetic and species diversity' is probably the contemporary crisis 'our descendants [will] most regret' and 'are least likely to forgive' (Wilson, 1981). Biodiversity loss is the 'scientific problem of great[est] immediate importance for humanity' (Wilson, 1992, p254). If indeed biodiversity loss has reached apocalyptic proportions, it is fitting to describe the engines of extinction in equine terms. Jared Diamond characterizes the deadly horsemen of the ecological apocalypse as an 'Evil Quartet': habitat destruction, overkill, introduced species and secondary extinctions (Diamond, 1984; 1989a, pp39–41). Edward Wilson prefers an acronym derived from the Greek word for horse: HIPPO represents Habitat destruction, Invasive species, Pollution, Population and Overharvesting (Wilson, 2002, pp50–51). Although conservation biologists have identified the leading causes of biodiversity loss, legal responses to the crisis do not address distinct sources of human influence on evolutionary change. Not surprisingly, legal scholarship tends not to pay close attention to the distinctions among causes of biodiversity loss. This article takes a modest step toward remedying at least the latter shortcoming.

Such 'environmental and land-use ethics' as are 'codified in law' today stem from an 'era when the human population, at one-tenth its present size, tamed wilderness with ox and axe' (Tilman, 2000, p210). Before the rise of Neolithic agriculture and the spread of sedentary human settlements, Wilson's deadly HIPPO took the reverse sequence: OPPIH. The transmogrification of OPPIH to HIPPO over time frames the human impact on evolution in historical as well as biological terms. In Paleolithic times, the overharvesting of large mammals and flightless birds had a greater ecological impact than what was then 'a still proportionately small amount of habitat destruction' (Wilson, 2002, p50). In North America, for instance, the sudden disappearance of large mammals such as mammoths and ground sloths 11,000 to 12,000 years ago, after the continent's megafauna had survived 22 glacial cycles, strongly suggests that this mass extinction was attributable to 'blitzkrieg' (Diamond, 1989b). The settlement of Polynesia, beginning 3500 to 3000 years before the present, introduced three domesticated species of Eurasian provenance – pigs, dogs and chickens – that simultaneously dictated the arc of economic development on each island and spelled doom for many of the islands' endemic species (Diamond, 1997, p60). Today, 'the principal cause of biodiversity loss is the fragmentation, degradation, and destruction of ecosystems and habitats through conversion of land to economically productive uses, especially agriculture, forestry, mineral and fossil fuel extraction, and urban development' (Karkkainen, 1997, p7).

Thanks to a pair of prominent controversies over the constitutionality of endangered species protection under federal law (*Gibbs* v *Babbitt*, 214 F.3d 483 (4th Cir. 2000), cert. denied, 531 U.S. 1145 (2001); *National Ass'n of Home Builders v Babbitt*, 130 F.3d 1041, 1053 (D.C. Cir. 1997), cert. denied, 524 U.S. 937 (1998)), most jurists and legal scholars understand, at a minimum, the utilitarian rationales for protecting biodiversity (Klein, 2003; Mank, 2002; Nagle, 1998; White, 2000). The law fails, however, to calibrate its remedies according to the severity of the biological threat. Perversely enough, the legal understanding of extinction mechanisms remains frozen in time, like an insect in amber or a cave dweller in ice. The legal enterprise of preventing extinctions should address the most powerful causes of biodiversity loss today. Habitat destruction and alien invasive species should figure more prominently than overkill in the law of biodiversity protection.

The few laws that do respond to biodiversity loss, however, take primary aim at overkill and the marketing of products derived from endangered species. The law seeks to preserve biodiversity by deterring overkill, habitat destruction and the introduction of alien invasive species. The law imposes its clearest and harshest sanctions precisely where the drivers of extinction are weakest: when humans take conscious steps to capture or kill other living things for human gain. The lack of congruence with conservation biology impedes legal efforts to preserve biodiversity.

HORSE-WHIPPED: LEGAL RESPONSES TO VECTORS OF BIODIVERSITY LOSS

Overkill

The Edwardian excess of Joseph Conrad's *Heart of Darkness* retains its firm grip on the conservationist imagination (Conrad, 1902). The 1916 treaty at issue in *Missouri* v *Holland*, 252 U.S. 416 (1920), perhaps one of the first legal enactments in the US (or anywhere else in the world) to treat biodiversity conservation as 'a national interest of very nearly the first magnitude' (ibid. at 435), focused exclusively on 'the killing, capturing or selling ... of ... migratory birds' (ibid. at 431). The paradigmatic act of converting wildlife to personal property through capture and slaughter (e.g. *Pierson* v *Post*, 3 Cairns Rep. 175, 2 Am. Dec. 264 (N.Y. Sup. Ct. 1805); *Liesner* v *Wanie*, 145 N.W. 374 (Wis. 1914); *Young* v *Hichens*, 115 Eng. Rep. 228, 230 (Q.B. 1844)) remains the central focus of laws designed to protect endangered species. In the US, section 9 of the Endangered Species Act of 1973 (ESA), 16 U.S.C. §§1533–1544 (2000), flatly prohibits the 'tak[ing]' of any protected species' (ibid. §1538). 'The term "take" in turn means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct' (ibid. §1532(18)). Section 9 so unequivocally condemns the harvesting of protected organisms that few litigated ESA cases discuss this aspect of the statute (but see *United States* v *McKittrick*, 142 F.3d 1170 (9th Cir. 1998) (upholding ESA penalties levied against a rancher who shot and decapitated a gray wolf), cert. denied, 525 U.S. 1072 (1999)).

The ESA reveals an overt bias in favour of preventing direct takings of large, charismatic fauna over all other threats to biodiversity. The Act excludes certain insects from its protective aegis (ibid. §1532(6) (excluding from '[t]he term "endangered species" ... a species of the Class *Insecta* determined ... to constitute a pest whose protection ... would present an overwhelming and overriding risk to man')), even though insects are so essential to human welfare that if they 'and other land-dwelling arthropods ... were to disappear, humanity probably could not last more than a few months' (Wilson, 1992, p133). Moreover, even though '[t]he biological differences between animals and plants ... offer no scientific reason for lesser protection of plants' (National Research Council, 1995, p90), the Act significantly undervalues plants (Zellmer and Johnson, 2002, pp481–482). Threatened and endangered plants are protected only insofar as they appear on federal land or are destroyed in knowing violation of state law (16 U.S.C. §1538(a)(2)(B) (2000)). Plants receive far fewer critical habitat designations than do threatened and endangered animals. See Conservation Council for *Hawaii* v *Babbitt*, 2 F. Supp. 2d 1280, 1281 (D. Haw. 1998) (noting that critical habitat designations covered only 24 of approximately 700 plant species listed in 1998). In so doing, the ESA perpetuates rather than corrects the common law's baneful practice of treating plants as private property merely by virtue of dwelling on private land (Rolston, 1990, p293).

Traffic in goods derived from endangered species remains the single act of biodiversity destruction on which international law has reached a punitive consensus. The Convention on International Trade in Endangered Species (CITES) (27 U.S.T. 1087 (1973)), entered into force 1 July 1975, would represent a major step toward conserving biodiversity, as long as one is willing to overlook the fact that it does not work. The extension of CITES during the 1980s to 'all aspects of trade and research' in orchids 'immediately increased the desire for the plants, raised their market value dramatically, and led to even more collecting of rare orchid species from the wild' (Hansen, 2000, p67). Nothing in CITES stops developers and farmers who would 'flood [critical] habitat with a hydroelectric dam, log it, level the hillsides of a road, build a golf course on the site, or burn the jungle to the ground for agricultural purposes' (Hansen, 2000, p17). Not surprisingly, 'no reliable data [show] that CITES and similar efforts ha[ve] reduced smuggling, saved any orchid species from extinction, helped protect orchid habitats, or even salvaged orchid plants facing ... certain destruction' (Hansen, 2000, pp262–263). Controlled harvests for profit outperform direct regulation under CITES in deterring the poaching of elephants (Barbier et al, 1990, pp132–138; Cairncross, 1992, pp132–141; Glennon, 1990). As with the American alligator (Krieps, 1996, pp479–480), the elephant's salvation may lie in commercialization (see *Gibbs* v *Babbitt*, 214 F.3d 483, 495 (4th Cir. 2000) – crediting the successful recovery of the American alligator from the US's endangered species list to a contemporary market for its hides – cert. denied, 531 U.S. 1145 (2001)). The focus on politically visible but environmentally secondary acts of overkill and commercial exploitation has rendered CITES tragically impotent.

Alien invasive species

In an increasingly interconnected world (Foin et al, 1998, pp180–181; Wilcove et al, 1998, pp608–609), human ecological mismanagement often takes the form of introducing an invasive species (Cohen and Carlton, 1998; Cox, 1999; Lodge, 1993; Williamson, 1996; Williamson and Fitter, 1996). '[M]ost invasions have a weak impact', but on occasion 'an invasive species [is] capable of precipitating monumental changes to an ecosystem' (McCann, 2000, p232). For example, introducing the Nile perch into Lake Victoria devastated endemic cichlids (Goldschmidt, 1996; Reinthal and Kling, 1994). Exotics have suppressed or eliminated native, often endemic, species in the Everglades, the Great Lakes, the Hawaiian Islands and Guam (Devine, 1998; Savidge, 1987; Williamson, 1996, pp77, 142–143, 145–148). Starlings, a scourge to many native birds, entered North America by virtue of Eugene Schiffelin's perverse obsession to import all birds mentioned by Shakespeare (Dillard, 1974, pp37–39). Barnacles, mollusks, worms and hydroids leaving warmer seas on a flotilla of wooden fragments and buoyant pumice threaten the integrity of Arctic and Antarctic waters (Barnes, 2002).

As overall biological diversity decreases, the environmental impact of invasive species will probably increase. If 'simplified communities are more vulnerable to invasion', then 'we should also expect an increase in frequency of successful invaders as well as an increase in their impact' (McCann, 2000, p233). Repeated cycles of extirpation and invasion, intentional or inadvertent, 'can, and eventually will, invoke major shifts in community structure and dynamics' (McCann, 2000, p233). In this game of ecological roulette, the disturbances with the 'greatest ecological impact frequently incur high societal costs' (Chapin et al, 2000, p239).

Existing law offers few, if any, responses to invasive species. Laws targeting the animal and plant pests (Animal and Plant Health Inspection Act, 7 U.S.C. §§150aa–150jj (2000); Plant Quarantine Act, ibid. §§151–167; 7 C.F.R. parts 319, 340) do enable the Department of Agriculture to constrict the movement of organisms known or suspected to have an adverse effect on agriculture, 7 C.F.R. part 340. Such laws, however, serve more to regulate the proposed releases of genetically modified crops than to provide broad-based authority to restrain the diffusion of invasive species. For example, the Department of Agriculture declined in 1994 to restrict genetically engineered laurate canola varieties containing 'sequences . . derived from the plant pathogens *A. tumefaciens* and cauliflower mosaic virus' once the department determined that these plants were no likelier than comparable, traditionally bred varieties to become weeds, to confer weedy characteristics on canola's wild relatives, or to harm agriculturally beneficial organisms 'such as bees or earthworms' (Availability of Determination of Nonregulated Status for Genetically Engineered Canola, 59 Fed. Reg. 55,250, 55,250–51 (4 November, 1994)).

The National Environmental Policy Act of 1970 (NEPA), 42 U.S.C. §§4321-4370d (2000) – a statute whose 'procedural requirements ... are analogous' to those of the ESA, *Thomas* v *Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) – provides a somewhat broader platform for legal intervention. Consider, for example, the environmental issues raised by the construction and decommissioning of dams (Klein, 2001; McCully, 1996). One federal court of appeals has used NEPA to require a federal agency to address how dam construction could introduce zebra mussels into previously uninfested waters (*Hughes River Watershed Conservancy* v *Glickman*, 81 F.3d 437, 445 (4th Cir. 1996)). More typically, however, NEPA proves impotent to curb invasions. Rejecting arguments that airport expansion could dramatically increase the rate at which commercial flights would introduce alien species into Maui, the Ninth Circuit declined to find a NEPA violation (National Parks & Conservation Ass'n v. U.S. Dep't of Transp., 222 F.3d 677 (9th Cir. 2000)). That court took refuge in the vagaries of airport demand projections, the multiplicity of invasion vectors, and the impossibility of determining *ex ante*, which species would become established and, among those, which would become 'economic pests' (ibid. at 680–681).

No single country can contain the menace posed by alien invasive species (Wade, 1995). Within the inherently global project of biodiversity conservation, any hope of addressing the scourge of alien invasive species demands especially vigorous international cooperation (Glowka, 2000, pp333–349). The CBD exhorts its contracting parties, 'as far as possible and as appropriate' to '[p]revent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species' (C BD, art. 8(h), 31 I.L.M. 818 (1992)). The US's persistent refusal to sign the Convention, however, effectively short-circuits international law's potential to spur domestic legal change (Blomquist, 2002).

Habitat destruction

Among the drivers of biodiversity loss, habitat destruction is by far the deadliest (Ehrlich, 1988; Matson et al, 1997). Contracting the physical range of endangered species spurs their extinction (Channell and Lomolino, 2000; Lawton, 1995; Wilcox and Murphy, 1985). An admittedly contestable assessment of the problem characterizes '[h]abitat alteration and incompatible land use' as larger threats than overcollecting, global climate change and sea-level rise (Morse, 1995, p208). Island biogeography posits that a 90 per cent reduction in the area of a biological island – which may consist of an island in the geographic sense or merely an isolated patch of wildlife habitat – dictates a 50 per cent reduction in biological carrying capacity as measured by the number of distinct species that can be sustained (MacArthur and Wilson, 1967; Simberloff, 1976; Whitehead and Jones, 1969). An area as large and diverse as Centinela, a diverse forest ridge in Ecuador, can fall victim to cacao cultivation (Dodson and Gentry, 1991; Wilson, 1992, p243). Destroying large chunks of the Earth's physical infrastructure within a temporal frame that by geological standards is effectively instantaneous significantly accelerates the rate of evolutionary change attributable to human activity.

Private land

The prohibition against the 'tak[ing]' of any species protected by the ESA' (16 U.S.C. §1538 (2000)), has been interpreted to extend to the destroying or significantly modifying critical habitat (50 C.F.R. §17.3; *Babbitt* v *Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687 (1995)). The Supreme Court's first ESA decision reflected the Justices' understanding of the potential of habitat destruction to disrupt breeding and eliminate indispensable food sources (*TVA* v *Hill*, 437 U.S. 153, 162, 166 n.16 (1978)). As the example of orchids illustrates, however, similar sophistication has not migrated from American law to the international sphere.

The use of section 9 against habitat destruction triggers other provisions of the ESA. Section 10, 16 U.S.C. §1539(a) (2000) authorizes incidental take permits upon submission and approval of a habitat conservation plan (HCP) (Harding et al, 2001). In turn, approval of an HCP triggers the federal government's obligation under section 7 to 'insure that any action' it undertakes 'is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification' of critical habitat (ibid. §1536(a)(2); see also 50 C.F.R. §402.01(b); *Friends of Endangered Species, Inc.* v *Jantzen*, 760 F.2d 976, 984–985 (9th Cir. 1985); *National Wildlife Found.* v *Babbitt*, 128 F. Supp. 2d 1274, 1286 (E.D. Cal. 2000)). This provision has been interpreted as imposing an affirmative obligation to pursue an active species conservation policy (Ruhl, 1995, p1137; *Carson-Truckee Water Conservancy Dist.* v *Clark*, 741 F.2d 257, 262 (9th Cir. 1984); *Florida Key Deer* v *Stickney*, 864 F. Supp. 1222, 1237–1238 (S.D. Fla. 1994)).

Before HCPs became a familiar fixture of ESA enforcement, developers and farmers facing potential section 9 liability often resorted to the 'scorched earth' technique of preemptively clearing wildlife habitat (Bean, 2002, p415; Coggins and

Harris, 1987, p287). Clinton-era enforcement transformed 'the previously obscure and rarely used permit provision' of section 10 into 'the centerpiece of endangered species and ecosystem conservation policy' (Karkkainen, 2003, p970). Threatened section 9 liability became merely 'the opening gambit in a prolonged bargaining process' (Farber, 1997, pp316–317). Within environmental law as a process of public-sector negotiation among interested groups (Dana, 2000), HCPs today represent 'perhaps the most visible example of a consensus-based, multi-stakeholder approach to resource management' (Freeman, 2000, p194).

The strategy has its limits. Like the ESA as a whole, HCPs proceed species by species, and only after an individual species has begun to decline. Despite well-founded doubts about the territorial and institutional suitability of states as participants in ecosystem management (Karkkainen, 2002, p216), state law restrictions on land use can enhance the effectiveness of federal HCPs (Ebbin, 1997, pp696–697; Tarlock, 1995). California's Natural Communities Conservation Act, Cal. Fish & Game Code §2800–2840 (Gaffin, 1997), facilitates natural community conservation plans that provide 'large-scale, multispecies equivalents of HCPs' (Tarlock, 2002, p10,539). That state's active intervention is crucial because it is home to the California floristic province, the hottest of biological 'hotspots' in the continental US (Calsbeek et al, 2003). Ultimately, however, the ESA only indirectly addresses habitat loss and altogether ignores 'other causes' of biodiversity loss 'such as the invasion of exotic species and air and water pollution' (Tarlock, 2002, p10,537). The Act as a whole falls far short of 'promot[ing] the conservation of ecosystems on the geographic scale necessary to promote biodiversity generally' (Tarlock, 2002, p10,540).

Public land

Although '[t]he Endangered Species Act of 1973 was motivated in part by the need to [regulate] beyond the limited confines of federal land' (*Gibbs* v *Babbitt*, 214 F.3d 483, 494 (4th Cir. 2000), cert. denied, 531 U.S. 1145 (2001)), a significant degree of habitat conservation takes place under the aegis of public land management. The law of public lands rests on the primary premise of 'multiple use' defined as a range of uses 'including, but not limited to, recreation, range, timber, minerals, watershed, wildlife and fish, and natural scenic, scientific and historical values' (43 U.S.C. §1702(c) (2000); see also ibid. §1701(a)(7) (directing that 'management [of public land] be on the basis of multiple use and sustained yield unless otherwise specified by law')). Because '[m]ultiple use posits that all uses from commodity extraction and production to biodiversity are equal', this principle 'both supports and hinders biodiversity conservation' (Tarlock, 2002, pp10,540–10,541).

When it first appeared, the concept of 'multiple use' represented a substantial improvement in federal land management policy (Donahue, 1999). '[I]ncreased competition for forage' among cattle and sheep ranchers during the nineteenth and early twentieth centuries 'led ... to overgrazing, diminished profits, and open hostility among forage competitors' (*Public Lands Council* v *Babbitt*, 529 U.S. 728, 732 (2000)). The Federal Land Policy and Management Act of 1976 (FLPMA), Pub. L. No. 94-579, 90 Stat. 2744, explicitly adopted two statutory principles: 'multiple use' for recreation, range, timber, mineral extraction, wildlife and fish habitat, and natural, scenic, scientific and historical uses (43 U.S.C. §1702(c) (2000)), and 'sustained yield' of renewable resources (ibid. §1702(h)). At the same time, FLPMA retained 'first priority' for existing grazing permitholders as long as federal land-use planning continued to leave land 'available for domestic livestock grazing' (ibid. §1752(c)).

Although a statutory commitment to multiple use may theoretically 'provide[] the legal foundation for a management decision to preserve biodiversity' (Tarlock, 2002, p10,541), disputes over federal land management expose a bias favouring commercialization over conservation. For example, the state of Idaho has argued that the reservation of water for a wildlife refuge would unfairly 'subordinate' rights to 'water intended to be stored and regulated by colossal federal projects for the past 98 years' for the primary purpose of '[r]eclamation' (*United States* v *State*, 23 P.3d 117, 128 (Idaho 2001)). When the Interior Department tried in 1995 to 'accelerate restoration' of rangelands by making its managerial approach 'more compatible with ecosystem management' (Grazing Adm'n – Exclusive of Alaska, 60 Fed. Reg. 9894, 9900–06 (22 February, 1995)), incumbent ranchers responded that the Interior Department was legally obliged to 'safeguard[]' livestock interests' reliance on the perpetuation of grazing privileges (*Public Lands Council* v *Babbitt*, 529 U.S. 728, 741 (2000)). This argument ran squarely against an explicit statutory proviso that neither 'the creation of a grazing district [n]or the issuance of a permit ... shall ... create any right, title, interest, or estate in or to the lands' (43 U.S.C. §315b (2000); *Public Lands Council*, 529 U.S. pp741–742).

Other decisions have demonstrated the willingness of federal land management agencies to favour grazing and other historically privileged land uses. A federal district court was forced to remind federal land managers in 1985 that grazing '[p]ermittees must be kept under a sufficiently real threat of cancellation or modification in order to adequately protect the public lands from overgrazing or other forms of mismanagement' (*Natural Resources Defense Council, Inc.* v *Hodel*, 618 F. Supp. 848, 871 (E.D. Cal. 1985)). In spite of its statutory mandate to maintain 'final control and decisionmaking authority over livestock grazing practices on the public lands', the federal government had all but ceded jurisdiction over grazing permits (43 U.S.C. §§1901–1908 (2000); *NRDC* v *Hodel*, 618 F. Supp. at 871).

On the whole, federal land management policy concentrates its habitat preservation efforts on tracts designated as 'wilderness'. 'A wilderness, in contrast with those areas where man and his own works dominate the landscape, is ... an area where the earth and its community of life are untrammeled by man, where man himself is a visitor who does not remain' (16 U.S.C. §1131(c) (2000)). In similar fashion, 'the explicit "protect and enhance" language of' the Wild and Scenic Rivers Act 'requires that watersheds be maintained in a primitive condition and the waters kept unpolluted' (*Oregon Natural Desert Ass'n* v *Singleton*, 47 F. Supp. 2d 1182, 1192 (D. Or. 1998)). Unlike other public lands, wilderness areas fulfil their function solely by virtue of remaining 'in their natural condition' (16 U.S.C. §1131(a) (2000)). Wilderness preservation helps ensure 'that an increasing population, accompanied by expanding settlement and growing mechanization, does not occupy and modify' the entire physical surface of the Earth (ibid.).

Cold and high-elevation wilderness areas, however, cannot anchor a comprehensive and effective biodiversity programme (Adams, 2000; Tarlock, 2002, p10,542). Biodiverse 'hot spots', rich in species, typically live up to their name: most such locales lie in the tropics (Kunich, 2001, pp1157–1158; Myers, 1988, 1990). The National Park Service – which is directed to 'conserve the scenery and the natural and historic objects and the wild life' in the most spectacular federal lands (16 U.S.C. §1 (2000); *National Park and Conservation Ass'n* v *Stanton*, 54 F. Supp. 2d 7, 17 (D.D.C. 1999)) – was designed to preserve geological wonders, not to serve broader ecological purposes (Sellars, 1997, pp2–3). Wilderness policy, in microcosm, reveals the weakness of the overall legal response to biodiversity loss. Laws designed to prevent biodiversity loss have perversely aimed the power of the state precisely where the human contribution to extinction is weakest.

A MODEST AGENDA FOR FORESTALLING APOCALYPSE NOW

The law has failed to keep pace with the scientific understanding of biodiversity loss. Advances in the field of conservation biology have had little or no legal impact. Federal courts routinely decline to treat innovations in conservation biology as 'a necessary element of diversity analysis' (*Sierra Club* v *Marita*, 46 F.3d 606, 620 (7th Cir. 1995)). In a case assaulting the government's failure to consider 'population dynamics, species turnover, patch size, recolonization problems, fragmentation problems, edge effects, and island biogeography' (ibid., p618), the Seventh Circuit ultimately held that these concepts of conservation biology were 'uncertain in application' and that the Forest Service could therefore ignore them in managing national forests (ibid., p621). Even a valid 'general theory', the court held, 'does not translate into a management tool unless one can apply it to a concrete situation' (ibid., p623).

A federal district court similarly declined to endorse specific techniques for managing 'distinct geographic ecosystems ... inhabited by grizzly bears' (*Fund for Animals* v *Babbitt*, 903 F. Supp. 96, 106 (D.D.C. 1995)). That court seemed to treat complexity as a legal excuse in its own right. The possibility that 'science or circumstances [might] ... change[]', the court reasoned, relieved the agency of any obligation to prepare an 'exhaustively detailed recovery plan' (ibid., p107). As a result, the court rejected a claim that the Endangered Species Act required 'linkage zones between ecosystems inhabited by grizzlies' (ibid., pp109–110).

Cases in this vein suggest that conservation biology, until further notice, will not govern US environmental law until federal land management agencies and the agencies charged with implementing the ESA decide that it does. In the meanwhile, federal judges take frequent refuge in the maxim that 'a reviewing court must generally be at its most deferential' when an agency 'is making predictions, within its area of special expertise, at the frontiers of science' (*Baltimore Gas & Elec. Co.* v *Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983); see also, e.g. *Industrial Union Dep't* v *American Petroleum Inst.*, 448 U.S. 607, 656 (1980) (plurality opinion); ibid., pp705–706 (Marshall, J., dissenting)). Administrative and judicial passivity bode ill for biodiversity conservation. An even more potent driver of ecological ruin and evolutionary change lurks in global climate change, whose consequences defy description, much less prediction (Parmesan and Yohe, 2003; Root et al., 2003; Sala et al, 2000). The failure to coordinate the law with scientific knowledge threatens to consign yet another environmental crisis requiring transnational cooperation to the perdition of zero-sum politics (Carter, 2002, pp232–244; Paterson, 1996).

In the meanwhile, '[t]hose of us who love nature, and who would like to ensure that nature persists for future generations to love, need to think about saving ordinary places and ordinary things' (Doremus, 2000b, p4). Without abandoning the admittedly implausible prospect of comprehensively reconfiguring domestic and international environmental law to address habitat destruction and alien invasive species, advocates of biodiversity conservation can pursue more modest but attainable reforms. First, international policy makers should develop a joint framework for the regulation of commercial bioprospecting. International coordination on commercial exploitation of biodiversity can improve the very process of collecting rare specimens. If even casual hiking affects the distribution and population of wildlife (Ortiz, 1999, p508; cf. *Mausolf* v *Babbitt*, 125 F.3d 661, 669–670 (8th Cir. 1997) (upholding snowmobiling restrictions in Voyageurs National Park on the basis of biological opinions that showed adverse impacts on grey wolves)), purposeful bioprospecting leaves a dramatically deeper human footprint. Bioprospectors, anthropologists or journalists may even engage in deliberate misconduct (Tierney, 2000). Even though the global commons has proved notoriously hard to manage (Thompson, 2000), bitter experience teaches that the lack of coordination would be worse. The slash-and-collect approach of Victorian orchid harvesters would probably prevail (Koopowitz and Kaye, 1983, pp199–205; Orlean, 1998, pp62–67). Rationalized harvesting would limit instances of 'the wonderfully unusual accomplishment of discovering and eradicating in the same instant a new species' (Bryson, 1998, p92).

In addition, the international community should facilitate the professionalization of parataxonomy (Joyce, 1994, pp118–121), especially in the developing world. Millions of species await collection and classification by properly trained field biologists. Transnational cooperation can help translate ethnobiological knowledge into terms understood by the global scientific community. Its economic impact is simple and immediate. 'Scientific research', to put it bluntly, 'generates jobs' (*Gibbs* v *Babbitt*, 214 F.3d 483, 495 (4th Cir. 2000), cert. denied, 531 U.S. 1145 (2001)). The science of systematics is so labour-intensive that the task of classifying 10 million species would require 25,000 professional lifetimes (Wilson, 1992, pp317–319). Whether framed as cooperative bioprospecting or north-to-south technology transfer for the enrichment of parataxonomy, commercially oriented initiatives satisfies the CBD's exhortation that the international community should adopt 'economically and socially sound measures ... as incentives' to conserve biodiversity and to contribute to its sustainable development (art. 11).

Willingness to pursue a more modest agenda, however, does not weaken the need for more aggressive conservation measures. *In situ* preservation remains the only effective way to save biodiversity. The larger the tract of land set aside for conservation, the better (Karkkainen, 1997, pp10–12). Zoos, gene banks, and other *ex situ* strategies fall far short of the mark (Doremus, 2000a, pp54–57). Despite consuming a significant portion of the capital expended on conservation, *ex situ* efforts have protected a trivial amount of biodiversity (Sedjo, 1992, p201). *Ex situ* conservation cannot preserve the adaptive and evolutionary value of individual species, let alone entire ecosystems (Hamilton, 1994; Wolf, 1987, p44). By introducing criteria designed to suit human tastes and preferences, *ex situ* preservation exerts selective pressure on those species that are targeted for protection (Doremus, 1991, p284). Only *in situ* conservation can effectively preserve the 'conditions where genetic resources exist with ecosystems and natural habitats', or at least the surroundings where 'domesticated or cultivated species have developed their distinctive properties', CBD, art. 2.

Finally, the academic community bears a singularly immense responsibility to educate the public. A country whose citizens lead the developed world in rejecting the evolutionary account of natural history is hardly well equipped to reorient the primary focus of biodiversity conservation from preventing overkill to preserving habitat and slowing the flux of alien species (Chen, 2005, pp304–315). At least one member of the Supreme Court of the US has habitat preservation because it allegedly 'imposes unfairness to the point of financial ruin – not just upon the rich, but upon the simplest farmer who finds his land conscripted to national zoological use' (*Babbitt* v *Sweet Home Chapter of Communities for a Great Oregon*, 515 U.S. 687, 714 (1995) (Scalia, J., dissenting)). The same jurist even derives perverse pleasure from mocking 'the much beloved secular legend of the Monkey Trial' (*Tangipahoa Parish Bd. of Educ.* v *Freiler*, 530 U.S. 1251 (2000) (Scalia, J., dissenting from denial of cert.)), and thereby delivers rhetorical succour to the enemies of biological enlightenment. Among creation myths vying to satisfy the human need for a compelling story of origins, especially in an emotionally challenging 'age of globalization' 'none is more solid and unifying for the species than evolutionary history' (Wilson, 2002, p133). No other story of human beginnings boasts a more expansive narrative scope or enjoys greater scientific support (Christian, 1991, p235). Realigning environmental law with the scientific understanding of biodiversity loss produces its own epiphany, its own spiritually satisfying path toward detecting an 'echo of the infinite, a glimpse of its unfathomable process, a hint of the universal law' (Holmes, 1897, p478). '[I]ntense spiritual feelings' arise from the 'unfathomable complexity and ... sublime beauty' of the biosphere at its fullest and most diverse (Takacs, 1996, p255). Training the law to harness, perchance to halt, the horses of our ecological apocalypse should help us recapture the 'beauty and mystery that seized us at the beginning' (Wilson, 1998, p237).

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Chapter 5

Impact of the Convention on Biological Diversity: The Lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits

James S. Miller

Natural products discovery programmes expanded tremendously during the last two decades of the 20th century because of a series of technological advances. The ability to develop molecular bioassay targets, the introduction of mechanisms to robotically control much of the screening process, and the incorporation of information systems to analyse results have given rise to the capacity for screening very large numbers of samples in short periods of time. This coupled with concern that available biological resources will be diminished (e.g. Wilson, 1988) helped fuel tremendous interest in natural products screening in the 1980s and 1990s. Plants were the major focus of screening and numerous efforts to collect large sets of plant samples were established during this period for several reasons. Plants have always been an important source of chemical compounds useful in medicine and agriculture, they are quite diverse with more than 250,000 species (Thorne, 2002), they are easier to collect than many other groups of organisms, and they are easily cultivated to produce raw material for production.

The same time period that saw the introduction of new technology that facilitated natural products work was also an era of intense discussion and examination of national and international laws that governed ownership of and access to biological resources and the property rights that controlled how benefits that arose from this type of work were distributed. The most important of these was the Convention on Biological Diversity (CBD), which entered into force in December of 1993 with the three specified aims of conservation of biological diversity, sustainable use of its components, and fair and equitable sharing of benefits (Glowka et al, 1994).

The research community has been an active partner in many collaborative natural products discovery efforts, particularly the research groups of botanical gardens and museums that often house strong collecting programmes. These institutions conduct two types of research. Most activities at research institutions perform basic or academic research that extends knowledge, but do not seek to produce patentable products and do not expect to generate monetary benefits. Commercial research is aimed at the development of new marketable products, often through partnerships. Partnerships of governmental or corporate groups with academic institutions have been formed to look for new pharmaceutical, agricultural or nutritional products from a wide variety of organisms. Access to large numbers of species for screening is a critical component of all of these programmes and, since the mid-1980s, substantial evolution has occurred in thinking about ownership of biological resources and legal instruments to ensure equity in the distribution of benefits that arise from their development. Access to the biological resources that are the raw materials for natural products discovery is one of the primary elements addressed by the Convention.

The present chapter reviews issues associated with access to genetic resources and an equitable distribution of the resulting benefits accruing from both basic and commercial research, based on the experience of the Missouri Botanical Garden (MBG) and other members of the botanical research community. While natural products discovery efforts have been conducted with many types of organisms, this paper will discuss only examples based on plants, as the issues surrounding access are parallel with other groups of organisms. Specifically, the chapter addresses three questions:

1. What kinds of benefits may be expected to result from natural products discovery programmes?
2. Has the CBD helped to achieve a more equitable distribution of benefits?
3. What has been the impact of the CBD on international botanical research?

WHAT KINDS OF BENEFITS MAY BE EXPECTED TO RESULT FROM NATURAL PRODUCTS DISCOVERY PROGRAMMES?

One of the principal tenets of the Convention is equitable sharing of any benefits derived from the development of biological resources. In general, drug development from natural products is expensive, time consuming, and the time between the discovery and marketing of new products is often well in excess of ten years (Farnsworth, 1984). Most modern natural product discovery efforts have not had adequate time for discoveries to be developed into drugs so there are no relevant, recently developed natural products that can be examined as examples. This lack of relevant, auditable examples, compounded by the lack of a universal approach for estimating the value of access to biological resources, has led to great latitude in estimates of the value of the contribution of the raw materials to drug development. As a result, discussions of how equitably benefits have been shared have been confus-

Table 5.1 *Types of benefits that may arise from bioprospecting programmes*

Public benefits
- Positive impact on human health (Direct)
- Promotion of research (Indirect)
- Promotion of conservation (Indirect)

Long-term benefits
- Royalties (Direct)
- Milestone payments (Direct)
- Income from cultivation and supply of plant material (Direct)
- Access to developed technology (Direct)

Short-term benefits
- Up-front payments (Direct)
- Shared research opportunities (Direct & Indirect)
- Exchange and repatriation of biological data (Direct & Indirect)
- Training (Direct & Indirect)
- Institutional capacity improvement (Direct & Indirect)
- Technology transfer (Direct & Indirect)

Royalties, milestone payments, and income from cultivation and supply of plant material are monetary. All other benefits are non-monetary.

ing because of all of these issues, plus the lack of a precise definition of what benefits may conceivably arise.

Benefits may be thought of as comprising three categories: public, long term and short term, each of which may also be monetary or non-monetary and direct or indirect (Table 1). Direct benefits, which may be monetary or non-monetary, are either the primary aim of a programme or are those that accrue to participants in the research programmes, such as royalties for discoveries or opportunities to participate in research. Indirect benefits are largely those elements that arise from the infrastructure supported by discovery programmes, such as improvements in the research capacity of participating institutions, where equipment provided to directly support product development may also be used for educational or other research projects.

Public benefits include the direct contribution that new pharmaceutical, agricultural or nutritional products may provide by improving human health and nutrition. The benefit of new drugs affects both those directly involved with research and marketing and also the general public, which benefits from the availability of new medicines. Research and conservation efforts also benefit indirectly from the support that bioprospecting provides to the communities involved in these activities, such as the improved ability to conduct botanical inventory, using vehicles and collecting supplies, for example, as provided to the University of Ghana by a programme that supplied plant samples for pharmaceutical evaluation by the Monsanto Company.

Long-term benefits are associated with the primary goals that are central to bioprospecting (discovery, marketing) and do not generally accrue until many years into a research programme or even afterwards. The accrual of long-term benefits is usually dependent on successful discovery and product development; these benefits therefore have a low likelihood of accruing and should also be considered high risk. Long-term benefits include sharing monetary gains (e.g. milestone payments, royalties) from developed products, ensuring that the products themselves will be available and affordable to the source countries that contribute to their development, and guaranteeing that source countries will play appropriate roles in the development and manufacture of new products, ensuring another form of financial equity.

Short-term benefits are associated with the actual implementation of a research programme and are thus inherent in certain consequences of its operation. They are low risk, as it is almost certain they will be realized. Most short-term benefits are indirect, such as training and institutional capacity improvement. Short-term benefits may be monetary, as in the case of up-front payments, but perhaps more importantly they include activities that improve research capacity through institutional support, training and technology transfer, which can have a significant impact in developing countries.

Post-Convention discussions have focused more on long-term, monetary benefits, but it may be in the best immediate interest of developing countries with pressing environmental problems to leverage acceptance of a smaller share of long-term benefits that have a low probability of accruing to obtain a greater share of short-term benefits that are more certain and will have more immediate impact. Large monetary benefits, such as royalties on marketed drugs, generally accrue only after many years and the chances of receiving such benefits are small. Short-term benefits, such as improving in-country technical capacity to advise on environmental issues, may be more beneficial in the near term than pursuing the slim possibility that pharmaceutical royalties might arise in the distant future.

Access to developed medicines is of great importance in countries where health-care options are limited and the majority cannot afford the cost of drugs. This type of benefit, which is often overlooked, may have a broader positive impact for the population of a country than direct, monetary payments, which are likely to be more restricted in distribution. As an example, the United States National Cancer Institute discovered Michellamine B, a compound with potent *in-vitro* anti-HIV activity, from a sample of *Ancistrocladus korupensis* collected in Cameroon (Manfredi et al, 1991). The compound later proved too toxic to be used directly as a medicine, but had it progressed, it could have had a wide impact in a country with a serious AIDS epidemic. A drug of this sort, made available at an affordable cost in Cameroon through licensing of production technology or direct donation of the medicine, might have benefited more people than a direct monetary payment.

HAS THE CBD HELPED TO ACHIEVE A MORE EQUITABLE DISTRIBUTION OF BENEFITS FROM BOTANICAL BIOPROSPECTING?

Using the definitions for the three kinds of benefits outlined above, it is possible to examine several programmes as case studies and review how effective they have been at generating benefits as intended by the CBD. Since the Convention entered into force, a variety of mechanisms have been developed to share benefits equitably and in ways that support conservation and economic development. Achieving a successful framework for sharing benefits that arise from both basic and commercial research has, in many countries, become a prerequisite for obtaining prior informed consent and ensuring that permission to operate will be granted. There are many examples of programmes that have achieved interesting models for benefit-sharing relationships with source countries (e.g. Carlson et al, 1997; Gámez et al, 1993; King, 1994), two of which are reviewed below.

The National Cancer Institute (NCI) has been involved in natural products discovery since its inception in 1937 (Schepartz, 1976). Its formal plant-collecting programme, which began in 1960, has been conducted in two phases. The first phase ran from 1960 until 1982 (Cragg et al, 1994b), and evaluated a large number of plants from many parts of the world (Schepartz, 1976), collected largely by the US Department of Agriculture (USDA). The second phase, which began in 1986 and continues to the present (Cragg et al, 1993), has been accomplished through five-year contracts with outside organizations. The first and second five-year contract periods of the second phase (1986–1996) included contracts to obtain material from South America, Africa and Madagascar, and tropical Asia. The third and fourth periods included contracts for collections from North America, Africa and Madagascar, and tropical Asia. The NCI programme has frequently been cited as a model for appropriate mechanisms to ensure equitable distribution of a wide range of benefits with source countries (Cragg et al, 1994a). The NCI's source country agreement, originally called the Letter of Intent (LOI) and later the Letter of Collection (LOC), originated in Madagascar in 1990 (see Appendix to this chapter), a full year before the Merck-INBio agreement (Reid et al, 1994). The LOC makes provisions for a range of potential benefits, including royalties from sales of developed products, income from cultivation of plant material for production, training and direct institutional support, and transfer of technology.

The origins of several currently used anti-cancer drugs can be traced to the first phase of plant screening from 1960 to 1982, including camptothecin (Potmeisel and Pinedo, 1995) and taxol (Wall and Wani, 1994). However, the discovery and marketing of both of these drugs predate the CBD, the NCI's LOC, and the evolution of modern ideas about equitable sharing of benefits. In the 18-year history of the second phase of NCI's programme, many novel bioactive compounds have been discovered and characterized (e.g. Gustafson et al, 1992; Hallock et al, 1995), several of which show promise for development (Cragg et al, 1994b). However, to date, no drugs have been approved and marketed as a result of NCI's programme, so the complete range of benefits anticipated in the LOC remains to be fully realized.

One plant-derived compound identified during the currenct phase of the NCI's programme, calanolide A, is in human clinical trials (Cragg and Newman, 2002). This compound, originally isolated from the latex of *Calophyllum lanigerum* but semisynthetically produced from the more abundant *C. teysmanii*, shows significant activity against HIV-1. Calanolide A has been developed through Sarawak Medichem Pharmaceuticals Incorporated, a joint venture of the Sarawak State Government and Medichem Research. Terms of the partnership ensure that research related to the development of calanolide A takes place in Sarawak and helps build institutional capacity there. If calanolide A progresses successfully through clinical trials and is approved as a drug, it will be the first test of the NCI's LOC as a legal instrument for generating long-term monetary benefits, such as royalties.

To date the NCI programme has generated only limited long-term benefits, and no direct financial royalties have accrued to participating countries. However, there are numerous examples of short-term benefits that have provided very significant aid, including training of scientific personnel, direct support for improvement of research capacity and facilities in source countries, and opportunities for joint collaborative research. The NCI programme has provided opportunities for scientists from the US to partner in research with colleagues from source countries and has generated support to ensure that facilities are adequate and technology is transferred through equipment and training.

Another natural products discovery programme that has developed interesting models for access and benefit sharing is the International Cooperative Biodiversity Groups (ICBG) sponsored by the National Institutes of Health (NIH), National Science Foundation (NSF), and the Department of Agriculture (USDA) and administered by the Fogarty International Center at NIH. These programmes aim to discover novel natural products through programmes that support economic development and conservation in the developing countries where they take place. The programme began in 1993 (Rosenthal et al, 1999), so it has a shorter history than the NCI efforts and is thus probably further from developing actual drugs. However, the ICBG programme has placed substantial emphasis on providing short-term benefits. All eight ICBG projects have been built on strong partnerships with source country institutions and several have been very successful at catalysing an improvement in the science conducted within those institutions.

The NCI and ICBG programmes both demonstrate an obvious trend in bioprospecting, namely that marketable discoveries are rare and, despite screening more than 50,000 plant samples, none have yet yielded a new drug. The experience of these two programmes is consistent with other discovery efforts, all of which suggest that the realization of marketable products requires many years. Not enough time has elapsed since the CBD was ratified a decade ago to evaluate the potential of discovery programmes to deliver direct, monetary benefits such as royalties. During this period, however, most bioprospecting programmes have provided significant indirect, short-term benefits such as increased scientific cooperation, training and capacity building, which have had a tremendous impact on the capacity to conduct scientific research in source countries. While discussions on equitable distribution of benefits have focused on royalties and other long-term benefits, the examples presented here stress the importance of short-term benefits that are more immediate and have a greater likelihood of accruing.

WHAT HAS BEEN THE IMPACT OF THE CBD ON INTERNATIONAL BOTANICAL RESEARCH?

While the CBD encourages source countries to promote access to their biological resources in a regulated manner in exchange for an equitable share of the benefits, Article 15.1 states that the authority to regulate access rests with national governments and is subject to national legislation. Article 15.5 explicitly requires that prior informed consent be obtained from the party providing access to genetic resources, yet many countries have been slow to develop transparent systems for regulating access and to assign authority to regulate access to biological resources to a specific government office. The responses to this mandate have been quite varied but only a few countries – most notably Costa Rica and the Philippines (ten Kate and Laird, 1999) – have passed enabling legislation specifically intended to regulate access. Glowka (1998) asserts that the variety of national responses to implementation can be grouped into five categories (Table 5.2), but in fact a clear designation of which government office has the authority to regulate access has been difficult to determine. The CBD Secretariat has developed a guide to national focal points (www.biodiv.org/world/map.asp), which should help facilitate negotiations in the future. In the absence of a transparent system for obtaining prior informed consent, usually through a permitting process, negotiating permission to operate and a system for sharing benefits can be complex and difficult.

Another problem with current regulatory systems is that they frequently have been designed with the primary aim of controlling access to wild relatives of crop plants or landraces that may be used in plant breeding programmes or to material for use in bioprospecting efforts, the natural resources assumed to have the largest economic potential. While controlling activities with obvious commercial goals is important, regulatory systems have often not accommodated the differences between commercial and basic or academic research. As a result, the expectations placed on basic researchers are often similar to those for a commercially oriented programme. Up-front payments, expensive permit fees, and/or significant commitments to training or capacity building may be reasonable expectations of research efforts conducted by large corporate entities, but they may be prohibitive impediments for individual non-commercial researchers or small commercial programmes. Moreover, most basic research programmes now face far more complex procedures when applying for permission to collect and export the material necessary for study. The time needed

Table 5.2 *Types of biodiversity access legislation*

Type of law	*Mechanism for access*	*Example countries*
Environmental Framework laws	Designate a national authority to develop regulations for access	Kenya, Uganda
Sustainable development; nature conservation, or biodiversity laws	Detailed laws that use principle of prior informed consent to implement convention to regulate access	Costa Rica, Mexico
Dedicated laws on access to genetic resources	Laws that specifically design system for regulating access	Philippines
Modification of existing laws	Amendments to existing law to establish requirements for access	Nigeria
Regional treaties	Multilateral agreements that create a system for regulating access	Andean Pact Countries: Venezuela, Colombia, Ecuador, Peru, Bolivia

Source: Based on Glowka (1998)

to obtain approval has grown significantly longer and application fees have generally increased. These procedures discourage small research programmes, both basic and commercial, that are unable to meet financial expectations for benefit sharing, or which lack the resources necessary to complete long, complex permitting processes.

Despite the weaknesses in the regulatory mechanisms of specific countries, the CBD has been successful at catalysing methods to achieve reasonable benefits from commercial programmes for pharmaceutical discovery or crop improvement. It has become accepted practice to negotiate contracts or agreements that specify commitments and arrangements for distribution of benefits with source countries before any research begins. Thus access to genetic resources for most post-CBD commercial research programmes now requires structured plans for benefit sharing.

Another success of the CBD has been to promote a re-examination of the basic elements of scientific collaboration within the academic research community. Examples of positive elements that have been at least implicitly expected by the drafters of the Convention include research goals that more closely meet the expectations of both parties, more equitable sharing of credit for research through joint authorship, fair distribution of collected specimens, and full access to collected data. While basic research programmes should not be expected to yield large monetary benefits for source countries, their indirect contributions to development of a scientific community with greater capacity can be very significant, especially in countries where scientific expertise is inadequate.

Ten years after the CBD entered into force, it is now apparent that the initial expectations of large monetary benefits from new drugs or improved crop plants were unrealistic. Since the CBD was originally conceptualized with these elements in mind, the regulatory systems developed to date have mostly aimed to capture the kinds of benefits that were anticipated from large-scale commercial research. The resulting regulatory structure is difficult and expensive for academic researchers to penetrate as they attempt to obtain prior informed consent and permission to operate. However, this same system has also led to a very positive re-examination of collaborative research, which has fostered short-term benefits that have greatly supported the development of biological research capacity in source countries. While large monetary, long-term benefits remain an unfulfilled goal of commercial research programmes, the short-term, indirect benefits realized through the impact of the CBD have had a tremendous positive influence on the growth of science in the developing world.

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APPENDIX: HISTORY OF A LANDMARK COLLECTING AGREEMENT: THE ORIGIN OF THE NATIONAL CANCER INSTITUTE'S LETTER OF INTENT, A PRECURSOR TO MODERN BIOPROSPECTING AGREEMENTS

James S. Miller*, Rabodo Andriantsiferana, Gordon M. Cragg***, and Porter P. Lowry II***

Since the Convention on Biological Diversity was opened for signature at the United Nations Conference on Environment and Development (the 'Rio Summit') in 1992 and entered into force in November of 1993 (Glowka et al, 1994), an international effort has been made to develop appropriate mechanisms for compliance. These include ways to secure prior informed consent for access to genetic resources and provisions for sharing benefits that may result from such access, reflecting the fact that the Convention was originally drafted at least in part in response to criticism that benefits had not previously been fairly shared with developing countries.

It is now standard practice to obtain prior informed consent for commercial research programmes that access genetic resources as raw materials through agreements with source countries. While most of these agreements have been developed since the Convention entered into force, several predate it. One of these is the United States National Cancer Institute's agreement, originally called the Letter of Intent (LOI) and later the Letter of Collection (Cragg et al, 1994; Mays et al, 1997). The purpose of the present paper is to review the process by which prior informed consent was originally obtained in Madagascar, which ultimately gave rise to the first signed LOI.

In 1986, the National Cancer Institute (NCI) awarded contracts to three institutions for the collection of plant material from Latin America (the New York Botanical Garden), tropical Africa and Madagascar (the Missouri Botanical Garden – MBG), and tropical Asia (the University of Illinois, Chicago) (Cragg et al,1993). The contracts called for the collection of plant samples from several countries, and for the material to be sent to the NCI for evaluation in bioassays designed to discover new anti-cancer drugs. The MBG had been active in Madagascar for over a decade, but programmes had focused on botanical inventory in collaboration with the Parc Botanique et Zoologique de Tsimbazaza (PBZT). In 1989, the MBG approached the Centre National d'Applications et des Recherches Pharmaceutiques (CNARP), a governmental research institution in Madagascar, to seek an appropriate collabora-

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tor for expansion of its activities to include the collection of plant samples for pharmaceutical research.

Initial discussions indicated that a number of issues would have to be addressed prior to implementing a programme to collect material for the NCI. In July of 1989, the CNARP Director at the time (and the second author of this paper) visited both the National Cancer Institute and the MBG. The visit and subsequent negotiations led to the resolution of several issues, most importantly outlining the ways in which Madagascar would benefit from collaborating in the project. An agreement between the NCI and the Government of Madagascar, represented by the Ministry of Scientific Research, was signed in November of 1990, almost a full year before the highly publicized agreement between Merck and INBio, which took effect in September 1991 (Borris, 1996). The NCI-Madagascar agreement has provided the framework for a collaborative arrangement that has continued to the present time.

The NCI-Madagascar agreement addressed a number of issues that pertain to equitable sharing of the benefits that were anticipated from the NCI programme. These included a commitment from NCI to make its 'best effort' to ensure that royalties and other forms of compensation would return to Madagascar through CNARP if the programe was successful in discovering marketable products. In 1994, at the recommendation of the Sarawak State Attorney General, this clause was revised to require that the licensee of an NCI-patented invention based on a discovery from a source country organism negotiate an agreement directly with the appropriate source country government agency or organization determining the level of compensation and/or benefit sharing. The terms of the agreement also gave NCI responsibility for seeking patent protection for discoveries made from Malagasy plants. NCI agreed to screen extracts of all plants provided by CNARP and MBG from Madagascar and to share the confidential results from bioassays with CNARP. The agreement included provisions to enable CNARP and MBG to share opportunities available through the basic operation of the collecting programme. The agreement further specified that Malagasy scientists would be included as co-authors on publications to which they had made significant contributions, and provided scientists selected by CNARP with opportunities for fully funded sabbatical training visits to NCI laboratories. The NCI also agreed to give priority to Madagascar for the supply of additional plant material, whether wild-collected or cultivated, for further research, development or production.

By signing the agreement, the Government of Madagascar agreed that CNARP would collaborate with MBG in the collection of plant material for screening. They further agreed to provide confidential information on ethnobotanical uses of plants when such information was available. In addition, the Government committed to support recollection or cultivation requests that might be necessary to continue research on compounds of interest identified from Malagasy source material.

The agreement between the NCI and the Government of Madagascar was one of four bilateral agreements that defined the mechanism for collecting and screening plant samples from Madagascar under the NCI programme. The others were:

- a contract between the NCI and MBG that defined the contractual obligations for collection and provided the financial support for the programme, with a budget that included the funds needed for the training and institutional support activities stipulated in the NCI-Madagascar agreement;
- an accord between MBG and PBZT that specified their respective roles and obligations in the collection of plant materials; and
- an inter-ministerial agreement between the Ministry of Scientific Research (CNARP) and the Ministry of Higher Education (PBZT) covering their collaborative involvement in the collecting programme.

These four agreements, along with a collaborative relationship between CNARP and MBG, provided the framework for implementing the NCI programme. However, the provisions for equitable benefit sharing were specifically contained in the NCI-Madagascar agreement.

The NCI-Madagascar agreement, negotiated and signed in November 1990, appears to have been the first to contain language guaranteeing that a series of benefits, including royalties and other potential monetary benefits, would accrue to a source country in exchange for access to plant material for screening. The agreement, which pre-dated the Rio Summit by two years and the entry into force of the Convention by three years, contains most of the elements found in more recent agreements that provide access to biological resources. It thus served as an important early model for the development of standard bioprospecting practices.

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Chapter 6

Biodiversity, Botanical Institutions and Benefit sharing: Comments on the Impact of the Convention on Biological Diversity

Kate Davis

In this paper, I add my considerations to Miller's analysis (Chapter 5) of benefit-sharing and the impact of the Convention on Biological Diversity (CBD) on botanical research. However, I will focus on the benefits arising from non-commercial research in botanical institutions rather than those from natural products discovery programmes. I also reflect upon some lessons learned from ten years' experience of using agreements and establishing models for equitable benefit sharing at the Royal Botanic Gardens, Kew. Kew decided quite early on to take a proactive stance on the CBD, largely because the usefulness of Kew's global collections to science and conservation is dependent on its researchers' ability to acquire, use and exchange material legally, in line with all relevant national and international laws and best practice. The adoption of Kew's first Policy on Access to Genetic Resources and Benefit-Sharing (in 1997) was accompanied by significant changes to its research and curatorial practices, and we continue to review the policy and procedures and their effectiveness.

It is a good time to review the impact of the CBD, as several initiatives of particular significance for botanical research were adopted by the Conference of the Parties in April 2002 in The Hague. Most notably these include the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, the Global Taxonomy Initiative, and the Global Strategy on Plant Conservation (UNEP, 2002a, b, c).

TYPES OF BENEFITS SHARED

Miller presents a matrix of benefit types, distinguishing long-term, short-term and public benefits, each of which might then be indirect or direct, monetary or non-monetary. In his discussion, 'long-term' benefits refer mainly to those benefits arising after a product's successful commercial release, and so are less applicable to non-commercial research. Non-commercial botanical research (in fields such as taxonomy, genetics, physiology, anatomy, ecology, seed-banking and horticulture) has the potential to generate all of the 'short-term' benefits listed in Miller's Table 5.1, as well as the public benefits of promoting research and conservation. But I feel something is lost when applying this 'long/short' division to non-commercial botanical research. I agree with Miller's conclusion that 'short-term' benefits are often overlooked and undervalued, but want to emphasize also that many leave an important legacy, such as those involving information transfer (for example repatriation of historical specimen data and images) and technology transfer (for example sharing technical expertise and know-how on seed-banking). Training and opportunities to develop formal and informal networks of colleagues and institutions may have particular long-term effect. As an example, Kew's diploma courses for international specialists (places on which are often offered as part of a benefit-sharing package) have given rise to new in-country courses developed by former students (Hankamer et al, 2002). There is great potential for cross-links and developments between benefit types: shared research opportunities may lead to collaborative published products, such as floras and field guides, which may be in use for decades (and so arguably become a long-term benefit) and assist countries with national implementation of conservation goals (leading to public benefits). The Bonn Guidelines mention short, medium and long-term benefits when referring to commercial research, but go on to group benefits generally simply as monetary or non-monetary, and I feel this helps to demonstrate how many important shareable benefits are non-monetary and can arise from non-commercial research.

HAS THE CBD HELPED TO ACHIEVE A MORE EQUITABLE BENEFIT SHARING?

I do not doubt that botanical institutions are increasingly more aware of their responsibilities, obligations and the potential for benefits to arise from their work, and are working on the challenge of the importance of sharing them effectively. Furthermore, countries of origin and stakeholders are becoming more aware of potential opportunities.

The CBD has prompted institutions to develop a number of voluntary codes of conduct and guidelines in order to build trust with governments and partners so that they can continue to acquire and exchange material, the basis of their vital research. Benefit sharing is on the agenda, where it might not have been previously for non-commercial research in botanic gardens. For example, 28 institutions from 21 countries were involved in the Pilot Project for Botanic Gardens, which resulted in a set of 'Principles on access to genetic resources and benefit sharing' to harmonize and guide institutional policies, covering acquisition, use, curation, supply, commercialization and benefit sharing (see Latorre García et al, 2001 and www.kew.org/conservation). More recently, a number of European botanic gardens have developed a Code of Conduct, and a system, the International Plant Exchange Network (or IPEN), that enables gardens that are signatures to the Code to continue traditional non-commercial seed exchange (www.bgci.org/abs). This should prompt more gardens to consider their responsibilities and capacities to share benefits. Institutions in biodiversity-rich developing countries are also beginning to develop institutional policies, sometimes because of pressures from their governments to account for the terms under which they pass on national genetic resources (Laird and Wynberg, 2002), and this process helps to define needs and expectations.

Governments and institutions are increasingly using written agreements to set out expectations for benefit sharing for non-commercial research. These may take the form of more complex collecting permits that spell out reporting obligations (or more complex terms and conditions), or material transfer agreements (for exchanges between botanic gardens or between institutions and countries of origin), or memoranda of understanding between institutions. Kew's Millennium Seed Bank Project uses detailed access and benefit-sharing agreements as the basis for setting out prior informed consent (PIC) and mutually agreed terms for its partnerships (Cheyne, 2003). For work involving less sensitive material (e.g. dried herbarium specimens), simpler memoranda of understanding between institutions are used to clarify use and identify benefits. In a growing number of countries it may be difficult for biologists to gain permission for access without some evidence of collaboration with a local institution. Although these measures are generally recent developments, I believe institutional partnerships are invaluable for successful benefit sharing over the long term as well as the short term. They provide an opportunity to identify interested colleagues, learn about other in-country stakeholders, find out what benefits are most needed, desirable and realistic, and to develop new projects.

WHAT HAS BEEN THE IMPACT OF THE CBD ON INTERNATIONAL BOTANICAL RESEARCH?

The CBD has had a significant impact on botanical research, one beyond the scope of this short chapter to explore fully. Undoubtedly there are more restrictions on access to, and use of material, and huge areas of uncertainty, which have lead to feelings of distrust and pessimism in the research community (see for example Revkin, 2002). For instance, many biologists would argue that they are spending more time and money on politics than biological research. Procedures for obtaining PIC from governments vary widely between countries and are sometimes non-existent, not transparent, or not designed for non-commercial academic research, as Miller points out. Procedures for obtaining PIC from indigenous peoples and local communities are similarly unclear (Laird and Noejovich, 2002). We can only hope that governments will use the new Bonn Guidelines, take some heed of valid criticisms, and that the strategies and legislation they develop will be clearer and more practical in future.

Researchers and institutions also need to be much clearer in return about how we use material and what benefits the research will generate and how they can be shared. This is a major challenge for institutions. It is one thing to obtain PIC for a particular project and negotiate mutually agreed terms, but we also need to think more broadly and further ahead to how collections will be used over the long term, back at the institution, and how to share benefits. At the moment, the majority of material in many gardens and herbaria probably pre-dates the entry into force of the CBD, but in 100 years far more material will have restrictive conditions. Terms need to travel around with material as it is used and exchanged, and a link to countries of origin for benefit sharing needs to be maintained, which requires the development of efficient tracking systems (such as databases and data record systems), inter-institutional communication and staff training (Williams et al, 2003). If institutions can show that they are working hard to share benefits fairly and equitably and that they are not 'leaky', trust will be raised in their work and botanical research may be facilitated rather than impeded in the future.

The development of institutional policies and written agreements are leading to changes in how, and what, research is done. Investment in fairer partnerships over the longer term may mean that many institutions cannot work in or with as many countries. For instance, Kew's policy on benefit sharing and pressures on institutional resources mean that Kew's research efforts are now focused on fewer countries, with an emphasis on longer-term, more substantial institutional relationships. This is mutually strengthening over the long term: partners benefit but so does Kew, as its reputation as a trustworthy institutional partner may help weather political change and facilitate and create future research collaborations. The CBD is also turning some botanical institutions away from research with potential commercial applications, in part because of the cost of staff time and effort to oversee all aspects of such projects and the risk of costly missteps and damaging accusations of biopiracy. As well as a history of physic gardens supplying medicinal plants, botanic gardens have traditionally had intimate links with the horticulture industry (ten Kate, 1999) that are now being weakened or severed entirely. For instance, for the above reasons Kew at present does not supply any plants for potential horticulture trials, and the IPEN does not cover any commercial use or supply of plants in the system.

The CBD has fundamentally changed the idea of open access to material and also to associated information. This throws up a range of issues for institutions to consider. At Kew we are working on how to honour both our responsibilities to particular partners and countries of origin arising from bilateral agreements and to the broader scientific and conservation community working on global and regional syntheses. We are learning that agreements need to consider the breadth of Kew's activities, and also that we need to ensure that the wider relevance of these activities is understood by partners. For example, although we carefully guard germplasm collected under Millennium Seed Bank project agreements, its value is greatly decreased if the corresponding herbarium specimens, used to verify the seeds' identity, are not made available to a range of taxonomic experts. In practical terms this requires that they be incorporated into the main Herbarium collection. Yet by making these specimens available to visitors, we run the small risk that they might on occasion be sampled without authorization, or that information might be taken from labels without appropriate citation of the source country. If, while negotiating agreements, partners and governments understand the benefits as well as the risks involved, they can make informed and courageous rather than fearful or purely political decisions. It would be a tragedy for biological research if collections are locked down and roped off in future decades and centuries. What we need to ensure is that the biologists using them are from all parts of the world and working in fair – and enthusiastic – collaboration.

Institutions also receive, generate, use and share specimen information and images. The practice of providing free access (at no cost, under no legal agreements) for all non-commercial users is, on the one hand, being facilitated and accelerated by the rise of the internet. On the other hand, it is being challenged by both the increasing application of intellectual property protection (to prevent, for example, the mining and repackaging of databases) and changing CBD-related ideas about the rights of countries of origin and other stakeholders to control the flow of information relating to their genetic resources (Graves, 2000; Laird et al, 2002). Several recent and current projects are exploring how institutions should tackle access and intellectual property issues in the context of increased networking by collections (see for example Owens et al, 2003).

Botanical research has, in return, also had an impact on the recent development of the CBD. The adoption by the Conference of the Parties of the Global Strategy on Plant Conservation (GSPC) and the Global Taxonomy Initiative (GTI) are very positive steps which have arisen from the botanic garden and taxonomic research communities (UNEP, 2002b, 2002c). The practical, target-oriented GSPC should produce clearer outcomes for plant conservation than previous CBD approaches. The GTI helps legitimize the work of taxonomists and remind policy makers that this non-commercial research and capacity is fundamental for implementation of all of the CBD's goals and must be facilitated. Botanical institutions are unlikely to receive funds directly from the CBD to implement the GSPC or the GTI, but their active involvement may help to attract funds from other sources.

I wish to emphasize that we are just starting a long learning process in a rapidly changing environment, but I echo Miller in saying we believe the CBD is having a positive effect on research collaboration. For botanical institutions to be able to continue to contribute to the goals of conservation, sustainable use and fair and equitable benefit sharing, it is vital to communicate clearly and honestly and work in fair and mindful partnership with countries of origin.

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Chapter 7

The Link Between Biodiversity and Sustainable Development: Lessons From INBio's Bioprospecting Programme in Costa Rica

Rodrigo Gámez

In its quest for a human sustainable development model, Costa Rica, like many other countries, faces the challenge of how to establish a proper balance among a complex interaction of economic, social and environmental factors (Proyecto Estado de la Nación, 2002). With a territory of 51,100km^2 (about the size of West Virginia), the country is home to an estimated 500,000 species of plants, animals and microorganisms, representing nearly 5 per cent of all the world's diversity of organisms (Obando, 2002). How to protect this biological wealth while simultaneously promoting the social and economic development of the country represents a challenge of singular complexity and magnitude.

Congruent with its newly established paradigm and development model, Costa Rica is devoting nearly a third of its territory to the conservation of its rich biological diversity in perpetuity. This represents a major investment for any country, but particularly for a small developing country like Costa Rica, as this means renouncing the short-term gains of non-sustainable utilization of resources in this significant portion of the territory.

The environmental concerns and decisions to protect the natural patrimony of the country must be put in the context of the history of the development path followed by Costa Rica since 1940. This period is characterized by a stable political system based on a disarmed democratic government, high economic growth rates and substantial advancement in social indicators. The United Nations Development Programme (UNDP) Human Development Index (0.71) places Costa Rica in a remarkably high position in the world. Some of the country's evolution indicators are summarized in Table 7.1. Remarkably, with a modest GNP per capita of less than US$4,028, the country has attained among others, life expectancy, health and liter-

Table 7.1 *Costa Rica's evolution indicators (1940–2000)**

Indicator	*Unit*	*1940*	*1960*	*1980*	*2000*
Human development index	Coef.	N.D.	0.55	0.75	0.71
Population	1000	656	1.199	2.276	3.943
Poor homes	%	N.D.	50	19	21
Life expectancy at birth	Years	46.9	62.5	72.6	77.4
Infant mortality	1000	123	68	19	10.2
Literacy	%	73	84	90	95
GNP per capita	US$1990	702	1.08	2.022	4.028

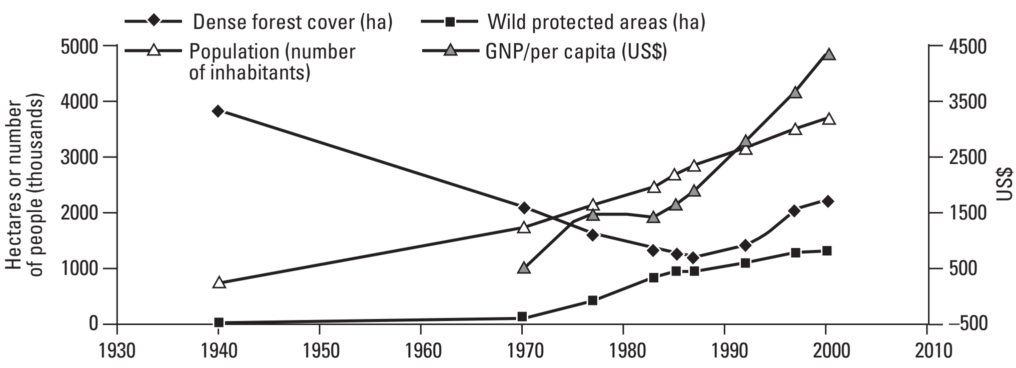
*The scale for the calculation was modified between 1980 and 2000. ND = not done.

Source: Proyecto Estado de la Nación (2002)

acy indicators similar to many developed countries in the North. Notably, human population has quintupled in this period and is expected to double in the next three decades, stabilizing at approximately 8 million people around 2030. Nearly 20 per cent of the population remains poor and mostly concentrated in rural areas (Proyecto Estado de la Nación, 2002).

Figure 7.1 presents some selected social, economic and environment indicators, highlighting the significant changes that have occurred in the last decades, and the close relationship that seems to exist among those indicators.

The major investments made in social welfare and education from 1948 and onwards – also associated with changes in the economic model – are clearly linked to the increase in the GNP/capita. As in many other Latin American countries, Costa Rica's development model from 1940 to 1970 was largely based on a non-sustainable agricultural use of its natural resource base, which led to a significant reduction of the country's forest cover and its rich biodiversity, as well as rapid degradation of land, resulting from the concomitant soil and water problems. By 1970 the evident environmental crisis began to trigger an increased public awareness and concern



Source: Modified from Gámez and Obando (2003)

Figure 7.1 *Costa Rica: Selected social, economic and environmental indicators (1940–2000)* about its short- and long-term consequences. A succession of prudent political decisions and actions in the following decades allowed the country to consolidate a system of wild protected areas, reduce forest loss and recover significant dense forest cover. These efforts involved numerous and diverse sectors of society, and attracted significant international support and recognition to the country. The shift in environmental degradation trends clearly coincided with the significant improvement of the social and economic conditions of the country, and the drift towards a service-oriented economy (Gámez and Obando, 2003).

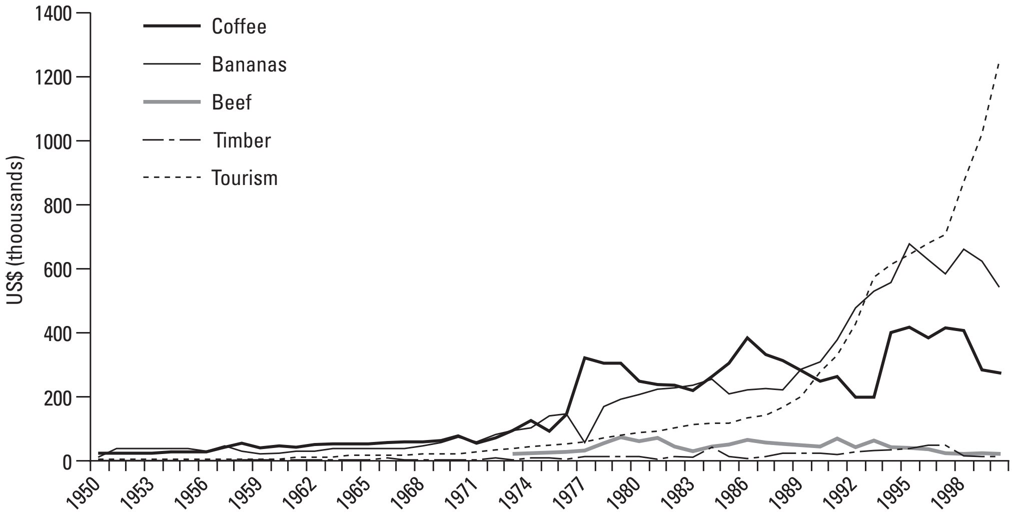
THE SUSTAINABLE UTILIZATION OF BIOLOGICAL DIVERSITY

As established in its National Biodiversity Conservation and Sustainable Use Strategy (MINAE, 2000), Costa Rica's biodiversity conservation policy is based on the 'save, know, use' trilogy of principles. 'Save' means protecting representative samples of the country's biodiversity through a system of protected areas; 'know' means knowing the biodiversity that exists in the country and particularly in its protected areas; and 'use', means using sustainably this biodiversity for the social and economic benefit of the country. An increased awareness of the many different values of biodiversity by society as a whole is expected to help attain biodiversity conservation, as the contributions of biodiversity to the improvement of people's quality of life become increasingly evident and recognized. Otherwise, those areas devoted to biodiversity conservation run the risk of being converted to other forms of utilization, not compatible with conservation.

The sustainable utilization of biodiversity is already making significant contributions to the social and economic development of Costa Rica in several different ways. These include nature-oriented tourism, payment of environmental services and bioprospecting.

Nature-oriented tourism has become one of the most important economic activities of the country. Figure 7.2 compares the foreign exchange (US$) generated between 1950–2000 by selected agricultural activities (coffee, bananas and beef), forestry (timber) and nature-oriented tourism. It is evident that, from an economic perspective, the investment in biodiversity conservation has been the most productive one to the country. Ecotourism is generating more income for the country with significantly less environmental impact, than that caused by other forms of direct exploitation of natural resources, such as timber or cattle ranching. The combined environmental impact of the latter two activities account for the loss of over one-third of Costa Rica's forest, with other collateral effects, such as soil erosion, flooding and other natural disasters.

Viewed as a non-consumptive, indirect use of biodiversity resources, nature-oriented tourism has proven to be a more intelligent form of sustainable use of land and natural resources. The combined effect of the existence of a system of protected



Source: MIDEPLAN (1998); MINAE – FONAFIFO (1998); SEPSA-MAG database (2000); Watson et al (1998)

Figure 7.2 *Costa Rica foreign exchange (US$) generated by selected agricultural and forest products and tourism (1950–2000)*

areas, with magnificent examples of tropical biodiversity and the scenic natural beauty of the country, the social and economic stability and cultural characteristics, proper governmental policies and the active involvement and participation of the private sector, have all contributed to make nature-oriented tourism a more sustainable form of intelligent utilization of natural resources. In addition, the particular characteristics of its development, judged by international standards, have positioned Costa Rica as a leader in this industry, in terms of benefits and efficiency (Obando and Zamora, 2001). As another form of economic valuation of biodiversity, Costa Rica has also pioneered the payment of environmental services provided by ecosystems. The valuation of water production, CO_2 fixation, biodiversity conservation and protection of the scenic beauty of forests in both private and public properties, and the corresponding payment for these provided ecosystem services, are bringing direct economic benefits to forest owners. Simultaneously, these benefits contribute directly to the cost of conservation and protection of forests (Barrantes, 2001).

An example of this approach is the successful initiative of the Empresa de Servicios Públicos de Heredia (ESPH), a local public water and power utility, that decided to create economic instruments to implement water resource protection in order to guarantee future water availability to the community. Figure 7.3 illustrates the user's direct payment for the water and watershed protection service. The Braulio Carrillo National Park, which protects a good part of the critical watershed, and private owners who are entitled to compensation for the opportunity cost, receive a direct payment for the service provided by forest ecosystems on their land (Gámez, 2001).

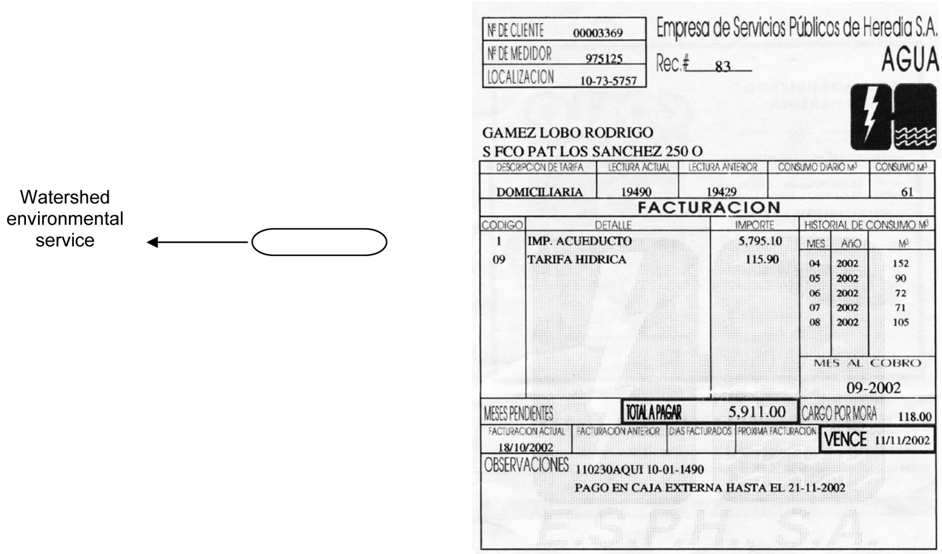


Figure 7.3 *Direct payment of forest watershed protection service in Heredia, Costa Rica*

Bioprospecting, done properly, has been viewed by The Instituto Nacional de Biodivirsidad (INBio) in Costa Rica as another form of sustainable utilization and economic valuation of biodiversity, as well as a means to support the conservation of biological diversity (Eisner, 1989; Reid et al, 1993). Accordingly, INBio's 12-year bioprospecting experience is summarized in the following section.

INBIO'S BIOPROSPECTING EXPERIENCE IN COSTA RICA

Ever since INBio entered a landmark commercial bioprospecting research collaboration agreement (RCA) in September 1991 with the pharmaceutical corporation Merck & Co., this agreement and the much broader experience gradually gained in bioprospecting by the institution, has been examined in detail from different perspectives (Mateo et al, 2001; Reid et al, 1993; Sittenfeld & Villers, 1994; Tamayo et al, 2003). In spite of the fact that numerous other RCAs exist all over the world, the INBio-Merck agreement has been the subject of frequent reference in many writings on the subject (Laird, 2002; ten Kate and Laird, 1999).

The continued international interest in INBio's experience in prospecting Costa Rica's biodiversity is exemplified in the statement made in August 2002 by the Executive Secretary of the Convention on Biological Diversity (CBD), during the VI Conference on the Parties (COP 6) held at The Hague: 'A well known example of an access and benefit sharing contract was agreed between Diversa Corporation and the

Costa Rican National Biodiversity Institute (INBio) in 1995 and renewed in 1999' (CBD, 2002).

The learning-by-doing experience of INBio in its search for fair and equitable benefit-sharing mechanisms for the development of biodiversity resources, for the purposes described above, seems to fulfil the expected role stated since the inception of INBio in 1990–1991. That role is to serve as a model to be followed, and stand as a promising pilot project that offers important and valuable lessons relevant to the success of similar bioprospecting ventures elsewhere (Reid et al, 1993). But there are negative views of INBio. INBio's initiatives and experience have been criticized by some environmental groups, which still view them as an advanced form of biopiracy (Kloppenburg and Rodríguez, 1992; Martínez, 2002).

The criteria and terms of the Research Collaborative Agreements used by INBio

The criteria and terms followed in the original INBio–Merck & Co. RCA (Sittenfeld and Gámez, 1993), which ensured INBio's conservation mission, constituted a milestone for future negotiations and with minor improvements are still maintained today. They were recently summarized (Tamayo et al, 2003) and appear below:

- Access is limited to a given amount of samples from natural resources and is facilitated for a limited period of time (exclusivity terms are also limited), under terms established by existing national legislation and a framework legal agreement between INBio and the Ministry of the Environment and Energy (MINAE).
- Taking into account existing technical and scientific capacities, a significant part of the research is to be carried out locally, and associated research costs, as defined in the research budget, are to be entirely covered by the industrial partner.
- An up-front payment of a minimum of 10 per cent of the research budget when applicable, is to be included in the research budget and transferred directly to MINAE to be used exclusively for conservation purposes.
- Benefit-sharing mechanisms are to be negotiated beforehand and are to include among others:
  - milestone payments for the discovery and development phases of a potential product, (to be shared 50:50 with MINAE);[1]
  - a percentage of royalties on net sales of the final product, covering derivatives from any original natural scaffolds and/or any technology derived thereof, (also to be shared 50:50 with MINAE);
  - recognition of intellectual property rights that contemplate the possible participation in discoveries of INBio's scientists (joint patents and publications).
- Technology transfer and local capacity building must be insured, including training of local scientists in state-of-the-art technologies.
- Discovery and development of products is to be restricted to non-destructive uses of natural resources and must be entirely consistent with the national legislation dealing with access to genetic resources and development thereof.

Among the different factors that determine the feasibility of establishing and implementing the above-mentioned criteria and terms, institutional capacities, as well as political and legal frameworks, are of fundamental importance.

According to the INBio/MINAE collaborative agreement, INBio conducts its bioprospecting activities, with a few exceptional cases, only in MINAE's protected areas. Contrary to the situation prevalent in many countries throughout the world, protected wildlands in Costa Rica have no inhabitants, local farmers or indigenous people. This is the reason why the distribution of monetary benefits in the INBio/MINAE agreement does not implicate directly these particular sectors of society.

It is important to understand that in Costa Rica, the majority of the local Indian population (around 1 per cent of the total) live in reserves that comprise nearly 6 per cent of the national territory, and possess their own rules and regulations. It has been INBio's policy not to seek access to either biotic resources in Indian reserves or their traditional knowledge. The terms through which both resources and knowledge may be accessed are clearly established in Costa Rica's biodiversity law (Asamblea Legislativa, 1998).

The development of institutional capacities

Using and applying criteria of modern organizations, and taking advantage of the particular conditions of the country and its scientific and technological conditions, INBio has been able to build a solid internal capacity for capturing information on natural resources, processing and transferring this information to society, in different formats for different users and uses. Its main thematic areas of activity include biodiversity inventorying and monitoring, bioinformatics, education and bioliteracy, wildland management and bioprospecting, all operating in a closely interlinked fashion. In 2001, the bioprospecting budget represented 11 per cent of the total institutional budget (INBio, Annual Report 2001), and has historically fluctuated around 11–17 per cent.

INBio's institutional capacity rests largely on strategic alliances with the Government, academia and the private sector, nationally and internationally (Gámez Lobo, 1999; Zeledón, 2000).

Costa Rica has established appropriate legal frameworks to deal with the conservation of genetic resources, access to and sustainable use of which have facilitated the establishment of RCAs. The Biodiversity Law, enacted by the Costa Rican Congress (Asamblea Legislativa, 1998), in full compliance with the terms of the CBD, defines the conditions under which bioprospecting activities should be carried out in Costa Rica. On this issue, INBio's experience was very important and was taken into account in defining the benefit sharing and intellectual property rights mechanisms for RCAs negotiated by institutions or individuals in the country.

Throughout the years INBio's approach has proven to be successful under the particular conditions of Costa Rica. To date, INBio has signed more than 20 agreements with industry, (Table 7.2) and the total of the research budgets have come to represent an investment of US$0.5 million per year for bioprospecting activities and

US$0.5 million per year for capacity building, technology transfer and institutional empowerment. The latter are of transcendental relevance, as they steadily increase INBio's capacity to negotiate fair and equitable agreements. It is a clear institutional objective to maximize institutional participation and information value added to the particular products shared with the commercial partner. In the very competitive and dynamic technological sector, it is vital to increase local capacity by means of training and technology transfer, ensuring the institutional participation in the overall process of discovery and development of final products.

Two major accomplishments have resulted from the implementation of policies and strategies established by INBio. One is the increasing scientific and technological participation of the institution in the development of final products and, second, the sharing of benefits (monetary and non-monetary), as well as the risks inherent in industrial development. Both factors contribute to the development of long-lasting partnerships.

A new type of partnership with local enterprises

The projects developed with Follajes Ticos, La Gavilana, Laboratorios Lisan, Bouganvillea and Agrobiot (Table 7.2), all local Costa Rican small–medium sized enterprises, received financial support (risk capital) from funds donated by the Interamerican Development Bank (IDB). INBio's main contribution was technological support and know-how, while the enterprises provided their own knowledge and capital. If successful in their projects, these enterprises will return the financial resources donated by IDB to a revolving fund that can be used to fund future initiatives. In case of failure, the risk capital would not be returned.

The above-mentioned projects represent a different category of partnership developed by INBio's Bioprospecting programme. As stated above, the partners are all small local enterprises, developing low-cost projects for a small local market, with partly donated modest funding and requiring relatively low, simple technologies and a shorter time for their development. Contrary to the big and complex projects carried out with large transnational corporations, these small and simpler projects, while not yet totally completed, are already considered successful initiatives, likely to make singular contributions in terms of profits, employment and more value-added agro-industrial developments.

The main achievements

It is common knowledge (Tamayo et al, 2003) that the development of a product might take 5–20 years of research depending on the field (agricultural, biotechnological or pharmaceutical applications), and might require the investment of hundreds of millions of US dollars until final products reach the market. Pharmaceutical and agriculture product discovery is a highly costly, high-risk and low probability form of research. A recent estimate indicates that the investment needed for an 11-year period of research is over US$800 million (Watkins, 2002). These considerations clearly indicate that it is still too early to expect products from Costa Rican biodiver-

Table 7.2 *Most significant research collaborative agreements with industry and academia (1991–2002)*

Industry or Academic partner	*Natural resources accessed or main goal*	*Application fields*	*Research activities in Costa Rica*
Cornell University	INBio's capacity building	Chemistry	1990–1992
Merck & Co	Plants, insects, micro-organisms	Human and animal health	1991–1999
British Technology Group	DMDP, compound with nematocidal activity	Pest control	1992–present
ECOS	*Lonchocarpus felipei*, source of DMDP	Pest control	1993–present
Cornell University and NIH	Insects	Human health	1993–1999
Bristol Myers & Squibb	Insects	Human health	1994–1998
Givaudan Roure	Plants	Fragrances and essences	1995–1998
University of Massachusetts	Plants and insects	Biological pest control	1995–1998
Diversa	DNA from Bacteria	Biotech industry	1995–present
INDENA SPA	Plants	Human health	1996–present
Phytera Inc.	Plants	Human health	1998–2000
Strathclyde University	Plants	Human health	1997–2000
Eli Lilly	Plants	Human health and agriculture	1999–2000
Akkadix Corporation	Bacteria	Pest control	1999–2001
Follajes Ticos	Plants	Ornamental horticulture	2000–present
La Gavilana S.A.	*Trichoderma* spp	Biological pest control	2000–present
Laboratorios Lisan S.A.	None	Phytopharmaceuticals	2000–present
Bouganvillea S.A.	None	Biological pest control	2000–present
Agrobiot S.A.	Plants	Ornamental horticulture	2000–present
Guelph University	Plants	Agriculture and conservation	2000–present
Florida Ice & Farm	None	Technical and scientific support	2001–present
ChagasSpaceProgram	Plants, fungi	Human health	2001–present
SACRO	Plants	Ornamental horticulture	2002–present

Source: Modified from Tamayo et al, 2003

sity to be launched into the commercial market. This is not only the case for INBio but for other bioprospecting initiatives around the world (Moran et al, 2001; ten Kate and Laird, 1999).

On the other hand, it is most likely that simpler products from the IDB funded projects could be commercialized locally or internationally in some cases, before any blockbuster in the US or Europe. In any case, the impact and relevance to the institutional mission, particularly because of the potential contribution to the valuation of biological diversity and improvement of quality of life of society, could be significant.

Some of the main tangible benefits arising from bioprospecting activities at INBio and discussed in previous sections, are summarized in Table 7.3 (Tamayo et al, 2003). In terms of direct monetary benefits, the total of all research budgets amount to nearly US$10.8 million. The value of the technology acquired and infrastructure developed is probably worth several million dollars. Over US$600,000 corresponding to 10 per cent of the research budgets,[2] went directly to conservation activities carried out by MINAE. A significant contribution of more than US$2 million in total, corresponding to research expenditures (salaries, equipment, infrastructures, laboratory supplies, etc.) was transferred to MINAE's Guanacaste Conservation Area, to the University of Costa Rica and to the National University of Costa Rica. These organizations have been part of strategic alliances for the execution of research projects.

Although not highly significant in monetary terms, approximately US$0.6 million in milestone payments have been shared 50:50 with MINAE, according to the established agreement. No royalty payments have been received yet, although some promising products could reach the market in the next few years.

The non-monetary benefits of the RCAs have been considered by INBio as equal, if not more important in many cases, than the monetary ones. A similar conclusion has been reached by other countries and institutions (ten Kate and Laird, 1999). The scientific and technological capacity developed by the institution in its 12 years of bioprospecting experience is considered as one of its more important assets, which, as discussed before, has contributed directly and significantly to the formulation of proper national policy and legislation regulating the access to, and benefit sharing derived from, biodiversity resources (Asamblea Legislativa, 1998; MINAE, 2000). The contribution made to the scientific and technological development of the country through this approach is substantial, and among other considerations has enabled the institution to receive important international scientific awards and recognition (Gámez, 2000).

Table 7.3 *Monetary and non-monetary benefits derived by INBio from bioprospecting*

Monetary benefits	
1	Totally funded local research budgets
2	Technology transfer and infrastructure
3	Up-front payments for conservation
4	Strengthening of research capacity of local scientific institutions
5	Milestone and royalty payments shared with MINAE
Non-monetary benefits	
1	Training of human resources
2	Empowerment of human resource
3	Technology transfer
4	Shared research results and information
5	Negotiations expertise developed
6	Market information
7	Improvement of local legislation on conservation issues

Source: Modified from Tamayo et al, 2003

The direct outputs in terms of products derived from the RCAs entered into by INBio include patents on compounds, specific promising compounds with biological activity identified or not, biological control microbes (fungi and bacteria) and nutraceutics, among others (Tamayo et al, 2003). As stated before, it is likely that one or more of these products will reach the market in the near future, the likelihood being higher for the 'low-tech' modest domestic projects with small enterprises, than for the costly and complex 'high-tech' initiatives carried out with the major international partners.

THE FUTURE OF BIOPROSPECTING IN INBIO AND COSTA RICA

Bioprospecting in the way done by INBio (Tamayo et al, 2003), has provided both the institution and Costa Rica with a vast and complex experience on access, legislation and uses of genetic and biochemical resources. Equally important, the gradual acquisition of intellectual scientific capacities and know-how, as well as state of the art technologies, has enabled INBio to position itself as a biotechnological entity capable of providing industrial partners innovative products and services with significant added value. The know-how and experience gained in initiatives with international industrial partners has also proved to be of singular value when applied to local small enterprises. The experience gained with the IDB-funded initiative is demonstrating that agreements with local enterprises are not only possible, but may result in the development of final marketable products in a shorter period of time, with the subsequent promotion of local economic development. This may also have a significant positive impact in the awareness and perceptions on the value and opportunities offered by biodiversity, among both the general public and governmental decision makers.

An example of the latter is the decision made by the Ministry of Science and Technology of Costa Rica, endorsed by the MINAE and the government as a whole, to negotiate a multi million dollar research loan from IDB, in order to promote the development of the local biotechnology industry. Based on the experience and capacities developed by the national universities and INBio, and the increased awareness of the potential opportunities offered by the rich biodiversity of the country, a major investment in biotechnological research and development was considered politically appropriate and opportune. The possibilities for the application of modern biotechnological solutions for local problems in health and nutrition, general agriculture and industry in general, may be limited only by financial resources, and not by imagination.

Based on the positive experience gained up to the present time, INBio will obviously continue to promote the development of biotechnological research activities with different academic or industrial partners. New approaches in microbial and gene prospecting will be explored, addressing their potential application in the pharmaceutical and cosmetic industry, as well as in agriculture.

In the field of chemical prospecting, INBio foresees more value-added agreements with academia and international biotechnological partners. This is largely due to the acquisition through donation, of several preparative automated fractionators, which allow the isolation of significant amounts of pure compounds in a high-throughput fashion. The screening of large numbers of natural products is now possible with the additional advantage of securing partners with the resupply of any compound.

Finally it may be concluded that, as in other cases (McManis, 2003), when social and economic conditions promote biodiversity conservation and scientific and technological development, biotechnology and biodiversity prospecting as a whole, emerge as valuable scientific tools to realize the potential of the biodiversity of a country. Clearly, as in the case of Costa Rica, bioprospecting is one of several approaches to realize such potential. Ecotourism and the direct payment for environmental services as discussed above, offer other significant opportunities for making non-destructive uses of tropical biodiversity for the benefit of the country. Because the scientific and technological, legal and commercial requirements of bioprospecting initiatives are inherently more complex than other forms of non-destructive use of biodiversity, the full scope of the ensuing benefits to society remains to be seen.

NOTES

1 As a public-interest, non-profit organization, INBio would invest its corresponding part entirely in the compliance of its biodiversity conservation mission.

2 Academic research budgets do not include the 10 per cent access fee, as governmental financial resources are mostly of governmental origin.

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Chapter 8

On Biocultural Diversity from a Venezuelan Perspective: Tracing the Interrelationships among Biodiversity, Culture Change and Legal Reforms

Stanford Zent and Egleé L. Zent

The phenomenon of rapid biodiversity decline was transformed in the late 1980s from a purely academic problem to a discourse for social, economic and political change thanks in large part to the communicative skills and scientific authority of distinguished biologists such as E. O. Wilson, Paul Ehrlich, Thomas Lovejoy, Norman Myers and Peter Raven. They expressed alarm that natural habitats were being modified and species eliminated at a pace and scale unprecedented in the Earth's history, with potentially dire consequences for long-term planetary health and human well-being (Wilson, 1988). This discourse has since become firmly implanted in the general public consciousness, propelling a powerful global environmental movement, persuading governments to take conservation measures, and giving birth to the 'crisis discipline' of conservation biology. The effective result has been a concerted research, policy, and action agenda that encompasses: scientific efforts to catalogue, classify, and map biodiversity throughout the world; inquiries into the ecological processes that regulate biodiversity; projects aimed at monitoring the rate of habitat alteration and species extinction; attempts to identify the threats as well as to anticipate the outcomes; and the search for effective policies that will halt or hopefully reverse this destructive trend.

At about the same time that the biodiversity crisis came to public light, several linguists and anthropologists began to voice concern that the state of the world's indigenous languages and cultures was suffering a similar process of extinction, endangerment and erosion caused by the forces of economic globalization, cultural modernization and linguistic assimilation (Harmon, 1996; Krauss, 1992). Though less well publicized, the catastrophic loss of cultural diversity also touched a sympathetic nerve and stimulated a pulse of salvage research projects, cultural preservation and revitalization initiatives, and reappraisals of the value and application of traditional knowledge. Although these were initially formulated as analogous issues, it was not long before scientists, policy makers and local communities began to view biodiversity loss and ethnolinguistic loss as not merely parallel trends but rather as interlocking processes (Maffi, 2001). This key insight has since penetrated the discourse on biodiversity at the levels of research, policy, practice and ethics.

The interrelationships and synergistic loss of biological, agricultural and cultural diversity is a theme that is voiced increasingly in the scholarly and technical literature on development and conservation topics in the past decade. Several strands of empirical evidence have been held up to support this argument: (1) the spatial overlap between biodiversity hotspots and centres of cultural and linguistic diversity (Durning, 1992; Harmon, 1996; Maffi, 2001; Nietschmann, 1992; Wilcox and Duin, 1995); (2) the anthropogenic creation and maintenance of heterogeneous landscapes through traditional low-tech resource management practices (Baleé, 1993; Denevan and Padoch, 1987; Posey, 1984, 1998; Zent, 1998); (3) the large contribution of traditional farmers to the global stock of plant crop varieties (Boster, 1984; Brush, 1980; Oldfield and Alcorn, 1987; Thrupp, 1998); (4) the countless examples of customary beliefs and behaviours that contribute directly or indirectly to biodiversity conservation such as sustainable resource extraction techniques, sacred groves, ritual regulation of resource harvests and buffer zone maintenance (Moock and Rhoades, 1992; Posey, 1999); and (5) the dependence of sociocultural integrity and survival on traditional territories, habitats and resources (Maffi, 2001).

The link between biodiversity and cultural difference has also become well established in various policy-oriented discourses and instruments that pay lip-service to the need for parallel conservation of biodiversity and associated local knowledge and practice systems. These include: professional society codes of conduct (e.g. Declaration of Belem in Posey and Overal, 1990), multilateral agendas and treaties (e.g. Brundtland Report, Convention on Biodiversity, Global Biodiversity Assessment), indigenous congress draft declarations (e.g. Charter of the Indigenous-Tribal Peoples of the Tropical Forests; Indigenous Peoples' Earth Charter; Statement from the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA)/UNDP Regional Meeting on Intellectual Property Rights and Biodiversity; International Workshop on Indigenous Peoples and Development; see Posey 1999, pp555–601), development agency guidelines (e.g. Consultative Group for International Agricultural Research, the International Board for Genetic Resources, the International Plant Genetic Resources Institute, the International Institute for Environment and Development, the Latin American Consortium on Agroecology and Development, the UK Department of International Development, and the US Agency for International Development; see Cashman, 1989; Warren, 2001), and national laws regulating environmental use and conservation (see below).

In the action arena, many non-governmental organizations (NGOs) in the conservation business have begun to treat indigenous and local peoples as crucial allies and partners in their efforts to conserve wildlands and their biodiversity, promote sustainable use of natural resources and prevent pollution. These include a number of high-profile organizations such as the World Wild Fund for Nature (WWF), Conservation International, the Nature Conservancy, World Resources Institute, Wildlife Conservation Society and the Environmental Defense Fund. Thus one of the major trends in conservation practice over the past decade has been to support people-inclusive, use-based projects, especially in developing countries, as an alternative and supplement to people-exclusive parks and protected areas (e.g. the Biodiversity Support Program's Integrated Conservation and Development Project initiative, Brown and Wyckoff-Baird, 1995).

Finally, environmental philosophers and advocates are increasingly convinced that the key to successful conservation of ecosystems and constituent biodiversity lies in the moral enlightenment of human society toward greater appreciation of all life forms. An emerging position in this field considers that reinforcement and enhancement of culturally rooted social and spiritual values offers the most effective approach (e.g. the Alliance of Religion and Conservation undertaking or so-called Assisi Process, see Posey, 1999). The holistic cosmovisions and lifestyles of indigenous peoples, many of which express the deep physical and metaphysical connections between the cosmos, life on earth and human society, are frequently cited as inspirational models for the new environmental ethic (Posey, 1999).

The point we are trying to make here is that at scientific, policy, practice and ethical levels of discourse it is no longer possible to separate discussions of biodiversity loss/preservation from the matter of local cultural knowledge protection, such that the very concept of biodiversity is being supplanted by a more complex paradigm of biocultural diversity. Maffi (2004) defines biocultural diversity as 'the diversity of life forms that has been jointly shaped by both natural and cultural forces through coevolutionary processes'. The conceptual breakthrough offered here goes beyond the mere recognition that nature and culture are inextricably linked but also that diversity itself must be understood as a historical and processual phenomenon (cf. Brookfield, 2001). It therefore follows that from a biocultural perspective the question of what biodiversity are we losing and why, and what is to be done about it must be answered by focusing on the cultural-historical processes affecting it. Accordingly, the goal of the present chapter will be to describe the pertinent processes taking place in Venezuela.

BIOCULTURAL DIVERSITY IN VENEZUELA

Proportionate to its size, Venezuela is regarded as harbouring outstandingly high biodiversity, being ranked among the top 20 countries in the world for plant, amphibian, bird and reptile species (Table 8.1). A major portion of the biodiversity in the country, including an estimated 75 per cent of plant species, is located in the southern Guayana region (Amazonas, Bolívar and Delta Amacuro States) (Figure 8.1). Different types of deciduous, semi-deciduous and evergreen forests cover approximately 83 per cent of the surface of this region, amounting to over 375,000km^2 of forested land area (Huber, 1995), making this one of the largest continuous blocks of

Table 8.1 *Venezuela's global ranking in terms of biodiversity components*

Category	*Number of endemic species*	*World rank*	*Estimated no. of species per 10,000km²*	*World rank*
Plants	8,000	5th	4,752	11th
Amphibians	122	11th	55	11th
Birds	40	15th	302	12th
Reptiles	66	19th	64	27th

Sources: Bevilacqua et al, 2002, p26; World Resources Institute, 2001

frontier forest existing in the world today (Miranda et al, 1998). From an ecological standpoint, the forested ecosystems of Guayana are characterized not only by a high degree of taxonomic (species, genus, family) and ecological diversity (interspecific relationships, life history patterns), but also by poor soils, a tropical climate and nearly closed nutrient cycles, which means that they are especially vulnerable to degradation as a result of exogenous alteration (cf. Herrera et al, 1978; Jordan, 1982; Uhl and Jordan, 1984). Although most of the Guayanan forests remain intact, certain focal points of development and deforestation are beginning to appear due to population growth and migration and the expansion of agricultural, mining and logging frontiers (Bevilacqua et al, 2002). This trend is troubling, not least because relatively few botanical and zoological inventories have been carried out within this vast region and therefore the true and full extent of biodiversity is still unknown.

The Venezuelan Guayana also contains a large fraction of the cultural diversity existing in the country. Twenty-three of the nation's 28 indigenous ethnic groups are found in this region and most of them have lived there since precolumbian times (OCEI, 1993). The majority of the indigenous population resides in small communities located in rural forested areas and is for the most part self-sufficient in subsistence matters, displaying the typical tropical forest economic complex of shifting cultivation, hunting, fishing and collection although variations from group to group in terms of specific resources exploited and of techniques employed are also normal (Huber and Zent, 1995). The ethnographic-ecological literature confirms the popular impression that they possess extensive knowledge and uses of the biodiversity of their local environments and are skillful manipulators of ecological relationships and processes (Finkers, 1986; Fuentes, 1980; Heinen et al, 1995; Hernández et al, 1994; Wilbert, 1996; Zent, 1992; Zent, E.L., 1999), but it is also true that few groups have been the subject of detailed studies so their knowledge is still largely unappraised. For example, Bevilacqua et al (2002) report 505 wild species being directly used by local groups in a survey of the available literature for all groups inhabiting this region, but in our research of the Jotï we were able to document as many species being used by a single group (Zent et al, 2001; see below).

Although it is irrefutable that the indigenous peoples maintaining a traditional lifestyle are very knowledgeable and skillful environmental managers, it would be inaccurate to generalize their situation to everyone and thus portray all of them as ecologically noble savages living in perfect equilibrium with nature. In fact many

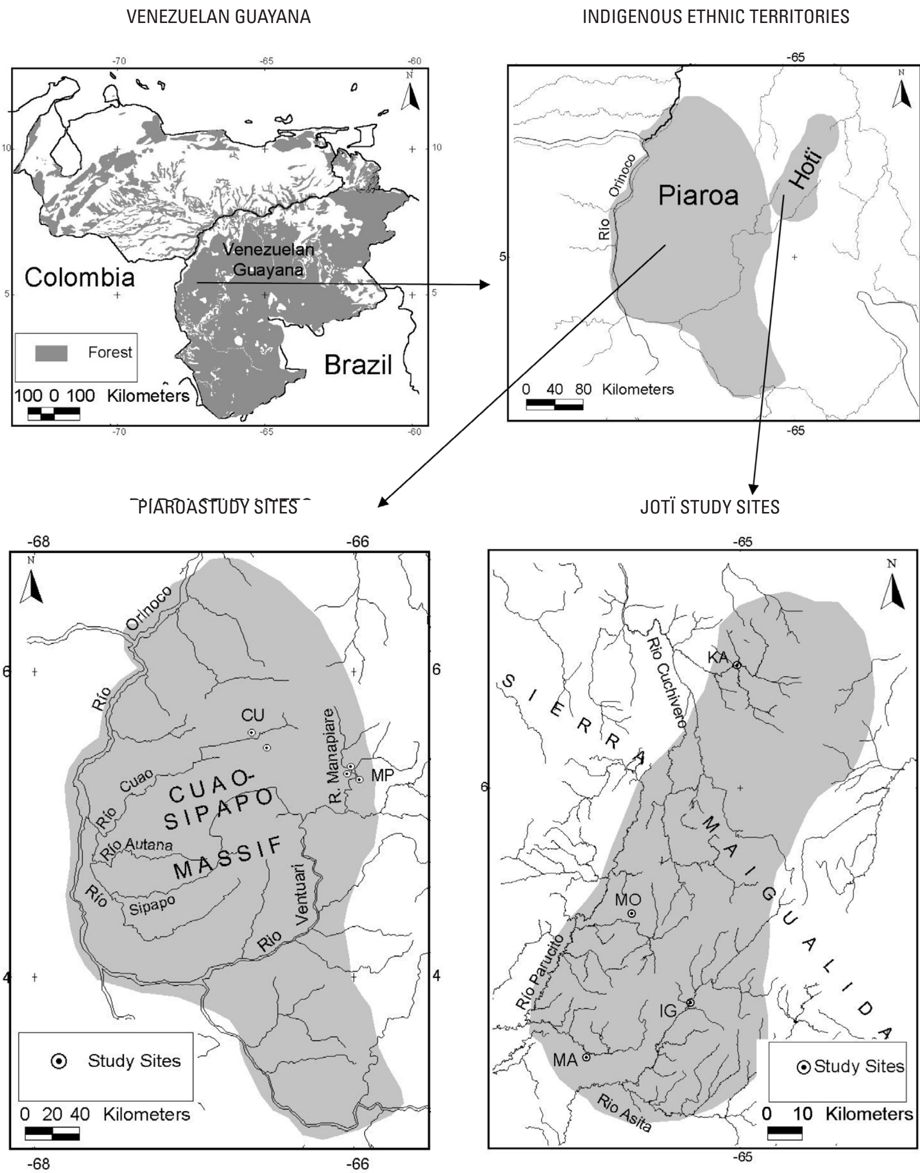


Figure 8.1 *Places and peoples of the Venezuelan Guayana*

indigenous groups of the Venezuelan Guayana have been experiencing profound demographic, technological, economic and cultural transformations during the past 30–40 years, which are seriously altering their customary relationships with habitat. Lured by government-sponsored social services (housing, education, health care) and economic incentives (public servant jobs, subsidies, credits) as well as by the exotic western goods available in regional and national markets, many indigenous communities have migrated away from the remote upriver and interfluvial zones where they were traditionally settled and toward more accessible downriver, roadside, mission-based, or peri-urban locations where contact with the national *criollo* (i.e. mestizo) population or other ethnic groups is much more frequent. Settlements in the interethnic contact zones are typically much larger, more nucleated, and more sedentary than they were under the traditional pattern. The indigenous population is also growing rapidly as a result of high birth rates and declining mortality. Accompanying this demo-geographic transition, the former economic focus on subsistence production is being replaced by a market-oriented economy in which people are increasingly dependent on wage-labour, cash-cropping or commercial forest product extraction in order to obtain money to buy industrially manufactured items for basic consumption (food, fuel, clothes) or luxury goods.

Greater contact with the national society has also brought about the widespread diffusion and assimilation of non-indigenous knowledge, customs, values and ideologies at the expense of native traditions. Of particular importance in this regard is the erosion of traditional environmental knowledge among the younger generations, which reflects diminishing interaction and experience with the local biota and a growing dependence on imported foods, medicines, tools and materials (Heckler, 2002; Wilbert, 2002; Zent, S., 1999, Zent, S. and Zent, 2004). Another type of knowledge decline, though one which is less well-documented, concerns the sacred and symbolic significance attached to place. Local landscapes are becoming less meaningful in such terms and hence less revered and respected as a consequence of territorial shifts, religious conversion and the devaluation of native oral histories.

While not all communities and ethnic groups have been equally affected by these generalized trends, nevertheless it is exceedingly rare nowadays to find any group that has not experienced some degree of demographic transition, socioeconomic integration, and transculturation along the lines described above. This process is the direct outcome of a state-sponsored development policy aimed more at geopolitical integration by means of the *cultural colonization* of the culturally separate native population (i.e. making the Indian more *criollo*-like) rather than the more conventional approach of promoting the expansion of national demographic or economic frontiers (Zent, 2005).

The multiple changes outlined above are accompanied by significant shifts in traditional patterns of land use and resource relationships, which in some localities are upsetting the balance between the human population and the natural environment. Population migration and growth as well as settlement aggregation and sedentarization have effectively raised local population densities in certain areas, leading to greater environmental impacts such as the depletion of wild resource species and the fragmentation of the primary forest cover (Kingsbury, 1996; Medina, 2000). The shift to cash-cropping has meant the expansion of land areas under cultivation, more intensive planting practices and shorter fallow periods, which in turn are associated with disruption of the natural succession, decline of local biomass and biodiversity, greater susceptibility to fire damage and soil degradation (Fölster, 1995; Freire, 2002; Melnyk, 1993; Zent, 1994). Commercial extraction of forest and river products, although not extensively practised, has been blamed for severe reductions in the natural populations of certain commercial species due to unsustainable harvesting practices (Montilla, 1994; Sánchez, 1999; Wilbert, n.d.). Meanwhile, the acquisition of introduced technology such as shotguns, flashlights, outboard motors and chainsaws has augmented the local capacity to intensify resource extraction beyond the natural regenerative rates (cf. Gorzula, 1995; Ojasti, 1995). Some groups have become heavily involved in the small-scale placer mining of gold and diamonds, which has been associated with deforestation, soil erosion, sedimentation of rivers and mercury contamination (Bevilacqua et al, 2002; CENDES et al, 1998; Gorzula, 1995). Others have become part-time workers in the tourist industry, guiding tourists to biologically unique and ecologically fragile sites, such as tepui (tabletop mountains) summits, an activity which has also had negative collateral effects, such as upsetting traditional swidden systems (Medina, 2000). In sum, culture change among the indigenous population of the Venezuelan Guayana is producing numerous deleterious ecological effects that pose serious questions about the viability of their traditional role as the nation's custodians of biodiversity.

Caught somewhere between tradition and modernity, as it were, many indigenous peoples face the dilemma of how to preserve and adapt time-tested ecological knowledge and resource management practices to meet the new challenges of rapidly shifting demographic, economic, social and cultural realities. One of the main obstacles to managing this complicated balancing act is the present uncertainty regarding land security, given that their land rights have historically gone unrecognized and even recent advances in this area exist more on paper than on the ground (Freire, 2003; Zent et al, 2004; see below). Another obstacle is the persistence of state-directed social and economic programmes designed precisely to bring about the cultural integration (read *homogenization*) of the native population (Zent, S., 1999). Whereas commercial farming, mining and logging operations have been identified as the main causes of deforestation in the Venezuelan Guayana today (Bevilacqua et al, 2002), most of which is occurring at the forest peripheries, it is also true that some of the more acculturated and displaced local groups have provided (willingly or not) one of the principal labour pools for such activities and, throughout the vast interior, the native forest residents continue to be the main frontline protagonists of rural development and environmental disturbance. In that sense, one of the biggest threats to biodiversity is arguably local cultural extinction. In making this argument, it is not our intention to blame indigenous peoples for the demise of their own native culture and habitat but rather to point out that this degenerative process needs to be confronted (and not ignored) as a key variable of the current developmental and environmental situation, that reduction of cultural diversity implies dangers to biodiversity, that if left unchecked constitutes a potential problem for the stated goal of conservation, and therefore that the cultural issue must be addressed in environmental protection policy. But this dynamic situation is perhaps more visible when viewed at the local level. Accordingly, two relevant ethnographic cases will briefly be described to develop our point.

Piaroa

The Piaroa are an indigenous horticultural-hunter society of the Middle Orinoco region who are celebrated in the popular and academic literature for their mastery of the forest environment, colourful ceremonies and powerful, drug-taking shamans (Anduze, 1974; Boglár, 1971; Dupouy, 1952; Monod, 1975; Wilbert, 1966; see Figure 8.1). Prior to the 1960s, most of them were settled in inaccessible upriver areas of the Cuao-Sipapo massif and for the most part they purposely maintained a safe distance from the encroaching *criollo* colonists whose settlements and movements were mainly confined to the Orinoco fluvial zone. In the traditional habitat, the Piaroa resided in small, semi-nomadic, one-house settlements and were largely independent in subsistence and social affairs although they also traded certain goods with neighbouring Indian groups. Between 1960 and 1980 they migrated *en masse* downriver attracted by missionaries, modern medicines, market opportunities, schools and various social and economic aid programmes offered by the government. Nowadays most people live in small, permanent villages which are distributed along the downriver peripheries of their traditional tribal territory, effectively within the former colonization zones. There they live in much closer proximity and contact with the *criollo* towns or cities as well as other Indian settlements, because numerous other groups have also moved toward and into these areas (for many of the same reasons). A few small, isolated communities remain in the tribal heartland, conserving many of the cultural traits of their forefathers (Zent, 1992).

The Piaroa still provide for most of their food needs, with three quarters of dietary energy being supplied by cultivated crops. Their staple crop is cassava (*Manihot esculenta* Cranz) and they cultivate literally hundreds of landraces of this species. In the Upper Cuao River (CU in Figure 8.1), which corresponds to the tribal heartland and is one of the few areas where traditional communities are still viable, it is not exceptional to find up to 40 varieties growing in a single swidden field. Meanwhile in the Manapiare region (MP in Figure 8.1), a multi-ethnic colonization zone into which the Piaroa have moved in the past few decades, a number of new varieties originating from other ethnic groups have been adopted and incorporated into their gardens, thus indicating that their knowledge and propagation of agrobiodiversity is neither a static nor a closed system (Heckler and Zent, in preparation).

But what explains hyperdiversity in the first place? Primarily culture, at least in this case. The impressive inventory of varieties is deeply embedded in a traditional food culture which puts a premium on taste diversity and displays a creative menu of cassava-based food items, such as tuber dishes, cakes, flours, soups and beverages (Table 8.2). Cultivar diversity is also stimulated by the social value system in which the number of varieties in a woman's garden is taken as a positive sign of her work ethic and enhances her social status (Heckler, 2004). However, this impressive biocultural legacy is beginning to change. For most Piaroa communities, cassava is now grown as much for sale as for home meals, diets are gradually becoming more dependent on store-bought foods, and traditional notions of social status are being distorted by the acquisitive power of money and the penetration of a foreign consumer culture. A major consequence is the decline in the number of varieties

Table 8.2 *A Piaroa taxonomy of cassava preparation and consumption forms*

1 cassava cakes/*casabe*/*ĩrĩsĩ*
- a fresh baked (soft) cake (*k^wæɨ ĩrĩsĩ*)
- b crisp-toasted cake (*hoek^{w}æsi/sarĩæsi/sarĩdæ̃k^wæ̃wæ̃si*)
- c sun-dried cake (*kiyɨ ĩrĩsĩ/kiñæsi*)
- d stale dried cake (*purukæ ĩrĩsĩ*)
- e pungent cake (*temɨre ĩrĩsĩ*)
- f starch cake (*ɨtæbɨ ĩrĩsĩ*)
- g dog and animal cake (*marap^{h}ak^{w}a ĩrĩsĩ*)
- h maize-cassava cake (*yamɨ ĩrĩsĩ*)
- i sweet cassava cake (*ẽtæ̃wæ̃ ire ĩrĩsĩ*)

2 cassava flour/*mañoco/iresap^{h}æ /mayukusap^{h}æ*
- a white flour (*teɨ iresap^{h}æ*)
- b yellow flour (*tuwo iresap^{h}æ*)
- c starch flour (*ɨtæbɨsap^{h}æ*)
- d fermented root flour (*muruw^{h}i wiwatɨ iresap^{h}æ*)

3 cassava beverage/*sãrĩ*
- a sweet potato beer (*wiriyæ sãrĩ/dawæwæ sãrĩ*)
  - • sweet (*sa'nɨ sãrĩ*),
  - • fermented (*at'ɨ sãrĩ*)
- b traditional red cassava beer (*tuwo ire sãrĩ/purukæ*)
- c traditional white cassava beer (*amuwæri sãrĩ*)
- d Yekuana white beer (*kusiwa sãrĩ*)
- e non-traditional beer(s) (*yæræke*)
- f shamanic (strongly fermented) beer (*at^{h}isoya*)
- g anime tree beer (*hič̃ũte sãrĩ*)
- h maize beer (*yamɨ sãrĩ*)
- i pungent cake beer (*temɨre ire sãrĩ*)
- j masticated beer (*k^wæwæ sãrĩ*)
- k dissolved cake drink/*yucuta* (*ĩrĩsawa*)
- l starch drink (*ɨtæbɨsawa*)

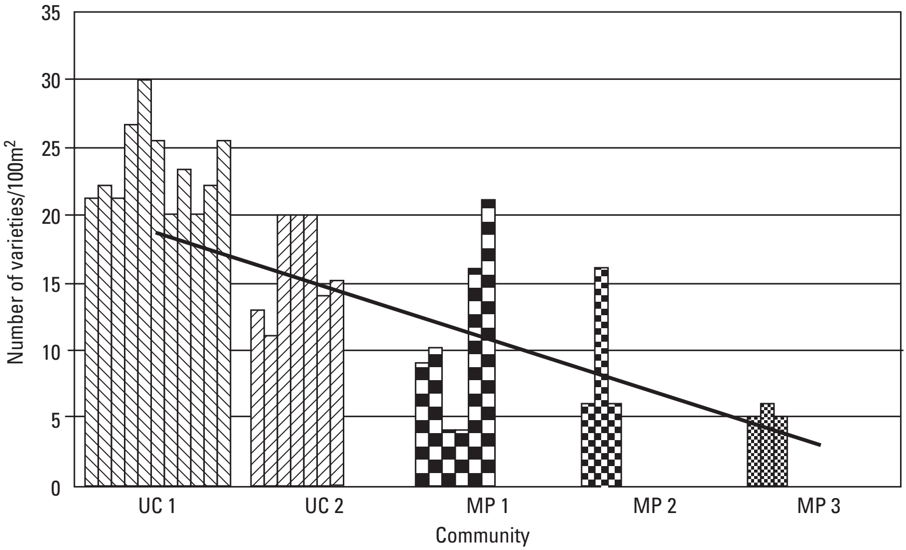
4 cassava root/*isæ̃te*
- a boiled (*dawæwæ*)
- b roasted (*ẽtæ̃wæ̃*)
- c fried (*pæræwæ*)

5 cassava juice/*yari*/*atoya*
- a boiled (*atoya*)
- b soup (*akoya*)
- c red pepper sauce/*catarra* (*ræte atoya*)
- d ause fruit sauce (*ause atoya*)

cultivated in Piaroa gardens, as shown in Figure 8.2 by comparing the number of varieties censused in 100m^2 plots in more traditional, isolated communities in the Upper Cuao (UC) region (the diagonally hatched bars on the left in Figure 8.2) vs. the number of varieties in more acculturated, integrated communities of the Manapiare (MP) region (the checkered bars on the right). Furthermore, at Manapiare girls and young women, traditionally the main cultivators, rarely go to work in the fields anymore because they are too busy with school studies, paid domestic labour, babysitting, or watching soap operas on TV, and consequently they are hard-pressed to name more varieties than they can count on a single hand and even less able to tell them apart out in the garden (Heckler and Zent, in preparation; see also Royero et al, 1999b).

Jotï

Another revealing case study involves the Jotï, a traditional nomadic hunter-gatherer group who inhabit the slopes and intermountain valleys of the remote Sierra Maigualida mountain range (Figure 8.1). They maintained a nomadic, foraging existence, organized into very small, fluid, acephalous bands, and were entirely isolated from westerners until the late 1960s when they were contacted by missionaries. At the time of contact, they were found to be carriers of a simple autochthonous



The two sets of diagonally hatched bars on the left represent the more traditional communities of the Upper Cuao River (UC) region located in the tribal heartland while the three sets of checkered bars on the right refer to the more acculturated communities of the Manapiare River (MP) region located in the inter-ethnic colonization zone (see Figure 8.1 for the precise locations). The tendency line indicates a sharp and significant drop in the frequency of varieties from the most diverse (UC 1) to the least diverse (MP 3) communities ($Y = -3.9218x + 22.587$; $r^2 = 0.8993$). The results indicate a definite decline in the diversity of gardens in terms of cassava cultivars from the Upper Cuao to the Manapiare region at least at the scale of a single garden.

Figure 8.2 *Diversity of gardens in Piaroa communities: Number of cassava varieties per unit area*

material technology, including stone tools, and possessed very few items of western origin. But then two missions were established in the Jotï territory, at Caño Iguana in 1971 and on the Río Kayamá in 1983, and they have since drawn more than half of the formerly dispersed, mobile population to come and settle permanently at these fixed locations. The missionaries have taught the Indians about the Christian religion and basic educational skills (such as literacy in the native or national languages) and provided western trade goods and medicines. Since the 1990s, social and economic interaction with neighbouring Indian groups, miners, adventurers and government agents has expanded substantially as some Jotï bands have moved down the rivers toward the lowland fringes of their mountain territory. The sum result is that within the space of a generation the Jotï have gone from total isolation to more or less permanent contact with outsiders, with the consequence that they are now experiencing a rapid phase of culture change, including the introduction of new technology, changes in settlement pattern and economic focus, and ideological conversions.

In the late 1990s, the present authors carried out quantitative floristic inventories and ethnobotanical studies at four Jotï communities: Caño Majagua (MA), Caño Mosquito (MO), Caño Iguana (IG), and Río Kayamá (KA). The first two communities

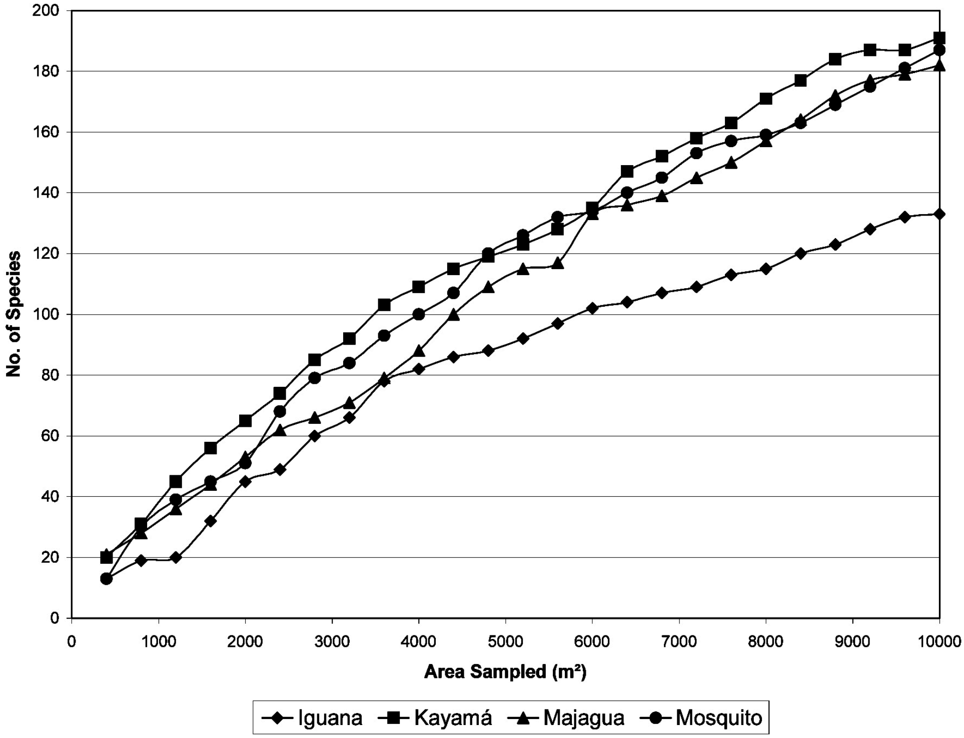


Figure 8.3 *Cumulative species area curve in four 1-ha forest plots inventoried in the Sierra Maigualida Region*

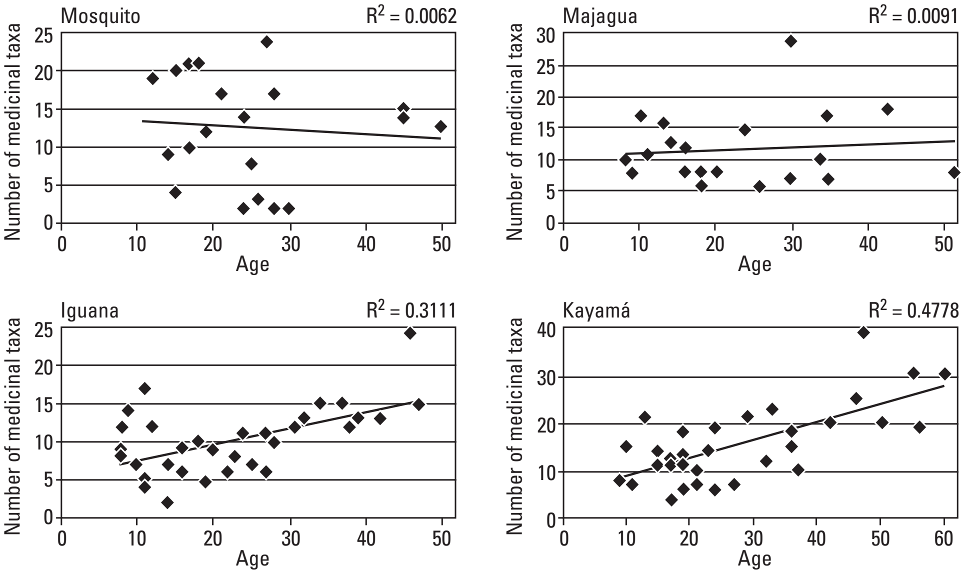
correspond to smaller, independent, less acculturated communities while the latter two communities refer to the larger, mission-based, more acculturated communities. The results of the floristic study indicate that the forests occupied by the Jotï exhibit surprisingly high levels of species richness. Three out of four 1-hectare forest plots contained more than 180 species of large trees per hectare (Figure 8.3). These figures are remarkable for two reasons. First, they show the highest levels of tree diversity thus far recorded for the Guayana shield region of South America (Zent, E.L. and Zent, 2004). Second, all of the plots from which the figures are drawn are within a few minutes walk of a Jotï community. Thus one may conclude that the Jotï demonstrate that human occupation, exploitation and disturbance (in the form of low-impact fruit, leaf, and bark harvesting, seed dispersal and gap creation) are not necessarily incompatible with high diversity maintenance.

The ethnobotanical study revealed that these people possess an extraordinarily extensive knowledge and use of primary forest species, including more than 220 edible species, more than 180 medicinal plants, and 550 species known to be eaten by wildlife (upon which people depend for food) (Table 8.3). However, it also appears that the availability of western medicines is beginning to impact traditional patterns of knowledge transmission especially among the younger generation, which has grown up with imported aspirin and antibiotics. We compared interinformant knowledge patterns across the four communities, two of them independent and self-reliant in *materia medica* and the other two mission settlements where western medicines are widely and freely available. One result was that age correlates positively with the number of medicinal plants known to an individual in the two mission communities (i.e. younger people know less) whereas there is no such correlation in the two independent communities (i.e. younger people know as much as older people) (Figure 8.4). Further analysis of this divergent trend demonstrated that most of the medicinal plants learned by young people at the missions are more commonly known cures (as measured by higher consensus levels) whereas the knowledge of more exotic, less shared medicinals is held almost exclusively by adults who spent their formative years outside the mission setting (see Zent, S. and Zent, 2004, for the details of this analysis). A plausible explanation of this result was suggested by one of our informants: young people at the mission are not bothering to learn as many plant medicines because it is easier to go to the local dispensary and ask for a pill.

Looking further into this dynamic process, we then ran a multidimensional scaling analysis of the (dis)similarity of the specific medicinal plant inventories among individuals tested in the mission communities in order to see how the individuals with more extensive inventories compared among themselves and with all other individuals making up the community sample (Figure 8.5). The results of this operation show that the more knowledgeable individuals (represented by the solid black circles in Figure 8.5) displayed somewhat divergent inventories by virtue of the fact that they do not cluster together. This seems to indicate that at least a portion of this type of knowledge is acquired through individual experimentation and/or passed down within small family groups and does not correspond to what may be considered a uniform corpus of specialist knowledge. This finding has important implications for the dynamic process of intergenerational knowledge retention: if only some but not all younger people fail to learn the traditional medicines used by their parents or grandparents then some portion of the traditional ethnopharmacopiea will nevertheless be lost – that is the smaller the chain of transmission, the more fragile it is. What will be the impact of this loss if and when the missionaries pack up and leave? No more free pills and who will revive the forgotten native cures? In any case, as the

Table 8.3 *Statistical summary of plants used by the Jotï*

Use category	*Families*	*Species*	*Unidentified*	*Jotï taxa*
Edible	58	222	43	253
Medicinal	67	182	76	229
Construction	59	285	46	294
Fishing	18	36	4	39
Firewood	54	325	51	351
Hydration source	9	11	4	14
Hygiene	15	23	7	29
Miscellaneous technology	59	193	50	245
Animal food	91	550	89	591



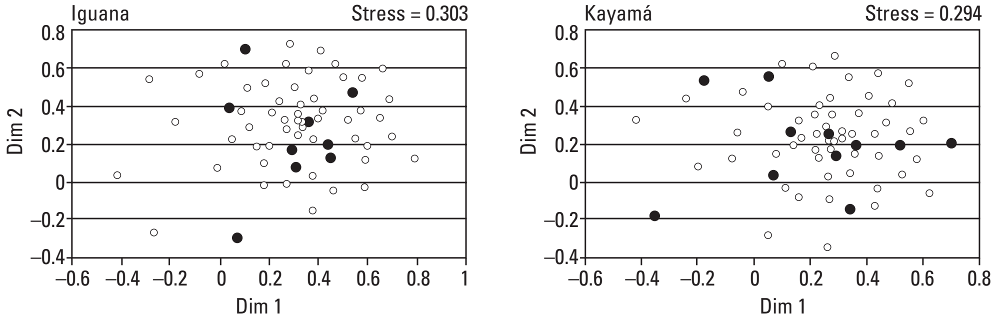
The top two data sets correspond to independent communities where no western medicines are locally available while the bottom two data sets describe mission-based communities where western medicines are regularly provided. A person's inventory score, as plotted along the Y axis, is calculated as the number of locally distinct botanical taxa that he or she was able to name as having medicinal properties out of a sample consisting of all the large plants (≤ 10cm dbh) growing in a 1ha plot of primary forest within a close distance of the person's place of residence. The regression lines corresponding to the two independent communities show no clear or significant relationship between the two test variables. By contrast, the regression lines describing the two mission communities do indicate a significant tendency ($p < .01$) for older people to have more extensive inventories of medicinal plants.

Figure 8.4 *Relationship between medicinal plant inventories and age in four Jotï communities*

number of plants considered to be useful shrinks, the value of the forests for their lives will also be diminished.

LEGISLATIVE PROGRESS AND RESEARCH PROBLEMS

Until recently, Venezuela has demonstrated remarkable success at preserving its megadiverse frontier forests (especially in comparison with other Amazonian nations), largely because population, industry and commerce have been historically concentrated in the northern half of the country but also thanks in part to a strong environmental protection policy, applied especially to the southern Guayana region. The cornerstone of this policy is an extensive network of protected areas (Areas bajo



The two data sets shown here refer only to the two mission-based Jotï communities. The solid black circles represent those individuals who scored highest in the medicinal plant inventory test (Figure 8.3) and the open circles represent everyone else. At neither community do the inventories of the most knowledgeable individuals cluster together in relation to all other members, thus indicating that knowledge of medicinal plants does not conform to a coherent and neatly separated body of specialist knowledge but instead is distributed in a highly individualized manner.

Figure 8.5 *Multidimensional scaling plot of response similarity for medicinal taxa*

Administración Especial (ABRAE)), ranging from strictly protected (i.e. no use) to permitted natural resource use, that cover 72 per cent of the Venezuelan Guayana. Not surprisingly, many of these areas overlap with Indian-occupied lands, but surprisingly the aboriginal inhabitants have largely been ignored in conservation policies and plans. At the same time, it has been noted that the Venezuelan state has been considerably less appreciative and protective of the nation's diverse cultural patrimony and instead has actively sought to transform and indeed eradicate cultural distinctions among the native peoples, often with nefarious environmental consequences. Elsewhere we have argued that the prevailing policy of active cultural colonization of the indigenous population may in fact undermine the goal of environmental conservation over the long run and instead a policy aimed directly at the integration of cultural diversity and biodiversity as well as the direct incorporation of the native peoples into conservation programmes may prove to be more effective (Zent, 2005; Zent and Zent, n.d.). Indeed, recent indications that deforestation rates in the Venezuelan Guayana have surged dramatically over the past few years, such that they are now among the highest in South America (Bevilacqua et al, 2002; Miranda et al, 1998), should serve notice that the time for a policy shift has come.

Fortunately, the past policy of neglecting or even excluding native cultures and peoples from conservation programmes has begun to turn around, especially since the democratic conquest by populist president Hugo Chavez, although some of these changes were actually set into motion before Chavez' rise to power. Progress toward creating a more coherent and integrated biocultural conservation strategy has been made mostly at the level of national legislation, including: ratification of the Convention on Biological Diversity (CBD), Decision 391 of the Andean Community of Nations, Constitution of the Bolivarian Republic of Venezuela, Biodiversity Law, Demarcation and Guarantee of Indigenous Habitat and Lands Law and National

Demarcation Commission Law. But the main effect of such legislation so far has been symbolic and not matched by concrete actions. Furthermore some of the new laws are fraught with definitional gaps, ambiguities and contradictions that in turn generate special problems for effective implementation, as will be discussed below.

The CBD was ratified by Venezuela in 1994 and has had a dominant influence in shaping subsequent environmental legislation. Among other things, this document provided the conceptual basis for recognizing: the strategic importance of biodiversity conservation for human need satisfaction, the economic value attached to biodiversity, the right to benefits sharing and technology transfer associated with the use of biological resources, the sovereign rights of nations over such resources, and the faculty to regulate access to them (Febres, 2002). It also urged states to take measures to preserve the traditional knowledge of indigenous and local communities that contributes to the sustainable development of biodiversity, to make wide use of such knowledge, innovations and practices, and to foment the equitable distribution of the benefits derived from the utilization of such knowledge (Albites, 2002).

Decision 391 of the Andean Community of Nations (Bolivia, Colombia, Ecuador, Peru and Venezuela), 'Common Regimen for Access to Genetic Resources', formally established a legal mechanism for putting into practice some of the guiding concepts set down in the CBD. Subscribed to in 1996, it asserts national sovereignty over genetic resources and their derived products and establishes various legal conditions, procedures, and obligations that all parties seeking access to genetic resources must follow, including providing economic or other compensation to the state and/or to local providers. Moreover, it links regulation of access to genetic resources and access to associated intangible components, especially where indigenous, Afro-Venezuelan and local communities are involved. The measure has been broadly interpreted thus far so that all researchers of biodiversity and associated local knowledge, whether commercially oriented or not, are now required to negotiate and sign a contract with the Ministry of Environment and Natural and Renewable Resources (MARNR). This regulation has had a devastating impact on basic and applied research, mainly because standard regulations and operating procedures regarding prior informed consent, benefits sharing, technology transfer and IPR issues have not yet been clearly defined. Of 20 applications received between 1997 and 2001, only six were awarded contracts and four of these were later suspended due to disputes regarding these undefined issues (Febres, 2002).

An illustrative example of some of the unforeseen problems with the present access regimen is found in the controversial case of the BIOZULUA database. The database was created as part of a research project undertaken by the Venezuelan-based, scientific NGO, Foundation for the Development for the Physical and Mathematical Sciences (FUDECI), that was originally aimed at the salvage recording of fast-disappearing traditional knowledge about the agrofood, technological and medicinal uses and preparations of plants and animals among different ethnic groups of the Venezuelan Amazon, purportedly in support of their sustainable development. Thus, one of the objectives was to compile and systematize a broad range of information about useful biodiversity and then reinsert this information system back into the source communities where traditional mechanisms of intergenerational transfer are starting to break down as a result of culture change (Royero et al, 1999b). Although the research project actually began before Decision 391 was implemented, FUDECI later applied for and was granted a legal access contract, which included provisions for the equitable distribution of benefits, technical training and information sharing. Major funding for the project was granted by the National Council for Science and Technology (CONICIT), a branch of the Ministry of Science and Technology (MCT). The research was carried out in 24 different Indian communities in Amazonas State and amassed approximately 3000 biological specimen collections and 20,000 data items. The data was entered into a computerized multimedia database, denominated BIOZULUA (meaning 'house of life'), consisting of text, maps, photos, video and recorded sound (Vivas Eugui, 2002). However, what happened next is a testament to how noble intentions are too easily perverted under the current legal and economic framework.

Encouraged by the economic potential of the database contents and concerned by the lack of legal protection existing at both the national and international levels, the legally designated proprietors of BIOZULUA, namely FUDECI and MCT, decided to register exclusive authorship rights over it and maintain the contents as a secret, even from the communities participating in the study, until such time that their intellectual property rights (IPR) can be guaranteed. Naturally the indigenous communities and organizations that have a stake in BIOZULUA were outraged by this action and also charged FUDECI with failing to secure their informed consent. The consent issue continues to present one of the biggest problems for the present access regimen because MARNR has yet to establish clearly defined criteria for obtaining it. In any case, following the bitter lesson offered by BIOZULUA, ORPIA, the principal indigenous organization in Amazonas State, issued a statement demanding repatriation of all the information contained in the database and calling for a moratorium on all research involving access to genetic resources and traditional knowledge until all the IPR, consent and compensation issues are worked out at national and international levels (Davies, 2002a, 2002b). This decision potentially affects not only scientists, commercial bioprospectors and government officials, but also local groups themselves, since many of them have become increasingly concerned about the erosion of their traditional environmental knowledge and aware of the practical benefits of conserving it. In fact, some indigenous groups have already initiated their own salvage research projects, enlisting scientists to aid them, such as the Dekuana Atlas project among Dekuana groups of the Upper Orinoco (Arvelo-Jiménez and Jiménez, 2001).

In December 1999, a new national Constitution was adopted that committed the State to preserving and protecting the safety and health of the natural environment as well as the cultural integrity of the indigenous peoples, and implies links between the two sets of responsibilities. Article 127 obligates the State to protect the environment, biodiversity, genetic diversity, ecological processes, national parks, natural monuments and other areas of ecological importance for current and future generations. The same article also prohibits the patenting of the genomes of living organisms. Article 119 recognizes the original collective rights of indigenous peoples over their ancestral and traditional habitats and calls for the demarcation of Indian lands in a timely fashion. Article 121 recognizes the right to separate ethnic identity and maintenance of cultural traditions, and commits the state to foment the appreciation and diffusion of these. Article 124 guarantees the collective intellectual property in the knowledge, technologies and innovations of indigenous peoples, requires that all activities related to genetic resources and associated knowledge produce collective benefits, and prohibits patents over such resources and knowledge. Some analysts hold that the IPR protection and patent prohibition provisions contained in the last article create a fundamental contradiction between national (or state) and local interests (Febres, 2002), a problem that seems to be at the heart of the BIOZULUA controversy. Meanwhile the prohibition of patents over the genomes of living organisms provides a disincentive for research and may conflict with existing IPR laws (Febres, 2002). Obviously these issues will have to be resolved if rational and sustainable utilization of biodiversity is to be optimized.

The Biodiversity Law, passed in 2000, contains various provisions designed to promote biodiversity conservation, such as: (1) the recognition that forests harbour a large portion of the nation's biodiversity and therefore favours their conservation; (2) the regulation of access to genetic resources for sustainable management; (3) the recognition and preservation of knowledge and uses of biodiversity by local communities; and (4) the just and equitable participation in the benefits derived from such utilization. Moreover, this is the first Venezuelan national law that explicitly acknowledges the importance of traditional knowledge held by indigenous and local peoples for biodiversity conservation and even suggests that they should be compensated for this contribution. The state is required to institute programmes designed to protect traditional knowledge, control activities that utilize such knowledge, and promote the development and innovative capacity of local communities. It remains to be seen what concrete measures will emerge from this law.

In January 2001, the Demarcation and Guarantee of the Habitats and Lands of Indigenous Peoples was passed (see Gaceta Oficial Año CXXVIII, IV No. 37.118), laying the legal framework of basic dispositions, participating entities, responsibilities, general procedures, lists of indigenous beneficiaries and other eventualities for implementing the constitutional mandate of Indian land rights. The law establishes that the executive branch of the national government, whose authority is delegated to MARNR, is in charge of the planning, execution, supervision and financing of the national process of demarcation but also assigns a participatory role to the indigenous communities and organizations. Later in 2001, the National Commission for the Demarcation of Indian Lands was created by decree (see Gaceta Oficial Año CXXVIII, X No. 37.257) with the function of promoting, advising and coordinating all aspects of the demarcation process. As a result of these measures, Venezuela may rightly be considered to have the most progressive legislation in all of Latin America in the area of Indian land rights, but in terms of implementation little real progress has been made. Although the national constitution stipulated that this process be completed within two years, after nearly seven years since its passage very few titles have been handed out thus far, and all of those that have correspond to relatively small area, single-community land grants, which carry certain restrictions on permitted land uses and assignations. Similarly, although the Demarcation law commits the national government to funding and performing the demarcation work, the reality is that MARNR, the public authority charged with this task, has played a more passive, rather than active, role in this process. Thus it has not organized or undertaken or contracted for any demarcation projects itself, but instead has attempted to promote the demarcation process by sponsoring or supporting meetings and workshops for indigenous groups with the idea that they will then do the bulk of the work that is needed (e.g. territorial delimitation, map-making, compilation of supporting documents, etc.). In any case, very little money has actually been made available to local or regional organizations for the purpose of doing this work. The response of several Indian groups to the government's inaction and frugality has been to undertake their own independent demarcation projects, including biodiversity inventories and detailed mapping of natural resource areas, with the help of NGOs and outside technical advisors.

The project 'Self-Demarcation and Ethnocartography of the Eñepa and Jotï Habitats', which included the authors'direct participation, provides a case in point of the latter. In early 2001, some Jotï members of the Kayamá community contacted and asked us to help them demarcate their land pursuant to applying for the land title. In September of that year, we travelled to Kayamá and talked over the proposal in community assemblies. At that time, members of the Eñepa group, who are also coresidents of the Kayamá mission settlement, expressed their interest in doing the same. Upon reaching an agreement to work together with both groups, we then formulated a collaborative work plan, one in which all the key decisions regarding the scope and realization of the project would be taken by the respective local communities. Designated teams of Jotï and Eñepa would receive training in cartographic methods (especially proper use and recording of GPS), cultural and ecological data recording and computerized data entry (e.g. use of Windows, Excel and Arc-View programs). They would then be in charge of the field mapping, entering the information collected in computerized databases, and reciting and recording their oral history. Our role in the project would be to provide the equipment and technical training, to coordinate the overall work effort, to conduct interviews on selected topics and to prepare the final documents that would be needed for the title application. These included a map of their communal lands and a cultural-historical report. The map would show the locations of pertinent cultural and physical features, including territorial boundaries, settlements, gardens, natural resources, sacred sites, ancestral areas, topographical features (rivers, rapids, mountains) and local toponymy. The cultural-historical report would cover various facets of the relationship between the people and their land, including: settlement pattern, natural resource exploitation and management practices, residential and life histories, kinship and ethnicity, notions of territoriality and property, eco-geo-cosmovision, ritual behaviours, environmental ethics, environmental lexicon and toponyms.

The project officially began with a training workshop held at the Instituto Venezolano de Investigaciones Científicas (IVIC) in Caracas in December 2001 and the fieldwork phase commenced at Kayamá the following month. When the Jotï community at Caño Iguana heard about the demarcation being done at Kayamá, they also sent word to us indicating that they wanted to be included. They were added to the project in May 2002. The collection and processing of field data was carried out on an intermittent basis until October 2005, the timing being affected mainly by fluctuations in the availability of time and resources of both the local and the scientific participants (see Zent et al, 2004, for a more complete description of the methodology and chronology). More than 7000 geo-referenced data points, 1000 photographs and 120 hours of interviews or recitations were recorded in all. The final maps and cultural-historical reports were completed in August 2006 and handed in that same month to the National Demarcation Commission. Although the demarcation work is now concluded, during the last meeting between the authors and the people of Kayamá, the latter expressed their desire to convert the database that was created into an educational project for their local school so that the children of the community can learn everything of cultural and ecological importance about their habitat and territory.

CONCLUSION

While other chapters in this section have stressed the importance of economic development, moral beauty, innovative environmental law or modern biotechnology, either as a problem or solution for biodiversity conservation, in this chapter we have focused instead on the crucial link between biodiversity and *local culture* as embodied in the traditional low-tech knowledge and practice systems of indigenous peoples. A processual perspective of the changing interrelations between culture and environment has been emphasized, in which traditional knowledge loss is seen as a major threat to biodiversity conservation. Thus from a dynamic biocultural perspective, *adaptive cultural management* in the service of sustainable resource management – referring specifically to the blending, or even hybridization, of useful traditional knowledge and practices and beneficial cultural and technological innovations – rather than genetic engineering, molecular synthesis or protected area extension – constitutes the tip of the lance for defending biodiversity in Venezuela. Several new laws have been passed to realize this biocultural revolution but at the same time have created problems for carrying out the research and planning that is also needed. Until the legal grey areas can be cleared up as well as the contradictions between existing law and practice resolved, which could take many years, the best hope for research relevant for biocultural conservation lies at the grass-roots level, that is with the Indians themselves acting as the principle investigators and scientists as the field and lab assistants.

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Chapter 9

From the 'Tragedy of the Commons' to the 'Tragedy of the Commonplace': Analysis and Synthesis through the Lens of Economic Theory

Joseph Henry Vogel

Economics is defined so broadly in the textbooks – 'the way resources are allocated among alternative uses to satisfy human wants' (Mansfield, 1986) – that an economist would not be outside the profession's domain to answer the two main policy questions addressed in this volume:

1 How should the benefits of biotechnology be shared with providers of genetic resources and/or associated knowledge (commonly known as access and benefit sharing (ABS))?
2 How should society handle genetically modified organisms (GMOs)?

Non-economists may even be predisposed toward accepting *prima facie* the advice of economists inasmuch as these two questions are complex and gains can be had from a division of intellectual labour. Nevertheless, the general public will probably remain more sceptical. The reason for both the acceptance and the rejection owes much to appearances. Economics-the-discipline legitimizes itself within academia through the equations, the graphs and the statistics even though the public may view these same equations, etc. as little more than smoke and mirrors. Capitalizing on both the positive and negative prejudices, I see no better strategy than to cut and paste a bit of the wisdom of some Nobel Memorial Laureates in Economics (and near-Nobels) as it might apply to these two questions. This commentary hopes to show that by analysing and synthesizing some key ideas explored in this volume, through the lens of economic theory, chapter contributors and readers alike will gain a new appreciation for both the potential and the pitfalls of economic theory.

As some of the scientists and lawyers who have contributed chapters to this volume may already suspect, economics is not really a science at all. It is a rhetorical enterprise, where the most effective rhetoric has long been logical consistency and abstraction rather than close description, experiments and statistical analysis. In the case of ABS and GMOs, this is a not a bad thing; current policy is so illogical and void of abstract reasoning that to do close description, etc. is not only premature but counterproductive. With that said, I hasten to add that both scientists and lawyers should curb their expectations as to what economic reasoning can offer. The history of science suggests an analogy. Just as the pre-Einsteinian conservation principles broke down in the peculiar case of radioactive decay, ushering in a new paradigm in physics, so mainstream economics is now breaking down in the area of biodiversity conservation, which subsumes ABS and GMOs. Until the actual paradigm shift comes, the best that economics can offer is a clarification of the arguments in the emerging debate over limits and an expanding role for government.

WHERE WISDOM BEGINS: DEFINITIONS

E. O. Wilson (1998) begins a number of his writings by stressing the importance of classification: 'The first step to wisdom, as the Chinese say, is getting things by their right names.' In the case of the nomenclature itself, the first step to wisdom would be definitions. The word 'biodiversity' has been defined in the Convention on Biological Diversity (CBD) as: 'the variability among living organisms from all sources including, *inter alia*, marine and other aquatic ecosystem and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems' (Glowka et al, 1994). Before the definition became codified with the ratification of the CBD in 1993, I had tried, unsuccessfully, to persuade audiences that the inclusion of every taxonomic level in the definition would ultimately frustrate conservation goals (Vogel, 1992). By the CBD definition, the simple directive 'conserve biodiversity' could never be made without some sort of qualifying clause. The second law of thermodynamics implies that to live is to destroy and that just eating will expunge biodiversity 'within species'. I suggested that we should define biodiversity as information especially as it concerns ABS. Indeed, biodiversity as information is no metaphor: one can affirm that the sequence of pyrimidines and purines of DNA is literally information in light of the Shannon–Weaver information theory or the Boltzmann equation of thermodynamics. By understanding biodiversity as information, conservationists could have imported the well-established economics of (artificial) information into the policy debate. In hindsight, I can say that much of the ten-year long talkfest over the BS in ABS, viz., benefit-sharing, would have been greatly simplified, if not averted, had my advice been taken. Unfortunately, like the popular 1980s comedian Roger Dangerfield, I got no respect! Whereas the biologists thought the legal definition was a tangible coup – the world having given them a banner behind which to rally the troops – mainstream economists could have cared less about any definition. The reason for the ambivalence among economists is truly perfidious: no matter how biodiversity would be defined in the CBD, economists would take that accepted definition and further classify it in terms of economic theory.

To its credit, economics-the-discipline seized upon mass extinction almost immediately. By 1993, the issue of biodiversity had already been distilled to the level of undergraduate student. For example, in *Environmental Economics: An Elementary Introduction*, R. Kerry Turner, David Pearce and Ian Batemen devote a short chapter to 'Conserving Biological Diversity' and tell the student, *inter alia*:

> *The local benefits of biodiversity often have no market. This is especially true of indirect use values such as watershed protection. We say they are* ***local public goods****. Some of the benefits of biodiversity are global in nature, making it difficult for countries to appropriate the benefits. We say the benefits have the characteristics of* ***global public goods****.*
>
> (Turner et al, 1993, p298, bold in original)

To the non-economist, the term in bold 'public good' seems vague, somehow connoting government management (say, police or fire protection). To the economist, the definition is precise and means 'goods and services that can be consumed by one person without diminishing the amount of them that others can consume' (Mansfield, 1986, A61). Textbooks usually follow up such definitions with the immediate implication: 'Often there is no way to prevent citizens from consuming public goods whether they pay for them or not.' So the economic classification of biodiversity as a public good can explain, in part, mass extinction:

> *Environmental economics sheds a great deal of light on why biodiversity is disappearing. The main reasons lie in the 'public good' nature of biodiversity and the economic distortions in the market place.*
>
> (Turner et al, 1993, p298)

AND WHERE WISDOM ENDS: MISAPPLICATION OF DEFINITIONS

How much biodiversity should we protect? By classifying biodiversity as a 'public good' *sensu economica*, one need not reinvent the wheel in answering this question. The generic problem of the optimal level of public goods was solved in 1954 by Paul Samuelson in 'The pure theory of public expenditure'. The paper is regarded as a classic in the economic literature and Samuelson even refers to the accomplishment as he closes his Nobel Memorial Lecture in 1970: 'it has been a special source of satisfaction to me that the calculus of modern welfare economics … was able to elucidate the old problem … of the analysis of public goods' (http://nobleprize.org/nobel_prizes/economics/laureates/1970/samuelson-lecture.pdf). Unfortunately for the non-economist, the application of the analysis of public goods to biodiversity cannot be made without introducing some mathematics and economic terminology. I will try to keep both to a manageable minimum in respect to all for whom mathematics is not their forté and for whom economic terminology is little more than a string of shibboleths. Nevertheless, the reader must also show some patience and recognize that 'no matter how well explained, serious economic analysis is often intrinsically difficult' – and this from Paul Krugman (1996), an accomplished professor at Princeton and editorialist at *The New York Times*. Indeed, a bit of patience in digesting the next few paragraphs can greatly facilitate understanding the subsequent elaboration of ABS and GMOs within the framework of the Samuelsonian analysis of public goods.

To find the optimal provision of biodiversity, one wants to find the optimal provision of natural reserves sufficiently extensive to allow the continued evolution of species. The Samuelsonian condition for that optimal mix of sustainable reserves (r) vs. the next most profitable alternative, say, timber (t) harvested in clear-cuts, would be expressed as follows:

$$\sum_{i=1}^{n} \mathrm{MRS}_{rt} = \mathrm{MRT}_{rt} \qquad \text{Equation (1)}$$

where,

$\mathrm{MRS}_{rt} = \mathrm{MU}_r/\mathrm{MU}_t$

$\mathrm{MRT}_{rt} = \mathrm{MC}_r/\mathrm{MC}_t$

The capital Greek letter sigma ($\sum$) indicates summation over n people counting with the first individual, $i = 1$. The MRS_{rt} is the marginal rate of substitution of reserves for timber and equals the ratio of the marginal utility of reserves over the marginal utility of timber; the MRT_{rt} is the marginal rate of transformation of reserves for timber and equals the ratio of the marginal costs of providing one more unit of reserve, MC_r, over one more unit of timber, MC_t. At this point, the abstractions may have already overwhelmed the reader, so let me switch back to plain English. Equation (1) can answer the question: how much acreage in reserves is one willing to substitute for sacrificing how much timber? In a competitive society, reserves should be expanded or contracted until the summation of the marginal rates of substitution of reserves for timber across all individuals, starting with the individual willing to pay most and summing in decreasing order, just equals the marginal rate of transformation of reserves for timber. This result can be put into plainer English by expressing the marginal rates of substitution and marginal rates of transformation in terms of price. The MRS becomes the willingness to pay and the MRT is the cost of provision of the reserve. So, expand/contract reserves as long as the summed willingness to pay is greater/less than the cost of the reserve.

One can decompose the aggregate willingness to pay on the left hand side (LHS) of the equation into sustainable activities that could be generated by the reserve. The monetary value of these activities would be captured through myriad user fees for things like ecotourism, water provision, soil erosion prevention, carbon retention, extraction of non-timber products, sustainable agro-forestry and bioprospecting. Just as the existence of the reserve would generate these positive externalities, clear-cut logging would also generate negative externalities. Whether the dollar value of the negative externalities is incorporated on the LHS or the right hand side (RHS) of the equation is largely a question of the distribution of property rights. For example, do the people downstream have a right to clean water and the fish endemic to deep rivers? If the answer is yes, then the existing timber operations that silt the rivers and exterminate the fish are suboptimal inasmuch that the MRT should be lower as it takes more resources (the value of sedimentation) to create timber (the MC_t of the denominator increases) and therefore, the MRT is reduced, and the LHS>RHS. The economic advice would be to increase the number of reserves until diminishing marginal utility sets into reserves and the LHS declines to equal the RHS or, concomitantly, until diminishing returns and increasing costs set into creating reserves and the RHS increases and equality is restored.

Exactly where do ABS and GMOs fit into Equation (1)? The answer depends on how rights are assigned. Since the ratification of the CBD in 1993, the country of origin enjoys a right over its genetic resources and can grant or withhold access (the A in ABS). Should it grant access, benefit sharing would be aggregated with ecotourism and all the rest into the LHS of Equation (1). GMOs would enter indirectly into the public calculus only to the extent that the organism modified provided a social benefit (say, decreasing the use of pesticides) or posed a potential social cost (say, resulting in transgenic weeds). If the social benefits and social costs of GMOs are assigned to industry, then the decision to release that GMO would hinge on the profit calculation of the firm; if those social benefits and social costs are assigned to government, then the regulator would determine what was in the public good, *sensu non-economica*. But getting back to the practical question of how much forest to cut and how much to save, economists must carefully identify and measure all the components that figure in both the LHS and RHS of Equation (1) – no easy task.

Economists are so confident that the solution to the mass extinction crisis lies in this public good analysis that the methodology has also made its way into undergraduate textbooks. Turner et al (1993, p113 italics in original) tell the unsuspecting student that '*Total economic value* [TEV] *is then made up of actual use value plus option value plus existence value*' where TEV is really just the LHS of Equation (1). In this nomenclature, the aforementioned sustainable activities such as ecotourism, etc., constitute 'actual use value' and the possibility for future consumption of such things constitutes 'option value'. 'Existence value' is the wild card. It cannot be easily explained much less monetized and so gets short shrift. Nevertheless, precise definitions do exist in the literature. For example, in *Biodiversity* (Wilson, 1988), Alan Randall (1988) defines 'existence value' in reference to its status in TEV:

> *To keep the value of existence separate and distinct from the value of use, existence value must emerge independently of any kind of use, even vicarious use. That is a*

> *stringent requirement. Nevertheless, valid existence values can arise from human preference for the proper scheme of things. If some people derive satisfaction from just knowing that some particular ecosystem exists in a relatively undisturbed state, the resultant value of its existence is just as real as any other economic value.*
>
> (Randall, 1988, p219)

Such definitions of 'existence value' present a profound problem for the Samuelsonian analysis. The reason owes to the intertemporal valuations of benefits and costs. Given that the values of LHS of Equation (1) value will flow over time, one must somehow compute the present net value of that TEV and then gauge at what point expanding reserves is of greater or less worth than, say, cutting timber today. The mathematical procedure to make such a comparison is called discounting which simply means that one divides the benefit in any year of the stream by the compounded interest correspondent to that year (e.g. $1 next year at an interest rate of 4 per cent is worth roughly 96 cents to me today as I could have invested the 96 cents and would have one dollar one year hence). Randall (1988) immediately zeroes in on the problem of discounting but does not perceive its contradiction to his own definition of 'existence value': 'By discounting at standard rates, the inevitable collapse of the living systems on this planet several hundred years from now could be counterbalanced by the relatively trivial economic gains in the immediate future.' One may recall that Randall's definition of existence value did not say 'If some people derive satisfaction from just knowing that some particular ecosystem exists (for the next few years or centuries) ...'. Just as discounting negates the meaning of existence value, the meaning of existence value negates discounting.

Would that discounting were the only problem for the public good analysis of biodiversity. Elsewhere (Vogel, 1997), I have elaborated why the mainstream approach is hopelessly wrong. The objections lie at both the theoretical level (such as existence value) as well as at the several practical levels regarding measurement.

Theoretical:

- the irreversibility of extinction and the sheer scale of the current mass extinction;
- the instability of human preferences over generations;
- the long-run preference for preservation over stages of development (underestimating the ΣMRS).

Practical:

- the macro complexity of primary habitats (the lack of identification of 'keystone species' as well as any exhaustive classification and enumeration of existing species);
- the micro complexity of every species in those habitats (the billions of nucleotide sequences in any individual from a given species under threat of extinction);
- the pervasiveness of negative externalities of habitat destruction and the rampant free riding of beneficiaries of positive externalities of habitat conservation.

To pre-empt all such objections, mainstream economists will quickly switch hats, from computer nerd at a laptop computer to a seasoned soldier fighting in the trenches of bureaucratic warfare. Rather than steadfastly defending the public goods analysis as the best science can do, these applied economists will now claim that a number is needed for rhetorical purposes. Once again, Turner et al (1993, p109) are representative when they claim that their 'central message' is that '... some valuation explicitly laid out for scrutiny by policy-makers and the public, is better than none, because none can mean some implicit valuation shrouded from public scrutiny'. Not to be cynical, but the 'central message' of a number is indeed important for economists wishing to do consultancy work and for vested interests wishing to legitimize the appropriation of habitat. Because economics requires both mental discipline and hard work, it isn't much fun and no one I know does it without compensation. While the purpose for the economists doing such studies is employment (hey, it's a buyer's market), the purpose of agencies employing those economists is to justify projects that benefit special interests that are unduly represented in government decision making. TEV satisfies a demand that arises in the agencies and foundations as evidenced by the venues through which the analysis is published (for example, see Landell-Mills and Porras, 2002 or Munasinghe, 1993). The horror in all this is that the problem of mass extinction is not getting resolved as attention has been diverted from the uncomfortable solutions. The conservationist biologist David Ehrenfeld (1988, p216) perceived the perversity early in the debate: 'I cannot help thinking that when we finish assigning values to biological diversity, we will find that we don't have very much biological diversity left.'

Lest the reader think that I am setting up a straw man or two, I suggest that he or she enter the website for the InterAmerican Development Bank and start clicking away on the buttons that lead to the environmental monographs, or green papers. One is particularly enlightening because its author, Ramón López (1996), is truly convinced of the legitimacy of public good analysis and does not mince words as to its implications: 'There is an optimal degree of deforestation from the point of view of individual countries which, given the current high stocks of forests in most of tropical South America, is probably far from being reached.' López even has a graph, which I have cut and pasted here; it is well worth a hard look even by a reader who has not quite caught all the subtleties of the prior explanation of the Samuelsonian analysis of public goods (Figure 9.1).

On the ordinate of Figure 9.1 is price and on the abscissa, forest area. At any moment in time, the forest canopy is fixed and so it is represented by the vertical line to the right, which intersects the abscissa at F (bar). The downward sloping curve D^LD^L refers to the local demand for the sustainable uses of biodiversity while the D^WD^W is the summation of that local with the world demand. The upward sloping curve NN is the opportunity costs of activities that would lead to the loss of forest cover (be they timber, cattle, mineral extraction, etc.). Where D^WD^W intersects NN, *voilá*, one is at that misty-eyed point C for all neoclassical economists – equilibrium. F^W is the so-called optimal provision of the international public good. Taking this logic further we can subtract F^W from F (bar) and get *the optimal amount of deforesta-*

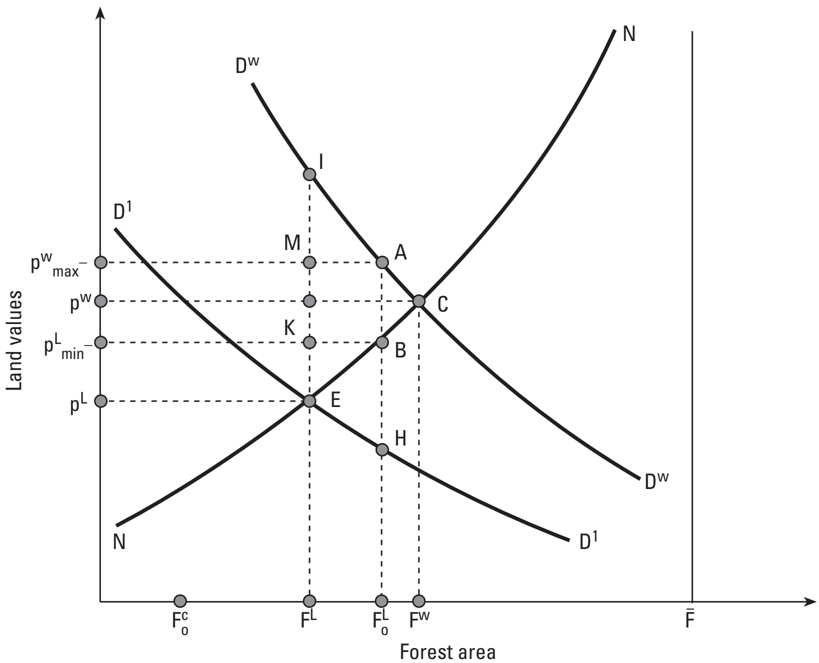

Figure 9.1 *Public goods analysis*

tion, which through the species–area relation of biogeography, translates into an *optimal amount of extinction*.

The graphical presentation of 'public goods analysis' in Figure 9.1 is very effective rhetoric inasmuch as it hides all the theoretical and practical objections concerning Equation (1). If this seems like a harsh rebuke against López, it is not. In the same monograph, López offers scores of economically sound recommendations to diminish deforestation and has made a convincing case for their adoption. Any country that follows López's advice in the short-run would greatly control the level of deforestation. The problem lies in the long run. Figure 9.1, like Equation (1), will programme stepwise extinction. The analysis is beguiling precisely because it generates some sound recommendations from a totally reckless framework.

TEASING OUT THE VALUE OF ABS, JUST ONE ITEM, IN THE LHS OF EQUATION (1)

No sooner was the ink dry on the ratification of the CBD than economists were busy working to disprove its one great hope: that rainforest could generate significant revenues as a warehouse for potential drugs to finance conservation. Alyward (1993) did this for Costa Rica and Simpson et al (1994), did the same on a world scale. Elaborate mathematical models were constructed on assumptions that seemed reasonable as demand was separated from supply. For example, Simpson et al first look at the impact of a marginal species to the probability of pharmaceutical discovery and then at the species–area equation of biogeography to determine the existence of that marginal species. They come to the conclusion that for the purposes of bioprospecting, biodiversity is so redundant as to be virtually worthless. Like so much of economic theorizing, the logic is impeccable as long as one buys into the assumptions. Here the assumptions are problematic on both the demand and the supply sides.

On the demand side, one can turn to the prestigious *Journal of Political Economy*, and find, five years after Simpson et al had published in that same venue, another long rigorous mathematical model, this one by Rausser and Small (2001). Two sentences from their abstract should give the non-economist much pause in any 'central message' that 'some valuation … is better than none':

> *Numerical results suggests that bioprospecting information rents could, in some cases, be large enough to finance meaningful biodiversity conservation. These conclusions stand in opposition to those advanced in an earlier analysis by Simpson et al (1996) who argued that biodiversity prospecting holds out no hope as a meaningful source of finance for conservation.*
>
> (Rausser and Small 2001, p173)

If the neoclassical critique from the demand side is not enough to sow doubt, then one can turn to the supply side and question the assumed robustness that Simpson et al attribute to the species–area relationship. One need only point out that: (1) the species–area equation does not consider political boundaries and (2) the field experiments that began some 40 years ago in the Florida keys and the Brazilian Amazon have only measured the parameters over decades, not centuries, much less millennia. Objection (1) implies that competition among sovereign nations will result in a price war undermining the financial viability of a conserved critical minimum habitat while objection (2) implies that, over evolutionary time, unmeasured variables could expunge biodiversity, be they artificial (e.g. colonization programmes under the misnomer of agrarian reform) or natural (e.g. the El Niño phenomena) or some combination thereof (e.g. global warming). As the former Brazilian Minister of the Environment, Jose Lutzenberger, put it so well: 'Suppose we destroy the rain forest? You don't get in its place sand dunes as in the Sahara or naked rock; you get poor scrub or bare soil … instead of the fantastic evaporation you see now, which keeps things cool, the soil will get real hot… A complicated system can take a lot of abuse, but you get to a point where suddenly things fall apart' (Revkin, 1990).

How to proceed with ABS? Recalling the Chinese wisdom that E. O. Wilson loves to invoke, it may be fruitful to go back and get things by their right names. If one defines biodiversity as natural information, then implications will follow. Neoclassical economics teaches us that competition will drive price down to the marginal cost. For any information good, the marginal cost of reproduction is almost nothing compared to the associated fixed costs of innovation. This explains why the music industry is hurting so badly; one can download music from the internet and burn a compact disc, which as of this writing, sells for about 30 cents. The only thing keeping the industry afloat is enforcement of monopoly intellectual property rights. Biodiverse countries have long faced the same problem of piracy due to the low cost of collecting samples. Ironically, the sovereignty granted each country over its genetic resources through the CBD has morphed biopiracy – free access – into something more insidious, the biofraud of material transfer agreements (MTAs) – absurdly cheap access. With so much genetic information diffused across species and so many species diffused across international boundaries, competition is fierce to capture an MTA. Not surprisingly, royalties are typically a fraction of 1 per cent of sales, no matter whether the biodiverse country is poor and lacking negotiating skills (Ecuador), poor but possessing negotiating skills (Brazil) or rich and possessing negotiating skills (Australia) (Vogel, 2005).

Inasmuch as natural information is diffused across species, and species across international boundaries, one cannot have the same monopoly as is enjoyed by artificial information. What one needs is an oligopolgy over natural information or, in plain English, a biodiversity cartel (Vogel 1995, 2000). To industry spokespersons, any mention of a cartel is greeted with the same enthusiasm as an act of terrorism. If the spokespersons even respond, they will rejoin by saying that patents only reward those who create information that is truly 'novel, non-obvious and useful' and that the great bulk of artificial information out there is free. Through the lens of economic theory, such a response seems to be saying 'we will only reward natural information which meets the criteria "novel, non-obvious and useful"'. The problem with this apparent *quid pro quo* is the interpretation of those legal criteria for patents in the context of natural information. For having solved the environmental problem of survival in its niche, the metabolites and genes of any species are 'useful' and 'non-obvious'. However, this same evolutionary reasoning means that they are also not 'novel' – every living thing has been evolving as long as everything else. Novelty only makes sense if one interprets it as the *lack* of diffusion of the information. Under such a condition, endemic species and especially those threatened with extinction would be novel information worthy of an oligopoly; pandemic species and especially those not under threat of extinction would be non-novel and like public-domain knowledge, and by analogy, should be free. Indeed, this is the tacit analogy that has emerged in the negotiation of almost all MTAs where one meagre royalty rate is scheduled for pandemics and another, much higher, for endemics.

To see how twisted is the analogy for divergent royalty rates, one need only return to the original example of music. The CD on my shelf does not depend on the other CDs on that same shelf for its existence. The same cannot be said of novel natural information. If one does not reward the pandemic species with which endemics share the niche, then the latter, not the former, will suffer. The industry spokesman may say, so what? In the hypothetical case just given, the value for bioprospecting arose in the pandemic and not in the endemic and we should not therefore be paying a user fee for something we did not use. The subtle error in such reasoning is that the valuable species only came to light *ex post facto* the screening and bioprospecting hit. One wants to keep one's options open and pay for the existence of the maximum amount of natural information. At the very least, option value means paying for the pandemics as long as there are endemics in their midst. However, I would go one step further and argue that even when no endemics are present, one should also pay the oligopoly royalty rate for the pandemics and the reasoning lies in the obtuse economics of taxation.

A royalty on biotechnology is in essence an *ad valorem* tax. There is a large economic literature known as 'public finance', which holds that almost all taxes distort decision making and that the distortion can be quantified as a deadweight loss, technically known as an *excess burden*. The term is not intuitive and can best be appreciated through a step-by-step graphical depiction (see Rosen, 1992). Nevertheless, most of us can get a rough idea of the meaning of excess burden through some simple examples: if government taxes consumption to finance its expenditures, then there will be less consumption in society than is desirable; however, if government taxes income, then there will be more leisure than is desirable. The degree of excess burden depends on how willingly people trade off consumption for savings or income for leisure. What all this means is that a measurement of excess burden must figure into the choice of tax instrument.

Applying the notion of excess burden to ABS yields some interesting results. Consider a divergent royalty scheme with the one royalty being set at 15 per cent on both endemics and pandemics in the midst of the endemics and the second at 0.2 per cent on all other pandemics. Such a taxation instrument would distort the economic decision of biotechnology research and development (R&D) to investigate pandemics. Not only would an excess burden be generated but the government would also not collect the revenues it had hoped to devote toward conservation, as fewer endemic species would be studied. Now suppose we tax all genetic resources used in biotechnology R&D. Surprisingly, this would also entail distortions and excess burden. Synthetic and combinatorial chemistry would appear more attractive in the decision on how to invest the R&D dollar than would natural product chemistry. What then is the solution? The solution is very well known in the public finance literature and industry is *really* going to hate it: lump sum taxes. Through lump sum taxes, government can raise the targeted amount of funds needed while not distorting the economic decision on how to invest the R&D dollar. Because the biotechnology industry can substitute in and out of research modes over time, a lump sum tax on industry could also be justified on the simple ground that all firms are enjoying an option value to genetic resources.

The recent history of neoliberal politics can be an augur for the reception of such a lump sum tax on the biotechnology industry. Political analysts point to Margaret Thatcher's head tax, a lump sum tax of sorts, as her fall from grace with the public; her successor John Major had it repealed in 1991. The lesson of the English head tax is that the biotechnology industry will cry murder if it is forced to pay significant funds, especially regardless of whether or not it uses biodiversity – it *seems* so unfair, so crazy, so radical! Despite how some may interpret my earlier *Genes for Sale* (Vogel, 1994), I do believe a lump sum tax and massive subsidy would be the way to go on one condition: if the money were actually remunerated to the agents making the decision to deforest or not to deforest. But that is a whopping assumption far worse than those committed by Simpson et al (1994). As one sees in Transparency International's rankings of corruption, many of the most biodiverse countries are in the bottom ten, that is, they are the least transparent (www.transparency.de/documents/cpi/index.html). It is too likely that the lump sums garnered would quickly get dissipated in the bureaucracy (economists call this the principal–agent problem). The royalty scheme of *Genes for Sale* (Vogel, 1994) and *The Biodiversity Cartel* (Vogel, 2000) would remit the payments to those agents who are protecting the genetic resources over the lifetime of the patent and proportional to habitat size. Incentives are greatest for the endemics and undercutting would be legally prohibited through a Special Protocol to the CBD. To my critics in the economics profession who will charge 'excess burden', I plead guilty, guilty, guilty. My defence lies in the late Stephen J. Gould's take on Darwin: we are not living in a Panglossian world of dreamt-up-ideals, there is a set of choices that present themselves. Paying a fixed royalty on genetic resources seems to be the best solution, which means only that it is the least bad.

To talk royalties is to talk turkey and the biotechnology industry is more interested in the mushy stuffing. So, the BS in ABS is usually focused on the 'non-monetary benefits'. To non-economists, such BS may sound great and so I return to my turkey metaphor; not only is there little nutrition in that stuffing but as health campaigns remind us around Thanksgiving time, the cavity is an incubator for all sorts of noxious bacteria. Let us start with the lack of nutrition. Typical of such arguments, found in this volume and in print elsewhere (see Laird and ten Kate, 2002, pp168–169) is that 'the primary contribution [of biodiversity prospecting] to high biodiversity countries has been and will remain in scientific and technological capacity building … [which is] the backbone of biodiversity prospecting partnerships'. This is pure mush. Not only does such 'capacity-building' ignore the opportunity costs of highly qualified individuals – implying that they would be picking coffee beans on some mountainside if not employed in bioprospecting – but it is also a form of internal brain drain within the South. Rather than having national scientists working on appropriate technologies that would add value to industries on the periphery, these talented people are being absorbed into an international supply chain where the surplus will remain in the center. The argument for 'non-monetary benefits' goes from mush to toxin during incubation. Too often transnational industries will identify some hard-working but poor professor of natural product chemistry in the South and try to entice him or her to lobby the Ministry of the Environment and obtain the 'prior informed consent' necessary for the MTA. What the biodiverse country will get in return for access is some outdated lab equipment from the North that the professor-lobbyist will now use to feed isolates into the supply chain. This is the drivel of the 'win–win strategies' that constitutes much of the ABS literature. All I can say is 'enough!'

TRAGEDY OF THE COMMONPLACE

The application of the Samuelsonian equation to biodiversity is trite, and because of the stakes involved, this triteness is indeed tragic. With the public's attention focused on the mass extinction crisis starting in the mid-1980s, an intellectual window opened for economists, ever so briefly, for something, if not original, at least intellectually honest, that limits exist and that the only economic question is: what is most cost-effective in achieving those limits? Economists would have none of that intellectual honesty. What the world got instead was more obfuscation dressed up at times as science and at other times as rhetoric. While all this may leave non-economists nonplussed, it has also left crooked politicians and their cronies delighted. As Clifford Russell and Philip Powell (1996) note wryly:

> *policy makers in a developing country will have someone on their side almost no matter what they decide to do. Instead of the infamous two-handed economists, they are presented with a veritable Asian god with six, eight, or a dozen arms from which they must choose one applicable to their particular problem setting.*
>
> (Russell and Powell, 1996, p27)

Hopefully, this chapter makes clear that the problem of mass extinction is being *aggravated* by the way economist fulfil their charge and analyse 'the way resources are allocated among alternative uses to satisfy human wants'. The graphs, the equations and the statistics are largely what the general public already suspects – smoke and mirrors – and even this insight is not new. The iconoclast Joan Robinson is often quoted for having told her students that 'the point of studying economics is so as not to be fooled by economists'. One can marry Robinson's quip to the wisdom of the Chinese: the right name for the whole public goods analysis of biodiversity is the 'economics of extinction'. A true 'economics of biodiversity' would begin with limits – no deforestation – and ask how can we get people to respect that simple limit. Sometimes it will be through significant economic incentives such as cartel royalties, but more likely it will be through educational campaigns and inculcation. Camilo Gomides (2003) makes this argument in 'Ecocrítica a raíz de la deforestación Amazónica' (Ecocriticism in the Wake of Amazonian Deforestation) and argues that a limit of 'no deforestation' must be inculcated through literature and film, not unlike the role that *Uncle Tom's Cabin* played in the 19th century to help emancipate the slaves. Such recommendations will make any neoclassical economist groan and shudder. It seems so illiberal and Marxist, yet inculcation is key to the whole critique.

Ground zero for the attack is the Samuelsonian (1947) premise that 'individuals' preferences are to count' without which there is no blackboard economics of demand and supply. The non-economist may ask, 'Does anyone really believe that demand is independent of supply? Just open up a newspaper and look at all those advertisements!' Economists will dismiss such evidence as anecdotal unless, of course, the anecdote is monumental. For example, on 12 June 2003, the Associated Press reported 'Cigarette Ad Spending Jumps, FTC says' and the figures were indeed impressive: A

17 per cent increase over the previous year's data, to a whopping $11.2 billion nationwide in 2001 and this, despite bans on cigarette advertising on television and radio. What this means for 'the way resources are allocated among alternative uses to satisfy human wants' is that the government will allow the tobacco industry to shape people's preferences in a way that, *ceteris paribus*, will ultimately kill them. Why cannot the same government also shape adult preferences so that Americans can do something that, *ceteris paribus*, will save species from extinction, including perhaps even *Homo sapiens sapiens*? The answer lies in the logic of collective action that Mancur Olson (1965) explained so well: lobbies, like the tobacco companies, maintain discipline over their members and can effectively coopt the legislative process. To Olson's analysis, one may add here that the cooptation also takes place on a psychological level. So, the neoclassical economic framework that logically derives from the 'individual's preferences are to count' not only legitimizes the corruption of the political system but, worst of all, legitimizes the perversion of preferences.

Although critics of neoclassical economics may deride the sovereignty of preferences, the tenet does have a noble justification in political philosophy. Friedman (1962) expresses it well in his classic *Capitalism and Freedom*:

> *Desirable or not, any end that can be attained only by the use of bad means must give way to the more basic end of the use of acceptable means. To the liberal, the appropriate means are free discussion and voluntary co-operation, which implies that any form of coercion is inappropriate.*
>
> (Friedman, 1962, p22)

Samuelson and Friedman were writing in the mid-1950s and early 1960s when the full horrors of Nazi Germany and Stalin's Soviet Union were becoming indisputable. Both the fascists and the communists had manipulated social psychology for nefarious ends and coercion was key to both systems. At the time, the liberal stance seemed an acceptable tenet from which to construct the rigorous discipline of economics. However, in this age of a biological holocaust, the sovereignty of preferences is no longer an acceptable one. Herschel Elliot and Richard D. Lamm (2002) explain why:

> *As [Garrett] Hardin suggested the collapse of any common resource can be avoided only by limiting its use. The ethics of the commons builds on his idea that the best and most humane way of avoiding the tragedy of the commons is mutual constraint, mutually agreed on and mutually enforced.*
>
> (Elliot and Lamm, 2002, pB9)

Unfortunately, the problem is denial that the common resource is truly collapsing and the real question becomes whether or not the government should impose a solution *as if* the public were rational. But here too we have a circular problem. In a democracy, even honest politicians may also be in denial and their cognitive dissonance may actually represent the public's preferences. To this bleak assessment, I can only repeat the wisdom of Bertrand Russell (1935, p215) when he wrote 'I do not see any prescription except the old one advocated by Disraeli: "Educate our masters".'

NOTHING IN THIS VOLUME MAKES SENSE EXCEPT IN THE LIGHT OF ECONOMICS

This heading is a take-off of Theodosius Dobzhansky's (1973) salvo to the creationists: 'Nothing in biology makes sense except in the light of evolution.' As wrong as I believe economic theory is, in both theory and practice, I do not see any alternative but to frame the questions of ABS and GMOs in terms of it. As we saw in the previous sections, one can learn much from the errors of economists. So with the stage now set, in these closing observations, I hope to make sense of some of the chapters in this volume in the light of economics. I believe I will have succeeded if the reader can further apply my economic thinking to those chapters that time and space constraints do no permit me to cover.

The chapter by Rodrigo Gámez (Chapter 7) captures best the economic issues I have so far elaborated. Neoliberal policy folk have long held up Costa Rica as the paragon for sustainable development even though the country never applied public good analysis to determine how much to deforest and how much to save. One can only say, thank goodness! Thirty years ago when Costa Rica was still a very poor country ($1,000/capita/year), the government embraced the limit that 25 per cent of its territory would be protected as parkland. It should be noted that these were real parks and not the paper parks common throughout the world in the 1970s and 1980s (Fearnside and Ferreira, 1984). Costa Rica developed an economy around this limit and tourism today is its greatest export. Because Costa Rica forests are legally protected, the aggregate value of the public good aspects of biodiversity does not have to surpass the opportunity costs of the habitats. In other words, the LHS of Equation (1) can be less than the RHS. Nevertheless, Gámez has prioritized the public good values of biodiversity, citing first tourism, then environmental services (e.g. watershed and CO_2 sequestration) and recognizing that the limit of 25 per cent of protected territory is not immutable:

> *An increased awareness of the many different values of biodiversity by society as a whole is expected to help attain its conservation… Otherwise, those areas devoted to biodiversity conservation run the risk of being converted to other forms of utilization, not compatible with conservation.*
>
> (Gámez, this volume, p79)

In terms of my critique of the 'economics of extinction' what Gámez seems to be saying is that the various user fees charged in Costa Rica are more to inculcate a 'green profile' than they are to financially justify conservation. In the case of ABS, the BS is truly a trifling extra for the financial sustenance of the park system, a *lagniappe* as the Cajuns say in Louisiana French. Indeed, without any bioprospecting whatsoever, there would still be the same forest cover protected in Costa Rica. Unfortunately, what is true of Costa Rica is not true elsewhere. Other less developed countries are not as environmentally enlightened as Costa Rica and will be denied economic rents that could relieve the political pressure to deforest simply because Costa Rica is dealing bilaterally with biotech industries over genetic resources that are not uniquely Costa Rican.

From my previous harsh criticism against MTAs, one would think that I would not take kindly to INBio. *Au contraire*, I believe INBio is a valuable model of how to perform the mechanics of bioprospecting even though its policy on ABS is absolutely wrong. My criticism of INBio is attenuated by the simple chronology of events: INBio came into existence in the late 1980s, well before the ratification CBD and any hint that a biodiversity cartel would be in the offing. Indeed, only recently (Stevenson 2002) has the Group of Like-Minded Biodiverse Countries formed with objectives that are unmistakably oligopolistic:

> *(d) To explore jointly ways to interchange information and harmonize our respective national laws for the protection of biological diversity, including associated knowledge, as well as for access to genetic resources and the distribution of benefits derived from its use …*
>
> …
>
> *(h) To drive the development of an international regime that promotes and effectively safeguards the just and equitable distribution of benefits from the use of biological diversity and its components. This regime should consider,* inter alia*, the following elements: the certification of the legal provenance of biological material, prior informed consent and mutually agreed terms for the transfer of genetic material as prerequisites for the application and issuance of patents, in strict adherence to the conditions of access granted by the countries of origin of this material.*
>
> (The Cancun Declaration of Like-minded Megadiverse Countries, issued on 18 February 2002 by the Environment Ministers and representatives of Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela, www.elistas.net/lista/lea/archivo/indice/1711/msg/2132/)

Costa Rica is a member of the Group of Like-Minded Biodiverse Countries and the future role for INBio vis-à-vis the South is most promising. Within a biodiversity cartel, INBio can license its know-how to set up similar laboratories in places where bioprospecting has always been successfully thwarted (e.g. Ecuador or Brazil). However, should INBio ignore the incipient cartel and continue consummating MTAs, then the risks will rise. Some time in the future, a pandemic genetic resource provided by INBio will become a blockbuster biotechnology. Citing the CDB, other countries in the region will challenge the legitimacy of the patent, inasmuch as they will not have received any 'fair and equitable' share of the benefits arising from the pandemic genetic resource. It is no small irony that the success of INBio lies in its failure to have a commercial hit.

Whereas the Gámez chapter lends itself beautifully to a true 'economics of biodiversity', the Schaal and Sittenfeld and Espinoza chapters (Chapters 10 and 12) can be best understood in terms of some rather prosaic economics. The choices for how society can manage GMOs are three and can be stated simply:

1 Ban activities or technologies that generate risks ('precautionary principle').
2 Regulate the risks through field tests and an approval process ('command and control').
3 Institute compulsory insurance ('market approach').

Sittenfeld and Espinoza so badly want the approval of rice varieties modified with RHBV antiviral genes that they actually weaken a very good case by loading the argument for number (2) and by totally discrediting number (1):

> *The challenge for Costa Rica is to decide whether to continue with unsustainable agricultural practices, or to explore other alternatives such as the introduction of genetically modified (GM) crops and other biotechnologies that might offer opportunities to reduce the use of agrochemicals and increase yields.*
>
> (Sittenfeld and Espinoza, this volume, p168)

The transgenes in GMOs can theoretically end up in a weedy species or even become weeds themselves and Sittenfeld and Espinoza explain why such an outcome is unlikely in the case under study: 'The fact that rice is self-pollinated and pollen survives only minutes, suggests that the potential environmental risks of transgenes could be minimized' (ibid., pp170–171). If this is indeed the case, then the insurance premium of (3) would be low and the efficiency of the market could even expedite approval of a GMO release. The problem with the command and control approach (2) of Sittenfeld and Espinoza's chapter, is that success in the exemplary genetically modified rice could lull regulators into scientific sloppiness and result in a truly horrific event when the next GMO comes under consideration. In contrast, the market approach of (3) disciplines sloppiness through bankruptcy. Ironically, Schaal's chapter is more convincing than Sittenfeld and Espinoza's against banning GMOs outright (1) precisely because Schaal gives a balanced account of both the social benefits and social costs of the new technologies. Her conclusion dovetails with the rationale for compulsory insurance:

> *An unfortunate aspect of the controversy is the tendency to see the issue in either black or white; biotechnology is either good or bad. In fact, biotechnology involves many species, both plants and animals, with a wide range of genetic modifications that are placed in a diversity of agricultural and natural systems located in a wide range of geographical sites. Whether or not an application of biotechnology has potentially harmful, beneficial or neutral effects on the environment is both species and context specific.*
>
> (Schaal, this volume, p137)

A role for insurance can also find support in Jim Chen's chapter when he writes: 'The law has failed to keep pace with the scientific understanding of biodiversity loss' (Chen, Chapter 4, p50). Given a framework of strict liability and compulsory insurance, the market would induce competing insurers to keep up with the pace of scientific understanding of the risks and benefits of GMOs. However, there is little other encouragement that one can take from Chen's chapter. One senses that there is no solution for habitat degradation other than the legislation and enforcement of limits which the US is reluctant to both impose and adjudicate. The law seems frighteningly maladapted to the age of mass extinction and global warming in which we live. Chen's conclusion is chilling:

> *Administrative and judicial passivity bode ill for biodiversity conservation. An even more potent driver of ecological ruin and evolutionary change lurks in global climate change, whose consequences defy description, much less prediction.*
>
> (Chen, this volume, p51)

From an analysis of the fine print of the law in Chen's chapter, we can pull back and look at how the moral principles necessary for meaningful legislation would arise. Ursula Goodenough tackles that economic taboo-zone of ethics and preference formation in Chapter 3. She starts with the premise that 'morality describes that which allows humans to flourish in community' and then goes on to elaborate how communities can flourish through philosophical reflection and personal action. In analyzing and synthesizing her chapter with the proposed 'economics of biodiversity', one is reminded of E. O. Wilson's (1988, p16) passing remark that 'in the end, I suspect it [conservation of biodiversity] will all come down to a decision of ethics'. In other words, humankind's ability to live within limits is a reflection of our morality. So, when Goodenough incorporates the Buddhist concept of mindfulness ('mindful of our place in the scheme of thing… mindful of future generations'), I would also add 'mindful that we have reached an age of limits'. To get from here to there, we need a life-long process of inculcation and it is fitting that I now close this commentary with an insight from Douglass North, a most distinguished professor at Washington University:

> *Time as it relates to economic and societal change is the dimension in which the learning process of human beings shapes the way institutions evolve. That is, the beliefs that individuals, groups, and societies hold which determine choices are a consequence of learning through time – not just the span of an individual's life or of a generation of a society but the learning embodied in individuals, groups, and societies that is cumulative through time and passed on intergenerationally by the culture of a society.*
>
> (North, 1993)

Although North (http://nobelprize.org/nobel_prizes/economics/laureates/1993/north-speech.thml) was not referring to the Gordian knot of biodiversity, biotechnology and access to traditional knowledge in his Nobel Banquet Speech, his wisdom uncannily applies.

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PART II

Biotechnology: Part of the Solution or Part of the Problem – Or Both?

Chapter 10

Biodiversity, Biotechnology and the Environment

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The use of genetically modified organisms (GMOs), both plants and animals, in agriculture has resulted in an acrimonious debate. The widespread planting of genetically modified (GM) crops has generated contention around such issues as health, the environment, economics, international relations, the business practices of large corporations and ethics, among others. One of the most active areas of debate is the potential effect of GM agriculture on the environment (NRC Board on Agriculture Report, 2002). The debate is highly polarized with one extreme claiming that GM agriculture will greatly harm both global agriculture and the environment. Strong advocates, on the other hand, maintain that there are few, if any, new risks and that GM crops may, in fact, be the saviour of both global agriculture and the environment. As with many highly polarized debates, there is a vast middle ground that, in the case of GM agriculture, acknowledges the great potential of biotechnology but also raises science-based concerns. An unfortunate aspect of the controversy is the tendency to see the issue in either black or white; biotechnology is either good or bad. In fact, biotechnology involves many species, both plants and animals, with a wide range of genetic modifications that are placed in a diversity of agricultural and natural systems located across a wide range of geographical sites. Whether or not an application of biotechnology has potentially harmful, beneficial or neutral effects on the environment is both species and context specific.

BIOTECHNOLOGY VS. TRADITIONAL BREEDING

Before we go on to examine the effects of biotechnology on biodiversity, our topic here, we need to define what is a genetically modified organism. And, we need to determine how genetically engineered varieties differ from conventionally bred plants and animals. Currently most of the concern about biotechnology and the environment centres on genetically modified agricultural plants (GM crops), although genetically modified animals, including mammals, fish and crustaceans, are all being developed for agricultural use. Genetically modified agricultural species, for our discussion here, are those plants and animals that have specific genes introduced into them by modern methods of biotechnology, that is, the organisms are genetically transformed. The term genetically modified organism (GMO), often used to describe a variant produced by biotechnology, is somewhat misleading. All of our domestic species, plants and animals, have undergone significant genetic modification from their original wild ancestors, first during the course of domestication by early agriculturalists and then by modern breeding (Wang, et al, 1999). Biotechnology is a way of genetically modifying organisms that is based on methods of DNA manipulation, the ability to insert genes from one species into the genome of another.

How does traditional plant and animal breeding compare to the production of new varieties by biotechnology? Modification of wild species to make them more useful or compatible to humans is an ancient process. Humans, from the earliest times, have interacted with native biodiversity and have used this biodiversity for their own benefit. Early farmers in the Middle East, Asia, South America and Africa began to grow near their villages plants that they had first collected for food or fiber in the wild. They chose plants with traits that were most useful, the individual with bigger seeds or longer and tougher fibres, and they used the seeds of these plants to begin the next generation of plants. Over many generations morphological and genetic differences accumulated between the domesticated crop and its wild relative. In some species, such as corn, the process so changed the crop that the wild parent species of the crop is no longer obvious by morphology alone. In the development of other crops, such as wheat or kales, different species have been crossed, to incorporate genes from one species into the genome of another (e.g. Simpson and Ogorzaly, 2003). The concept of using genes from different species as a basis for improvement is a well-established principle of plant and animal breeding. Early farmers developed plant varieties for their local region and when the new varieties were useful, they traded seeds and animals over vast geographical scales. Often these new, introduced varieties crossed on their own with local landraces and native species. The introduction of a species or variety into new geographical regions in many cases had a profound effect on biodiversity, by altering agricultural practices, by introducing species that displaced native species, or by altering community dynamics. Agriculture has a long history of impacting both native biodiversity and the environment.

What are some of the characteristics of traditional crop breeding today? First, a source of new genes or traits is obtained. The source in traditional breeding is either from other varieties of the same crop, or from wild relatives or closely related species. Traditional crop breeding is an inexact science and many genes beyond those for the selected trait are introduced. Sometimes whole sections of chromosomes are transferred, which may introduce genes that produce an undesirable trait, such as early dropping of seeds or that reduce crop yield (Simmonds and Smartt, 1999). After the initial cross, the progeny and their progeny are crossed repeatedly over several generations in order to eliminate these undesirable genes and to concentrate desirable traits. This process may be very slow, particularly in the case of perennial crops such as bananas or cassava where the generation length, the time to first flowering, may be several years. Even in annual crops the process is slow. Of course, this is not to imply that traditional breeding is unsuccessful. All of our crops are based on traditional plant breeding, including those used in the US as well as those of the green revolution, which has increased the yield of important crops, such as rice in Asia. Regardless of future technological advances, traditional plant breeding will be an important source of new varieties, or will provide the background stock for new crops produced by genetic engineering. In fact traditionally bred varieties of crops are extremely important in this age of GM varieties. The choice of which background or variety to use for genetic transformation is critical. Some of the earliest efforts at producing GM crops were far from successful because a relatively poor variety was chosen as the stock for transformation – this happened in tomatoes, making the GM lineage commercially unviable.

Genetic engineering presents an alternative to traditional plant breeding. Using the techniques of molecular biology, a single gene that codes for a desired trait, such as insect resistance, increased protein content, or tolerance to drought is isolated and then combined with a promoter sequence that will allow the gene to be expressed. This combination of genes is then introduced directly into the plant genome. The concept is actually quite simple, although the techniques are technologically complex (see Chrispeels and Sadava, 2003). The introduction into the plant genome of foreign DNA can be done by physical means, particle bombardment or it can be accomplished biologically by the Ti plasmid of the bacterium, *Agrobacterium tumefaciens*, which causes crown gall disease in plants. Once the target cells incorporate DNA, these genetically transformed cells are grown by tissue culture into whole adult plants that now contain the foreign gene. These plants can produce seeds by standard cross pollination of one plant by another. Thus the plants can reproduce and seed stocks build up. These seeds will produce the next generation of plants that also will have the new, inserted gene.

How do plants produced by genetic engineering differ from those produced by traditional breeding? First, the process is highly specific: only DNA for the selected genes are introduced into the plant. A few, specific genes are added to the target species, as contrasted to many genes introduced by traditional breeding. Second, genes can be introduced from a wide variety of organisms. Traditional breeding is limited to closely related species within the same plant genus for the most part. Genetic engineering can use genes from across kingdoms. Plants can be engineered to contain genes from bacteria, fungi and animals, which in turn can dramatically increase the range of traits that a plant can express, such as anti-freeze compounds from flounder that adapt plant varieties to colder environments. Likewise domestic animals can be genetically transformed; salmon engineered with growth hormone grow 2–3 times faster than normal salmon. (GM salmon are particularly controversial because they are highly mobile and therefore there is the possibility of them escaping into native marine environments.) Plants are currently being engineered to serve as factories to produce useful compounds that are not found in plants in nature, such as the production of pharmaceuticals, plastics and human vaccines. A final difference between traditional breeding and genetic transformation to produce new varieties is the time scale. Breeding studies take many years whereas transformation can be accomplished relatively quickly. Genetic transformation is also more efficient. In a perennial crop such as cassava or bananas, not only does it take a long time to complete breeding studies due to generation time, it also requires vast amounts of space and labour to grow the large numbers of individuals to screen for selected traits. Genetic transformation occurs in the laboratory and after it is successful, plants are transferred to the greenhouse and ultimately field grown.

GENETICALLY MODIFIED PLANTS AND ANIMALS

Currently, the most widely used varieties of GM crops carry introduced genes either for insect resistance or for herbicide resistance. Insect resistance comes from a natural insecticide gene found in the soil bacterium, *Bacillus thruringiensis* (Kumar et al. 1996) – *B. thuringiensis* produces a family of crystalline proteins (cry proteins), which inhibit insect growth. The cry proteins are considered an environmentally friendly insecticide; in fact, the bacterium is used as a natural insecticide in organic farming. Crops such as soybeans, corn and cotton have been genetically engineered to produce one of these cry proteins and are resistant to several major insect crop pests. The other major group of GM crops is engineered to be resistant to herbicides (Dekker and Duke, 1995). Fields of herbicide-resistant crops can be sprayed with herbicides such as glyphosate (Roundup); weeds are killed by the herbicide while the crop is unaffected. Crop yields are greatly enhanced by this efficient herbicide treatment. US farmers have embraced GM crops and the percentage of overall crop acres devoted to GM crops has risen dramatically since 1995, when GM crops became widely available. Moreover, there is much demand among US farmers for additional GM crops such as wheat, sorghum and rice.

The development of the next generation of GM crops is actively proceeding and we can expect a diversity of new approved crop varieties. These crops will expand the range of GM agriculture for the kind of species that is genetically modified, for the geographical regions where GM crops are grown and for the type of trait engineered into the crop. Currently being developed are new crops that have disease resistance to pathogens, that have increased protein content, that have more healthful lipids, and that are engineered to produce pharmaceutical compounds, among others. Development of GM varieties is not limited to row crops such corn, soy and cotton. Work is being conducted on producing new varieties of trees for wood and pulp, ornamental plants for gardening and landscaping and new forage grasses. A large effort is underway to engineer new crops for the developing world. These varieties are being produced to provide food security and alleviate nutritional inadequacies that are found so often in the developing world. At the same time, animal biotechnology is rapidly proceeding. For example, many Asian countries have large aquaculture industries and efforts are underway to produce genetically transformed fish and crustaceans that are resistant to disease, that grow rapidly and that are adapted to the conditions of aquaculture. These applications of biotechnology present particular challenges since these animals are highly mobile. While it outside of our discussion here, there are also well-established efforts to genetically transform insects such as mosquitoes, to eliminate them as vectors of disease.

BIOTECHNOLOGY IN THE TROPICS: ISSUES

The development of GM plant and animal varieties for the developing world presents challenges for assessing their environmental impact. Why do we need to specifically assess the environmental impact of GM agriculture in tropical regions? Why are the lessons already learned from GM agriculture in the developed world inadequate? There are several reasons: both the type of agriculture and the environmental context of agriculture is different in tropical developing countries than in the temperate developed world. First is the type of agricultural system. In developed countries modern agriculture is characterized by fields of a crop grown in monoculture with large inputs of fossil fuel in the form of agrochemicals, fertilizers, pesticides and herbicides. Developing and tropical countries have a greater range of agricultural practices. Indigenous people can use traditional intercropping or swidden agriculture that utilizes many plant species and varieties with little to no agrochemical use. Many crops are grown in small gardens, orchards or fields and come into close contact with local native biodiversity. And, increasingly, modern agricultural methods are being employed for the major crops such as corn and soy.

For our discussion of biodiversity and the environment, the most significant difference between the agricultural systems of the developed and developing worlds is the ambient levels of biodiversity, both in natural habitats and as part of an agricultural ecosystem. The tropics have the greatest natural biodiversity on earth, with a stunning number of plants, animals, fungi, bacteria, etc. Moreover, the biological relationships among species are complex. Species often have highly specialized ecological niches and are frequently closely tied to other species in the community by feeding relationships, by competition, parasitism or mutualisms. These intricate connections between species potentially make tropical species and communities vulnerable when biological perturbations occur. The concern is that tropical communities may be highly sensitive to perturbations and because of the elaborate interrelationship, subject to ripple effects (the relationship between community complexity and stability is a long-standing debate in ecology (e.g. Tillman and Downing, 1994). The combination of high species diversity and potential sensitivity to disturbance requires careful evaluation of the potential environmental effects of GM agriculture in tropical regions.

Another important aspect of biodiversity in tropical regions needs to be considered. In the US, most of our major crops have been imported from other regions of the globe and are not grown here in contact with their wild ancestors. Thus corn, wheat, rice and soy are all crops of either the old world (wheat, rice, soy) or Mesoamerica (corn). In many cases there are no close relatives to the imported crop and the crop is grown in genetic isolation from the native biodiversity. The environmental concerns regarding gene flow between crop and wild relative and its effect on biodiversity are not a major concern. As GM plants and animals are developed for tropical species and their use incorporated into the agriculture of developing nations, the effects of gene migration between GM species and wild relatives will have increasing importance. We might expect that for many species the contact between crop or GM animal and wild ancestor will be more frequent in regions of high biodiversity. Close contact, which raises the possibility of gene flow, is more likely in some tropical regions for several reasons. First, many genera are species rich in the tropics which offers many more native candidates for gene flow (cross-pollination) between wild and domesticated species. Second, many tropical crops are not as highly domesticated as are the major crops of the world. These local varieties may be genetically much more like their wild ancestors or relatives that live near by and hence are more likely to produce fertile offspring when crossed. Finally, many regions in the developing world still use locally adapted landraces of a crop; these landraces are of great importance since they contain valuable agricultural biodiversity, and are a genetic resource for future crop improvement. It is important to consider the effects of GM crops on this aspect of agricultural biodiversity as well as the potential effects on native biodiversity.

Up to now we have drawn a distinction between the agriculture and biodiversity of developed and less developed countries. This distinction is far from complete. In the US several crops are grown in close association with their wild ancestors (e.g. sunflowers) or weedy relatives have been introduced (rice, sorghum, pannicum). And, large monoculture fields of GM crops are increasingly common in developing countries. While the environmental issues that centre on biotechnology are the same globally, their relative importance varies with crop, geographical region and community context.

Finally, before we consider the specific effects of biotechnology on biodiversity, two important and related points need to be made. First, many of the issues that are currently a concern for GM agriculture have been long-standing concerns for traditional agriculture as well. Harms to non-target organisms from pesticides and herbicides, gene flow and the production of weeds have all plagued agriculture. The fact that these are concerns for conventional agriculture implies neither that these issues can be ignored for biotechnology derived crops (supposedly since these are not new concerns), nor that GM agriculture should be avoided because it, along with conventional agriculture, affects the environment. Second, the debate regarding biotechnology is often confined to whether there is harm from GM agriculture. It needs to be emphasized that GM agriculture has not only potential liability for native biodiversity, but also potential benefits for biodiversity as well. The potential effects of biotechnology can only be determined correctly if they are assessed in the context of and compared to current agricultural practices. Given that we are not going to stop the practice of agriculture, we need to determine the relative risk of GM plants and animals compared to the risk associated with current varieties.

EFFECTS OF BIOTECHNOLOGY ON BIODIVERSITY: POTENTIAL CONCERNS

What are the concerns about the effect of GM agriculture on biodiversity and the environment? First, we consider the effect that biotechnology derived species might have on non-target organisms. This issue was dramatically brought forward in a 1999 study of monarch butterflies and *Bt* corn (Losey et al, 1999). Monarch caterpillars were fed *Bt* corn pollen in a laboratory experiment. The caterpillars responded negatively to the *Bt* pollen (*Bt* is particularly effective against lepidopterons) and the larvae either exhibited stunted growth or were killed. After this initial report, which caused an uproar, the question was asked if this mortality actually occurs in the field. Scientific risk assessment showed that, in fact, few larvae are likely to be affected by *Bt* pollen in the field due to a number of factors (Sears et al, 2001). The *Bt* corn used for the initial experiment had the *Bt* toxin expressed in high levels in the pollen whereas new varieties of *Bt* corn have little cry protein in pollen. Other studies show that the timing of pollen release, the dispersal curve of pollen over distance and the proximity of milkweed (the larval food source) to cornfields were all such that *Bt* corn would have a minimal effect on the mortality of milkweed larva. While the conclusions here were that *Bt* pollen may not be a major factor in monarch mortality, it raises significant questions about the effect of *Bt* toxins on other insect species, particularly lepidopterons, and also about the effect of *Bt* in the soil and on soil arthropods, bacteria, worms, etc. Such risk assessment studies have been done for only a few organisms.

Another issue is the cross-pollination between crop and closely related species (Ellstrand et al, 1999). Gene flow is the migration of genes from one population or taxon to another. Gene flow has a homogenizing effect, making populations that exchange genetically similar genes. Why is such gene flow or cross-pollination a concern? First it can alter the gene pool of native species. When the native species are wild relatives or ancestors of domesticated species, homogenization of populations can result in the loss of critical genetic biodiversity. One of the hallmarks of domestication is a genetic bottleneck that results in a decline in genetic variability within the domesticated plant or animal species. In some cases up to 80 per cent of the genetic variation that was originally in the wild species is lost during domestication (Olsen and Schaal, 2001). Thus, populations of wild ancestors are extremely important for future crop improvement, since they potentially contain many useful genes. As an example, the green revolution in Asia was fostered by new, high-yield varieties of rice. Genes were incorporated from rice's wild ancestor, *Oryza rufipogon*, and included such traits as disease resistance, small stature and response to fertilizers. Another concern with gene flow from GM crops into the wild ancestor is that GM traits may cause selective changes that sweep through wild populations and result in a decline in variation. Any loss of variation would include some useful traits. Such loss of variation could also compromise the ability of wild populations to adapt to environmental change, either biological or physical.

Our own work on rice in Thailand indicates significant gene migration between crop and wild ancestor. The gene flow curve for rice is leptokurtic; while most genes migrate at small or moderate distances, there is a long tail of low levels of gene dispersal across large distances. In the case of rice, we can detect hybridization between crop and wild ancestor by detecting plants that are morphologically intermediate between cultivated and wild species. Our rice work illustrates another concern, the production of weedy hybrids. The worry is that when a GM crops hybridizes with a wild ancestor, the hybrid offspring will lead to the formation of a vigorous weed (called super weeds by some). This is again a situation found in conventional agriculture, where there are many crop–weed systems. Such hybridization is of particular concern in Thailand, where the wild ancestor of rice grows in close contact with cultivated rice. In Thailand, gene flow results from changing agricultural practices and results in plant hybrids that are very aggressive in growth, interfere with rice cultivation, and cause a decline in yield. The concern for biodiversity is that these weeds will then spread outside of the fields and negatively impact native species. The work of Allison Snow and colleagues on hybrids of *Bt* sunflowers and native sunflowers has indicated that hybrids may have an enhanced fitness relative to the wild sunflowers (Snow et al, 2002). The hybrid sunflowers have incorporated the *Bt* gene from the transgenic sunflowers and are resistant to attack by some lepidopterons. *Bt* hybrids have greater seed production than the wild sunflowers, thus raising the spectre of gene flow altering both the gene pool of the native sunflowers and producing a new, weedy taxon. But, whether or not these negative affects actually occur still needs to be accessed.

In global regions with high biodiversity, we expect that many related species will be growing in close proximity to crops. The likelihood of gene migration between closely related taxa is an issue that needs to be carefully evaluated. We expect that the results of such evaluations will vary depending on crop species. In some cases where the crop is growing adjacent to the wild ancestor, where the crop has not accumulated major genetic differences that isolate it from the wild ancestor, and where there is no reproductive isolation or lack of pollinators, gene flow is likely. On the other hand, for some species there will be no gene migration between crop and wild relatives due to lack of compatibility, variation in flowering time or spatial isolation of the crop from wild relatives. This conclusion is both encouraging and discouraging, since either the detection of risks or the absence of risks in one species does not bear on the risk assessment of gene flow in other agricultural species. Each species needs to be carefully accessed separately and any generalizations need to be drawn with great care.

THE EFFECTS OF BIOTECHNOLOGY ON BIODIVERSITY: POTENTIAL BENEFITS

Up to this point we have explored potential negative consequences of GM agriculture on biodiversity. But, there are also some potential positive aspects as well. These benefits frequently stem from a mitigation of current agricultural practices such as pesticide or herbicide application. Most of the world uses agrochemicals in varying amounts for their fields and crops. Different regions of the globe use different kinds of chemicals and in vastly different amounts, with tropical agriculture of developing countries often having very high rates of pesticide application. Some rice fields in South East Asia are sprayed with pesticide several times a week, jeopardizing farmers, their families, and the entire ecosystem with pesticides (Phipps and Park, 2002). *Bt* crops such as corn and cotton produce their own pesticides by genetic modification and potentially require less insecticide spray. Data from cotton fields show a clear reduction in pesticide use over conventional agriculture, but possible reductions for some other crops are not always well documented. Any reduction in insecticide use would be of great benefit not only for human health but also to non-target organisms and the native biodiversity of the region. Reductions in agrochemical use simply expose species to less pesticide, either in the form of direct contact or as sequestered in the food chain.

Another major concern is the application of herbicides that are used extensively in western agriculture and increasingly in developing countries. Some herbicides can be toxic, degrade slowly, or are difficult to assay. Glyphosate (Roundup) is environmentally benign with little if any toxicity and degrades quickly. Roundup Ready crops use applications of glyphosate as an alternative to more toxic herbicides, thus the switch to glyphosate resistant GM crops potentially reduces any toxic effects of herbicides, a change in agrochemical use that, in turn, can enhance biodiversity. Moreover, herbicide use reduces plant biodiversity and thus indirectly affects other species in a food chain. Less diverse plant communities may lead to less diverse arthropod, mammal, bacterial, etc. populations. Such changes can then have a ripple effect through the food chain.

New varieties of GM crops that are currently being developed will be engineered to respond more readily to fertilizers or to be drought resistant. Such crops afford the possibility of reducing fertilizer application and irrigation, both processes that significantly modify native habitats and lessen biodiversity

Other potential benefits include providing alternative, cash-generating crops for local farmers in the developing world. In many regions of the developing world with low agricultural production, local farmers subsidize their diets by hunting animals. Such ‘bush meat’ may often be species that are rare or even endangered. Economic stability from new cash crops can reduce the harvest pressure on native biodiversity. One of most intriguing aspects of GM for environmental benefit is the use of genetically engineered plants that have been modified to take up and sequester toxic substances such as heavy metals (Bizily et al, 2000). These specialized plants, developed for bioremediation, are sown as a lawn on a toxic spill site, grown and the resulting plants are then harvested and disposed of as toxic waste. Several years of treatment can effectively remove contaminants and dramatically reduce the levels of toxins in the soil.

GM agriculture offers the hope of reducing agrochemical use by developing plants that produce their own insecticides, thereby reducing the need for pesticide application, by developing plants that are resistant to herbicides, thus allowing modification of application schedules (see below), and by developing plants that require less fertilizer application. Such potential benefits are particularly important in tropical regions where pest pressure on crops is exceedingly high and very large amounts of pesticide can be used. In a recent study of potential uses of GM crops in developing countries, Qaim and Zilberman (2003) illustrated that the demand for GM crops could be high in developing countries due to their expected enhancement of yield. At the same time, data from India on cotton indicates that *Bt* cotton greatly reduces the use of pesticides to reach the same yield. To prevent a loss of 20 per cent yield, *Bt* cotton requires pesticide application of 0.8kg/ha while non-*Bt* cotton requires an application of 4.8kg/ha, a six-fold increase (Qaim and Zilberman, 2003). Not only are such reductions in pesticide use good for biodiversity, they are critical for the health of local farmers who often suffer from the effects of frequent applications of toxic pesticides, pesticides whose use is frequently banned in the US.

While many studies have speculated that any reduction of agrochemical use would enhance biodiversity, relatively little supporting data are available. A recent study examines the effect of the timing and use of herbicides on arthropod community diversity in forage beet populations in Denmark (Strandberg and Pedersen, 2002). In this study the biodiversity of arthropods was compared in fields treated with conventional herbicide application (non-GM crop), to a GM Roundup Ready crop (GM) with applications of herbicide according to label recommendations and with a late application of Roundup. Interestingly, there was no significant difference between the arthropod communities for the conventional crop and the roundup ready beets treated according to label directions. But, the late application herbicide had nearly double the number of arthropod species. The authors speculate that letting weeds remain longer in the field enhanced arthropod species diversity. Such research demonstrates not only that GM agriculture can enhance species diversity relative to conventional agricultural practices, but also the necessity of fine tuning agricultural practices for specific crops and location.

Such studies will be criticized, with the observation that if no herbicides were used at all, then there would be an even greater biodiversity. This is of course correct, but the assessment of agricultural practices needs to be made realistically and in comparison with current practices. Biodiversity would be greatest if we had no agriculture at all; agriculture since the time of the earliest plant domestication has reduced native biodiversity. But, such arguments ignore the global requirements of human populations. We need agriculture to feed populations in cities and the expanding populations of the developing world. The best way to minimize the negative effects of agriculture, both GM and non-GM, is to carefully apply the learned scientific principals from ecology, genetics, molecular biology, agronomy, etc. to each agricultural situation.

CONCLUSION

It is clear that many of the issues that relate to the potential environmental effects and biodiversity of GM agriculture are location and crop specific. For example, there is no risk of gene flow between GM corn and the wild ancestors of corn in the US. But in central Mexico such gene flow may be a threat to the few remaining populations of teosinte, corn's wild ancestor. The wealth of biodiversity in tropical regions is a particular challenge for GM agriculture. In the tropics many species are cultivated in contact with their wild ancestor and some tropical crops may have little genetic differentiation from their wild ancestor, thereby increasing the chances of gene flow. Moreover, environmental interactions in the tropics are complex where food chains and connections between species are often intricate. Thus one might expect perturbations of local species to pass through other components of the ecosystem. At the same time, pesticide use is high in tropics with a cost to humans, the environment and biodiversity.

The only way to determine the effect of biotechnology on the environment and on biodiversity is to conduct appropriate scientific studies, including the assessment of relative risk, measuring of gene flow, determining the fitness of hybrids, assessing the effects on non-target species and ecological monitoring when things have gone wrong (Kjellsson and Strandberg, 2001). This is not a well-received answer to the general question: is biotechnology harmful, neutral or beneficial to the environment? This question can only be answered for a specific case and depends on the GM plant or animal, the geographical region where the organisms are placed and the local biological environment. Moreover, the effects of a genetically modified organism need to be compared with the effects of the current local agricultural practices on the environment and biodiversity as well. While such work is complex and often tedious, careful scientific assessment of the environmental risks of biotechnology will assure that biotechnology will develop in concert with local biodiversity and will ultimately help in gaining the public's confidence in and acceptance of these technologies.

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Chapter 11

Principles Governing the Long-run Risks, Benefits and Costs of Agricultural Biotechnology

Charles Benbrook

Public concern and controversy over agricultural biotechnology has triggered a debate around the world on the future applications of molecular genetics and biotechnology to food and fiber production. This debate is overdue and may still prove constructive in the long run. The underlying issues are what kind of food, and food system, do people want, and will biotechnology move us in a positive direction?

The strengths and weaknesses of food systems obviously depend greatly on where one sits at the table. In the North, abundance and choice are taken for granted. Food is affordable for most people, despite the fact the average American spends more per calorie consumed than well over 95 per cent of humanity. The average share of per capita income spent on food in the US is the lowest in the world because the US is such a rich country, not because food is cheap.

In the developed world, safety, quality and convenience shape the market place. In the developing world, rural and urban poverty is the dominant cause of hunger. Food insecurity is driven more by poverty than inadequate production. In India there are millions of underfed people and millions of bushels of surplus grain in storage. The rural poor with access to land will be helped somewhat by improved farming technology, as will the urban poor if supplies increase and prices fall as a result of new technology. But for agriculture and rural economies to become more productive, improve farm family economic status, and do a better job conserving natural resources, prices for basic agricultural commodities simply have to go up. New technology in the absence of policy and market reforms will likely make matters worse for many of the people most in need of a lift from poverty's grip. As UN Secretary General Kofi Annan and others have argued recently, cutting back markedly on developed world farm subsidies is urgently needed to help both the urban and rural poor in developing countries.

Over one-third of the cost of producing corn in the US comes from government payments; the figure is somewhat higher in Europe. The price of rice in Japan is ten times the world market level. Excessive farm sector subsidies in rich countries are flooding the global market place with surpluses, depressing prices and undercutting the ability of poor farmers to improve their economic and food security.

The global debate over how agriculture and food systems can better meet people's needs is passionate and often muddled. It is easy to get lost in the complex interactions among the many forces that shape the system. Views differ widely over what is right and wrong about the system and the direction it is headed. People see the risks posed by farming systems and technology very differently. Some think biotechnology is the ultimate answer, while others see it as unsafe, unneeded, and even unethical. Given that perceptions of the impacts, risks, costs and benefits of agricultural biotechnology are so divergent and visceral, it is little wonder that consensus remains elusive when discussions turn to how policy, development assistance or research capital should be directed and invested. As long as the current state of affairs persists, companies, governments and international organizations will struggle to find a safe path through the minefield that has become public discourse on agricultural biotechnology.

To move forward, both more diplomacy and a new way to talk about biotechnology are needed. Hardliners on both sides of the debate need to back off from extreme and unscientific positions – all biotech is good, wonderful and proven safe; all biotech is too risky and only good for agribusiness.

Reasonable people can and will continue to see the risk–benefit equation differently for a given application of biotechnology. That's a given. What remains unclear is whether reasonable people might also one day agree on certain applications that should move forward, at least under some conditions. For this to happen we need to change the focus and tenor of debate. It must become safe for open-minded people to move out into the agricultural biotech minefield. At least some who do so must survive the exercise and be willing – and allowed by their employer and professional community – to explore the landscape a bit further the next time an opportunity arises.

A first step in changing the terms and hopefully the tenor of debate is to seek a common understanding of the characteristics of agricultural and food system technologies – whether chemical, biological or genetic – that should determine placement on a list of priorities. As a society, we cannot afford to develop, test and commercialize all technically plausible applications of biotechnology. Priorities must be set, choices must be made. A method is needed to screen and rank potential applications. Some will emerge as clearly needed, feasible, likely to be safe, cost-effective and compatible with cultural values, while a few others, upon reflection, will be seen as too risky or not worth the cost and effort required to bring them to market.

Here, I describe a set of 'first principles' against which technology can and should be appraised. These principles encompass performance attributes related to how a technology is intended to work, as well as the technology's impacts and consequences. No technology – whether biotech-based or organically approved – will possibly be fully compatible with all relevant principles and performance attributes. The goal is to work toward more assuredly safe and beneficial technology, while avoiding technology with foreseeable pitfalls and adverse unintended consequences.

WHY ARE 'FIRST PRINCIPLES' NEEDED?

Secure and sustainable food systems in a country or region must accomplish two things. First, adequate supplies of safe, nutritious food must be produced and accessible to all people, with most of the supply of food coming from regional production or economically sustainable trade. Second, food must be produced without undermining human communities and the farm labour force, as well as the genetic, soil and water resources on which agricultural production depends.

Principles, performance parameters and evaluation criteria are needed to determine the degree to which a given technology, practice or system will contribute to these two fundamental goals. Twelve 'first principles' follow in three categories:

1. tactical choices;
2. management and problem solving;
3. equity and outcomes.

The purpose of trying to reach agreement on 'first principles' is to create a mutually acceptable framework within which agricultural technology, systems and practices can be evaluated. Tactical principles and performance attributes focus on how a technology or system achieves its stated goal – for example poisoning a pest with a chemical or biological toxin, vs. disrupting pest reproduction or development.

Management and problem-solving principles encompass where and how a technology allows or helps a farmer to intervene in the crop or animal production cycle, as well as a technology's impacts on management flexibility and a farmer's ability to innovate. Equity and outcome principles and attributes address the nature and distribution of benefits, risks and costs, and the scope and reversibility of potential unintended consequences.

First principles should be used to evaluate all agricultural technologies and food system issues, not just biotechnology. First principles are equally applicable to policy and technology choices in the North and South, and to biotechnologies and organic production methods and systems. The weight placed on various principles and performance parameters will appropriately vary by region and in accord with current agricultural and food system challenges, resources, capabilities and cultural values. Not all principles will be relevant or important in assessing a given type of technology. Uncertain impacts will inevitably be part of the equation and trade-offs across principles will arise.

Applying these twelve 'first principles' to a list of technology options should help a country, company, NGOs or research institutes distinguish technologies that should be pursued aggressively, vs. explored hopefully, vs. shelved indefinitely. As the most promising, least risky applications are pursued, important experience will be gained and knowledge of natural systems and interactions will deepen, setting the stage for progress to accelerate and broaden.

TACTICAL 'FIRST PRINCIPLES'

Two principles should guide perhaps the most strategically important set of decisions any farmer, society, scientist or company faces – 'What to produce?' and the related question, 'What to research?'

1 Promote diversity

Attributes and evaluation criteria should include the following:

- Select crops, livestock, technologies and practices that have the potential to diversify diets, production systems and income opportunities. (Those that do not should be assessed more critically on agronomic, pest management and economic grounds.)
- Promote the biodiversity of soil microbial communities and above ground invertebrates to maximize biological control opportunities, and to augment nutrient cycles and flows.
- Diversify the range of tactics and practices used to suppress pest populations.

2 Understand and work within natural limits

Attributes and evaluation criteria should include the following:

- Select crops and livestock indigenous to and/or likely to adapt well to a region's climates, soils and pest complexes.
- Establish production goals that are realistic and sustainable in light of the availability and quality of production inputs – soil, nutrients, genetics, water, sunlight and human capacity to accomplish field tasks.
- Overcoming one yield constraint almost always creates others. The likelihood and costs of overcoming secondary constraints should be projected and taken into account in setting realistic yield goals. (Those that do not should be assessed more critically on agronomic, pest management and economic grounds.)

MANAGEMENT AND PROBLEM-SOLVING 'FIRST PRINCIPLES'

Once decisions are made regarding what crops and livestock to produce or conduct research on, or to favour via policy reform, attention must turn to farming system design and management. Six principles are key in evaluating whether technologies, inputs and practices are likely to be part of sustainable solutions.

3 Target solutions at the root of problems

Attributes and evaluation criteria should include the following:

- Prevent problems rather than treat symptoms. Eliminate or counteract the circumstances and biological interactions that give rise to problems.
- Plant breeders should focus on problems only genetic improvement can realistically address. In general, genetic solutions should not be relied on to fix management problems.
- Pest management practices and tactics should focus on population suppression through multitactic integrated pest management (IPM) systems, rather than killing pests with synthetic or natural toxins when and where pests exceed damage thresholds.

4 Incrementally improve, or at least sustain, soil quality and productivity

- Technologies or systems must not increase soil erosion, worsen compaction or water logging, or lead to or exacerbate natural chemical or mineral imbalances in the soil. The return on almost all investments in agriculture is ultimately bounded by soil quality.

5 Tighten and calibrate nutrient cycles relative to crop needs

- Technologies, practices or inputs should not result in or depend upon periodic excesses of nutrients or water compared to crop or livestock needs, nor should they create new leaks or losses in nutrient cycles.

6 Preserve capacity to adapt and innovate

- As experience is gained with a technology, practice or input, farmers should be able to continuously experiment with and improve the ways it is used.
- Technologies, practices and inputs should be amenable to change by farmers to best match unique local conditions and should not reduce degrees of freedom in farming system design and management.

7 Exploit free ecosystem services

- Technologies should enable farmers to actively manage and/or more cost-effectively take advantage of free ecosystem services with potential to support crop and animal production and/or contribute to soil fertility and quality.
- Technologies that undermine or erode free ecosystem services should be held to a higher standard of agronomic and economic performance.

8 Favour self-sustaining solutions

- Ideally farmers should not have to purchase the same inputs or use the same practices every year to address a given production problem. They should have the capacity to replicate and improve upon a technology.

EQUITY AND OUTCOME RELATED 'FIRST PRINCIPLES'

Technical possibilities in the world of agricultural biotechnology are exploding at the same time market and consumer acceptance is imploding. Strong medicine is going to be needed to turn this situation around. Risk adverse countries and sceptical consumers will need to see clear evidence that a technology will deliver meaningful benefits, and not just to companies and owners of intellectual property rights. Risk assessment tools, science and rigour must steadily improve, especially in countries like the US that have embraced 'substantial equivalence' and as a result, have ignored risk assessment challenges.

9 Assure a sound match between the attributes, requirements and impacts of technology and the needs and capabilities of intended beneficiaries

- For developing world applications, technologies that increase routine reliance on purchased inputs and/or require technical skills and capabilities not currently in place should be avoided.
- The capacity to manage potential ecological and food safety risks and impacts must be taken into account in risk–benefit projections.

10 Avoid external costs and risks

- Inherently hazardous technologies and inputs should be avoided, as should those that place markets and essential production tools and natural resources in jeopardy.

11 Do no harm

- Ideally, the consequences following adoption of a technology, practice or input should be predictable and benign. To the extent that consequences are impossible to project, a more cautious, incremental approach should be taken.
- Prevent the emergence of new pests and/or slippage in pest management systems by minimizing selection pressure across time and space.

12 Promote equitable distribution of income streams associated with agricultural production

- Technologies or inputs that increase the profitability or economic status of consumers or private companies at the expense of poor and relatively disenfranchised farmers should be avoided.

APPLYING THE 12 PRINCIPLES TO SELECTED TECHNOLOGIES

A variety of qualitative and quantitative methods could be used to apply these 12 principles, or some other set of principles, to contemporary agricultural technologies. Ranking technologies against these 12 principles is not a substitute for rigorous environmental and food safety risk assessments, but rather an exercise to determine which technologies are worth moving forward with, possibly to the point where a full risk and benefit assessment can be completed.

There is no intrinsically correct way to apply these or any other set of principles. The methods used and weights applied to various principles will obviously impact the outcome. Companies, investors, regulatory agencies, international organizations, professional societies, research organizations and interest groups have their own, or are developing, methods to compare agricultural technologies. Most share at least some common elements.

It goes without saying that no one has the right to impose his or her personal values and priorities on others. Still, unless we are happy with the status quo, we must reason together and try to move the debate forward. Toward this end, a brief discussion follows of some of today's major agricultural biotechnologies relative to their compatibility with the above described first principles.

The two major agricultural biotechnologies in use are herbicide tolerant plants and plants engineered to express *Bt* (*Bacillus thuringiensis*) endotoxins in their tissues for control of certain insect pests. Despite market success in the US and a few other countries, these technologies remain controversial. Even reengineered to produce higher levels of vitamin A has been the subject of criticism. Why is this?

Herbicide tolerant crops

Herbicide tolerant plants, particularly Roundup Ready (RR) soybeans, have greatly simplified weed management. In some areas, adoption rates are very high, and in Argentina they approach 100 per cent (Benbrook, 2002).

As currently used in the US and Argentina, herbicide tolerant (HT) soybeans have limited crop diversity somewhat by increasing soybean acreage. The expansion of soybean farming onto what was previously forest and rangelands has clearly reduced local biodiversity (Benbrook and Baumuller, 2003).

More seriously, the technology is designed to, and clearly does, increase reliance on one weed management tool – herbicides. Moreover, it has increased dependence on a single herbicide, glyphosate (Benbrook, 2001). Excessive reliance on any single pest management tool heightens the selection pressure imposed on pest populations and sets in motion evolutionary processes that ultimately will undermine efficacy (Lewis et al, 1997). Hence, it is no surprise that Roundup resistant weeds have evolved in the US and are beginning to force farmers to add additional herbicides to their control programmes.

In the absence of a concerted pesticide-industry wide glyphosate resistance management campaign, the efficacy of this technology will be incrementally eroded. No one knows whether it will take 5 or 15 years for this process to unfold. How the industry and farmers respond will surely impact evolutionary dynamics.

The emergence of Roundup resistant weeds raises a key point and caveat. Problems with resistance and weed shifts are an adverse impact triggered by how HT technology is used, and are not inherently inevitable based on the properties of the technology. The same is true of resistance to *Bt* and *Bt* transgenic crops, as well as genetic resistance to any pest, whether brought about through conventional breeding or biotechnology. How a technology is deployed, in particular how heavily it is relied upon, drives whether potential problems and risks become real ones. Accordingly, it is important to take into account levels of adoption and degrees of reliance in evaluating the impacts of many technologies.

Paradoxically, the best way to maximize the benefits of many individual technologies is to use them sparingly, in combination with other technologies. Many little hammers, used in complex rotations, are far better than one big hammer, especially a big hammer everyone has access to.

Does HT technology target the root of weed management problems? Farmers eagerly adopted HT soybeans to get away from the use of highly active low-dose herbicides in the imidazolinone and sulfonylurea classes (Benbrook, 2001). Herbicides in these families of chemistry were leading, in some circumstances, to crop injury and carryover problems. Herbicide tolerant soybeans seemed a logical solution to carryover problems, but do not address the root of the problem, which is why weeds tend to do so well in soybean fields.

The ‘avoid external costs’ and ‘do no harm’ principles both sound a note of caution with respect to some HT crops. Research has shown that applications of glyphosate on fields planted to RR soybeans impair root development and the activity of the micro-organism responsible for nitrogen fixation by soybean plants (King et al, 2001). Since most cropland producing soybeans in the US contains high levels of nitrogen, RR soybean yields are typically not affected. In drought years, the impact on yields can become significant. Accordingly, this HT technology has a modestly to moderately negative impact on soil quality and the nutrient cycles. In developing countries where nutrients are not nearly so abundant, the impacts of this unintended consequence may prove more serious.

Much has been said about whether HT soybeans reduce herbicide use and hence, pesticide risks. They clearly do not reduce the volume of herbicide applied, since glyphosate is a relatively high-dose herbicide. The planting of RR cultivars has dramatically decreased the use of low-dose herbicides that pose production-oriented risks to farmers. This shift has benefited farmers who choose to largely rely on herbicides for weed management. But HT technology in the US has not resulted in significant benefits to the environment or society as a result of reducing pesticide use, nor has it created significant new risks, other than the emergence of resistance.

The most substantial potential benefit of HT technology stems from its compatibility with no-till production systems. If HT varieties were predominantly planted using no-till systems on highly erodible land, the public benefits would be unequivocal. Resistance would still need to be managed, as would other environmental impacts, but the steps needed to do so would be more than justified by the reductions achieved in soil loss and sedimentation. This is not how HT technology has been marketed or adopted, however. HT soybeans have had a very modest impact on adoption of no-till and conservation tillage, and there has been near-zero effort made to target the technology to highly erodible lands.

Economically, HT technology has been about a wash for farmers, not because the technology is inherently efficient or has increased yields, but because the price of glyphosate and other herbicides has dropped about one-half on average since the introduction of HT soybeans. The price of glyphosate fell because it went off patent and generic competitors entered the market. Manufacturers have also markedly cut the prices of other herbicides in an effort to slow their loss of market share to glyphosate products.

In the US biotechnology companies have charged a technology fee and/or price premium for genetically modified (GM) seeds roughly equal to the perceived average economic advantage of the added trait to the farmer. Many farmers with serious weed management or Lepidopteran insect problems benefited substantially from the planting of GM seeds; farmers who were managing these pest problems effectively with other technology and/or systems typically had little to gain economically from HT or *Bt* crops. Most who switched did so to simplify their production systems and minimize a problem-area that required considerable management attention.

A growing concern in farming country is what happens if the RR soybean system no longer works because of weed shifts and resistance. This technology has increased farmer dependence on seed–biotech–herbicide companies. Perhaps equally effective, affordable replacement technology will reach the market as the efficacy of RR technology declines. But if it does not, both the cost and difficulty of managing weeds in soybeans will increase, at least until farmers gain access to, and become skilled in the use of alternative technology or systems. The fact that HT technology has markedly reduced farmer use of non-chemical alternatives and undercut promising research in multitactic integrated weed management systems works to perpetuate farmer dependence on herbicides. Some people view this as an inherent disadvantage and others could not care less how weeds are managed in soybeans.

Bt cotton

The benefits of *Bt* cotton have received much attention in the wake of the Qaim–Zilberman piece in *Science*, 'Yield effects of genetically modified crops in developing countries' (Qaim and Zilberman, 2003). *Bt* cotton works well in controlling several major Lepidopteran insect pests, as shown repeatedly in grower fields and research trials in several countries. The article's conclusion that *Bt* cotton will increase cotton yields 60–80 per cent in developing countries, and sometimes 100 per cent, is extrapolated from limited company field trials in a year with intense insect pressure. The article acknowledges that in plots planted to conventional seed with standard insect pest management practices, losses were about 60 per cent of yield. By eliminating most of such losses, *Bt* cotton or other alternative technology would double yields.

The suggestion that all farmers have to do to achieve such huge yield increases is to plant *Bt* cotton assumes there are no other constraints to yields, nor other effective insect pest management options. Both assumptions are implausible and have been challenged by entomologists in India, including some who support development of transgenic technologies (e.g. see Sahai and Sen's comments in the 5 March, 2003, special issue of *AgBio View*).

Still, providing access to safe insect pest management technology via seed is highly desirable as a general goal, and indeed is the focus of a major share of conventional plant breeding efforts. But delivering lethal doses of a natural toxin like *Bt* through plant tissues will lead to many of the same problems as chemical sprays, as pointed out by US Department of Agriculture scientist Dr Joe Lewis and colleagues in their seminal 1997 *Proceedings of the National Academy of Sciences* paper 'A total systems approach to pest management' (Lewis et al, 1997). In this paper, the authors' state:

> *The use of therapeutic tools, whether biological, chemical, or physical, as the primary means of controlling pests rather than as occasional supplements to natural regulators to bring them into acceptable bounds violates fundamental unifying principles and cannot be sustainable.*
>
> (Lewis et al, 1997)

In addressing emerging applications of biotechnology to pest management, they argue that:

> *As spectacular and exciting as biotechnology is, its breakthroughs have tended to delay our shift to long term, ecologically based pest management because the rapid array of new products provide a sense of security just as did synthetic pesticides at the time of their discovery in the 1940s… [T]he manipulated pathogens and the crops engineered to express toxins of pathogens are simply targeted as replacements for synthetic pesticides and will become ineffective in the same way pesticides have. It will be unfortunate if these powerful agents are wasted rather than integrated as key parts of sustainable pest management systems.*

They cite the basic tenets of ecologically based, or biointensive IPM in arguing that the most desirable pest management technologies, in terms of costs and risks, will trigger or reinforce natural cycles, developmental processes and multitrophic interactions that work to sustain balance among pest and beneficial organism populations in natural systems.

Bt crops do not do so. As Lewis et al (1997) point out in comparing foliar insecticides to *Bt* crops, the transgenic approach 'amounts to a continuous spraying of an entire plant with the toxin, except the application is from the inside out'. By contrast, a crop genetically engineered, or conventionally bred, to over-express jasmonic acid when attacked by caterpillars, or other chewing or sucking insects, would be consistent with this basic principle (Seo et al, 2001). Such over-expression can attract parasitoids that in turn lessen insect feeding damage (De Moraes et al, 1998; Thaler, 1999).

Where insects susceptible to *Bt* have driven on-farm insecticide use, cotton farmers growing *Bt* cultivars have been able to markedly reduce applications of typically high-risk, broad-spectrum insecticides. Encouraging and important recent research in Arizona has shown that where 65 per cent or more of the cotton acreage has been planted to *Bt* varieties, area-wide suppression of the pink bollworm has occurred (Carriere et al, 2003). This is a positive development for several reasons.

In Arizona, *Bt* cotton has eliminated the need for most applications of broad-spectrum insecticides on cotton, giving populations of beneficial organisms a chance to rebuild. These populations are now starting to make important contributions in suppressing several potential insect pests, including the pink bollworm (Carriere et al, 2003).

Area-wide pest suppression of pink bollworm populations could also allow farmers to better manage resistance. As populations decline, it will be possible for farmers to periodically forgo the planting of any *Bt* cotton in an area. Reduced risk insecticides, coupled with multitactic IPM, will be effective in such years, and can be augmented late in the season if needed by a broad-spectrum insecticide. The elimination of any *Bt* selection pressure for a whole year will surely increase the effectiveness of ongoing resistance management plans (RMPs). Whether this new understanding of the impacts of *Bt* cotton will be taken advantage of in strengthening area-wide resistance management remains to be seen.

Vitamin enhanced crops

Rice engineered to produce higher levels of vitamin A has been one of the most widely debated applications of agricultural biotechnology. Recently, a method has been found to increase the vitamin C content of crops by increasing the expression of the enzyme responsible for recycling ascorbate (Chen et al, 2003).

The evaluation of these technologies is underway, with vitamin A rice much closer to possible commercial adoption than vitamin C enhanced crops. Some people still question the wisdom of enhancing vitamin content through genetic engineering. Those questioning such technology usually argue that there are other, simpler, less costly ways to increase vitamin consumption. They project that more progress would be made in solving the underlying problem – vitamin deficient diets – if the resources required to bring transgenic vitamin enhanced crops to market were instead invested in efforts to improve the agronomic performance of vitamin-rich, locally grown fruit and vegetable varieties.

It is hard to imagine how anyone, or any analysis, could definitely prove or disprove these projections and assertions. Still, a degree of diversity in R&D efforts addressing a given problem is intrinsically beneficial. If one accepts this 'don't put all your eggs in one basket' principle, then ideally the substantial new investment in the development of transgenic vitamin enhanced plants in the last decade has been or will be accompanied by increased investment in efforts focused on achieving the same goals through other means.

In terms of the safety evaluation of these two technologies, vitamin A rice may raise more food safety and agronomic performance issues than vitamin C enhanced crops. This is because two biosynthetic pathways novel to the rice genome must be moved into rice cultivars to increase vitamin A content, whereas it appears possible that vitamin C content might someday be enhanced simply by changing the expression level of enzymes already produced by plants. Differences between the scope of genetic modification required to add a given trait to a crop is highlighted in a recent article in *Nature Biotechnology*, 'Transgenic organisms – time for conceptual diversification?' (Nielsen, 2003). Nielsen points out that 'The extent to which transgenic organisms differ from traditionally bred organisms underlies much of the controversy surrounding the use of GMOs' and that:

> *Current approaches to gene technology assisted breeding have been called 'brute-force' in their use of distantly related genes with little consideration for the multiple evolutionary changes that have occurred in the biochemical networks separating species.*
> (Nielsen, 2003)

LEVERAGING LOCAL KNOWLEDGE AND INDIGENOUS RESOURCES VIA BIOTECHNOLOGY

Transferring developed world biotechnologies like HT and *Bt* crops to developing nations is almost certainly not the best way for resource poor, food insecure countries to benefit from biotechnology.

Recognition and acceptance of what biotechnology can and cannot do in promoting food security is a critical missing ingredient in contemporary debate. Too many biotechnology 'true believers' appear to only see transgenic solutions, regardless of the nature of a problem. In their zeal to promote biotechnology as the one true path, they sometimes discount or dismiss outright the actual and potential contributions of other problem-solving strategies, approaches and systems-based technologies. For example, a prolific proponent of biotechnology wrote in a post to *Ag BioView* that:

> *Not too long ago, it made sense to argue that 'native Mexican landraces' needed to be preserved because of their 'biodiversity' and the 'possible benefits' that might lie undiscovered in their germplasm. Seeds from these various landraces are held by CIMMYT [International Maize and Wheat Improvement Center] at great expense, and are about to become obsolete and worthless.*
>
> *Yes, that's true. Obsolete and worthless. The more advanced the knowledge of gene function and transfection becomes, the more pointless 'biodiversity' and seed banks become. Seed banks and biodiversity are only important if your only available technology is conventional breeding… Ten years from now, the expense for seed banks will be deemed pointless, their contents will be fed to cows and pigs.*
>
> (Aple, 2002)

Such unbounded confidence in the power of biotechnology worries many people. It worries me. I am excited by the power of biotechnology and accelerated scientific discovery, but do not foresee biotechnology rewriting the laws of nature or making germplasm obsolete. I cannot imagine how it will render soil fertility or ecologically sound approaches to pest management irrelevant.

For biotechnology to be a part of sustainable solutions, its power must be directed, at least for the foreseeable future, toward helping farmers to more effectively manage natural systems, cycles and interactions, rather than efforts to work around, supplant or overwhelm them.

Moreover, the benefits of new technology are too often eroded or overwhelmed by the impacts of bad food and farm policies and failure to support rural development. Dr John Kilama, CEO of the Global Biodiversity Institute and a former Dupont scientist, echoed this theme in remarks on the recently announced 'African Agricultural Technology Foundation':

> *The initiative is not getting to the core of the problem in Africa. I wish people would focus seriously on how to change governments in Africa. I'm a strong proponent of biotechnology, but other things need to be done that are more critical than giving seeds to farmers.*
>
> (Suh, 2003)

MOVING FORWARD IN ADDRESSING FOOD SECURITY NEEDS

There is wide agreement that instead of focusing on Western world commodity crops (corn, soybeans, cotton and wheat), emphasis should be placed on nutrient dense crops that are currently key foods in developing countries – for example cassava, millet, pulses, bananas, beans and squashes. While it is important to focus on food crops, altering plant genomes is only one way to increase crop productivity and prevent pest losses.

In some cases, the most direct, affordable benefits from biotechnology might come from altering soil microbial communities in ways that directly benefit plants. The identification and/or improvement of beneficial soil amendments, compost inoculants and seed treatments sometimes will prove a relatively easy and quick way to increase production.

In order to better manage plant diseases, many teams are working to genetically engineer plants to augment systemic acquired resistance (SAR), the plant's generic immune response to many pathogens. In 1997 a team based at the University of California-Berkeley described the role of the NDR1 gene in controlling SAR (Century et al, 1997) an important breakthrough that dramatically increased research interest and funding. Several teams have since been pursuing what is sometimes called the 'master switch' for plant defence mechanisms (e.g. Verberne et al, 2000).

While most of the excitement in the plant science community – and any new money for combating plant disease – has gone to work on triggering or reinforcing SAR via genetic modification, field research in China in 1998–1999 produced dramatic and encouraging results through an approach to disease management called intraspecific crop diversification (Zhu et al, 2000). Rice fields in five townships were planted to a mixture of rice cultivars that were susceptible and resistant to rice blast disease, the region's major pathogen. Yields rose 89 per cent and blast severity fell 94 per cent in the fields planted to seed mixtures compared to monoculture controls. The authors note that:

> *it is significant that the diversification program described here is being conducted in a cropping system with grain yields approaching 10Mg ha^{-1}, among the highest in the world. The value of diversity for disease control is well established experimentally and diversity is increasingly being used against wind-dispersed pathogens of small grain cereals.*
>
> (Zhu et al, 2000)

In the future, low-cost and effective disease management strategies in some row and grain crops may depend largely on the planting of diverse mixtures of cultivars. Biotechnology may play a supportive role in making this strategy feasible by helping to produce varieties that yield compatible grain, and grow and mature in unison, allowing efficient harvest. Both transgenic tools and marker-assisted breeding could play a role in developing such commercially matched, but genetically distinct, varieties. This sort of strategy, where plant breeders focus on relatively modest changes in cultivars to better exploit an existing, ecosystem-based pathogen control mechanism, is consistent with the conditions for pest management sustainability set forth by Lewis and colleagues in their seminal 1997 *Proceedings of the National Academy of Sciences* article (Lewis et al, 1997). It is also striking how different this approach is conceptually to ongoing efforts to trigger or reinforce SAR.

If it appears that a toxin is needed to poison an insect, the first preference should be to identify an indigenous biochemical that is effective in disrupting pest reproduction, feeding or development, modes of action that tend to require far less 'killing power' and greater species-specificity than traditional insecticides. Then, options to extract or produce such biochemicals cheaply and locally should be explored. In some cases, relatively simple methods such as fermentation or composting will be cost-effective and accessible to small scale, resource-poor farmers. Alternatively, a synthetic analogue of the material may need to be produced and purchased. Developing a source of the biochemical that can be sprayed or otherwise applied to a field will provide farmers the opportunity to practise biointensive IPM – scouting pest levels and applying pesticides or control interventions only when and where needed. This approach can save much time, effort and money.

Developing a transgenic cultivar expressing the biochemical should be viewed as an extreme response and last resort. When farmers' rely on transgenic cultivars, they treat pests prophylactically. Pests are subjected to selection pressure even when pest populations are below damage thresholds. Whenever possible, genetic engineers should focus first on ramping up plant defence and response mechanisms indigenous to plants, as opposed to trying to add wholly new biochemical responses.

Plants produce over 50,000 compounds, with a significant share triggered by pest and abiotic stresses (Dillard and German, 2000). The function of a few thousand are known; great potential awaits discovery of the roles of the rest, since the levels of these compounds should be readily subject to genetic modification. Of course, not all will prove benign when consumed by mammals, but some secondary plant metabolites will prove beneficial. Recent research has shown that plants emit flavonoids when attacked by pests, some of which that have potent antioxidant activity and may help prevent cancer in humans (Asami et al, 2003). When plant breeders manipulate plant metabolites, whether through use of transgenic or conventional breeding techniques, food safety consequences must be thoroughly explored.

If there are vitamin or mineral deficiencies in an area, crops suited to the region with a more desirable composition of vitamins and minerals should be identified. Constraints to wider production of these crops should be assessed and an effort made to overcome them. If increased production is not feasible because of some pest or abiotic factor, steps should be explored to deal with these constraints, including perhaps creating transgenic cultivars engineered to overcome a specific problem. If this and other strategies are too expensive or ineffective, then and only then should the focus turn to moving new biosynthetic pathways into locally adapted plants. This latter strategy for addressing the problem of nutritional deficiencies is likely to often be the costliest and most prone to setbacks and disappointments. In the case of a major crop such as rice, the potential long-term benefits are also enormous. Finding the right mix and balance of high probability, short-run incremental improvements vs. longer-term R&D investments that are riskier and but have a bigger impact is an ongoing challenge.

Many applications of biotechnology are envisioned to provide plants a better chance of dealing with problem soils. For example, a team of researchers in Mexico is exploring whether plants engineered to express a citrate synthase gene from *Pseudamonas aeruginosa* will enhance aluminum tolerance (de la Fuente et al, 1997). Aluminium toxicity is a major cause of depressed yields in acid soils and is a particularly serious problem in the tropics, where heavy rainfall and leaching increases acidity.

Whether a soil is plagued by chemical or mineral imbalance or problems of soil structure, breeding a transgenic plant that is better able to cope with the problem bypasses several other, possibly lower-cost and more sustainable solutions. Three things must happen simultaneously to convert a poor quality soil that is lacking in nutrients and biological activity to a healthy soil capable of supporting good yields on a sustainable basis:

1 whatever is causing the soil to be compacted, imbalanced, waterlogged or saline must be stopped or altered;
2 soil microbial biodiversity must be enhanced to provide the foundation for deeper nutrient cycles, bioremediation of imbalances and other essential curative processes; and
3 sources of organic material must be secured and added to the soil to provide food for the organisms that have important work to do.

In some cases, transgenic soil inoculants, or seed treatments, will prove valuable in enhancing soil microbial biodiversity. These can be manufactured relatively cheaply and delivered to the farm via compost inoculants, seed treatments or soil amendments. Often the only quick way to assure new sources of organic material is to increase the supply of commercial fertilizers. Where fertilizer is scarce or too expensive, soil fertility replenishment methods have to be worked out, based on locally available minerals and organic supplements (Sanchez, 2002). In the end, though, it is much better to heal a problem soil, especially soils where the problems are man-made, than it is to try to create a transgenic cultivar that does the near impossible – perform well in sick soil.

In the developing world most food-related problems stem from not enough of the essential ingredients for a safe, secure food supply. In the developed world, and surely in the US, excesses lie at the heart of our most serious farming and food system problems. We pollute drinking and surface water with nutrients because fertilizer is so cheap and because we have too much manure relative to the surrounding cropland's assimilative capacity.

Our food system supplies the average American adult with 3,800 calories per day (Nestle, 2003) – almost twice the level needed to sustain health for most adults (about 2,000 calories). Sixty-five per cent of adults in the US are overweight, nearly a third are obese, and the prevalence of obesity is spreading and becoming more common among children (Hill et al, 2003). The remarkably inefficient utilization of food energy in the US and the growing volume of waste are problems that rarely get discussed. When excess is accepted as a given, almost a birthright, inefficiency becomes an attribute and ironically, a focus of scientific discovery and technical innovation.

Too many animals are crammed together in most confinement operations, where they experience too much stress and are far too dependent on drugs. And as a result, too many antibiotic resistant genes are making the rounds in bacterial populations, finding ways to move from the farm, into the food supply, and then into hospitals, nursing homes, cruise ships, and other environments conducive to their spread in human populations. As a result, more and more people are experiencing serious medical problems from infections that were once easy to treat.

Many applications of biotechnology have been conceived and are being pursued to address America's sins of excess on the farm and in our food system. Phytase transgenic pigs (Golovan et al, 2001) and low-phosphorous transgenic corn are being developed to deal with the swine industry's contribution to water quality degradation. Transgenic vaccines and animal drugs are being developed to protect animals from diseases triggered by how animals are raised. Multiple technologies are being pursued to reduce or alter the fat content of food, or to impair the body's ability to digest food or metabolize energy. The hope driving this work is that Americans can become more effectively inefficient in what they produce, process and consume. In short, we want to keep our bad eating habits but want to be spared the consequences.

It strikes many people that using biotechnology to 'fix' problems rooted in excess is like chasing one's tail. Most suspect there are better ways to solve the underlying problems. Avoiding excesses in our food system and on the farm is not going to happen by divine intervention. It will take a change in policies, prices and social priorities; it will take straight talk from the government and from health and agricultural professionals. Governments will need to stop investing scarce public resources in farm subsidies that create or worsen surpluses, especially of high fat and sugar-rich foods. Better ways must be found – and the will – to invest in technologies and food system changes that attack the roots of problems, not their symptoms.

Biotechnology can and will make important contributions to plant breeding and food security, but its benefits have often been oversold and its costs underestimated. Grandiose claims, coupled with the shift of resources and scientific talent away from other ways to solve problems, make people nervous. A more conservative and disciplined approach in bringing new technology to the market will help counteract these concerns.

People are beginning to appreciate that the impacts of agricultural biotechnologies depend on where and how the technologies are deployed, as much as the intrinsic nature of a given technology. Often, targeting emerging biotechnologies to just certain circumstances is a sound strategy to enhance potential social benefits, while containing risks. Such a modest approach, however, undercuts the typical need for companies to maximize near-term sales, profits and return on investment.

One necessary step in gaining public confidence will be methods to assure that new technologies are introduced incrementally to the market. Given that risk assessment methods and science are imperfect, systematic and independent monitoring of impacts is vitally needed in areas where a new technology is first adopted. But now, the US and most regulatory systems work like a traffic light – they either restrict technology developers to very small, controlled experimental plots, or open the door to 100 per cent commercial adoption.

Instead of trying to find ways to shift developed world applications of biotechnology to the developing world, a sounder strategy might be to survey how the tools of biotechnology might lead to better understanding of the linkages between indigenous resources and knowledge and agricultural production and farm family well-being. Such understanding will surely lead to insights into how to improve pest management, tighten nutrient loops, improve health and increase yields and hopefully incomes. Over time incremental progress toward these goals may set the stage for more dramatic biotechnology-driven breakthroughs in the future.

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Chapter 12

Costa Rica: Biodiversity and Biotechnology at the Crossroads

Ana Sittenfeld and Ana M. Espinoza

Costa Rica, like many other tropical countries, is at the crossroads of agricultural biotechnology and biodiversity conservation. On the one hand, agricultural expansion has resulted in the last decades in poor natural resource management, using a model based on plentiful use of agrochemicals to maximize production, with potential adverse effects on biodiversity and health (Mateo, 1996; Sittenfeld and Espinoza, 2002). On the other hand, Costa Rica is one of the 20 countries with the greatest biodiversity and has enjoyed a long history of conservation of its natural resources. Its National System of Conservation Areas comprises today over 25 per cent of the national territory and is the main attraction for tourism, which generated US$1,249 million in 2000 (9 per cent of GDP) indicating that protected areas are contributing substantially to the economy (Proyecto Estado de la Nación, 2000). Imports of agrochemicals increased by a factor of ten between 1990 and 1996, and yet there was no significant increase in crop yields per hectare in the last decade. The use of pesticides in Costa Rica has lead to increasing numbers of poisoned field workers. The challenge for Costa Rica is to decide whether to continue with unsustainable agricultural practices, or to explore other alternatives, such as the introduction of genetically modified (GM) crops and other biotechnologies that might offer opportunities to reduce the use of agrochemicals and increase yields. However, as with any other new technology, they require a careful consideration of potential environmental effects, including gene flow from GM plants to natural variants. Having a quarter of its territory reserved for wildland protection, and realizing that only 15 per cent of the soils are adequate for agriculture, Costa Rica needs to find ways to take advantage of both biotechnology and its own biodiversity. If Costa Rica is to conserve its biodiversity, it is imperative for the country to design and implement innovative strategies to link conservation and biotechnology, leading to increased agricultural production on less land, with lower pesticide use, and to maximize the benefits of using in an intelligent manner biological/genetic resources from wildlands.

LINKING BIODIVERSITY AND BIOTECHNOLOGY: THE RICE BIOTECHNOLOGY PROGRAMME

Rice is a very important staple crop for Costa Rica, providing approximately 25 per cent of the daily caloric intake to the population. Rice production faces several phytosanitary constraints that include the rice hoja blanca virus (RHBV) disease and weeds, among others. The distribution of this viral disease is limited to tropical America, and there is no natural resistance to RHBV among *indica* rice varieties. Because of a lack of resistance or tolerance to these factors, the use of pesticides has increased costs, which reduces profit margins and the competitiveness of rice production in Costa Rica. An alternative approach, therefore, would be to use non-conventional strategies, such as the genetic transformation of commercial rice varieties with RHBV antiviral genes for conferring resistance to the virus and to the herbicide PPT (ammonium glufosinate), in order to perform a more effective weed control in post-emergence. The production and deployment to farmers of transgenic rice with these traits, and a biodiversity inventory and characterization of wild rice relatives and weedy rice biotypes within the country, together with an assessment and monitoring of any potential environmental impacts before commercial release represent the main research activities performed by the Rice Biotechnology Program of the Centro de Investigación en Biología Celular y Molecular (RBP-CIBCM) of the Universidad de Costa Rica (UCR) (Sittenfeld et al, 2001). Since this is the first locally produced transgenic crop that addresses production constraints not considered by private and public research institutions in developed countries, the RBP-CIBCM has faced many challenges. These include basic research leading to the transformation of local germplasm, while at the same time considering the biodiversity assessment, regulatory and intellectual property (IP) issues necessary for a successful commercialization of the new variety. Transgenic rice varieties, resistant to RHBV and produced by RBP-CIBCM, represent the first transgenic crop to be deregulated for commercial release in the country that responds to phytosanitary constraints specific to tropical America.

In 1990, the RBP-CIBCM started the molecular characterization and sequencing of the RHBV genome (de Miranda et al, 1996), the development of plant tissue culture protocols for regeneration of Costa Rican *indica* rice varieties CR-1821 and CR-527 (Valdez et al, 1996–1997) and epidemiological studies of RHBV and its insect vector, *Tagosodes orizicolus* (Homoptera: Delphacidae). The next phase of the programme focused on the development of resistant rice lines through genetic engineering of the Costa Rican rice cultivars with RHBV sequences in order to confer resistance to the RHBV and to the herbicide PPT, by expressing the bar gene. Transgenic calli, produced in collaboration with Cornell University, were regenerated and evaluated in Costa Rica for their resistance to the RHBV and PPT under local field conditions, as well as for their agronomic performance. Progress in the research programme is leading to a shift from testing of concepts and building up of experience in the production of transgenic plants, to field evaluation and deployment of modified rice varieties to farmers (Arrieta et al, 2002). Field-testing is just one of the several steps required before the genetically engineered rice plants produced can be commercially grown. These steps range from health and environmental risk assessment and management of transgenic crops under tropical conditions, to the establishment of an IP management plan dealing with proprietary inputs and technologies used during the genetic modification of the lines, possible negotiations due to IPRs of third parties enforceable in the countries where commercialization will take place, and protection of inputs and technologies developed within the programme (Espinoza et al, 2003). Public opinion surveys to determine levels of acceptance (Sittenfeld and Espinoza, 2002), together with cost–benefit analysis and negotiations with seed producers, are all important activities for the commercialization and distribution of the new varieties. The identified steps, which are part of an integrated strategy developed by RBP-CIBCM, are most probably common to those from other groups working with transgenic rice in tropical countries.

Primary transformed lines were shown to tolerate toxic concentrations of the herbicide, while T1 progeny segregates 3:1 as a dominant locus. T2 homozygous lines turned out to be herbicide resistant under field conditions. In addition, T2 and T3 lines were evaluated for morphology, phenology and agronomic performance under field conditions. All experiments were conducted under the supervision of the Costa Rican National Biosafety Committee (NBC). The NBC has developed regulations and granted permits for transgenic seed increases for nearly a decade in the country, but no genetically modified (GM) products have yet been deregulated and released for commercial purposes. At present, new transgenic lines using other RHBV genes and bar are under development at CIBCM. The RBP-CIBCM research agenda is not static, but constantly searching for scientific improvement, including studies on the genetic diversity and reproductive biology of wild rice relatives (Quesada et al, 2002; Zamora-Meléndez et al, 2002) and weedy rice (Arrieta et al, 2002), aiming towards the development of gene flow experiments. At the same time, prospecting for new genes from wild rice relatives and other sources is also being conducted.

Assessment and management of gene flow from GM plants to wild *Oryza* relatives and to the weedy rice complex is one of the most important activities of the programme, since Costa Rica is a biodiversity-rich country. The RBP-CIBCM has conducted research to identify, map, and characterize native relatives of rice that occur in Costa Rica. Populations of three of the four *Oryza* species reported for tropical America have been found in natural ecosystems throughout the country, accounting for three of the six described genome types of Oryza (Zamora-Meléndez et al, 2002). Inventories for wild rice relatives have provided information for the best locations for the evaluation of transgenic lines in field trials. At the same time, morphological and molecular characterization of weedy rice populations allowed the identification of 27 biotypes (Arrieta et al, 2002). Information on the overlapping of flowering periods between weedy biotypes and commercial varieties obtained by RBP-CIBCM will be useful to select the weedy rice biotypes used in field experiments for assessing gene flow from transgenic rice to weedy rice populations (Arrieta et al, 2002). Preliminary results indicate that the number of potential recipients is low. The fact that rice is self-pollinated and pollen survives only minutes, suggests that the potential environmental risks of transgenes could be minimized.

MICROBIAL DIVERSITY AND BIOTECHNOLOGY

Debates over the role of GM plants in agriculture continue in the international environmental agenda. Transgenic plants containing genes from *Bacillus thuringiensis* (*Bt*) have produced positive reports advocating their use, together with agricultural practices to prevent ecological consequences, as well as negative reports suggesting environmental impacts for biodiversity. The RBP-CIBCM has also explored the presence of *Bt* in wildlands in Costa Rica (Rodríguez-Sanchez et al, 2006). *Bt* synthesizes crystalline inclusions that are toxic to caterpillars (Lepidoptera) and other orders. Materials associated with caterpillars from 16 species, collected while they were feeding on 15 different species of host plants in dry, cloud and rain forests located at the Area de Conservación Guanacaste (ACG) in northwestern Costa Rica, were examined for the presence of *Bt*. *Bt* isolates were cultured from host plant leaves, caterpillar guts and from caterpillar faecal pellets. Caterpillars are among the major herbivores in tropical forests and every leaf they eat contains a diversity of microbes. This inoculum plus potential food material is added into the established microbial community within the caterpillar gut, remains there for a few hours or days and passes through as faecal pellets that fall to foliage below and to the forest floor. The caterpillar-based microbial community may thus be visualized as a diffuse network of short-lived nodes between which microbes move. These results demonstrated that *Bt* is found in the same habitat of these caterpillars, associated to the leaf material from which these larvae were feeding. Since the gut of caterpillars constitutes a selective habitat for micro-organisms, it can be speculated that *Bt* isolates unable to colonize the gut could be transient passengers and, as a result, are eliminated in the faecal pellets. We postulate that caterpillars contribute to the dispersion of *Bt* in their natural ecosystems. *Bt* might also play a role in limiting forest defoliation, however further research is needed to better understand the role for *Bt* in wildlands.

Biological/genetic resources from wildland diversity are mainly used for improving locally adapted varieties and races, and wild relatives of crops to increase yields. Microbial diversity is also an important resource to explore for its potential use in improving food production. In this connection, bacteria in caterpillar guts represent an interesting source of new enzymes. Although micro-organisms from different genera have been isolated from guts and pupae of tropical caterpillars, little is known about them. Studying enzymatic activities of gut microbes is a starting point for understanding their metabolic and physiological relationships with their hosts, and to find enzymes with biotechnological applications. We are using traditional and biotechnological assays to detect secretion of gelatinases, caseinases, lipases, esterases, cellulases, xylanases, amylases and chitinases in a collection of bacterial isolates from caterpillar guts collected at the ACG. Bacterial isolates from caterpillars were more active when compared to other sources of microbes such as human guts.

Chitinolytic activity of isolates was further studied. At present research using chitinase genes is in progress aiming to generate GM crops tolerant to insect and fungal diseases.

PUBLIC PERCEPTION OF GM CROPS

Public perception of GM crops is fairly positive in Costa Rica. A nationwide survey of 1,000 Costa Rican citizens aged 18 and over conducted in May–June 2001, to assess the existing level of awareness and perceptions about GM crops, concluded that the national level of awareness of safety and the benefits of GM crops among Costa Ricans are more in line with those of the US than those of Europeans. The survey found an overall positive acceptance towards the use of GM crops (Sittenfeld and Espinoza, 2002). Between 40 and 50 per cent of Costa Ricans had heard about GM, thought that GM crops are nutritious, would buy food obtained from GM plants at no price difference and thought GM crops pose no risks to the environment. Only 21 per cent feared that biotech food would offer a health risk. About 30 per cent were supportive of research into GM crops. A similar percentage trusted regulatory institutions. In general, more educated people responded more positively to GM crops, in terms of acceptance and environmental and food safety issues, while low income and low education groups answered more frequently that they do not know or they simply did not respond. The latter responses were also higher for women. It is interesting that 55 per cent of the people surveyed had not heard about GM plants and animals, indicating the importance of promoting education to provide them with accurate and science-based information.

CONCLUSION

Although Costa Rica, a country with a population of 4.3 million, has allocated in the last decades an important portion of its national budget to education and health (27 per cent and 29 per cent respectively for the year 2000), the effects of globalization, and recent international economic policies from international agencies has lead to the increase of social and economic differences, and a delay in sustainable human development, that will affect the capacity of the country to deal with complex issues related to agricultural biotechnology. Agriculture has been one of the most important sectors for the economy of Costa Rica, promoting democracy, national values and political stability. Today, the country needs to develop agricultural practices that are friendlier to native biodiversity, at the same time that research seeks the path of higher productivity, without intensifying environmental degradation, social integrity or health problems. The research and possible commercialization of transgenic rice generated by the RBP-CIBCM represents a careful exercise. Lessons from the RBP-CIBCM indicate that is possible to implement sound science practices in agreement with environmental concerns, leading the way to the production of transgenic plants, and the sustainable use of biodiversity at the biodiversity and biotechnology cross-roads.

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Chapter 13

Biotechnology for Sustainable Agricultural Development in Africa: Opportunities and Challenges

Florence Wambugu

The Green Revolution (GR) in Asia was made possible by the availability of high yielding pest and disease resistant varieties of wheat and rice from the International Maize and Wheat Improvement Center (the Spanish acronym for which is CIMMYT) developed by Nobel Prize Laureate Dr Norman Borlaug, demonstrating that research when well-focused does pay major dividends. These improved varieties became catalytic to the Green Revolution, but the overall success was achieved due to increased government funding to agriculture, policy development, peace, security and good governance, increased use of inorganic fertilizers (organics were not sufficient), increased irrigation and mechanization through the use of tractors and improved communication and outreach to all relevant sectors. Currently Africa's socioeconomic status is similar to where Asia was 50 years ago and Africa truly needs an 'agricultural revolution' to drive the growth of its agricultural-based economies, transforming cycles of hunger, malnutrition and poverty to economic prosperity. The growing population and its demands are putting enormous pressure on the environment, causing environmental degradation, deforestation and serious loss to biological diversity, even in centres of genetic origin. In Africa, poverty has become the main cause of environmental degradation. Other challenges in Africa include the high incidence of HIV-AIDS sufferers and orphans that need additional resources for support (Wambugu, 2001).

Biotechnology has a demonstrated impact on increased productivity per unit of land through control of insects and pests and can help reduce environmental damage due to poverty. The endemic food shortages in most parts of Africa associated with drought and floods as experienced in early 2003, where 15 million people were threatened with starvation in Southern African countries clearly indicates a new approach is needed to increase and stabilize food supplies. Agricultural biotechnology has demonstrated its potential in both developed and developing countries and offers promise if driven by a clear 'African agenda' (Wambugu, 2001).

INTRODUCTION AND BACKGROUND

In Africa, households spend, on average, 60 per cent of their earnings on food. In Europe the figure is 12 per cent and in the US 5 per cent. Food must be made cheaper so that money is available for other purposes: health care, housing and investments in activities that will increase family income. To reduce the cost of food, Africa needs to use science and technology to reduce production costs and to increase productivity. This is illustrated by the fact that in Africa yields for major crops such as maize, sweet potato, etc., are on average less than half of that of countries where biotechnology use is high.

Food distribution to Africa is not the solution: it implies costly transport on rural roads (where they exist); it does not take local food preferences into account; and it erodes human dignity. People want to produce their own food. Many pan-African organizations, such as the New Partnership for African Development, see the possibility of lowering food prices by improving the yields of African food crops through biotechnology as a feasible solution. The problem is that developing countries in Africa and elsewhere are caught between the US and European positions on genetically modified organisms (GMOs).

DIVERGENT VIEWS ON GMOS

Generally in the US and Canada there has been widespread acceptance of GMOs because of the commercial opportunities and environmental benefits they offer. Internal markets seem to have benefited greatly through meeting the demands of the local economy successfully. Outside the US, there has been less agreement on the acceptability of agricultural biotechnology, particularly due to the moratorium imposed by the European Union (EU), which is generally seen as a form of trade protection. To date, the issue remains controversial and unresolved (Nuffield Council, 1999).

China, for instance, has made strategic decisions similar to those of the US. The country has invested heavily in gene technology, with an orientation toward developing a domestic and south/south export market. This choice has greatly influenced emerging economies. Policy makers in many developing nations are exploring the benefits of biotechnology to improve food security and boost income generation. Countries such as Argentina, Brazil, India, South Africa, Kenya and Nigeria are driven mainly by the potential for food security, and also by commercial opportunities. While most players recognize biotech crops as a means to achieve food security and improve income generation in their own domestic markets, African countries such as Zambia are not willing to risk future trade problems with the EU by meddling with GM foods. There is also considerable misinformation regarding the safety/dangers of GM technology, the negative risk aspects having mainly been generated – and greatly exaggerated – by anti-biotech NGOs (Amman, 2003).

Overall, African core issues on GM crops can be summarized as concerns on access and benefit sharing, that is, opportunities to engage in GM trade, possible trade barriers with Europe, and limited availability of local expertise in biotech with poor infrastructures and local capacity.

Despite continued controversies, the global production of GM crops rose from 10 million acres in l970 to more than 150 million acres in 2002 (James, ISAAA Briefs, 2002). To date, not a single case of harm to human health or the environment has been documented.

BIOTECH OPPORTUNITIES

GM technology opens opportunities for insect/pest/disease control, food fortification with essential vitamins such as vitamin A in cereals; micronutrients, such as zinc and iron, etc.; and essential proteins, such as lysine; and the production of plants that are drought tolerant or otherwise capable of growing well in harsh environments. An important feature of GM technology is its user-friendliness as a technology, as it is packaged in the convenient form of the seed. The ability to deliver new technology through seeds opens a new user-friendly access avenue for millions of small-scale farmers in Africa. Over 3 million small-scale farmers in China are also benefiting from *Bt* cotton. Also, with pest-resistant GM crops, farmers will not be handling and inhaling health-endangering pesticides. Many development projects fail because they do not fit in with local practices, such as the sharing of cuttings among farmers. This practice tends to spread a plant disease, but not if the plants from which the cutting are taken are disease resistant through GM technology. It gives delivery advantage to millions of small-scale farmers in Africa and other developing countries. Despite all the challenges, controversies and uncertainties surrounding biotechnology, the role of life science companies in making these technologies and products available globally continues to grow because of their successes. Most products have shown excellent performance, with a demonstrated impact even on smallholder farms in South Africa, India and China (Qaim, 1999).

ADDRESSING CONCERNS AND BARRIERS

The remaining issues to be addressed include affordability, intellectual property (IP) protection barriers, biosafety policies, private sector monopoly, capacity building in Africa, the European moratorium and information outreach. There is a growing fear that biotechnology could give a few big companies a monopoly and control of the seed market. The solution is probably to develop a comprehensive strategy involving suitable local public and private partners with expertise and implementation capacity. This approach can bring about genuine benefit sharing, as it allows for the transfer of genes into local varieties preferred by local communities. In particular, local small-scale farmers are able to see the benefits directly. The involvement of local scientists is also important when it comes to assessing the environmental and health impacts of GM crops and new life science technologies.

Companies need a strong IP incentive to develop new products, but seeds and technologies must be made available to farmers in developing countries through strategic partnerships. Several companies have demonstrated a willingness to do this, and to participate in various partnership initiatives. For instance, the Rockefeller Foundation facilitated African Agricultural Technology Foundation (AATF) has provided ways for North/South partnerships to open the African market in a mutually beneficial and sustainable manner. Such efforts must be encouraged and nurtured as they offer new models of doing business within the changing environment.

CONSEQUENCES OF THE EU MORATORIUM

The EU moratorium on GMOs is having serious consequences for Africa: loss of collaboration links, loss of research links, lost trade (exports to the EU) and diminished funding of biotech research. There are also consequences for the EU: decreased economic and political influence in Africa (this influence being shifted to the US, Canada and China), loss of scientific leadership to the US, delocalization of biotech companies to the US (and the resulting job losses) and a heavy moral responsibility when countries such as Zambia decide to reject GM technology and products due to fear of losing trade with Europe.

AN AFRICAN STRATEGY

For some diseases or infestations affecting African crops (such as banana, maize or the sweet potato), there exists a GM solution but no conventional one. To develop and implement such solutions, we need to develop African leadership in human and infrastructural capacity building. We need a good dialogue with the farmers, and to include them in the process so that they can accept new technology, with demonstrated benefits, which they must see clearly for themselves. Farmers should also be involved in the trials to generate information they can use to make decisions.

Additional elements of a comprehensive strategy for biotechnology in Africa include collaboration between public institutions (NGOs, universities, etc.) and the local private sector, a focus on food security and on indigenous African crops such as cassava, yam, banana, maize and the sweet potato. Funding of biotechnology by African governments, where South Africa is taking the lead and countries such as

Nigeria have started programmes, needs to be increased. Internal trade among African countries needs to be encouraged for food security to reduce over-reliance on EU trade and concern about trade barriers.

Put succinctly, a clear African agenda driven by an African strategy needs to emerge from the global biotech arena – that is we need to move from debate to more constructive engagements that will result in sustainable agricultural development that is greatly needed – to stimulate a 'biotech agricultural revolution' in Africa (Wambugu, 2001).

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Chapter 14

Biotechnology: Public–Private Partnerships and Intellectual Property Rights in the Context of Developing Countries

Gurdev S. Khush

According to FAO estimates, global food grain production must increase from the present level of 2 billion tons to 3 billion tons by 2030. These estimates are based on three factors:

- *Growing population* – The world's population is currently 6.2 billion and is expected to reach 8.0 billion by 2030. More than 80 per cent of this increase will occur in developing countries. By 2050, 90 per cent of the world's population is expected to live in the countries of the South.
- *Poverty alleviation* – At present, 1 billion people are food insecure and somehow survive on an income of less than one dollar a day. Another 2 billion have an income level of less then two dollars a day. As the poverty alleviation programmes succeed, the purchasing power of these people will increase and demand for food grains will go up.
- *Changing food habits* – The most important factor that influences per capita consumption of staple grains is the level of income of consumers. At low levels of income, staple foods such as starchy roots, rice, wheat and coarse grains provide the cheapest source of energy. As income increases, consumers shift from low-quality to high-quality foods such as fruits, eggs, milk and meat, and consumption of cereals goes down. The FAO data show that per capita cereal consumption has started to decline in mid-income countries such as Singapore, Malaysia and Thailand. China and Indonesia are reaching the threshold of peak cereal consumption. Thus, projecting the growth in demand for cereals, we must consider their indirect demand as livestock feed. Asia as a whole has emerged as a major consumer of livestock products (Brown et al, 1998). It takes 2, 4 and 8kgs of grain to produce 1kg of poultry, pork and beef respectively. This increase in

demand for livestock products implies a rapid growth in demand for cereal grains as livestock food.

Compounding the present food situation is the realization that the additional food grains will have to be produced from less land, with less water, less labour and fewer chemicals. Thus, one of the major challenges facing the world in the 21st century is to achieve food security without degrading the fragile resource base. Agricultural research and technological improvements will continue to be prerequisite for increasing crop productivity. A major emphasis will continue to be on the development of crop varieties with higher yield, durable resistance to diseases and insects, tolerance to abiotic stresses, such as drought and salinity, and more nutritious grains (Hossain et al, 2000).

Scientific advances in plant breeding led to the 'Green Revolution', regarded as one of the most important agricultural achievements of mankind. This revolution targeted staple cereal crops, particularly wheat, rice and maize, with staggering results. Towards the end of the 20th century, 370kg of cereals per person were harvested as compared to 275kg in the mid-20th century – more than a 33 per cent per capita gain. In simple terms, this prevented the starvation and malnutrition of almost 1 billion people (Dodds et al, 2001). However, the green revolution appears to have been maximized and other approaches are needed to continue improvement of food crops. This need is increasingly urgent because the per capita agricultural land to support food production has declined from 0.44 hectares in 1960 to 0.27 hectares in 2002 and will decline to 0.15 hectares in 2030. In simple language, our growing population and changing food habits require increased agricultural productivity to stave off mass famines in the developing world (Dodds et al, 2001).

Breakthroughs in molecular and cellular biology, collectively referred to as biotechnology, complement classical breeding and provide powerful tools to improve our crops. Many of the staple foods of the poor, which feed millions of people, have received little attention from the biotechnology industry because they are not regarded as cash commodities. Applying biotechnology to crop improvement is nowhere more essential, however, because of the pressing challenge of providing food to more than 1 billion hungry people in the developing world. Amongst these frontier technologies for crop improvement, molecular marker-aided selection and genetic engineering have captured the imagination of crop scientists and policy makers alike. Construction of dense molecular genetic maps of major food crops has ushered in the era of molecular markers, which are being employed for moving genes from one varietal background to another and for pyramiding or combining several genes for the same trait, such as for disease and insect resistance, through molecular marker-aided selection. Genetic engineering or recombinant DNA technology is being exploited to introduce cloned genes from unrelated sources into crop varieties for increasing yield potential, disease and insect resistance and for introducing novel grain quality traits.

The immediate potential benefits from the use of biotechnology include: (1) increased food supply for consumption; (2) increased farm input for cash; (3) reduced costs per unit of output; (4) employment generation for food processing; (5) growth of non-farm local economies; and (6) poverty alleviation, particularly for the rural poor.

STATUS OF BIOTECHNOLOGY RESEARCH IN DEVELOPING COUNTRIES

Biotechnology research is currently being carried out in private as well as public organizations and can be broadly divided into five categories:

1. largely global, private sector companies such as Monsanto and others;
2. public sector research organizations in national agricultural research systems (NARS), including universities;
3. the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR);
4. public research organizations including universities in industrialized countries;
5. various other international initiatives funded by donors and non-profit foundations of industrialized countries.

There is little doubt that globally, the private sector is the major player in biotechnology research. According to one estimate, the major life science companies invested some US$2.6 billion in agricultural research and development in 1998. Only a small proportion of this private R&D is directed at developing countries, most of this occurring through direct investment by the global life science companies in alliances with local companies.

The public sector finances around 90 per cent of total agricultural research in developing countries, compared to about 50 per cent in industrialized countries (Pray and Umali-Deininger, 1998). There is huge diversity among NARS in developing countries with respect to their capacity in agricultural biotechnology R&D. Byerlee and Fischer (2001) have divided the developing country NARS into three groups according to their biotechnology research capacity:

1. Type 1 NARS have strong capacity in molecular biology to develop new tools and products for their own specific needs. India, China, Mexico and Brazil are in this category.
2. Type 2 NARS have considerable capacity to borrow and apply molecular tools, for example molecular markers and transformation. Thailand, the Philippines, Indonesia, Colombia, Argentina and Kenya fall into this category.
3. Type 3 NARS have a very fragile capacity to borrow and apply molecular tools developed elsewhere. Several NARS in Asia (Laos, Cambodia, Myanmar) and most in Africa fall in this category.

Type 1 and 2 NARS have instituted a regulatory framework for the testing of transgenic crops and for protecting intellectual property (IP). Most type 3 NARS have no regulatory framework in place even to import and test transgenic products.

ACCESSING PROPRIETARY TECHNOLOGIES

Several mechanisms for public sector access to proprietary technologies of the private sector and other public sector organizations are available. These include business and legal options to gain access to proprietary technologies, such as confidential agreements, material transfer agreements, licensing, purchase and joint ventures (Erbish and Fischer, 1998). Up to now, there has been limited experience in developing countries with these various types of agreements. Some of the options are as follows:

- unilaterally accessing technologies,
- purchasing technology;
- material transfer and licensing agreements.

Unilaterally accessing technologies

One option for the public sector is to unilaterally access a tool or technology, especially those technologies that can be easily copied such as a specific gene from a transgenic variety, without seeking permission of the owner. This is perfectly legal if the patent for the technology has not been lodged in the country where the technology is to be used (Byerlee and Fischer, 2001) and if the product is not exported to a country where there is a protection on the invention. This is most likely to be the case with type 3 NARS. However, many critical technologies for biotechnology have been widely patented in numerous countries especially in type 1 and type 2 NARS.

A recent review of the proprietary technologies for golden rice (Kryder et al, 2000) illustrates the patterns of protection. It identified 44 potential patents related to this rice in the US, but the number of patents in different relevant countries varies from none to 11. All type 1 NARS would face restrictions, but there is no clear relationship among the number of potential patents, the importance of rice and the strength of public sector research programmes. For example, no patents have been taken out or filed in Thailand, a type 2 NARS, while patents have been taken out or filed for several of the technology components in countries with little capacity in biotechnology (e.g. in some African countries).

Purchasing technology

Proprietary technologies can be bought by the public sector for use in developing countries. For example, a consortium of public-sector institutes in Asia led by the International Rice Research Institute (IRRI) purchased the rights to the *Bt* gene owned by Planttech, a Japanese company. The consortium could then decide whether to make these materials public property or allow others to use the technology subject to a royalty payment. Likewise, Cohn et al (1998) report over 50 instances where Latin American NARS have purchased proprietary biotechnology tools and products.

A variant of this approach would be to contract with the private sector, through competitive bidding, to develop a specific tool, but with ownership of the product remaining in the public sector. This is most appropriate where the know-how exists in the private sector to adapt a product to a specific situation with considerable certainty (Byerlee and Fischer, 2001).

Material transfer and licensing agreements

Material transfer agreements (MTAs) are often used to define conditions for the transfer of research materials and tools for use in research only, leaving the need to develop a licence for commercial use of final technologies to a later stage. Public research organizations favour MTAs that define a 'front-end decision' about priorities and resource contributions (Rausser, 2000). Up-front costs are minimal and risks are reduced because the negotiation for the use value occurs after the value of the product, if any, is known. However, this practice can also weaken the negotiating position for licensing in the use phase, since the greater the success of the research, the greater the value of the technology and therefore the greater the expectations of return by the owner. In some cases, the flow of research products to users has slowed after considerable investment in product development because of the failure to reach agreement about the commercialization and royalty sharing (Byerlee and Fischer, 2001).

OPPORTUNITIES FOR PUBLIC–PRIVATE PARTNERSHIP

There is no denying the fact that the public sector is in a unique position to play a key role in biotechnology R&D in developing countries, but, working alone, the public sector will make only slow progress. Therefore, public–private partnerships are highly desirable for developing countries, in order to harness the benefits of biotechnology. There is no greater incentive for collaboration with the public sector in agricultural research than the enormous challenge posed by global food security. A large investment by the private sector in biotechnology has clearly demonstrated the need for, and significant advantage associated with, collaboration between the public and private sector in agriculture.

Public sector organizations invest in agricultural research to maximize societal benefits and private firms need to earn profits in order to give good returns to their shareholders. Both public and private sectors have complementary assets, which are a magnet for collaboration. Public sector assets include germplasm, evaluation networks, expertise in breeding, familiarity with local growing conditions, access to seed delivery systems, relationships with extension organizations and, in the case of International Agricultural Research Centres, the reputation and goodwill they enjoy with NARS. Global life science companies have assets in the form of biotechnology tools, genes, promoters, markers, technical know-how, financial resources, and skills in dealing with regulatory agencies.

The goal of partnerships is not to transform public sector institutions into private companies. The private sector is unlikely to replace the role of the public sector in research or in facilitating broad applications of biotechnology in developing countries (Lewis, 1999). Rather the role of the public sector will remain vital, as the private sector is unlikely to deliver biotechnology applications for many crops grown by the poor farmers and orphan crops and to address all biotic and abiotic production constraints important in developing countries. It is the responsibility of the public sector to fill these gaps. Moreover, the public sector will continue to provide a critical role in addressing broad policy issues, and guiding programmes that optimize public benefits from technological innovations in agriculture.

SOME EXAMPLES OF PUBLIC–PRIVATE SECTOR PARTNERSHIPS

There are several successful examples of public–private partnerships that have facilitated access to biotechnology and the development of improved crop varieties for developing countries. Such partnerships have been brokered by non-profit organizations with a mandate to help the transfer of technologies to developing countries.

Components of such partnerships include: (1) outright donation of technology by private firms to national public research institutions; (2) institution capacity building in biotechnology tools and IPR; and (3) information and knowledge sharing. In some partnerships, donors of technology also benefit.

Collaboration for resistance to insects in corn

Potentially novel strains of *Bacillus thuringiensis* (*Bt*) were characterized by the Agricultural Genetic Engineering Institute (AGERI) in Egypt in collaboration with US-based Pioneer Hi-Bred. The *Bt* gene isolated from these strains was introduced into locally adapted varieties of corn to develop insect resistance in those varieties. The collaboration involved training of AGERI scientists in characterizing *Bt* and maize transformation, while Pioneer was granted access to evaluate novel *Bt* proteins and genes patented by AGERI. The project was brokered and supported by the Agricultural Biotechnology Support Program (ABSP) of the US Agency for International Development (USAID) based at Michigan State University, US. A particularly significant aspect of the collaboration was that the ownership of IPRs related to these *Bt* strains belonged to the public sector (AGERI) and was made available to Pioneer under the terms of a contractual agreement. AGERI is pursuing commercialization of *Bt* maize varieties in Egypt while Pioneer used the licence in the US (Lewis, 1999).

In Indonesia, ABSP supported a collaboration between ICI seeds (now Syngenta) and the Central Research Institute for Food Crops (CRIFC). The focus of the project was the development of tropical maize varieties resistant to Asian corn borer. It included training CRIFC scientists in the use of transformation technologies. The experience of ABSP highlighted the challenges faced by public–private sector partnerships. The most significant constraint encountered was related to IPRs, due both to a lack of awareness and management capacity in public institutions, as well as differences in the extent of IPR protection provided by national laws. Despite capacity building efforts to address this issue, due to the absence of IPR protection, the CRIFC/ICI project ran into difficulties at the stage of negotiating a technology transfer agreement and the project between CRIFC and ICI could not be implemented (Escaler, 2003). Many of the public sector research institutions in developing country NARS, especially in types 2 and 3 NARS, are not well versed in negotiating with the private sector. Moreover, companies are not used to slow bureaucratic processes and government requirements. Type 1 NARS have developed sufficient capacity in handling IPRS and Type 2 and 3 are advised to enhance their capacity in this vital area if they are to benefit from public–private partnerships.

Papaya biotechnology network

The importance of papaya in developing countries in terms of daily consumption is next only to bananas in South East Asia. Unfortunately, papaya is affected by several diseases and pests, the most important and widespread of which is ringspot virus (PRSV), which drastically reduces papaya yields and has a devastating effect upon the livelihood of subsistence farmers.

The International Service for the Acquisition of Agri-Biotech Applications (ISAAA) developed and brokered a project with support from both the public and private sectors to develop ringspot resistant papayas (Hautea et al, 1999). Monsanto and scientists of the University of Hawaii are now collaborating with the network to develop PRSV-resistant papaya, while the former Zeneca Plant Science (now Syngenta) and the University of Nottingham are sharing their technology and know-how to develop delayed ripening papaya. The network includes national scientists from Indonesia, Malaysia, the Philippines, Thailand and Vietnam. The programme seeks to enhance income, food production, nutrition and productivity for resource poor farmers. As a part of the project, scientists from the five countries have been trained in transformation technology, biosafety, food safety and IPR management through workshops, courses and internships. Malaysia has made good progress in terms of the development of delayed ripening papaya and is conducting its first contained field trial. Thailand has already developed and field-tested several promising PRSV-resistant papayas. However, bureaucratic processes and stringent government requirements for biotechnology work, especially for field-testing, have consistently delayed progress of the network. Other problems include a lack of skilled personnel and national capacity and chronic inadequacy in public sector research funding in developing country partners (Escaler, 2003).

Virus resistant sweet potato in Kenya

Sweet potato is an important food security crop in Africa especially during a maize crop failure. It yields higher amounts of food energy and micronutrients per unit area than any other crop. The production of sweet potato is, however, constrained by a number of factors, in particular the disease, caused by sweet potato feathery mottle virus (SPFMV). It may cause up to an 80 per cent yield loss in susceptible varieties in many parts of Africa.

In 1991, ISAAA developed and financially brokered a research partnership for developing SPFMV-resistant sweet potato through biotechnological approaches. The initial partnership involved the Kenya Agricultural Research Institute (KARI), Monsanto, USAID's ABSP and the Mid American Consortium. Monsanto donated, through a royalty free licence, virus resistance technology for application to the sweet potato. Through this partnership, genetically modified (GM) SPFMV-resistant sweet potatoes have been developed using Kenyan varieties (Wambugu, 1996). In addition, several Kenyan scientists have been trained, both in the US and in Kenya, on various aspects of transformation, the establishment of biosafety structures, preparation and submission of biosafety permit applications, laboratory and field biosafety evaluation of GM crops, IPR protection and technology transfer mechanisms. The GM sweet potatoes are now being tested in station trials in four KARI centres in Kenya.

Golden rice humanitarian board

Golden rice is an excellent example both of the potential and hurdles in public–private partnerships. At least 400 million of the world's population suffers vitamin A deficiency and of that number 100 million are children. Every year, at least half a million children go partially or totally blind because of vitamin A deficiency and are at increased risk of respiratory diseases and diarrhoea (Sommer, 1990). Rice grains do not contain β-carotene, the precursor to vitamin A. Therefore, poor people who derive the vast majority of their caloric requirements from rice suffer from vitamin A deficiency. A research team led by Swiss scientist, Ingo Potrykus, developed GM rice by introducing three genes: two from a plant (daffodil) and one from a bacterium (*Erwinia uredovora*), which produces β-carotene (Ye et al, 2000). Due to the presence of β-carotene, the grains are yellowish in colour hence the name 'golden rice'. Dr Potrykus wanted to transfer the golden rice materials to developing countries for further breeding to introduce the trait in local varieties consumed by poor people. However, the Potrykus team had to take into account the IP used in the development of golden rice. A survey by Kryder et al (2000) uncovered 70 patents, belonging to 32 different companies and universities, embedded in golden rice. This clearly presented a major challenge to inventors who wanted their invention to reach poor farmers free of charge and without restrictions. After lengthy negotiations arrangements were made to enable the delivery of this technology for humanitarian purposes. First, the inventors assigned all their rights to a company called Greenovation that licensed to Zeneca (now Syngenta) all rights to golden rice related inventions. Syngenta arranged for further technology licences to be granted for humanitarian use in connection with Syngenta's Humanitarian License terms. Syngenta had to secure rights from several companies such as Bayer, Mogen, Novartis, Monsanto, Zeneca and a Japanese company. All of these licences are for defined humanitarian use. Syngenta then granted back to the inventors a licence with rights to sublicense for humanitarian use but retained all commercial rights. Syngenta also agreed to license further improvements and share regulatory data as well. The rights are transferred by the inventors to developing countries and institutions that assist them, such as IRRI, through a sublicence with or without a right to further sublicense. A sublicence with the right to sublicense has been granted to IRRI. No materials may be passed to researchers/institutions that have not executed a valid licence. Humanitarian use has been defined as use in developing countries (according to FAO definition) by resource poor farmers who make less than US$10,000 per year, leaving the company free to explore commercial prospects for the technology (Potrykus, 2001). To date licences have been given to five major rice-growing countries, namely the Philippines, India, China, Vietnam and Indonesia. It represents an excellent example of a public–private partnership.

A major hurdle remains before this rice will reach subsistence farmers. The trait needs to be transferred to many locally adapted rice varieties in rice growing countries. A careful needs assessment and analysis of pros and cons of alternative measures, bioavailability, food safety, biosafety and environmental and economic assessments followed by field trials are needed. A golden rice humanitarian board has been set up to provide advice and support throughout this process.

Rice functional genomics

Rice is the most important food crop for half the world's population. In Asia, the yield gain in rice has been crucial in keeping up with growing population. Since 1962, the population in Asia has more than doubled from 1.6 to 3.7 billion. Rice production has grown by 170 per cent, whereas the land area planted to rice increased only marginally by 121 per cent during the same period. The increased production efficiency has reduced the price of rice to less than 50 per cent in real terms over the past three decades. Continuing population increases coupled with decreasing arable land, water and other resources for sustaining agriculture, make it especially important to maximize rice production. Tapping into the genetic potential of the rice gene pool is the most feasible strategy for developing rice varieties for increased productivity. The availability of diverse genetic resources and knowledge is fundamental to any successful plant improvement programme. Yet, this is also the most contentious issue confronting public research institutes at a time when the private sector is increasing investment in crop research that has been done largely by the public sector. This issue is particularly sensitive with rice.

On the one hand, private investment can bring about new innovations. On the other hand, a shift in the balance of public and private investment in rice research has also raised concerns that some proprietary technologies might become unavailable to those who cannot afford them. Such concerns must be considered because gene identification, validation and application are occurring at an ever accelerating pace. The question is: can the model of free access to genes, germplasm and knowledge exist and contribute under an increasingly protective environment that exercises intellectual property rights?

The public rice genome sequencing project (IRGSP) was initiated in 1998 under the leadership of the Japan Rice Genome Research Programme (RGRP). Eight other countries: China, Taiwan (China), India, Korea, Thailand, France, US and Brazil have participated in the project. The completion of the sequencing project was announced in December 2002. Two private companies, Syngenta and Monsanto, as well as the public Beijing Genomics Institute (BGI) contributed their genome sequence data that facilitated and expedited the completion of the project.

The completely sequenced and freely accessible rice genome promises an enormous pool of genes and genetic markers for improvement of rice and other cereals through marker-aided selection and genetic transformation. However, to exploit this information will require detailed genetic and phenotypic analysis to identify and understand functions of each of more than 60,000 rice gene sequences. Both public and private resources are needed to exploit the potential offered by genomics. Diverse resources held by rice-growing countries and IRRI are crucial for success and these include mutants, germplasm, near-isogenic lines, populations for gene mapping and elite breeding lines for diverse rice growing conditions. The private sector has greater capacity in molecular skills, tool ownership and, most importantly, access to capital markets to undertake detailed molecular analysis that employs new sequencing and bioinformatics tools and large databases required (Khush and Leung, 2000).

In order to enhance public–private collaboration, IRRI proposed formation of an International Working Group on Rice Functional Genomics in 1999 (Fischer et al, 2000). It was agreed that the following activities are of high priority: (1) creating an information node to deposit and disseminate information on rice functional genomics; (2) building a public platform to promote access to genetic stocks and phenotypic information; (3) developing databases on phenotypes and mutants with linkage to sequencing laboratories; and (4) initiating partnerships to develop resources for microarray analysis.

The pattern of rights envisioned is that genetic resources for functional genomics will be made available to the public and private sectors under a material transfer agreement (MTA). This agreement permits recipients to obtain patents on genes discovered through the use of material, but requires them to make available rights under those patents at a reasonable royalty for application in commercial markets of the developing world and at zero royalty for application in non-commercial subsistence farming. In addition to ensuring the possibility of use in the developing world, it is essential that data and materials are freely available for research. Hence the MTA has provisions permitting free use for research purposes of any of the patents, as well as provisions ensuring that recipients cannot obtain any form of intellectual property on the genetic stocks per se. The information gained from research with such genetic resources must be provided back to the public, albeit after an appropriate delay to allow patenting. Public institutions engaged in developing and studying these genetic resources must agree among themselves to supply materials and to exchange all information developed and maintained in a common database. They must also follow the same rules as those imposed on the private sector through the MTA.

The experience of the last three years shows that this is a workable model. The International Working Group on Rice Functional Genomics was converted into the International Consortium on Rice Functional Genomics on the basis of discussions among participants at the International Conference on the Status of Plant and Animal Genomic Research 11 in San Diego in January 2003.

CONCLUSION

As the foregoing discussion shows, both public and private organizations have important roles to play in harnessing the benefits of biotechnology and the emerging field of genomics. Collaboration between the two sectors is even more crucial for addressing the problems of food security and poverty alleviation in developing countries. As the examples of public–private collaboration cited in this paper show, large life science companies such as Monsanto, Syngenta and Pioneer are willing to donate their proprietary technologies (genes, promoters, processes and sequences) for humanitarian causes. The role of donor agencies such as USAID and ISAAA in brokering and financially supporting these collaborations is commendable. International leadership is needed to explore the establishment of an international fund to bid for key enabling technologies that are especially relevant to poor producers and consumers. In addition, the formation of global public–private alliances and international agreements will be critical to ensure that the current explosion in genomics knowledge can be tapped to solve the problems of poor producers and consumers. The public sector has critical assets in the form of germplasm and associated biological knowledge important in the new science of genomics. However, to fully exploit these assets, the public sector must develop a capacity in IP management, strengthen biosafety protocols and upgrade business skills. Most public–private alliances to date have been based on free access to proprietary technologies for non-competing markets. Market segmentation is likely to be a key element in public–private negotiations in the future. To ensure that public sector organizations in poor developing countries have access to proprietary technologies, multinational life science companies should have an enlightened patent policy such as that of the Donald Danforth Plant Science Center, Saint Louis, US which states 'Any licensing agreements from discoveries made at the center shall diligently and in good faith negotiate the terms of the exclusive worldwide license, making provision for preserving the availability of the intellectual property for meeting the needs of developing countries' (Beachy, 2003).

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Chapter 15

Agricultural Biotechnology and Developing Countries: The Public Intellectual Property Resource for Agriculture (PIPRA)

Sara Boettiger and Karel Schubert

A worldwide move to strengthen intellectual property protection has led to an increased focus on how proprietary ownership of agricultural innovations affects developing countries. Questions have been raised as to whether intellectual property rights limit research innovation and form a barrier to the application of new biotechnologies to address global challenges in health, nutrition and the environment to benefit the international community, and in particular to meet the pressing needs in developing countries. This chapter provides a brief overview of some of the many complex issues that arise at the intersection between intellectual property rights (IPRs) in agricultural biotechnology and the needs of developing countries. We begin with the recognition that, while IPRs in agricultural biotechnology are just one element in a much larger development agenda that varies widely in accordance with the heterogeneous needs of developing countries, consideration of IPRs can be essential to achieving the intended goals of scientific research. Next we include a summary of recent changes in intellectual property protection in agriculture. With this background, we move on to address how IPRs affect developing countries' access to technologies, and the importance of IP management in developing country research and development. Finally, we describe how the Public Intellectual Property Resource for Agriculture (PIPRA) is working to address IPR issues in developing country research.

AGRICULTURAL INNOVATION, BIOTECHNOLOGY AND IPRS

Within agricultural innovation for developing countries, transgenic crops at present play a minor role. The majority of work in improving developing country crops currently occurs through traditional breeding, or in some cases, molecular marker-assisted breeding. While providing high social value, improvements in developing country crops do not provide sufficiently large commercial value to warrant major investment by the private sector. Genetically engineered crops face additional challenges related to public acceptance, high regulatory barriers and intellectual property rights. For these reasons and others, innovations in agricultural biotechnology have concentrated on creating value for developed country producers of major crops such as soybeans, maize, cotton and canola.[1]

China, Brazil, India and Argentina, however, are notable exceptions and have invested significant resources in the adoption of agricultural biotechnology. In addition to work in these countries, a strong international community of public sector plant scientists is working to apply the tools of recombinant DNA technology to create developing country crops that have traits conferring, for example, drought tolerance, salt tolerance, increased levels of micronutrients and the ability to resist local pests and pathogens.

While intellectual property rights can be an important consideration in plant breeding (e.g. plant breeders' rights), IPR issues faced in the research, development and distribution of transgenic crops are far more complex. It is worthwhile asking, therefore: given the dominance of plant breeding over transgenic research in developing country agriculture, and the recognition that IPRs represent just one of several barriers in the development path of transgenic crops, why are IPRs in developing country agricultural biotechnology important?

Agricultural biotechnology may hold important future advances for developing countries. Benefits may arise from the adoption of improved subsistence crops to address malnutrition, or from an increased potential for export income. It is too early to know how developing countries can benefit from the science of agricultural biotechnology. But we cannot wait to find out; IPRs, among the many challenges in this area of science, require forethought. Decisions today about the ownership of and access to technologies (through patents and licences) will affect the paths of research and development for decades ahead.

Considerable investments have already been made into researching the genetic modification of developing country crops (for instance, biofortification, disease and pest resistance, and drought tolerance). These projects must consider intellectual property rights in order to ensure the intended delivery of the products of their research. In its short history thus far, there is already an accumulation of anecdotal evidence of agricultural biotechnology research projects being delayed, redirected or halted all together because of IPRs problems (Wright and Pardey, 2006a, 2006b).

In developed countries, IPRs have been used strategically for many decades to advance commercial interests. Now that the TRIPs Agreement and subsequent bilateral treaties have required most developing countries to implement IP policies, knowledge of how to use IPRs to promote the interests of developing countries in a new world arena is increasingly important. Unfortunately, for countries with limited resources to invest in IP policy development and IP management, there is a risk, instead, of increased uncertainty and misinformation.

PROLIFERATION OF IPRS IN AGRICULTURAL BIOTECHNOLOGY

The advent of IPRs in agriculture is a relatively recent phenomenon. Hybrid corn varieties first developed in the US in the 1920s represent one of the first major commercial opportunities in seed markets. Because hybrids lose a percentage of their yield upon replanting, the adoption of hybrid varieties involved a shift from the seed-saving behaviour of farmers to purchasing new seed from seed companies. Hybrids, in a sense, provide a biological method for protecting the intellectual property involved in the creation of the hybrid.

The 1930 Plant Patent Act in the US[2] represents the first statutory intellectual property protection for asexually reproduced plants. In the ensuing decades, a proliferation of IP protection for plants has occurred. The 1961 Convention for the Protection of New Varieties of Plants (UPOV)[3] extended the opportunity of *sui generis* plant variety protection to sexually reproduced plants. A landmark US Supreme Court case in 1980, *Diamond* v *Chakrabarty*,[4] confirmed that living, human-made micro-organisms can be patented as inventions and set the stage for a burgeoning biotechnology industry. The Bayh Dole Act of 1980[5] altered the incentives to patent and increased the number of technology transfer offices at US universities. Global strengthening of IPR protection occurred among WTO member countries through implementation of the TRIPs Agreement[6] and subsequent bilateral treaties.

The result of these legal and policy developments has been an extraordinary shift in the ownership of agricultural innovations and an exponential increase in the number of patents in this field. Agriculture, characterized in the past by a dependence on the public sector for scientific advances, now depends on access to technologies developed within and owned by or licensed (often exclusively) to the private sector. Ownership of such technologies by the private sector and the corresponding ability to control their use by public sector institutions has been perceived to restrict access to emerging biotechnologies and to create a barrier to public sector research and the development of new and improved crops to benefit agriculture, particularly in minor and subsistence crops.

However, certain crops, such as subsistence crops (e.g. sweet potato, cassava, banana, white maize, sorghum, peanuts) crucial for developing countries, still rely on research and development in the public sector. Over the decades, commercial agricultural biotechnology companies have begun to use agricultural intellectual property strategically. Public sector researchers, on the other hand, have found themselves navigating a sea of patents and, despite considerable patent activity (particularly in the US) in public sector research institutions, lagging in opportunities to use their own IP strategically to promote public sector goals. PIPRA was founded through the leadership of public sector institutions and with the support and encouragement of the Rockefeller Foundation and the McKnight Foundation in response to a rising public concern that intellectual property protection restricted access to promising plant biotechnologies with potential to benefit crop agriculture and to address humanitarian needs in the developing world.

IPRS AND ACCESS TO PLANT BIOTECHNOLOGIES FOR DEVELOPING COUNTRIES

The effect of IPRs on access to plant biotechnologies for research important to developing countries can be examined from two perspectives – first, from the perspective of researchers in developing countries and second, from the perspective of researchers in developed country, public sector institutions working on developing improved crops to meet humanitarian needs in developing countries.

Research institutions in developing countries

It is often argued that IPRs do not present a barrier to access in countries where there are few patents. Because of the territorial nature of patent law, a patentee must decide country by country where patent protection is sought. Outside the major markets (typically consisting of US, Canada, Japan, Europe and perhaps China or Brazil), it is rarely financially prudent for agricultural biotechnology firms to invest in patenting. Therefore a research lab in, for example, Tanzania, may face very few patent restrictions in the course of its work. Legally, a researcher using a technology in a country where no patent has been filed is not infringing so long as a product incorporating such patented technology is not exported to a territory in which the technology is protected. Limitations described below still exist on the export of a technology from a territory in which the technology is protected to another territory where there is no IP protection as this may infringe the valid claims of the patentee.

In practice, however, the situation is more complex. Several surveys (see for example Binenbaum et al, 2003; Taylor and Cayford, 2002) indicate that researchers in developing countries perceive IPRs as a barrier to research. This may in part be the result of uncertainty about patent law. An obvious constraint occurs when the product of the research is destined for export into a country where patent protection does exist. In this case, despite the lack of patent protection domestically, diligence may be necessary in order to investigate the patent landscapes of export markets.

There are still further considerations. In order to make use of a patented technology, a researcher may require the transfer of materials or know-how from the patentee. These often involve material transfer agreements (MTAs) with restrictive terms and reach-through obligations that may hinder research and interfere with broad access by researchers in developed and developing countries alike. Even where no patent rights are found, this situation may involve the negotiation of agreements with the technology developer. In addition, even where large agricultural biotechnology companies are not concerned with infringement issues or losing market share, they may be concerned about liability and stewardship issues. Finally, developing country research institutions, or the organizations that sponsor research, may attach considerable value to the building of relationships with the major owners of biotechnologies. Despite the lack of patent protection, and the legal freedom to use a technology, there may still be important reasons to negotiate licences and IPRs become an important element in accessing biotechnologies for research in developing countries.

Public sector research institutions in developed countries

Research to address developing country needs through applications of agricultural biotechnology often depends on collaborations between developed and developing country research institutions. For this reason, an understanding of the implications of an increasingly complex landscape of IPRs for public sector developed country researchers is also an important consideration. In developed countries, where patent thickets exist, there is concern over the effects of a potential anti-commons. The importance of IPRs was most recently brought to the attention of the global community with the development of pro-vitamin A enriched rice ('Golden Rice') and perceived freedom to operate (FTO) barriers to the development and adoption of this technology within the developing world (Kryder et al, 2000; Kowalski, 2002). Research and the development of any improved plant variety or hybrid, whether by conventional crop breeding or modern methods involving biotechnology and molecular marker-assisted breeding, are entangled by the IPRs associated with the germplasm, enabling technologies (e.g. transformation methods, promoters, vectors) and/or gene traits (platform technologies).

IP MANAGEMENT IN DEVELOPING COUNTRY AGRICULTURE

IPRs can be a key element in the realization of research and development goals. IP management begins with the access issues discussed above, but there are important decisions to be made regarding the use of IPRs for the products of the research as well. The end goal will determine the best strategic use of IPRs, and the choice of IP management tools (such as patenting, trademarks, licensing and defensive publishing) will have enormous consequences in the eventual implementation or adoption of a new biotechnology.

Suppose, for example, widespread adoption is desirable for a new transgenic variety that has exceptional drought tolerance. Early in the research and development process, decisions about whether, for instance, to patent or publish must be made. Patenting is an expensive prospect, but the decision to invest in IPRs may ensure access to one's own technology and confer future bargaining leverage that, in combination with a licence agreement, may be used to engage private capital in shepherding the product through the regulatory process, or in promoting production and distribution in particular regions.

Knowledge of IPR issues and preliminary FTO analysis at early stages of research planning and concept design may help guide a researcher to a path providing future FTO, reducing potential barriers to future implementation. In the same way, access to tools and technologies with FTO and not encumbered by IPRs provide a mechanism to avoid at least some of these potential barriers.

IPR issues and the concern regarding access to agricultural biotechnologies to meet the development goals for developing countries have resulted in public institutions such as the Donald Danforth Plant Science Center (www.danforthcenter.org) developing best practices to ensure access to IP to meet humanitarian and development objectives. These practices include the development of policies to limit the scope of licences to specific territories or fields of use and/or to reserve and protect IP rights for humanitarian use. These practices and the inclusion of such humanitarian use language has now been more broadly adopted by many institutions as a common basis for negotiating research and licensing agreements between public and private sector organizations.

PIPRA

PIPRA is an organization committed to addressing IPRs issues in the research, development and distribution of subsistence crops in the developing world and specialty crops in the developed world. Because the commercial markets for these crops are insufficient to engage the private sector, R&D occurs almost entirely in the public sector. At an institutional level, neither the resources nor the infrastructure exist to manage intellectual property in a way that supports public sector research, development and distribution goals. PIPRA was founded with support from the Rockefeller and McKnight Foundations to facilitate collaboration among institutions and to provide a common resource to address IP management issues for crops developed in the public sector.

The services offered by PIPRA were developed in response to public sector needs in the two central areas articulated above – access to technologies, and IP management. Before providing further details on how PIPRA assists the public sector in these areas, we first discuss the foundational base of institutions and individuals that gives PIPRA its strength.

PIPRA's foundation

PIPRA's ability to deliver useful services to the public sector is a function of the strong base of our member institutions, the attorneys who support us, and a network of affiliated institutions active in a variety of related disciplines. PIPRA currently has 37 members from eight countries (up-to-date membership information can be found on our website: www.pipra.org). Our international membership has grown significantly over the last year. Three CGIAR centers – CIP, CIMMYT and IRRI – are now PIPRA members. Our membership base allows us to access not only important information regarding public sector inventions and licensing information, but also the technical expertise of researchers, and the management and legal acumen of technology transfer professionals. In addition to our broad membership base, we have organized a large network of IP attorneys that work *pro bono* for PIPRA. This network is a critical resource that facilitates legal analysis of IP issues relevant to public sector research in agriculture unrivalled in its depth and breadth. PIPRA's activities are also supported by affiliated institutions around the world that work in complementary areas. Some of these institutions directly support our work – (e.g. law schools providing legal analysis, PIPPA (www.pipra.org) helping us increase our *pro bono* attorney network, and M-CAM (www.m-cam.com) providing patent analysis tools and our database infrastructure) – and others serve to expand our knowledge base. Together, these three pillars of support (our members, network of attorneys and affiliated institutions) allow PIPRA to provide a range and quality of services to public sector researchers that facilitate developing products and crops to address developing country needs and create value-added opportunities in specialty crops.

Access to technologies

PIPRA was designed to facilitate access to agricultural technologies used by public sector researchers. PIPRA has the ability to provide information on technologies in our members' portfolios that are available for licensing and to facilitate the negotiation of licences. PIPRA's collaborative network also enables the communication necessary to transfer related know-how and materials. PIPRA also provides analyses that can be useful in highlighting the legal issues researchers must consider in their choice of technologies. Finally, PIPRA is engaged in a project to construct and distribute a plant transformation vector that has been designed with attention to legal, technical, regulatory and public acceptance considerations.

PIPRA's member portfolio

PIPRA's database currently contains information on more than 6,600 public sector agricultural patents and patent applications from 39 international issuing authorities. The database includes licensing information, updated regularly, to indicate which technologies are available. We hope, in the future, to extend the database to include plant variety protection certificates. Because PIPRA's mission is to promote IP management that supports public sector research, we consider the dissemination and analysis of public domain technologies to be a crucial element of our work. Our database currently includes expired and abandoned patents and has the capability to incorporate unpatented technologies, searchable in parallel with technologies subject to IPRs. While there are many public sources for patent information, PIPRA has the potential to offer further services that may be necessary to transfer technology – licensing information, facilitation of licensing negotiations, connections to inventors for the transfer of know-how and/or materials, legal analysis and consideration of public domain technologies.

In addition to our members' portfolio, which now represents close to one half of all public sector intellectual property in agricultural biotechnology, we are developing a database that reflects research into nearly 400 promoters used in plant transformation. This database, which will also be publicly accessible, is designed to link our legal research with scientific literature, patents, and other data on a wide range of promoters. We anticipate that the research community will find this a useful resource for identifying ownership and access to technologies.

PIPRA's research

PIPRA's staff is engaged in wide variety of research concerning public sector access to agricultural technologies and IP management. We respond to individual requests for patent landscapes providing general information regarding the IP related to a technology in question. When public information on the legal status of a technology is deemed to be of interest to a broad range of researchers, PIPRA will engage in a more in-depth analysis, resulting in a written legal opinion from one of our IP attorneys. PIPRA's staff is also involved in the analysis of other topics that relate to public sector agricultural research. Recently, for example, PIPRA staff have analysed (1) implications for the adoption of Bayh Dole-like legislation in developing countries; (2) open source licensing in biotechnology; (3) the use of defensive publishing; and (4) nutritional and product quality innovations in the global agbiotech R&D pipeline.

Providing research tools

The public sector research community currently uses plant transformation vectors that are built primarily with regard to the specific technical needs of the research project at hand. Little regard is given to legal, regulatory or public acceptance consequences that may result from the combination of component technologies chosen. This is a reasonable approach, given that proof of concept and publications are at issue. If, however, the research is intended to advance to a practical application outside the research lab, foresight concerning the choice of technologies can preempt future problems.

Using the base of resources discussed above, we are creating a plant transformation vector, in PIPRA's molecular biology laboratory. The vector's components are being chosen for their technical merit and their established utility, but also for their legal status. We are choosing, where possible, technologies from the public domain. If technologies are the subject of patents owned by our members, or other institutions, we are negotiating up-front licensing terms. PIPRA's goal is to distribute the vector with as much transparency as possible regarding the legal status of the component technologies. In addition, the vector is being designed to account for potential regulatory and public acceptance issues. The vector will be distributed royalty-free for research and humanitarian uses, with fee-based distribution for commercial use.

IP management

PIPRA provides services to public sector research institutions to assist in the navigation of IP issues in agriculture. Services directed to developed country research institutions are provided for research into speciality crops and developing country subsistence crops. Recognizing that research institutions in developing countries have very different IP management needs, PIPRA is currently assessing the best way to provide our services to these institutions.

PIPRA's IP management services begin with an individual consideration of the goals of the project and the institution(s) involved. IP strategies can be tailored to support a variety of management goals that may include, for example, achieving the broadest possible delivery of a product or ensuring the preservation of access to newly developed technologies. To support desired outcomes, PIPRA can assist in assessing the best path forward using some combination of IP management tools that might include sponsored research agreement language, in-licence considerations, use of the public domain, defensive publishing, patenting, trademarks, humanitarian use reservation of rights licensing language, etc.

In addition, PIPRA is working with the Centre for the Management of Intellectual Property in Health Research and Development (MIHR) (www.mihr.org) to produce a Handbook of Best Practices for Management of Intellectual Property in Health and Agricultural Research and Development that is designed to be a 130-chapter practical guide to IP management.

PIPRA has built a unique integration of scientific and legal skills needed to address intellectual property concerns in developing country agriculture and in public sector agriculture in developed countries. PIPRA's broad base of support provides expertise, talent and resources that enable the delivery of a wide range of services.

CONCLUSION

Although IPRs may, in some cases, represent a barrier to both public and private sector research and adoption, and utilization of promising agricultural biotechnologies in developing and developed countries, the barriers are not insurmountable. Knowledge of IP issues and development of best practices related to IPRs and FTO are key to overcoming these barriers. Organizations such as PIPRA play an important role in promoting best practices, providing access to knowledge and tools to address IPRs issues, empowering solutions to address global challenges and enabling development of value-added opportunities for public sector institutions. Thus, we conclude that IPRs to agricultural biotechnologies, when properly managed, should not be an insurmountable problem but may contribute to innovation and enable biotechnological solutions to address the global challenges facing the world.

NOTES

1 The private sector's relatively powerful position of ownership and control of agricultural biotechnology marks a major change; as the following section explains in more detail, advances in agriculture have historically depended on research in the public sector, not the private.
2 35 U.S.C. §§ 161–164. Plant patent protection extends only to non-tuberous asexually propagated plants.
3 UPOV was subsequently amended in 1978 and 1991. For the various texts, see www.upov.int/en/publicatins/conventions/index.html.
4 447 U.S. 303 (1980).
5 35 U.S.C. §§ 200–212.
6 Agreement on Trade-Related Aspects of Intellectual Property Rights, available at www.wto.org/english/tratops_e/trips_e/t_agm0_e.htm.

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Chapter 16

Commentary on Agricultural Biotechnology

Lawrence Busch

The various chapters on biotechnology raise a number of fundamental issues of critical importance not only for scholars but for practitioners in a wide range of fields from bioprospecting to molecular biology. What I shall endeavour to do here is to critically examine the points made in several of the papers on agricultural biotechnology.

Dr Khush (Chapter 14) makes several important points with respect to the potential for agricultural biotechnology to contribute to enhanced food production in developing nations. There is little doubt that the potential for biotechnology is enormous, but few products have been made available to date. Consider the following points:

The world is currently awash in a sea of cereals. Grain prices are quite depressed worldwide, in part due to continuing subsidies to production in the US and the EU, and in part due to lack of effective demand. Moreover, were Eastern Europe to produce at levels similar to that of Western Europe, grain prices would fall even lower. We would do well to remember that a century ago, the centre of the world grain trade was the Ukraine.

Furthermore, while enhanced grain production is important, it cannot and will not end poverty in rural areas. Increased productivity certainly has a role to play, particularly in meeting the needs of farmers who are barely able to meet their subsistence needs. But one simply cannot produce one's way out of poverty. Rising production of grain is always followed by declining prices. The cost/price squeeze and technology treadmill will continue to limit the profitability of the production of undifferentiated agricultural commodities (Cochrane, 1993). Rural poverty can only be reduced by increasing income and that is far better accomplished by switching to higher-value crops (e.g. fruits and vegetables) and by post-harvest and non-farm rural development.

It is also worth noting that while there is little question that biotechnology could enhance crop production in developing nations, the results to date are disappointing. The industrial world, for better or for worse, has delegated the development of agricultural biotechnology to the private sector, while simultaneously ignoring the needs of the developing world. Public expenditures for international agricultural research are a trivial portion of total global agricultural research expenditures. Even the relatively well-funded US public research institutions are unable to compete with the private sector in the production of agricultural biotechnologies. This is evident in the data on field trial permits issued by USDA. Only a small fraction of these are issued to public institutions (see www.nbiap.vt.edu/cfdocs/fieldtests1.cfm).

Dr Khush notes that the private sector has been seemingly willing to give free access to IPR in low-income markets. This is hardly a surprise, as these markets are not commercially interesting and offer an inexpensive form of publicity. However, there is little or no evidence that such access has resulted (or is soon likely to result) in improved varieties of staple crops for poor nations.

Dr Khush makes much of the potential for partnerships between the private sector and the International Agricultural Research Centres (IARCs). While the IARCs may find partnerships with the private sector desirable so as to enhance food security, the private sector has little reason to do more than display a minimal level of cooperation. Partnerships to date have been relatively inconsequential for at least four reasons: first, the agricultural biotechnology bubble has burst; investments in agricultural biotechnology globally are down. Many of the companies that invested in agricultural biotechnology have ceased to exist; others have experienced a marked drop in their revenues. Second, the easy to accomplish, highly profitable activities have already been done. Crops such as herbicide tolerant soybeans, maize and cotton have been developed and are now commercialized. Third, farmers in developing nations have relatively little in the way of capital to spend on improved seeds. Thus, they offer little or no incentive to private sector investment. Finally, intellectual property regimes in developing nations are weak, making returns to investments there lower. One need only look at the impact of Roundup Ready seeds in Argentina – a middle income nation – to see the limitations on using intellectual property protection as an incentive for investments in the developing world (e.g. United States General Accounting Office, 2000)

Finally, golden rice is still a largely unproven technology. As Khush notes, it has not yet been incorporated into local germplasm, compared to other sources of vitamin A, or even examined carefully for nutritional and food safety implications. Furthermore, it is unclear whether the product will even work as advertised – increasing vitamin A availability. Nor is it yet clear whether those at whom it is aimed – the poorest of the poor – will in fact accept it.

In contrast to the technical overview provided by Khush, Professor Hamilton[1] focuses more on the regulatory environment surrounding agricultural biotechnology. However, there are several points on which I must take issue.

The failure of Zimbabwe and Zambia to accept US grain that was genetically modified shows the lengths to which the biotechnology industry will go, and the degree to which the US government is willing to support it. Let me propose a simple thought experiment: let us suppose that a Muslim nation was experiencing a food shortage and that their inhabitants were offered pork. While there would be no doubt that pork is safe to eat, and widely consumed by others, this act would be seen as unacceptable – irrespective of the political views of the nations involved. At the time of the famine in Southern Africa, there was plenty of non-genetically modified maize in the world that could easily have been sent to those nations that had reservations about GM food. While it might well be argued that the Zimbabwean government used GM maize as a means of advancing its political objectives, the specific reasons for not wanting to consume GM maize are beside the point. In a world in which food is available in abundance, why should hungry people be forced to eat things that they may not wish to eat, merely to satisfy the needs of industry?

Professor Hamilton also notes the importance of the Starlink affair. I agree with Professor Hamilton as to its importance, but would also note that it demonstrated what the industry (and to a lesser extent the regulators) refuses to accept – namely, that since pollen drifts *and* people move grain around (either deliberately or accidentally), complete segregation of genetically modified crops is impossible. Moreover, once GM crops are released into the environment, their spread is virtually impossible to control.

The creation of pharmaceutical crops take this to its logical conclusion. In a recent paid lecture at the 2003 annual meetings of the American Association for the Advancement of Science, a Monsanto representative described that company's proposed solution to the problems posed by putting pharmaceuticals in corn. In addition to the truly heroic efforts required to engage in such an activity without risk to the nation's corn crop, what was described was a panopticon world of high security befitting a nuclear weapons plant. It is no wonder that the food manufacturers are nervous about this development. In contrast, it would appear that any reasonable national policy would prohibit the introduction of all potentially toxic compounds into field-grown edible crops. There exists a vast array of inedible, self-pollinated plants which might be quite suitable for the production of pharmaceutical and industrial crops, provided that they meet other environmental requirements. In contrast, denial of these basic facts of biology and social organization means that there will inevitably be a serious accident involving illness or death if we insist on going down the road we are currently following. The only thing debatable is how long it will take for such a problem to emerge.

Finally, let me comment on Dr Benbrook's paper (Chapter 11). He raises a particularly important point: one cannot treat all biotechnologies in the same way. Virtually everyone is in favour of biotechnology-based drugs that might cure cancer, while no one applauds the development of biotechnologically improved strains of anthrax. Benbrook frames the issue largely in terms of costs or risks vs. benefits. In contrast, I would like to argue that we must go far beyond the utilitarian language of cost or risk (cf. Busch et al, 1991; Thompson, 1995). The new agricultural biotechnologies also pose issues with respect to rights (e.g. the right to know, the right to refuse, the right to participate in determining the future). In addition, one might argue for obligations. For example, we have an obligation not to foreclose choices of future generations; indeed, we might wish to increase the number of options open to our progeny. It might also be argued that we have an obligation to protect the natural world from our meddling. It might be further argued that there are certain virtues – truth, justice, beauty, integrity – that should be upheld in our quest for material gain. We need not limit our actions to a utilitarian concern for consequences.

Benbrook argues eloquently for his 12 principles. In general, it is hard to quibble with them. But I would suggest what I hope will be taken as a friendly amendment. Specifically, these new technologies promise to transform dramatically and perhaps irreversibly the entire agrifood system. Yet, in most nations (including this one) there are no procedures, no rules, no policies to ensure that such decisions are made in a democratic way. Here we have decisions that affect everyone on the planet and yet we refuse to recognize that neither the market nor science is capable of providing answers to these questions. Of course, in a market economy innovations must be profitable. Of course, we must take scientific information into account in making decisions about safety, nutrition and environmental impact. But the market and science must not be allowed to become tyrants that rule over us.

There is a small but growing body of literature that attempts to develop means by which problems such as the introduction of profoundly new technologies can be made the subject of democratic debate (e.g. Middendorf and Busch, 1997; Sclove, 1995). The Danish consensus conferences in particular have shown a way in which such decisions might be made in a more democratic manner (Danish Board of Technology, 2002).

That said, the points made by Benbrook about herbicide tolerant, insect resistant and vitamin enhanced plants appear to me to be reasonable ones. But they are too important to leave to experts. They raise the kind of questions that should be the subject of prolonged deliberation in virtually every nation.

Benbrook also argues for greater attention to local knowledge. I find his remarks compelling. However, their implication should be made explicit: they rightly suggest that no particular technology is likely to be a magic bullet, resolving all the world's food problems. It is the worst form of hubris to think that food security can be improved solely by clever people doing clever things in well equipped laboratories.

Finally, Benbrook is surely right in suggesting that our regulatory systems work like traffic lights – either restricting or giving the green light to new technologies, rather than allowing gradual introduction so as to avoid large scale mistakes. But the regulatory system is also in need of repair in other ways. As is well known, the current regulatory system for GMOs was established by patching together a 'coordinated framework' in response to Monsanto's demand for regulation (Charles, 2001; Eichenwald, 2001). In particular, it is absurd to argue that only scientific concerns should be incorporated into regulatory decisions. The new agricultural biotechnologies are means for transforming how we live and who we are. Those issues must be central to any debate about biotechnology that is worthy of the name.

NOTES

1 See Hamilton (2005, p37).

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Chapter 17

The Birth and Death of Traditional Knowledge: Paradoxical Effects of Biotechnology in India

Glenn Davis Stone

Whereas previous chapters have emphasized interactions between biotechnology and environment, this chapter takes up the relationship between biotechnology and traditional knowledge. In particular I will consider the nature and resilience of traditional agricultural knowledge, as crop genetic modification – arguably the most powerful and controversial technology ever to enter the agricultural sector – moves into developing countries. How this technology may affect traditional knowledge and practice is poorly understood. Some argue that genetically modified (GM) crops are particularly suited to developing countries because they offer self-contained solutions 'in the seed' that can be adopted without farmers having to adjust or even to understand (Wambugu, 1999); others warn that the new technology threatens to undermine traditional knowledge (Harwick, 2000, p53; Simms, 1999).

The concern over these issues is nowhere as keen as in India, where GM cotton has been spreading rapidly. I have been conducting ethnographic field studies among Indian cotton farmers since before this cotton was released, and it has become increasingly clear that an examination of the interplay between traditional agricultural knowledge and GM cotton can yield important insights into each. This chapter shows that, just as agri-biotechnology is hardly the monolith that industry and green critics agree it is (even as they disagree on whether it is monolithically beneficial or sinister (Stone, 2002c)), its impacts on traditional agricultural knowledge are diverse and even paradoxical. I here present two case studies on Indian cotton growers. The cases share a spectacular rapid spread of GM cotton, but I will argue that they are sharply, perhaps even diametrically, opposed regarding their implications for traditional knowledge.

The first case, set in Andhra Pradesh, is a study in the disruption of traditional agricultural knowledge. Contrary to industry claims that the rapid adoption reflects farmer experimentation and evaluation, the farmers here have faced such wild variability in the seed system that they have all but given up on experimentation, and now show a striking degree of faddism in seed choices. Contrary to activists' claims, this 'deskilling' predated the GM seeds (although now the GM seeds appear to be exacerbating the problem).

The second case, set in Gujarat, lacks the ethnographic depth of the first, but it offers an intriguing contrast. Here the spread of GM cotton has been dominated by illicit seeds, leading to widespread flouting of seed laws aimed at protecting both the environment and the farmer; but there are signs of success both in cotton production and also the 'reskilling' of farmers.

BT COTTON IN INDIA

Crop genetic engineering is being led into the developing world mainly via *Bt* cotton. *Bt* is *Bacillus thuringiensis*, a soil bacterium that produces crystalline proteins that damage the digestive systems of certain lepidopteran insects. This order comprises butterflies and moths, including several moths that are severe cotton pests in their caterpillar stage (generally known as bollworms). The genes expressing the insecticidal proteins are known as CRY genes. All commercial *Bt* cottons in India contain the same genetic construct, developed by Monsanto, containing the Cry 1A(c) gene. (For further background on genetic modification of plants see Stone, 2002a).

India is one of the most closely watched arenas where GM crops have been introduced. Indeed there are few places where the stakes are higher, given the vast potential market of 700 million farmers as well as the energetic and highly sceptical NGO sector. India officially approved its first *Bt* cotton seed for the 2002 season;[1] three seeds were released, produced by MMB Ltd., a collaboration between Mahyco (the Indian firm providing hybrid cotton seed) and its partner and partial owner, Monsanto (the St. Louis-based biotechnology firm providing the gene construct). In the following years, several other cotton seed companies licensed the *Bt* construct for their cotton seeds. As Table 17.1 shows, the number of *Bt* seeds on the market has climbed, and the overall sales have climbed dramatically, from 72,000 packs in 2002 to 3 million in 2005.

In some localities, such as Warangal District of Andhra Pradesh, the surge in sales was much sharper than these national trends. Warangal is a pivotal cotton-growing area; cotton cultivation here has been problematic in recent years, and indeed has been implicated in hundreds of suicides (Reddy and Rao, 1998; Stone, 2002b). What my recent survey of Warangal seed vendors shows is remarkable: from 2003 to 2005, the market share held by *Bt* hybrids climbed from 1 per cent to 20 per cent to 62 per cent (since this does not count the under-the-counter *Bt* sales discussed below, the actual figure is somewhat higher). In some villages 90 per cent of the seed choices in 2005 were for *Bt* seeds, including 83 per cent for a single brand. Even before this sales extravaganza, Monsanto had claimed *Bt* cotton to be the 'fastest adopted new product in the history of agriculture' (Dinham, 2001), but the rush to *Bt* cotton for the 2005 season in Warangal was a veritable craze.

Table 17.1 Bt *seeds on market and sales in India*

	Seeds on market	*Sales (1000s)*
2002	3	72
2003	3	230
2004	4	1300
2005	20	3000

INDIA COTTON AND IOWA CORN

What leads to such rapid spread of a new technology? Innovation–diffusion theory has much to say on the topic; this field began with a study of seed adoption by farmers and has emphasized agricultural innovation ever since (Rogers, 2003). Ryan and Gross's (1943) study of adoption of hybrid maize focused on how Iowa farmers evaluated the new seeds and acted on the evaluations. The study showed adoptions following the s-curve that results from plotting a normal curve distribution cumulatively. The s-curve was later shown in adoptions of tetracycline and various other innovations (Cohen, 1966; Rogers, 2003). Ryan and Gross, and later researchers, recognized stages in the farmer's adoption process: *initial knowledge* (farmer learns of innovation); *persuasion* (farmer forms attitude towards innovation); *decision* (farmer evaluates innovation); *implementation* (farmer adopts innovation); *confirmation* (farmer evaluates performance of innovation).[2]

Buried deep in the paradigm for innovation–diffusion research was the assumption that the 'innovation' is somehow a better mousetrap: hybrid corn gave greater yields, and tetracycline had fewer side effects. Such relative advantages were what was confirmed in the 'Decision' phase, either through conducting one's own trials or by vicariously accessing information on 'trial by others' (Rogers, 2003, p177). Those who recognized the relative advantage and adopted early were termed 'innovators' or 'winners'; those who did not were 'laggards' or 'losers'. For farmers, the mainstay of this process – the route to being a winner – was the planting of a small experimental plot to trial the new technology.

Yet innovation–adoption research has increasingly come to recognize social processes that override or replace empirical evaluations. Some diffusion research now stresses perceived advantages of innovations, and documents cases where local cultural practices and beliefs exert control over which innovations are adopted. In some cases, medical innovations (like water boiling in disease-ridden villages) that were not only 'better mousetraps', but potentially matters of life and death, were rejected on cultural grounds (Rogers, 2003). Comparative studies of contraceptive use in both Korea and Thailand showed that whole villages adopted one form of contraceptive even if it offered no particular advantage over methods used by other villages (Entwhistle et al, 1996; Rogers and Kincaid, 1981). A more relevant recent example is the Perales et al (2005) study of maize diversity in Chiapas, Mexico: neighbouring Maya communities used distinct landraces of maize, not for reasons of agronomic performance but because of the channelling of information within social networks.

In India, prominent explanations of the spread of *Bt* cotton have wielded the original functionalist dogma of innovation adoption theory, citing farmer assessments of relative advantage and acumen:

> *we should leave the choice of selecting modern agricultural technologies to the wisdom of Indian farmers*
>
> (pro-industry agricultural leader P. Chengal Reddy, quoted in Pinstrup-Anderson and Schioler, 2001, p108)

> *we need to 'let the farmers finally decide on the usefulness of Bt cotton. Farmers are wise enough to adopt anything good and discard things that do not work'*
>
> (Andhra Pradesh Agriculture Minister, quoted in Venkateswarlu, 2002).

Monsanto and others have explicitly invoked the dogma of assessment based on small-scale experimentation:

> *Like the adoption of any new technology, people planted it on smaller acres initially, but the ever-increasing Bollgard plantings demonstrate that the Indian farmer is willing to embrace a technology that delivers consistent benefits in terms of reduced pesticide use and increased income. Clearly the steadily increasing Bollgard acres being planted by increasing numbers of Indian farmers bears testimony to the success of this technology and the benefit that farmers derive for it.*
>
> (Monsanto Director of Corporate Affairs for India, Ranjana Smetacek)[3]

The faith in farmer experimentation echoed through Western critiques of biotech opponents, which cited seed experimentation as a key to 'historically producing' better crops and better incomes' (Herring, 2006).

My own research has been in a tradition that is very attentive to traditional knowledge and practice, and I have seen seed experimentation and farmer assessments of crops up close. Yet from the outset, I saw disquieting patterns in Warangal farmers' approach to cotton seeds. First, was a striking localization of seed choices: the seed that was the favourite in one village might find no market whatsoever a few villages away, and neither farmers, dealers nor agricultural officials could offer any agronomic explanation for the patterns. Second, was that these local favourites were surprisingly ephemeral: the seeds that farmers were swearing by when I began interviews in 2000 had almost all dropped from favour by 2005, when I began the study reported below. Finally, there was a rather alarming tendency for farmers to rely on uncritical emulation in making seed choices: farmers who could justify seed choices on assessment of relative advantage were greatly outnumbered by those who simply stated they had planted what their neighbours had planted. The contention here is that this behaviour had crucial implications for traditional agricultural knowledge; that there is a theoretical basis for explaining it; and that it is vital to understanding the dramatic history of *Bt* cotton adoption.

AGRICULTURAL SKILLING AND DESKILLING

Let us think more carefully about what shapes farmer decision making. It is first important to note that farmer beliefs and practices are not as simple or static as they are often conceived. The farmer must manage a system involving intricate fits between environment, markets, seeds and other agricultural technologies, cultivation tactics, and cultural institutions for mobilizing work and other resources (e.g. Dove, 2000; Lansing, 1993; Stone et al, 1990). Farmers do not simply acquire information on a seed or other technology, but rather learn how practices and technologies perform together under variable conditions. Average yield under controlled conditions is only a small component of farm management. Moreover, since many of these factors change through time, so does the farmer's management acumen. This broader and dynamic concept of learning is what we can term *skilling* (Stone, 2004).

But skilling is susceptible to obstruction (see Bentley, 1989, 1993; Stone, 2004; Ziegenhorn, 2000). In her history of maize breeding in the US, Fitzgerald (1993) argued that adoption of hybrids led to 'deskilling' as American farmers turned into passive customers of seed firms. Hybrid crops may offer yield advantages, but the seeds produced by hybrids normally are not planted because they exhibit varying degrees of yield depression. Within a few years of the spread of hybrids, corn farmers who had previously been developing landraces and collaborating with public sector breeders were told, 'You may not know which strain to order. Just order FUNK'S HYBRID CORN. We will supply you with the hybrid best adapted to your locality' (Funk Bros. 1936 Seed Catalog, quoted in Fitzgerald, 1993, p339). This claim of deskilling alludes to the process described in Braverman's (1974) *Labour and Monopoly Capital*, in which capitalism degraded the role of labourers by separating mental from manual work.[4] To Braverman, the process was particularly apropos of factories, where it led to replacement of skilled workers, who were more expensive and less controllable, by machines and less-skilled workers.[5]

Fitzgerald did not probe the nature of agricultural deskilling thoroughly, but I have elsewhere argued (Stone, 2004, 2007) that agricultural deskilling differs from Braverman's process in three key respects. First, agricultural practice is more dynamic than factory work: most farmers are constantly skilling on new technologies, markets, and social conditions. Farming does not consist of mechanical application of knowledge or the making of binary decisions (e.g. adopt vs. don't adopt); the role of each technology in the performance must constantly be in play. Therefore *agricultural deskilling is not the displacement of a static set of skills, but rather the disruption of an ongoing process of skilling*.

Second, agricultural skilling is partly a social process that relies on farmers observing, discussing, and often participating in each other's operations. When technology passes between farmers, information usually does too (Brush, 1993, 1997; Cleveland and Soleri, 2002; Richards, 1989; Sillitoe, 2000). Other farms increase the amount of payoff information available, and other farmers participate in the process of interpreting it. Agro-ecological skill may become embedded in cultural concepts (Brodt, 2001; Thrupp, 1989) and even in institutions that individuals may not fully understand (Lansing, 1993; Netting, 1974). Factory workers may learn some aspects of their jobs from fellow workers, but this plays a much smaller role in their training, and they are not responsible for overall production strategy like the farmer. *Agricultural deskilling results from the disruption of processes of social learning that are uniquely instrumental in farm production*.

Finally, unlike industrial workers, farmers still need the skills that are degraded. That slaughterhouse workers do not know a sirloin from a fillet, or that McDonalds staff lack culinary skills, is no problem; in the slaughterhouse the process of turning an animal into discrete food products has been compartmentalized, and in the fast food outlet the process of cooking has been automated so that workers would have no use for the displaced skills. In contrast, farmers still have to make decisions about the use of technologies, even if they have not been able properly to 'skill on' them. There is a crucial difference between an industrial situation in which skill has no place, and an agricultural situation in which skill is needed but cannot be acquired. *Agricultural deskilling is not simply farm tasks being automated; it is the degradation of the farmer's ability to perform*.

I have also identified three common impediments to agricultural skilling: unrecognizability (uncertainty about what technology is being used or trialled), inconsistency (high temporal, spatial, or situational variability in performance), and excessive rates of technological change (Stone, 2004).

But there is another stream of research that provides crucial concepts for understanding the advent of agro-ecological maladaptation. Cultural–evolutionary theorists working in the tradition of Boyd and Richerson's (1985) *Culture and the Evolutionary Process* distinguish between environmental (or individual) learning, which is based on evaluations of payoffs from various practices, and social learning, in which adoption decisions are based on teaching or imitation (Boyd and Richerson, 1985, p40; Henrich, 2001).[6] The central feature of social learning are processes whereby individuals are emulated according to 'biases'. Examples are *prestige bias* (emulating another farmer on the basis of prestige rather than that farmer's actual success with the trait being copied) and *conformist bias* (adopting a practice when it has been adopted by many others).[7] Work in this tradition shows how payoff assessments may not be the prime driver of innovation adoption. We should expect reliance on 'pure social learning' when environmental learning is costly and/or inaccurate (McElreath, 2004; Richerson and Boyd, 2005, pp113–114).

This distinction between environmental and social learning is useful in building a formal body of theory, but from an ethnographic standpoint it is a bit contrived because the two forms of learning contribute to each other to varying degrees. Even a direct environmental observation made on one's own crop ('Brahma cotton yielded 6 quintals/acre for me last year …') is likely to be interpreted or contextualized through a form of social learning ('… which was much more than my neighbour said he got with the same seed'). Even a classic case of conformist adoption ('I am planting Brahma because my neighbours are …') assumes at least an indirect environmental basis ('… and they wouldn't all be planting it unless someone had an indication it would do well'). It is this variation within the realm of social learning that is crucial. It is not social learning per se that may spread maladaptive beliefs and practices (Richerson and Boyd, 2005, p166); it is social learning with relatively little grounding in environmental learning. When the flow of environmental payoff information is disrupted or rendered inaccurate or expensive, social learning may run largely on transmission biases and other factors weakly connected to payoff evaluations.

There, alongside the functionalist orthodoxy of innovation adoption that has been used to explain the spread of *Bt* cotton in India, is a theoretical basis for understanding how processes of farmer assessment of environmental payoffs (the basis of *skilling*) may be impeded and replaced by social learning. Whereas social learning may certainly be adaptive – the farmers being emulated may be running their operations adaptively – it also may not be adaptive, as the Warangal case shows.

SEEDS IN WARANGAL: ADOPTION AS DISRUPTED SKILLING

Warangal farmers (Figure 17.1) have a long history of small-scale cultivation of non-hybrid cotton; for many years they grew Old World cotton without external inputs and with scant pest problems, using it mainly for local cloth production. In the early 1970s, breeders in Gujurat developed the world's first hybrid cottons, using the New World species *Gossypium hirsutum*. These cottons are highly susceptible to southern India's impressive assortment of diseases and severe pests, which include several bollworms (which eat the fruit containing the lint and seeds) and also sucking pests (which feed on the plant's sap). Pest outbreaks are highly variable in time and space, making this a singularly challenging environment for *hirsutum* cultivation. Thus, these cottons spread along with an armory of pesticide sprays, which cause as many problems as they solve. The spread occurred in the early 1990s, when the combination of strong prices, trade liberalization, and government campaigns led many farmers to take up commercial cotton.[8] Today, India is the only area in the world where cotton production is based on hybrids. In Warangal, the movement into commercial hybrid *hirsutum* production was led by Andhra immigrants from Guntur District and other coastal areas with a tradition of commercial cotton cultivation.

This shallow history of skilling on hybrid cotton surely plays some role in the problems described below, yet it is easy to overestimate its importance. Depth of experience with a crop is hardly an overriding determinant of the skilling process; the literature abounds in examples of successful adoption and successful integration of new crops. The Nigerian Kofyar provide an example, becoming expert commercial yam farmers as they moved into a new area from a homeland where they had grown no yams at all (Stone, 1996). It is not so much the relative newness of commercial *hirsutum* cotton cultivation that has impacted the skilling process, as it is the nature of the seed market.

Figure 17.1 *Maps of India showing location of Andhra Pradesh and Gujarat and Warangal District showing census villages*

In Warangal, the market not only offers hybrids that must be repurchased each season, but an extensive, rapidly changing and often deceptive roster of seeds. There are over 800 input shops in the district, including at least one in virtually every village of any size. Warangal City has around 190 shops, including several dozen concentrated around Station Road (Figure 17.2). A 2005 survey of 37 input vendors in Warangal City gives a snapshot of the market for 2003–2005.[9] These vendors collectively sold 125 different cotton brands from 61 companies during this three-year period; the total number of cottons sold in the district is over 200. The number available at any given time was smaller since seed products come and go rapidly. Of the 78 seeds sold by our sample vendors in 2005, only 24 had been around since 2003.

Farmers must also deal with several levels of deceptiveness in seed products. On one hand, there is often variation among packs of a single seed product. Causes of variation range from lax controls over the hybrid production to the corrupt practice of packaging different seeds as a single brand. Every year sees new cases of severely flawed seeds on the market. Flawed or mislabelled products, known as 'spurious seed', are a bane not just for farmers but for vendors, who have on occasion been closed down for selling a seed that turned out to be spurious. At the same time, the seeds sold under different brand names may be identical: it is widely known that cotton parent lines have been appropriated from state agricultural universities and research institutes by cotton seed companies, which then market the hybrid offspring under different names. Bunny cotton (a local favourite in recent years, as shown below) is

Left: Station Road in Warangal City, a concentration of several dozen shops selling seeds, fertilizer and pesticide. Right: A Station Road vendor with a pack of Mahyco *Bt* cotton and some of his other cotton seeds

Figure 17.2 *Seed vendors*

known to be identical to four other seeds on the market, according to a local cotton expert. (Ziegenhorn (2000) gives a surprisingly parallel account of the systemic deception in the American maize market.) Government seed inspection is largely ineffective. In Warangal City, a single inspector visits under half of the seed vendors, taking a few samples that are then tested for physical purity and germination rate but not for the important question of whether the seed is what the box claims. When substandard seed is found, the dealer is charged a fine of Rs.500 – around $12, slightly more than the cost of a single box of seed.

The 'anarcho-capitalism' (Herring, 2007) of this cotton seed sector, with its large, unstable and deceptive array of seeds, is clearly incompatible with the processes of experimentation and evaluation. External sources of seed information, rather than mitigating the impediments to skilling, exacerbate the problem. Government-sponsored extension is virtually non-existent. Local Telugu-language publications provide agricultural information, but the reliability varies, and advertisements often masquerade as objective information. Newspapers may also dramatize seed scandals to boost readership, for example the recent case of a cotton seed company that got into a dispute with a local daily paper. Despite the lack of evidence of any problems with their seeds, there were enough damning articles published to put them out of business. But the most common source of information on cotton seed is corporate promotion. Cotton seed advertising is seemingly ubiquitous in Warangal: signs hang from trees, walls are painted, flyers are distributed and pitches blare from company vehicles. Only cotton is so heavily promoted; rice seed, which is selected more on the basis of environmental learning, and which is overwhelmingly non-hybrid, is rarely advertised. Assessing the impact advertising has on seed choice is beyond the scope of this chapter, but even if advertisements rarely influence particular seed elections, the ubiquity of low-credibility noise contributes to farmers' general indifference to analysis of seed performance.

The plight of Warangal cotton cultivators, then, goes well beyond Fitzgerald's description of the deskilling caused by adoption of hybrid maize. They face a frenzied turnover in the seed market (which they encourage with their penchant for new products), deceptiveness in seed brands, unpredictable ecological events such as pest and disease outbreaks, secular changes in insect ecology, and a highly noisy and unreliable information environment. These factors make seed evaluation costly and inaccurate, and suggest that environmental learning should be scant. This situation should provide a marked contrast to the various studies showing rational, and often highly strategic, seed selection practices where farmers know what they are planting and where technological change is gradual.

Therefore the fast food and slaughterhouse workers that are such notable contemporary examples of industrial deskilling (Schlosser, 2001) turn out to be poor models for agricultural deskilling. A better metaphor would be a chef whose job is to continuously develop new dishes in a kitchen where someone keeps changing the labels on the ingredients, and the stove and oven will not hold a constant temperature. With this in mind, let us examine how seed adoptions are patterned against this backdrop of deskilling in Warangal.

DESKILLING AND COTTON CRAZES

This analysis of seed choice is based on extensive interviews conducted in nine periods of fieldwork between 2000 and 2006 and three household agricultural censuses conducted between 2003 and 2005.[10] Table 17.1 shows the villages studied and the numbers of cotton-planting households represented in these surveys (actual sample sizes were considerably larger; for example 26 per cent of the households censused in 2004 planted no cotton that year). The 2003 and 2004 surveys elicited detailed household social and economic information along with agricultural decision making; the 2005 survey was more focused on agricultural decision making and seed choice. Surveys were mostly conducted between July and October, allowing for the collection of seed choice data for the census year and the preceding year, but input–output information only for the preceding year (cotton seed is usually planted in late June and harvested October until March). In the following analysis, data on the 2002 seed choices and yields come from the 2003 census and data on the 2003 seed choices and yields come from the 2004 census. Data on the 2004 seed choices come from both the 2004 and 2005 censuses (only the non-repeat interviews added in 2005). Data on 2005 seed choices come from the 2005 census. Figure 17.1 shows the location of the sample villages, and further information on the criteria for village selection appears in the appendix.

Table 17.2 *Village summary (households surveyed)*

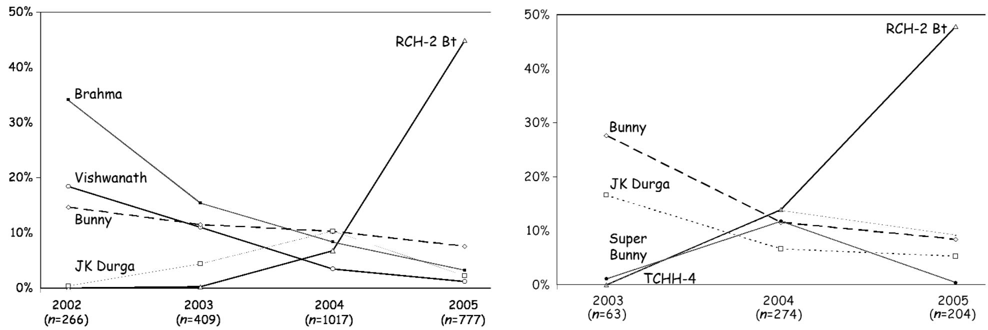
Year of census *Crop year*	*2003* *2002*	*2004* *2003*	*2004–2005* *2004*	*2005* *2005*
Bandarupally			38	38
Gudeppad	62	150	90	68
Kalleda	41	37	34	27
Oorugonda			58	62
Pangidepally			66	68
Pathipalli		71	81	54
Ravuru	44	31	63	71
Tekumatla		89	81	67
Total	147	378	511	455

Sampling frames were derived from the government's 1996 Multi-Purpose Household Survey, which lists all households in the district along with socioeconomic variables including land ownership. Stratified random samples were drawn in each village to ensure representation of farmers differing in wealth and connectivity to information networks. From ethnography it seemed clear that larger landowners tended to be more 'cosmopolitan' (to use the term from classic innovation–diffusion studies), and better connected to non-local information sources, and this was confirmed by the census.[11] As research was initiated in each village, households were ranked on land ownership and divided into terciles (landless households were excluded since they rarely plant cotton). Terciles were randomized and sampled equally; since this analysis looks at clustering in seed choices, this randomization is essential. For subsequent-year censuses, farmers were re-censused when possible, and other households were added using the same randomizing strategy. Further information on sampling procedures is in the appendix.

The survey was designed to reveal variation in agricultural decision making across space and time, and to collect social-organizational, spatial-organizational, economic, educational and ethnic effects on this variability (only a small portion of which appears in this analysis). It was not explicitly designed to allow characterization of Warangal District, and several distinctive sectors of the district were not studied.

The farmer interviews recorded *seed choices*, defined as a farmer having bought a type of seed, whether it was one box or more, and whether or not it was the only seed type the farmer bought that year. The numbers of seed choices, which are given in Figure 17.3, tend to be somewhat higher than the numbers of cotton-planting households because many households plant more than one seed. The seed choices are expressed as percentages,[12] and the top choices are plotted for the years for which data are available.

Figure 17.3 shows the top selling seeds in the sample villages combined, based on the seed choice data. The highlight is the precipitous rise of one seed: Rasi Seed's RCH2-Bt. The first *Bt* cottons marketed in Warangal were not particularly popular, not simply because of the *Bt* trait but because it had been put into unpopular Mahyco hybrids. RCH2 (a seed that, according to open secret, was produced from parent



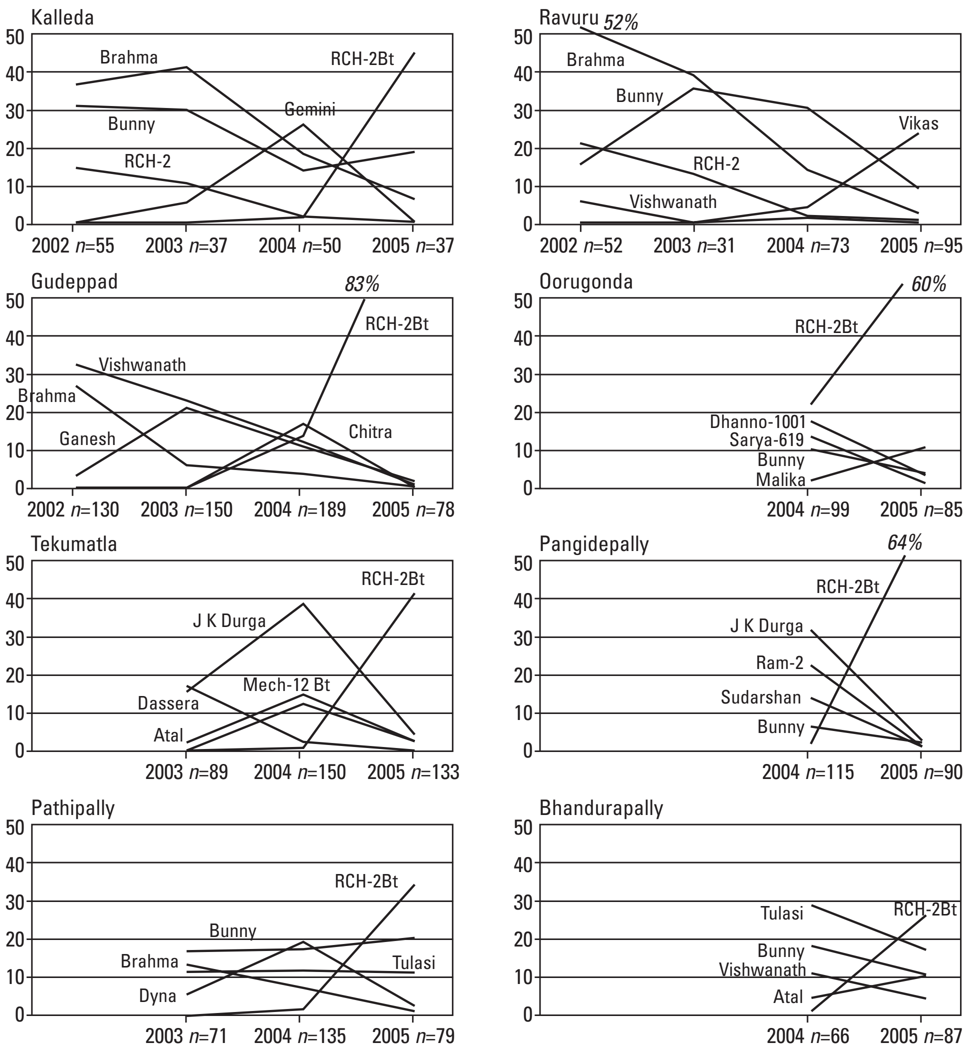
The left graph is based on seed choices as reported in farmer surveys; the right is based on percentages of total sales reported in the survey of Warangal City seed vendors. The census villages reflect some of the local favouritism described in the text; for instance, Brahma happened to be a local favourite in several villages in 2002–2003.

Figure 17.3 *All village charts: Trends in the most popular five cotton seeds*

lines appropriated from a state-run research centre) was a fairly popular hybrid in many parts of the district. The *Bt* version appeared on the market in 2004, and in 2005 it achieved sudden wild popularity in much of the district, accounting for 45 per cent of the 777 seed choices in the sample. When the other *Bt* seeds are included, *Bt* seeds account for 54 per cent of all seed choices. Figure 17.3 shows that the take-off of RCH2-Bt reported by the sampled farmers is mirrored in the seed vendor survey.

But what is particularly interesting are the striking local variations in adoption patterns. Figure 17.4 shows village-specific patterns in seed choices for the eight villages. Almost all villages show the sharp climb in RCH2-Bt adoptions, but a closer inspection shows a pattern of abrupt and ephemeral seed crazes preceding the *Bt* craze. In Gudeppad, for instance, Brahma and Ganesh were strong local favourites in 2003 but had virtually disappeared by 2005; Chitra went from being negligible, to town favourite, back to negligible. In Kalleda, Brahma was a runaway favourite in 2003 before dropping sharply, as Gemini became the town favourite – for one year only. In Ravuru, Brahma was the runaway 2002 favourite, but had dropped to virtually nil by 2005; Bunny, the strong favourite in 2004, lost its popularity to Vikas in 2005. In Tekumatla, the 2003 favourite Dassera dropped precipitously in 2004, when JK Durga rose to almost 40 per cent of cotton choices before crashing to 4 per cent. In Pathipally there was a steady market for Brahma and Bunny, but it also had a craze, with Dyna rising to town favourite in 2004 before dropping to almost nil.

Moreover, the crazes tended to be highly localized, with the notable exception of RCH2-Bt. As Figure 17.4 shows, Kalleda and neighbouring Ravuru shared the Brahma and Bunny crazes, but Kalleda's 2004 Chitra craze did not touch Ravuru. Chitra was the top seed in Guddepad in 2004, but was negligible in neighbouring Oorugonda. JK Durga, the runaway favourite in Tekumatla in 2004, was also the top seller in neighbouring Pangidepally, but Pangidepally's other 2004 favorites – Mahalaxmi, Sudarshan and Bunny – were negligible in Tekumatla. Pathipally's 2004



For each village, the most popular five cotton seeds over the past 3–4 years (depending on data availability) are graphed. The Y-axis shows the percentage of all the village's yearly seed choices each seed accounted for. Each pair of graphs shows villages that are very close.

Figure 17.4 *Village specific trends*

favourite, Dyna, was negligible in neighbouring Bhandurapally in 2004 (although Tulasi was popular in both villages).

Agricultural economist Matin Qaim got a different glimpse of this cotton faddism in his survey of 375 Indian cotton growers. He found that after the 2002 season, over half the farmers who had adopted *Bt* cotton subsequently 'disadopted' it. Then, '[i]nterestingly, a remarkable share of the disadopters re-adopted *Bt* technology after a break of one or two years' (Qaim 2005, p1321). But to Qaim, the patterns 'clearly demonstrate that genetically modified crop adoption and disadoption are not irreversible decisions for farmers; they are part of a normal learning process' (ibid.). However, as argued above, 'normal' learning (better termed skilling) is a environmental-social process, and it is difficult to imagine what environmental assessments would lead farmers to such short-term, localized cotton seed crazes. None of the interviewed seed vendors were aware of any agro-ecological rationale, and the farmers too were consistently unable to justify the seed crazes on the basis of seed traits. The paired villages in each case have the same soils, microclimate and access to input markets.

There are some conditions under which abrupt adoption of new seeds may have a definite agro-ecological basis. For instance, disease is a major problem for pearl millet growers, and Rajasthani farmers adopt each new disease-resistant seed variety quickly (Tripp and Pal, 2000; Tripp, pers. comm.). The faddism contributes to the chronic cycle of breeders adjusting plants to pathogens and pathogens adjusting to plants, but farmer decision making is responding to agronomic problems and has a basis in environmental learning. No such agro-ecological advantage is evident in the Warangal seed crazes, and certainly none that would explain neighbouring villages exhibiting such different patterns. The growers themselves offer no agro-ecological justification for the faddism. In fact, not one of the 12 Gemini planters I interviewed in Kalleda attributed their adoption of Gemini to specific traits (beyond the ubiquitous anticipation of good yield), and none knew much about Gemini's specifications. Only two of the 12 farmers mentioned first-hand knowledge of Gemini's performance (both had seen a field of Gemini the year before). Indeed, the farmers were generally agnostic on qualities of the seeds (the only specific trait that farmers regularly evaluate in cotton in the boll size, discussed below).

NOVICE AND EXPERIMENTAL PLANTING

Small-scale experimentation and evaluation are used in many cases by Indian farmers as a basis for seed selection (e.g. Gupta, 1998, p197), but the Warangal seed crazes seem irreconcilable with this practice. We can investigate this empirically by isolating cases of 'novice planting' – defined as the planting of a type of seed for the first time – since the Warangal surveys include information on how many times each seed type had been planted previously. I have used data on 2003 plantings for this, avoiding the surge in plantings of new *Bt* seeds, which would have caused unusually high rates of novice plantings. In the 2003 season (as recorded in the 2004 census), among cotton-planting households a median of two acres were planted to cotton (mean = 2.86; sd = 1.97; n = 231). Within this sample of households, 55 per cent planted one seed type, 26 per cent planted two, and 19 per cent planted three or more, for a total of 410 seed choices. Of these seed choices, 59.3 per cent were novice plantings.

But are these novice cotton plantings actually tests of new seeds on small plots, as claimed by innovation-adoption orthodoxy and by Monsanto? We can answer this first by considering that the total area planted to cotton by our sample in 2003 was

Table 17.3 *Planting sizes: Counts and column percentages*

	Times seed planted before			
Acres planted to the seed	*0*	*1–2*	*3+*	*N*
<1	6 (2%)	1 (1%)	2 (3%)	**9 (2%)**
1–1.9	146 (60%)	49 (61%)	44 (55%)	**239 (59%)**
2–2.9	65 (27%)	21 (26%)	24 (30%)	**110 (27%)**
3–3.9	17 (7%)	4 (5%)	7 (9%)	**28 (7%)**
4–4.9	5 (2%)	5 (6%)	3 (4%)	**13 (3%)**
5+	4 (2%)	0	0	**4 (1%)**
	243	**80**	**80**	**403**

663 acres, of which novice plantings comprised 390 acres, or 58.9 per cent. This is very close to the percentage of fields that were novice plantings, showing that overall novice plantings are the same size as experienced plantings. But given the importance of experimentation to the larger theoretical issues at stake here, including innovation adoption, the spread of *Bt* cotton and agricultural deskilling, we need to look more closely at small-plot cultivation. We must first ask what constitutes a small experimental plot, and given the median household cotton acreage of two acres, it seems clear that a small experimental plot would have to be under an acre. Commercial cotton seed is sold in 'acre packs' with enough to seed one acre; less than 1 per cent of the cotton purchased in my surveys consisted of 'loose seed'. This packaging makes experimentation slightly inconvenient, but hardly prevents it; farmers can (and occasionally do) split packs to plant sub-acre plots.

Table 17.3 breaks down the sizes of plantings by the farmer's experience with the seed. Note that only 9 of 403 plantings, or 2.2 per cent, were what we would consider small experimental plots. Most plantings were between one and three acres, regardless of the farmer's experience with the seed, and farmers were just about as likely to buy multiple boxes of a novice seed as of a seed they had experience with. Perhaps the most salient finding regarding experimental planting is that when a farmer planted a seed for the first time, 98 per cent of the time it was on one acre or more, and 37 per cent of the time it was on two or more acres, in an area where the median area planted to cotton was only two acres. This lack of small experimental planting characterizes small and large cotton farmers alike.

Interviews provided consistent evidence that Warangal cotton farmers' propensity is for trying new seeds on the market, rather than trying seeds on experimental scales with a view to picking one for long-term adoption. A frequent response when farmers were asked why a particular seed was chosen was that it was new in the market – meaning that no experimental information whatsoever was available. This attraction to new seeds exacerbates the turnover of seeds in the market, as seed firms sometimes take seeds that have fallen out of favour, rename them and relaunch marketing initiatives.

The absence of seed evaluation is further confirmed by farmer knowledge of key seed traits. Farmers in the 2004 survey were asked if, for the cotton type they planted

Table 17.4 *Knowledge*

	Boll size	*Water requirement*	*Time to maturity*	*Insect resistance*
No	17%	45%	29%	38%
Yes	83%	55%	71%	62%
N	520	519	518	516

the most of that year, they knew what to expect in the cotton's (1) boll size, (2) water requirements, (3) time to maturity, and (4) resistance to any crop pests. Despite the fact that farmers are understandably reluctant to admit to knowing little about the seeds they were planting, substantial numbers plead ignorance, as shown in Table 17.4.

Even taken at face value some of these figures are striking; water requirement is a basic cotton trait that under normal conditions would be a prime criterion for seed selection. The only trait for which few farmers confessed ignorance was boll size; large boll size is one trait that Warangal farmers consistently claim to value most highly.[13] However, given the crazes that dominate cotton plantings, it is not surprising that there is confusion on even this trait. For instance, of the farmers in the sample who planted RCH2-Bt in 2005, 83 per cent claimed to know what boll size to expect (interviews were conducted before bolls were mature). Boll size is frequently discussed and routinely divided into small, medium and large; according to producer, the RCH2-Bt boll is 4.5–5 grams, which is medium-sized. However, of these 280 farmers, only 44 per cent identified the size as medium; 30 per cent and 27 per cent thought the boll was large or small. There were also interesting indications that expectations were forming on a village-specific basis.[14]

In sum we have seen that:

- Warangal cotton farmers face an extensive, ever-changing and often deceptive roster of seeds;
- many of the key determinants of a good crop are unpredictable (germination; reliability of seed; insect and disease outbreaks) and there is wide intra-brand variability;
- villages show sharp ephemeral fads lacking agro-ecological rationale;
- most of all cotton plantings are novice and non-experimental;
- as a result, very little environmental learning can occur.

The question of what actually does drive seed choices therefore becomes quite important, not only to an understanding of the spread of *Bt* cotton, but also to a more general understanding of agricultural deskilling. Let us first look ethnographically at the actual drivers of cotton choice in Warangal District, and then consider it as a problem in theory.

ETHNOGRAPHY OF COTTON CRAZES

Given the obstacles to skilling in cotton cultivation, it should not be surprising that various forms of social learning are instrumental in decision making; what is surprising is the loose standard for accepting social information or choosing models to emulate. For illustration, let us consider two of the 2004 crazes shown above: Gemini in Kalleda and Chitra in Gudeppad.

Extensive interviews with 2004 Gemini planters in Kalleda revealed a set of primarily social explanations that do not trace back to any agro-ecological rationale. Gemini cotton seed was introduced in 2003, by a newly formed company of the same name (it is likely to be a seed previously marketed under a different name, although this cannot be confirmed). Its marketing strategy capitalized on the farmer penchant for untried seeds, and on local connections in Kalleda; the principal owner is from a nearby village. Many Kalleda farmers buy their seeds from a Warangal shop owned by Sampath Rao (pseudonym), a member of a large and influential Kalleda-area family that has traditionally had a paternal relationship with may small farmers in the area. As the sole distributor of Gemini in Warangal, Sampath got a high profit margin on this seed, and recommended it strongly to his customers. The company owner was also an affine of the mandal president, who recommended the seed. Gemini also ran a marketing campaign in Kalleda before the 2004 cotton season, with farmers who made advance purchases of Gemini seed getting scratch cards for prizes. The only hint of environmental learning was that one of the 2003 Gemini planters was a *pedda rytu* ('big farmer'); he apparently got a good yield, although no better than the yields farmers obtained from various other seeds. Interviews with 2004 Gemini planters turned up virtually no knowledge of traits of the seed; the most common rationale for adopting was that 'other farmers around here were planting it'. By 2005, Gemini had virtually disappeared from Kalleda fields.[15]

Gudeppad's 2004 craze was driven by emulation by a single local farmer and by marketing. Chitra was introduced in 2003 by Nath Seeds. A Nath marketer who grew up in Gudeppad used his local knowledge to recruit Nagaraju Reddy (pseudonym) for demonstration plots. Nagaraju Reddy was a *pedda rytu*, and an attentive farmer whose crops often outpaced others in the area. In 2003 the marketer gave Nagajaru a free box of Chitra, and when it did well, transported many of the area's farmers to see it. Because they liked the look of his field, or simply because Nagaraju was planting it – again, environmental and social learning do not cleave neatly – Chitra became the most popular seed in Gudeppad the next year. Of the 25 Gudeppad Chitra planters who reported a primary factor in their adoption, 16 (64 per cent) cited Nagaraju by name. None of the Chitra planters interviewed could specify what they had seen in Nagaraju's field, beyond 'good yield'.

Nagaraju actually planted five different brands in 2003. He reported that one brand yielded around 10 quintals/acre; three yielded around 14 quintals/acre, and Chitra yielded around 15 quintals/acre. Such a small difference in yield would hardly have been visible to visiting farmers. What set Chitra apart from Nagaraju's other

Visible behind them are a few of the many hybrid seeds available at the shop. The man in the middle is paying Rs.1600 a pack for RCH2-Bt (four times the cost of conventional seed). When asked why he had chosen RCH2-Bt, he said it was what other farmers were buying.

Figure 17.5 *Buying* Bt*: Farmers buying cotton seeds at a shop in Warangal*

brands was that it was new, and that it was being touted by the Nath marketer. Chitra then virtually disappeared from the village in 2005.

An ethnography of the 2005 RCH2-Bt craze is harder to construct. The surge to 45 per cent of seed choices at the district level is unprecedented, but at the village level the surges are not such a dramatic departure from past crazes (Guddepad being the notable exception). The difference was that instead of each village having a craze for its own favourite, in 2005 most villages had a craze for the same seed; the crazes were synchronized. This may result partly from the history of *Bt* seeds. The Mahyco hybrids that were the first *Bt* seeds sold (in 2002) were unpopular in Warangal, and moreover they were 'old' seeds (on the market for over ten years) in an area where farmers were compulsive buyers of new seeds. Following reports of a poor year in 2004 (resulting mostly from problems unrelated to the *Bt* trait), these Mahyco seeds were banned in Andhra Pradesh; also in 2005, '*Bt*' versions of 16 seeds appeared on the market, including several popular seeds (of which RCH2 was only one). None of the Warangal vendors or farmers could offer an agro-ecological rationale for sales to take off for this particular seed (as compared to Mallika-Bt, for instance, another popular seed in Warangal), and it is difficult to explain the RCH2-Bt craze as the result of superior performance in the previous year (as shown in the following section). Controlled experiments by Kranthi et al (2005) show that the CRY gene does not express particularly well in this germplasm. What several farmers did tell me was that they chose RCH2-Bt because it seemed to be the seed most others were buying; there was, in effect, a 'buzz' about it on Station Road, and conformist bias was clearly in operation (Figure 17.5).

EFFECTS OF BT COTTON ON COTTON CULTIVATION IN WARANGAL

Several commentators have warned that the introduction of *Bt* cotton would lead to deskilling of Indian farmers (Harwick, 2000; Simms, 1999). I have analysed what 'deskilling' actually means in agriculture, and showed how and why it has occurred in the Warangal cotton sector. Clearly this deskilling has occurred prior to, and independent of, *Bt* cotton. However, this does not mean that the spread of *Bt* cotton has not affected the problems with skilling. I would point to three ways in which *Bt* cotton has exacerbated the deskilling.

The first is that with *Bt* cotton has come a sharp increase in the amount of public media and discourse (Yamaguchi et al, 2003). The media have been highly contradictory, with biotechnology proponents and opponents alike producing deceptive media. As Herring (2007) put it, 'Farmers in India faced transgenics through the mediation of rumour, NGO's, public intellectuals, contradictory official signals'. It is difficult to isolate the effects of these new flows of information on seed choices, but it has sharply increased the noise level.

The second has been the introduction into farm management of a new variable that is poorly understood by farmers and dealers alike. There is, for instance, considerable confusion over whether the *Bt* technology works the same regardless of the seed into which it is bred. Company representatives have assured farmers and dealers that the *Bt* works the same in all hybrids, but a detailed study by Kranthi et al (2005) showed considerable differences among hybrids. The Kranthi et al study also showed sharp declines of expression of CRY proteins – and of mortality of the worst cotton pest – beginning 90 says after sowing, well before the bollworm threat has passed.

Third is the exacerbation of the already problematic rate of technological change. On top of the high rate of turnover in the cotton seed market, there are now numerous *Bt* versions of seeds appearing. Moreover, there are already new *Bt* genes in the pipeline (GEAC, 2006; Jayaraman, 2005), so that the already groaning shelves of input vendors may soon have multiple *Bt* variants of conventional seeds. More troublesome yet, as regards the skilling process, is the appearance of under-the-counter *Bt* seeds. These seeds, referred to locally as 'zerobill' seeds because the vendor sells them illegally without any bill of sale, represent a worsening not only of the rapid rate of change, but of inconsistency and unrecognizability as well, since the buyer normally has no idea of where the seeds came from or whether the same seed will be available in the future.

From the perspective of traditional agricultural knowledge, this *Bt* technology is decidedly not merely 'in the seed'. The key problem on Warangal cotton farms may have long predated *Bt* cotton, but *Bt* cotton has rapidly become an exacerbating factor.

NAVBHARAT 151 IN GUJARAT: *BT* COTTON AND RESKILLING

Coeval with these developments in Warangal, a different story has unfolded across the country in Gujarat. While there has been no comparable study of skilling and deskilling (and I have only conducted very brief fieldwork there), there are intriguing suggestions that *Bt* cotton has had the paradoxical effect of getting farmers more involved in the processes of experimentation, evaluation and even breeding. The agent of this change was a cotton hybrid by the name of Navbharat 151.

Navbharat is an Ahmedabad-based seed company headed by the respected breeder D. B. Desai, and 151 was a hybrid cotton seed it began selling in 2000. At that time, transgenic cottons were being tested in India, but none had yet been approved by the Genetic Engineering Approvals Committee (GEAC); Navbharat had not licensed the *Bt* technology from Monsanto and there was no reason to suspect that this seed was transgenic. The hybrid sold well but attracted no unusual attention. Then 2001 brought a particularly severe wave of bollworm outbreaks, to which fields of Navbharat 151 seemed impervious, leading to raised eyebrows, PCR testing discovery of the Cry 1A(c) gene, 'corporate fury' (Jayaraman, 2001), government demands that the illicit crops be destroyed (this did not happen), and criminal charges against Desai and his colleagues. Ironically, it was not intellectual property theft that brought the Navbharat officials to the dock; genes were not patentable at the time. The infraction was against the Environmental Protection Act, because 151 was a transgenic seed not approved by the GEAC. Desai claims he had sought no approval because he had not known his cotton was transgenic, and as soon as he found out he tried to license the technology from Monsanto (Monsanto's refusal, Desai later pointed out, cost both them and Navbharat a lot of money). The criminal proceedings have languished, but the company was promptly banned from selling any of its own cotton hybrids.[16]

Soon after the 151 affair – and partly because of it, according to some observers – the GEAC approved the three Mahyco-Monsanto *Bt* cotton seeds. Thus, for the 2002 cotton season, the illicit *Bt* seeds were expected to be replaced by the authorized MMB seeds in Gujarat's shops and fields. But this did not happen for several reasons. There was the issue of seed quality. The Mahyco hybrids one had to buy to get the *Bt* were out of favour and water-intensive. On the other hand, word had spread that with Navbharat 151 the breeders had hit the jackpot: in the fields of Gujarat, this hybrid was a highly productive, long-season cotton with excellent resistance to bollworms. There was also the issue of seed cost: the approved *Bt* seeds cost Rs1600 (around $35), as compared to the normal price of Rs400 per acre-box. As farmers began to search for cheaper *Bt* seeds, one source appeared right below their noses: 151's F2 seeds, which exhibited very little yield depression, and some farmers began to replant them. Some ginning mills began to offer seeds back to the farmer for a small price after separating the lint, and farmers who had previously sold their cotton crop to a trader began to sell directly to the gin.

But the booming demand for the now-banned Navbharat 151 seeds was also met in other ways. The bulk of the seed production for 151 had been farmed out to Kurnool District of Andhra Pradesh – an area intentionally well outside of the target sale area, to reduce 'leakage' – but a number of Gujarat farmers had been enlisted to produce 151. The banning of 151 late in the 2001 season left these contract farmers with fields full of Navbharat 151 seeds that the company could not buy from them. Precisely what happened to these seeds will never be known, but the uses included being kept for 2002 planting by the contract growers, being sold as brown-bagged seed and being sold to cotton seed companies to be packaged as branded seeds and sold the next spring. The seeds clearly became quite mobile; many of the Kurnool contract farmers were immigrants from Guntur District (discussed above as innovators in commercial agriculture), and seeds appear to have readily found their way into Guntur. They apparently also flowed back to Gujarat where demand would be especially keen the next year.

We now know that before long, *Bt* seeds were not only being replanted but also were luring farmers and others into the breeding game. Indeed, it is now well documented (Gupta and Chandak, 2005; Jayaraman, 2004; Roy et al, 2007) that these orphan seeds became the basis for an thriving cottage industry of *Bt* cotton breeding (illegal, because none of the seeds were approved by GEAC). Some of the breeding was being carried out by those with technical training (such as graduate students at Gujarat Agricultural University (Gupta and Chandak, 2005, p218)), but much was being done by farmers. Rather remarkably, some farmers were even maintaining inbred lines and producing their own hybrids. The Gujarat cotton fields turned into what Anil Gupta (a leader in studying and promoting farmer innovation) termed 'the greatest participatory farmer plant-breeding mela [carnival] in history' (quoted in Herring 2005).

By 2003, Gujurat shops were awash with illicit *Bt* seeds, many with coy names alluding to the technology ('**B**es**T** Cotton') or to Desai's original product ('Kapas-151'), or underscoring that they were first generation hybrids ('Kavach F-1'). For brand after brand, PCR testing at the Central Institute of Cotton Research confirmed the presence of the Cry 1A(c) gene (Kulkarni, 2003). In 2004, industry's claims that over half of all the GM cotton growing in India was from unapproved seeds (Jayaraman, 2004, p1333) were generally regarded as realistic. By the 2005 season, Navbharat's own surveys indicated 80 per cent of the cotton growing in Gujarat to be from illicit *Bt* seeds. (Unconfirmed word on the street was that the percentage was just as high in Guntur, Andhra Pradesh, where many of the Kurnool-grown seeds had ended up.)

Measuring the actual performance of the illegal *Bt* cottons has been fraught with difficulty,[17] but anecdotal evidence (e.g. Shah, 2005) indicates that the illicit *Bt* cottons performed particularly well. This would be consistent with the state-wide figures: the data from the Gujarat State Department of Agriculture show a rise in yield from 1.2 quintals/ha. in 2000 to 4.7 quintals/ha in 2003.

Although no ethnography of agricultural practice is available for Gujarati farmers, it seems clear that a large number of farmers here are more actively involved in seed experimentation and payoff assessments. Some of this involvement would have predated the arrival of illicit *Bt* seeds; the seed repertoire here already included indigenous non-hybrid (replantable) cotton (*G. herbaceum* according to Kranthi, 2005; *G. arboreum* according to Morse et al, 2005). But with farmer-bred varieties, the farmer is obviously better able and more inclined to assess performance, and when these seeds are sold to other farmers, there is more information to be passed along with the seeds. In addition, this seed is often provided in loose form (rather than the 'acre packs' that dominate Warangal purchases), which facilitates small-plot experimentation.[18] These differences in seed systems, and especially the farmer breeding of *Bt* seeds, should greatly reduce the problems with inconsistency, unrecognizability and accelerated technological change, and it is therefore not surprising that a recent investigation into agricultural decision making there has shown a much greater degree of control than I have shown in Warangal (Roy et al, 2007).

The intent here is not to depict *Bt* cotton, at least in purloined form, as having led to an across-the-board mitigation of agricultural deskilling among Gujarati cotton farmers. The fact is that most of the illicit *Bt* seeds that have appeared since the demise/liberation of Navbharat cotton were still packaged hybrids, sold by fly-by-night companies. Surely for many farmers, the problems of unrecognizability have worsened. Yet for other farmers – and there is presently no basis for saying how many, except that the number clearly is significant – the tortured history of *Bt* technology in Gujarat has been instrumental in them becoming reinvolved in experimentation, assessment and even developing their own seeds. Where this has occurred, likely impacts would include increased consistency and recognizability and a slowed rate of technological change. Given the foregoing discussion, we would have to count this as a step towards reskilling.

CONCLUSIONS

Traditional agricultural knowledge, reconceived here as dynamic management skill, is a subject so diverse, complex, changing and poorly understood that it can be used in contradictory ways. Thus it has been demeaned by development agencies and input industries, admired by social scientists and romanticized by activists. But today in India, the arrival of GM cotton forces us to take a fresh analytic look at traditional agricultural knowledge, and to be prepared for findings that differ from past orthodoxies.

Industry's extolling of the traditional wisdom and experimentation behind *Bt* cotton adoption is disingenuous coming from the same parties that have disdained 'traditional' practices that eschewed external inputs. This sudden self-serving appreciation for traditional wisdom accords with Michael Dove's observation that the concept of indigenous knowledge, like other concepts in rural development, has succumbed over time to appropriation by the interests it initially opposed (Dove, 2000, p216). More importantly, this perspective on the skilling process is, in the case of *Bt*-cotton-loving Warangal, empirically inaccurate. Agricultural knowledge, or *skill* as it has been defined here, is dynamically generated and its development turns out to be vulnerable to inconsistency, unrecognizability and overly rapid rates of change in environmental payoffs. The cotton seed sector in Warangal was beset with all of these problems well before *Bt* cotton arrived on the scene. The central problems have stemmed from the reliance on hybrid cottons here. Hybrid seed technology per se does not necessarily produce agricultural deskilling; in fact, early hybrid maize production in the US was accomplished by close collaboration between farmers and breeders (Fitzgerald, 1993, p335). However, hybrids do open the door to deskilling by introducing their own form of inconsistency (viz., between the F1 and F2 generations), allowing unrecognizability (even US farmers may not know what they are getting (Ziegenhorn, 2000)), and encouraging accelerated technological change. These problems have become particularly acute in the anarcho-capitalism of the seed systems in Warangal.

Therefore, while 2005 was a remarkable year for GM cotton, there is a surprising cultural context to the widespread adoption here. This dramatic case of adoption of an innovation does not reflect experimentation and assessment as much as the dynamics of socially driven crazes arising in the virtual absence of environmental learning. The *Bt* seeds did not cause, but have contributed to, the continuation of deskilling here.

Across the country in Gujarat, cotton farmers have prospered, due largely to an accidental(?) skirting of a regulatory apparatus designed in part to protect the farmer. Ambiguous results from a few studies notwithstanding, the cotton boom in Gujarat is surely due in large part to illicit *Bt* cotton. We cannot parse the extent to which this success is attributable to an act of breeding by D. B. Desai, or to the poorly understood changes in the seed system attending the banning of Desai's creation. But there are clear indications that this most modern of agricultural technologies has led to the reinvolvement of farmers in cotton experimentation and even breeding, and thereby resuscitating processes that generate traditional agricultural knowledge.

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APPENDIX 1: SAMPLING STRATEGY

Kalleda and Ravuru-thanda are within 15km of each other in Parvathagiri mandal. These villages have very similar soils, roads, markets, input vendors and proximity to Warangal, but differ markedly in socioeconomic profile. Kalleda has a mixed population, with virtually all local castes present, and a high degree of economic stratification. Ravuru-thanda is a largely tribal (Banjara, or 'Lambadi') village. Literacy is low and most residents are poor, and there is much less economic stratification than in Kalleda. Gudeppad is located in an area of 'black cotton soil' in Atmakur mandal, where commitment to cotton cultivation is, on average, the highest in Warangal District.

In the 2004 survey, the villages of Tekumatla and Pathipally were added. In Bandanagaram virtually no cotton is planted, and it is excluded from this analysis. Tekumatla and Pathipally are medium-sized villages in Chityal and Mulugu mandals, respectively.

In the 2005 survey, the villages of Oorugonda, Pangidepally and Bhandurapally were added; these are villages neighbouring Gudeppad, Tekumatla and Pathipally, respectively. Social and ecological conditions are in all three cases quite similar to the neighbouring village; they were included to expand the sample size and to provide information on the spatial extent of seed crazes (not analysed here).

As noted in the body of the article, samples in all villages were randomized. One aim of the 2004 census was to update (and also verify the accuracy of) the 2003 data. Therefore, in the re-censused villages, census takers were given lists of the 2003 randomly selected households. However, to achieve the same sample sizes knowing that some farmers would be unavailable, a randomized list of other farmers in the village was provided for 'fill-ins', and the census takers added names from the top of this list as needed. For the three villages added in 2004, the same sampling strategy was used as in the original four villages.

The 2005 census added villages and also expanded sample sizes within each village (except for Pathipally). Again, all available previously censused households were interviewed, and additional households were added randomly.

The survey was designed to reveal variation in agricultural decision making across space and time, and to collect social-organizational, spatial-organizational, economic, educational and ethnic effects on this variability (only a small portion of which appears in this analysis). It was not explicitly designed to allow characterization of Warangal District, and several distinctive sectors of the district were not studied.

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NOTES

1 The cotton season straddles two calendar years: it is planted in June–July and then harvested from October to March. To make the discussion less cumbersome, I refer to cotton seasons by the year the crop was planted and most of the work occurs.

2 See Rogers (2003) pp168–218 for a summary; see Ryan and Gross (1943) and Beal et al (1957) for variations on the stage schemes.

3 Email to G. D. Stone, 14 November, 2005; the same point has appeared in print numerous times (e.g. Srinivasan, 2004; *Hindu*, 2002, 2005).

4 Adam Smith and Karl Marx described the same process, albeit with somewhat different terminology (Marglin, 1996, pp194–195).

5 Vandeman (1995) argues that pesticides commodified farm pest management in a destructive and self-perpetuating cycle: the less the farmer knows about insect ecology, the more insecticide is used (Thrupp, 1990; Vandeman, 1995), producing intractable problems of environmental contamination and pesticide resistance.

6 This is a brief distillation of a large and nuanced body of theory. What I am summarizing as 'environmental (individual) learning' is a sketch of what Boyd and Richerson (1985, pp95–97) call 'guided variation' and Henrich (2001) calls 'the environmental learning model'.

7 This differs from the diffusion–innovation theorists' parallel concept of critical mass, which refers to the point at which further diffusion is self-sustaining. Critical mass is based on actual payoffs for adoption, and it mainly applies to interactive technologies like phones and faxes where the value increases as more people adopt. In contrast, conformist bias is identified by evolutionary theorists as a purely social phenomenon.

8 Public sector breeders have released a few open-pollinated varieties but they have convinced only a tiny percentage of the farmers to grow them.

9 A survey of Warangal input vendors was conducted in June 2005. Since no complete list of vendors is available, we developed a list of vendors by reconnaissance of the Station Road area, adding any others that appeared in interviews with farmers, vendors or officials. Thirty-seven shops provided cotton sales data for 2003–2005: five were new and only provided data for 2005, 18 provided data for 2004–2005 (some had only opened in 2004, others would not or could not provide accurate data for 2003), and 14 provided data for 2003–2005. Therefore the data cannot be used to compare overall sales, but should provide a fair reflection of market shares by product.

10 All censuses were designed and tested in collaboration with economist Dr A. Sudarshan Reddy of the Centre for Environmental Studies, Hanamkonda and formerly of CKM College, Hanamkonda. The 2003 census also benefitted from input by Robert Tripp of ODI, London.

11 The 2004 census collected information on acreage owned, which corresponded to acreages reported in the Multi-Purpose Household Survey moderately well. It also contained four variables reflecting the farmer's information connectivity: radio listening, newspaper reading, TV watching and, in particular, watching the 'Annadata' agricultural-extension TV programme were rated on a scale of never–sometimes–frequently. These were combined into a composite score of information connectivity (Low–Medium–High), which shows a clear correlation with land ownership ($p < .001$):

	Information connectivity			
	L	M	H	
Acres owned				
Small (<2)	121	11	8	*140*
Med (2–4.5)	92	10	23	*125*
Large (5+)	85	28	38	*151*
	298	*49*	*69*	*416*

An analysis of the extent to which access to external information sources affects participation in cotton crazes would be interesting, but lies outside the scope of this chapter.

12 This is similar to market share, but not exactly the same because it does not allow for farmers buying more than one box.

13 Plants with large bolls do not necessarily give high yield, as the number of bolls produced is variable. Large bolls may lead lead to marginally lower costs for harvesting labour, but they also maximize the economic losses due to bollworm attack (Jalapathi Rao, pers. comm. 2005).

14 In Pathipally, a plurality expected large bolls but in neighbouring Bandarupally most expected small bolls; in Kalleda, a majority expected small bolls but in neighbouring Ravuru most expected large.

15 In 2005, in a group interview, I asked why no one planted Gemini again. One farmer mentioned that the bolls were too small, but others had no specific reasons; several said they simply wanted to try something new.

16 The story has been related in various fora recently, most colourfully by Herring (2007).

17 For instance, Gupta and Chandak (2005) presented data from a survey of 363 farmers in 75 unnamed villages, administered by graduate students in breeding/genetics. While the results show slightly higher mean yields for MMB *Bt* cotton over Navbharat 151, the differences do not appear statistically significant, and anyway the comparison seems to span two years (Navbharat 151 was only sold through 2001; MMB *Bt* seeds were first sold in 2002). Morse et al (2005) failed to find higher yields for illicit *Bt* cotton than legal seeds, but the study was problematic; it appears to have taken all farmer responses at face value regardless of the illegal nature of the seeds they were being interviewed about, and it appears to have recorded only harvests through December, thus missing the late season harvest which is a strength for some illicit seeds. Despite these limitations in published research, the field success of the illicit *Bt* seeds is validated by the Gujarat Agriculture Department's estimates that cotton yields in the state have more than quadrupled over the past four years, during which time illicit 151 descendant seeds have spread to 60–80 per cent of the state's cotton area (Shah, 2005).

18 The finding from Morse et al's (2005) questionaire-based study that only 0.6 per cent of farmers planted more than one kind of seed is dubious. The detailed interviews in Warangal indicated that 45 per cent of farmers were growing more than one seed in 2003, and this is in an area where there has been very little of the loose seed that facilitates sub-acre experimental plantings (Stone, 2007).

PART III

Traditional Knowledge: What Is It and How, If At All, Should It Be Protected?

Chapter 18

From the Shaman's Hut to the Patent Office: A Road Under Construction

*Nuno Pires de Carvalho**

This chapter[1] takes stock of what has been done in recent years to build the road from the shaman's hut to the patent office. The purpose of this chapter is not to describe in detail the many multilateral debates held in various intergovernmental organizations such as the World trade Organization (WTO),[2] the Convention on Biological Diversity (CBD),[3] the United Nations Conference on Trade and Development (UNCTAD),[4] the Food and Agriculture Organization (FAO),[5] but rather to look at the evolution of legal concepts and strategies aiming at providing effective protection for traditional knowledge (TK). Because the legal concepts around TK have been more deeply examined in the context of the World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter referred to as 'the Intergovernmental Committee' or simply 'the Committee'), this chapter will look more attentively to that particular forum.[6]

The first section introduces a working definition of TK and discusses the economic relevance of its protection. In addition, it addresses some of the economic and non-economic reasons that should compel governments to take measures for the protection of TK.

The second section examines the first approach possible to the protection of TK: the 'defensive' approach, that is, legal measures that aim at preventing third parties from unwarrantedly claiming rights to elements of TK. Those measures can be of two types: elements of TK can be collected and organized in databases in a manner so as to permit their consideration by trademark and patent examiners as prior art or otherwise as bars to registration. The second possibility is the requirement of disclosure within patent applications of the origin of genetic resources and the previous informed consent of TK holders eventually used in the making of claimed inventions (hereinafter this will be designated as 'the Requirement'). The second

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*All views expressed are the author's and not necessarily those of WIPO and/or its member states.

section of this chapter will scrutinize the compatibility of the Requirement with various international obligations.[7]

The third section of this chapter examines the ‘positive’ protection of TK, that is, legal measures aiming at asserting property rights by TK holders. Two different paths have been taken so far: some governments have used traditional mechanisms of intellectual property (IP); other governments have preferred to establish a legal regime adapted to the special characteristics of TK – a *sui generis* regime – on the understanding that the traditional regimes are not adequate for that purpose.

The fourth section of this chapter notes that the construction of the road from the shaman’s hut to the national patent office is well advanced in some places, but there is still some major work to do, the most important of which is the road across national borders, which will permit the international articulation of national *sui generis* regimes in order to establish minimal international coherence. This section of the chapter looks briefly at the international treaties – the CBD,[8] the FAO Treaty on Plant Genetic Resources for Food and Agriculture[9] and the United Nations Convention to Combat Desertification (UNCCD)[10] – that have been associated with international attempts to establish protection of TK. It will be shown that, contrary to common understanding, the only Treaty that actually calls for IP protection of TK is UNCCD. In addition, some considerations on a possible international treaty on the protection of TK are spelled out. This section of the chapter also identifies the three essential standards that an international treaty on the protection of TK should contain so as to achieve coherence and yet permit contracting countries to keep a certain level of freedom at the national level: standards concerning the acquisition of rights; standards regarding the loss of rights; and standards of enforceability. The definition of the scope of protection and the identification of the owners could be left for national legislation to deal with.

The chapter concludes with a positive, yet (hopefully) realistic note on the progress of the construction of a road that shamans will be able (and, eventually, willing) to use so as to protect their TK, not only to their communities’ benefit, but also to the benefit of society as a whole.

TRADITIONAL KNOWLEDGE: SOME PRELIMINARY CONCEPTS

A working definition

Actually, as WIPO has said, there is no need for a complete and authoritative definition of TK in order to develop a legal system for its protection. Most patent laws, for example, do not define ‘inventions’. What those laws do is to identify the different mandatory characteristics that inventions must meet in order to be patentable. The same can be said of trademark law. No piece of legislation on trademarks attempts to define what a sign is. Instead, what lawmakers have invariably done was to establish that *distinctive* signs should be registrable as trademarks.[11] The same approach, as WIPO has suggested, could be applied to TK. What an operational definition of TK requires is the designation of its essential elements, and not an exhaustive description of its concept, which might prove an impossible and elusive task.

Under this approach, TK comprises two main (and to some extent, distinct) categories: on the one hand, TK consists of knowledge itself, that is, ideas developed by traditional communities and indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as means of cultural identification. This is what we may call 'TK *stricto sensu*', and it contrasts with 'expressions of TK', also named 'expressions of folklore' or 'expressions of traditional culture', such as verbal expressions (tales, poetry, riddles), musical expressions (songs and instrumental music), expressions by action or performances (dances, plays and artistic forms or rituals), whether or not reduced to a material form, and tangible expressions (productions of art, such as drawings, paintings, carvings), musical instruments and architectural forms.[12] The two categories form TK *lato sensu*.[13]

The advantage of this definition is that it acknowledges the traditional dichotomy between expressions and ideas that has been the basis of the development of international intellectual property law for more than a century. Indeed, the subject matter of the Paris Convention and all its developments, including the special unions created within the Paris Union, is 'industrial property', and corresponds generally to *ideas*. On the other side of the spectrum, the Berne Convention covers literary and artistic *expressions*. It is true that the distinction has become more or less blurred, particularly in technical fields like industrial designs (which may be protected by industrial property or by copyright[14]) and software (which is copyright subject matter[15] but in some countries has been increasingly the subject matter of patent protection[16]). However, the proposed approach – a general concept, corresponding to the notion of intellectual property, divided into two subcategories, parallel to those of industrial property and copyright – offers an operational basis for a further analysis of the legal mechanisms aiming at protecting TK.

According to the working definition suggested above, the main elements of TK *stricto sensu* are the following:

- In general, creation of TK is an incremental and collective process, but it does not follow that TK is not the product of individuals. Depending on the customary laws and principles applicable to particular situations, nothing stands in the way of recognizing an individual creation as a genuine piece of TK. The reference to traditional communities and indigenous peoples in the definition above proposed is not concerned with ownership, but rather with authorship, and it is linked to the definition's fourth element, described below. On the identification of traditional communities and indigenous peoples as such, the general requirement is that they must be identified as a separate group (on linguistic, ethnic or religious criteria, or a combination thereof) and must maintain a close relationship with their geographical environment.[17]

- Only ideas that are created in a traditional and informal way constitute TK.[18] 'Traditional' means that TK is developed according to the rules, protocols and customs of a certain community, and not that it is old.[19] In other words, the adjective 'traditional' qualifies the method of creating TK and not the knowledge itself. As to the informality of TK, it is understood that its creation does not integrate formal processes of invention and innovation, but that it is generated through an incremental, 'trial and error' method. TK, by definition, cannot be generated in laboratories or other places of systematic research and development.
- TK is the result of informal creation because it is developed as a response to the needs imposed by the physical and cultural environments that dictate the lifestyles of traditional communities and indigenous peoples. As a consequence of this, TK is 'holistic' in the sense that both its spiritual and practical elements have the same purpose of integrating the community with its environment.
- TK is a means of cultural identification, be it TK *stricto sensu* or be it the expressions of TK.[20] In other words, even the technical elements of TK, because of their particular insertion in a cultural context, are associated in an indissoluble manner with the identity of the community. There must be an unbreakable link that connects TK to its creators, a sort of a subtle (but spiritually significant) thread of Ariadne that does not permit that link to be broken and thus lost.[21]

For reasons of legislative technique, some national laws have narrowed the scope of protection, and have accordingly designated other elements that, in addition to all or some of those above, TK must contain in order to obtain legal protection. Examples of such additional elements are: the identification of the communities that are entitled to protection; the limitation of the scope of protection; and the susceptibility of commercial utilization of protectable subject matter.

The economics of knowledge protection and beyond

Does it make economic sense to protect TK? The reaction to this question falls between two poles: on the one hand, it is understood that knowledge in the public domain should remain in that state, and thus it should be publicly available without any constraints; on the other hand, TK is knowledge subject to foreclosure and therefore there are efficiencies in providing for intellectual property mechanisms that keep it as such. The debate over these two extremes concerns the static dimension of knowledge protection, this is, the effects that protection has on the distribution and dissemination of knowledge.

As a matter of course, TK may comprise factual knowledge, but the operational definition offered above is mostly concerned with creative ideas and expressions. The parallel of TK with facts, which are generally purely public goods, is that TK is generally very simple from a technical point of view and therefore it is very easily copied (Suchman, 1989). A shaman shows a bioprospector a plant that he uses on patients who complain of headache. The bioprospector does not need further instructions to understand that the plant contains a potentially useful active ingredient. The vast number of books and papers published around the world on the medicinal use of plants illustrates how simple it is to copy medicinal TK. The incorporation of indigenous crops into the mainstream market for seeds, through plant breeding, also attests that agricultural TK can be easily imitated. Intellectual property protection of TK, therefore, critics might say, would only harm the free flow of knowledge from 'preliterate' societies to 'modern' societies that could make better use of it without the constraints of enclosures and higher prices.

Nor would it make any sense to protect TK from a dynamic efficiency approach, opponents of TK protection would say, because TK has been created as a response to the needs imposed by the natural environment, and thus a legal mechanism would not have the dynamic efficiency of promoting the creation of new TK. Actually, TK has been created for thousands of years without the need for such an incentive. Why then create an expensive legal infrastructure that will not produce any significant dynamic efficiency, and also will generate foreclosure on something that can be obtained for free or close to free? Indeed, intellectual property has been seen as too complicated and expensive and thus as putting a financial burden on society which would not be commensurate with the economic value of TK.[22]

The views above may make sense on their face. But if we look attentively we might conclude otherwise. First, with respect to the static efficiency of intellectual property protection, it is not clear that TK is so easily accessible and susceptible of being copied that it may be compared to mere facts. Suchman, for example, draws a very interesting analogy between adding layers of magic to TK in order to protect it against imitation by the shaman's competitors. To some extent, the commentator suggests that magic operates as a substitute for the lack of formal legal structures of appropriation in traditional communities (Suchman, 1989).[23] Besides magic, which might apply to knowledge owned by the shamans only, traditional communities may resort to social structures, such as rites of initiation, to restrain the use of some elements of TK. However, both magic and social structures may constitute endogenous deterrents against competition within the communities or between communities. But they do not deter a bioprospector from collecting knowledge.[24] There is, therefore, another mechanism that indigenous peoples and traditional communities have increasingly resorted to, in order to avoid that outsiders learn their knowledge: they simply do not communicate it.

Intellectual property protection of TK will permit, therefore, the replacement of magic, social barriers and secrecy as measures that establish some sort of appropriation. Actually, as Article 7 of the TRIPS Agreement acknowledges, IP is not only about promoting creativity, but also about promoting its transfer and dissemination.

Intellectual property foreclosure of TK will have the undeniable benefit of generating an incentive to document and preserve it, thus protecting it from complete loss. Of course, that benefit will depend ultimately on the particular configuration that is given to the legal mechanisms adopted, but the different legal regimes of *sui generis* protection adopted so far have insisted on the need for documentation, either as a requisite for protection (that is, as a constitutive mechanism), or as an element of evidence of ownership (as a declaratory instrument).[25]

Actually, the doubts about the economic relevance of protecting TK stem from the erroneous perception that TK, being traditional, is necessarily old – hence a matter in the public domain.[26] But, as said above, TK is not necessarily old and it still continues being created by indigenous peoples and traditional communities. A system that protects TK holders against free riding and misappropriation may indeed promote the allocation of additional resources into creative activities by indigenous peoples and traditional communities.

However, the static efficiency of TK protection must also be assessed in terms of reduction of transaction costs in commercial operations involving the transfer and licensing of TK as well as its misappropriation. This raises the problem of 'biosquatting'.[27] The lack of a clear legal framework for TK has given rise to a generalized perception that every single attempt to approach a traditional community by a company interested in assessing the technical and commercial utility of a plant or animal the practical use of which is known to that community is a potential rip off. The reaction to that perception (which frequently proves to be based on erroneous assumptions and a misunderstanding of basic intellectual property concepts) generally gives rise to a public controversy that may seriously harm the public image of corporations and research institutions.

It is a fact that TK has economic value. Generally, resorting to TK as a guide for the collection of plants, animals and micro-organisms provides a tool for the study and testing of plants used in traditional medicine or a 'prescreen' of resources that 'have a higher probability of yielding bioactive compounds' (Miller and Brewer, 1992).[28] The relevance of TK as a useful source of information for researchers in the pharmaceutical field who seek to identify new chemical and biological elements, as well as new approaches to disease treatments, is generally undisputed (McGirk, 1998; Swerdlow, 2000). TK as a lead to identifying plants that can be used as raw materials for perfumes is also well documented.[29] TK is also used by traditional communities and poor populations as an alternative to non-existent or inaccessible public health systems in developing countries.[30]

The economic value of TK may have been exaggerated, and expectations about its potential value for the pharmaceutical and cosmetic industries may not correspond to reality.[31] But we should not attempt to forecast the value of TK; rather, we should let the market do that. The interaction of competing market forces is the best known (since Adam Smith) tool for evaluating economic interests. And the best manner to incite economic actors to extract the highest aggregate output from conflicting economic interests is to establish effective property rights.[32]

On the other hand, the fact that the very notion of resorting to formal regimes of intellectual property for protecting TK is a recent idea does not mean that traditional communities have not developed their own mechanisms to prevent free riding and misappropriation of their TK by internal competitors or outsiders. For instance, as described above, it has been suggested that elements of magic rituals have added to medicinal TK as a means of providing for some exclusivity (Suchman, 1989). WIPO, during its fact-finding missions on the needs and expectations of TK holders, also documented some measures aimed at keeping TK under control by traditional communities (WIPO, 2001).

The use of traditional elements of intellectual property or of a *sui generis* system for protecting TK would have the advantage of overcoming barriers to its commercial circulation that those informal measures of control impose on knowledge. To some extent, the same anti-secrecy rationale that applies to patents can also be valid in the field of TK.

The WIPO Secretariat has identified another economic reason for protecting TK: some indigenous peoples and traditional communities live in the direst poverty, and yet they are potentially rich in intangible assets; however, assets (intangible or not) can only be capitalized and become tools of economic development upon their formalization and recording. So, if indigenous peoples and traditional communities so wished (and if the law so permitted), they could formalize their intangible assets, thus acquiring property rights, which would permit their transformation into capital, and facilitate the establishment of commercial ventures.[33] Furthermore, once recognized through titles, TK could be used as collateral security for giving traditional communities facilitated access to credit. This would apply in those cases where traditional communities actively chose to commercialize selected elements of their TK. This would also be helpful in promoting the development of self-sustaining enterprises based on TK-related handicrafts, where protection of TK may help strengthen the enterprises' access to markets, and secure access to the capital needed to build up community-based enterprises.[34]

IP enforcement tools are necessary to protect TK against distortion or other derogatory actions, even for those TK holders who do not wish to put it in the channels of commerce. IP protection, therefore, does not 'commodify' TK per se: on the contrary, one immediate consequence can be to empower TK holders against the unauthorized commercialization of their TK, as they may not only refrain from giving a commercial dimension to their TK, but may also prevent others from doing so. On the other hand, an IP regime will be of crucial interest for those TK holders who wish to 'commodify' their knowledge or at least certain selected parts of it they choose to commercialize.[35]

DEFENSIVE PROTECTION OF TRADITIONAL KNOWLEDGE

One possible approach to protection of TK is to take measures that make it impossible (or more difficult) for third parties to claim and acquire formal property rights in some of its elements. According to discussions in the Intergovernmental Committee, those measures concern mainly the fields of patents and trademarks.

Making information available to trademark and patent examiners

Several countries have informed the WIPO Intergovernmental Committee of measures aiming at preventing third parties from appropriating signs, symbols and names belonging to traditional communities and indigenous peoples with a commercial or otherwise distorting purpose. Those measures may be of two types: interested TK holders may file for and obtain trademark registrations in order to preempt third parties' claims; or TK holders may inform the trademark office of vested interests in symbol, signs and names that should prevail over third-parties' rights to register trade signs.[36]

The defensive use of the patent system also comprises two possible alternatives. Under the first alternative, TK holders might apply for and obtain patent rights with the single purpose of preventing others from acquiring rights in their knowledge.

The second defensive approach to patent law is to make TK-related information that may constitute prior art available to patent examiners in a documented and organized fashion. This would address two sorts of concerns. On the one hand, in some jurisdictions, the novelty and non-obviousness conditions of patentability are assessed with reference to written prior art only. In the case of the US, for example, the prior knowledge or use of an invention is considered prior art only when those actions take place in US territory. Prior knowledge or use of an invention in a foreign country is not relevant for prior art purposes – only a written description in a printed publication is.[37] Because much of TK is orally preserved and transmitted by traditional communities, patent examiners in those jurisdictions have no means to consider it as prior art, and that facilitates biosquatters' claming and obtaining rights in such TK.

On the other hand, even when TK is documented, that documentation is not generally arranged or selected in a manner so as to make them easily retrievable by patent examiners, particularly in technical fields where patent and other literature is abundant and the examination of patent applications is a naturally burdensome task. One tool that may facilitate the access of patent examiners to TK as prior art is the International Patent Classification, which indexes patent applications according to the technical field of claimed inventions.[38]

However, the preparation of databases for defensive purposes raises several IP-related questions. In the first place, documentation of TK implies its public disclosure. Such disclosure, under patent and trade secret laws, generally bars any possibility of acquiring formal protection. Therefore, inclusion of TK in databases may diminish the possibility of TK holders procuring IP protection.[39] Second, the arrangement of databases may be the product of creative activity. Under current law, the original selection or arrangement of data contained in databases is protected by copyright.[40] But in most jurisdictions non-original contents of databases are not.[41] Therefore, TK holders are naturally reluctant to release information in their control, even if it is for defensive purposes, because they rightfully fear that they may be losing any possibility of acquiring rights in their intangible assets – thus, paradoxically, facilitating biosquatting practices.

Increasing the burden of disclosure in patent applications: 'the Requirement'

Another measure that some governments are taking, and which seems to gain accuracy, is to require patent applicants to identify in their applications the geographical origin of any genetic resources used (directly or indirectly) in the making of the claimed inventions as well as to prove that any element of TK (directly or indirectly) used has been obtained with its holders' prior informed consent (hereinafter designated as 'the Requirement').[42] This Requirement has a single objective: to help stakeholders monitor compliance with legal or contractual obligations to share benefits derived from the commercial use of the material and immaterial resources obtained, in the light of the recommendation contained in Articles 8(j) and 15.7 of the CBD.[43]

The practical reason for some countries' insistence on imposing the Requirement is that without voluntary or mandatory disclosure it is extremely difficult, if not impossible, to assert with reasonable certainty that a given invention has been made possible because of a certain hint given to the inventor on a certain use of a plant, animal or micro-organism. Where the invention consists of the very use of the plant (or of its active component) for a practical purpose, the link between the final result of the research (the invention) and its trigger (the TK element) is more visible. In that case, the TK creator should be identified as co-inventor, because his or her contribution was clearly one of an inventive nature. But in most cases TK is the hint that leads bioprospectors to select plants for collection and further analysis – this is what Miller and Brewer refer to as a 'prescreen' (Miller and Brewer, 1992). In these cases there is no visible link between the final product and the initial lead. The invention consists of identifying the useful components and assessing their efficacy (frequently the identified components are useful for purposes other than those known to the shaman[44]). The shaman, who gave the hint and eventually supplied the samples of the resources to the bioprospector, can be deemed instrumental to the final output of the inventive activity, but is not a co-inventor and possibly – because of the lack of that visible link – would have a very hard time to identify his or her contribution in the claimed invention. The Requirement, accompanied with effective and deterring sanctions, thus becomes a crucial tool to obtain compensation for the unauthorized use of TK.

The Requirement has undoubtedly a *formal* nature, as opposed to a *substantive* one. Substantive requirements are those that concern the nature of the invention itself, such as the elements of novelty, non-obviousness and utility. Those three elements are not only substantive requirements but also substantive *conditions* of patentability, because the failure to meet them is sanctioned with either the rejection of the patent application or, if detected *a posteriori*, with the invalidity of the patent.[45] Another substantive requirement – and which is not a substantive condition – is the unity of invention. In general, the failure to meet this requirement, if detected during the examination of the patent application, causes the patent application to be divided, not rejected. If detected after the patent is granted, the patent is preserved.[46]

In contrast, formal requirements are those that concern the form in which the invention is presented to the Patent Office. The main formal requirement – which is also a formal *condition,* because it is mandatory and therefore failure to comply with it causes the patent application to be denied – is disclosure of the invention, which must be enabling. This formal condition is, actually, a consequence of the three substantive conditions above listed: it is by reading specifications that disclose the invention in an enabling manner that patent examiners make decisions on whether they find the invention new, non-obvious and useful. Other formal requirements that may constitute conditions of patentability are those that relate to the evidence of ownership: a document assigning the right to apply for the patent to the inventor's employer, for example, or a statement that the applicant is the true inventor. This formal condition is explained by the fact that some patent laws retain the principle that patent rights are originally vested in the first and true inventors. Assignees are only entitled to acquire patent rights as a result of a transfer of original rights.[47] A third type of formal requirement is evidence of the payment of fees to patent offices. There are two categories of fees: procurement fees, that patent applicants must pay to patent offices for services rendered, and maintenance fees.[48]

Evidence concerning the origin of genetic resources and prior informed consent of TK holders is a formal requirement in the sense that it does not concern the nature of the invention but the manner in which the application is presented to the patent office. The Requirement may assume different forms according to the specific nature of the TK involved. When the knowledge about the origin of the genetic resource or about the TK used in the invention is essential for understanding the working of the claimed invention, it becomes an element of the enabling disclosure. Existing international and national patent law already impose the Requirement as a formal condition of patentability in such circumstances. However, TK holders' authorization to use their knowledge and/or genetic resources incorporating their knowledge is not a technical element, but a legal one. A patent application may, theoretically, describe a piece of TK without identifying its holder(s). But when TK is incorporated into the claimed invention as an inventive concept in its own right, then the identification of the TK holder(s) and evidence of their prior informed consent become an important element for the attribution of inventorship and/or ownership. But, to that extent, the Requirement has already been imposed by existing patent law.

It is not certain that the costs that arise from the implementation of the Requirement in the extended manner described above will correspond to the benefits society is able to extract therefrom. On the one hand, when biosquatting is the result of the claim of private property rights in knowledge that is in the public domain in foreign countries, the losers of unwarranted claims are not the TK holders, but the society at large of the country granting the patent. As a matter of law, TK in the public domain can be used by anyone for free. Biosquatters can put a higher price on products and services that otherwise would be sold for less. Moreover, unduly patented TK cannot be incorporated into products and services of squatters' competitors, thus blocking the development of competing derivatives. But squatting on TK in other countries does not prevent TK holders from continuing to use it in their daily life. Therefore, when the creation of TK databases has no other purpose than opposing patent and trademark claims, and considering the high costs that such creation entails, it may well represent a waste of resources. On the other hand, when biosquatters claim property rights in TK that remains under the private control of indigenous peoples and traditional communities, the enactment of measures for positive protection corrects and represses situations of misappropriation more effectively. In that event, TK holders will be in a position to enforce their rights – rights that are recognized, sometimes even formally, by law, and which entitle them to adequate compensation rather than merely challenging inappropriate patents. Enforcement of IP rights may not be a simple and cost-free matter, but it is more effective than challenging the validity of patents based on traditions (which are frequently undocumented) and customary law.

Moreover, an undue burden imposed on patent applications may create serious difficulties for the management of national and international patent systems and distant the focus of the patent system from contributing to the progress of useful arts to the acknowledgement of third-parties' stakes in claimed inventions. As said elsewhere: 'patents are not certificates of good behavior. Patents are certificates of *inventive* behavior'.[49]

Another important aspect is that shamans who supply relevant, if not crucial, genetic material may provide important support for the activities of research and development of pharmaceutical and biotechnological companies, but they are not co-inventors of the products and processes obtained as ultimate derivatives of those genetic resources.[50] Therefore, the Requirement is not relevant for detecting inventorship – and, consequently, ownership – of the patented invention. It seeks only to establish a contractual interest in the commercial gains of an invention derived from genetic resources, in the event these resources have been extracted from a territory where there is a duty to obtain formal consent in order to acquire legitimate access. The Requirement, therefore, is not ancillary to patent law – it is ancillary to administrative and/or contract law.

Several countries have taken legislative measures aimed at obliging patent applicants to comply with the Requirement.[51] We can classify those measures in two different sort of categories: (1) measures may be classified as to the consequences of a failure to comply: under some statutes, failure to comply will cause the rejection of the patent application and the invalidity of the patent, if granted; under other statutes, the Requirement is not a condition for the grant of the right; (2) measures may also apply solely to patents or they may extend to all industrial property rights.[52]

The Requirement as a condition of validity of IP rights and applicable international law

As a condition of validity of IP rights, the Requirement may be scrutinized under the provisions of five international treaties: the TRIPS Agreement, the UPOV Convention, the Patent Cooperation Treaty (PCT), the Patent Law Treaty (PLT) and the very treaty it aims at implementing, the CBD.

Three provisions in the TRIPS Agreement are relevant for assessing to what extent WTO members may establish formal requirements (such as the Requirement) as a condition of patentability.[53] First, under Article 29.1, WTO members are obliged to impose on patent applicants the duty to disclose the invention. In addition, WTO members are authorized to impose on patent applicants the duty to identify the best mode of carrying out the invention.[54] The second provision is Article 32, which provides that an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.[55] A question may be raised whether WTO members may revoke patents on grounds of violation of rules on access to genetic resources and/or failure to obtain informed authorization by TK holders. Even though Article 32 is silent on this issue, it seems that there are sufficient elements in TRIPS to conclude that the general understanding of WTO members, with the exception of India, is that they may not.[56] The third provision is Article 62.1, which provides that procedures and formalities required as a condition of the acquisition or maintenance of the intellectual property rights must be reasonable and consistent with the provisions of the Agreement.

Formal conditions that are not covered by Article 29 must be, therefore, (1) reasonable and (2) consistent with the provisions of the TRIPS Agreement. The definition of 'reasonableness' is not self-evident. Because the TRIPS Agreement 'occupies a relatively self-contained, *sui generis* status in the WTO Agreement', as the Panel in *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*[57] put it, that is, as the TRIPS Agreement deals with intellectual property in its trade-related aspects only, one might be led to the conclusion that those formal conditions that help patent offices assess whether the three substantive requirements of Article 27.1 have been met are reasonable.

Reasonable also are formal conditions that help patent offices and/or courts to identify the inventors and or their successors in title. This issue comprises two different aspects: one has to do with the identification of the *inventor*, the other with the identification of the *owner*. It is generally understood that those persons who contribute with their creative minds to the inventive solution of a given technical problem are entitled to the patent. They are the original owners of the idea, and the patent cannot be attributed to third persons if they do not receive it in consequence of a transfer of title. The inventor's right to the patent is both a material and a moral right, in the sense that the inventor has not only vested rights to acquire property in the fruit of his/her work, but also to be publicly acknowledged as such. However, patent law has gradually relaxed the identification of the inventor. Many national laws admit the omission of the name of the inventor on the patent letter, under certain special circumstances.[58]

In contrast, the identification of the owner is a necessary element for providing legal security. Formally recognized property rights must have their respective owners duly identified for the many social purposes that stem from property such as levying taxes, establishing rights to inheritance and providing collateral. Society at large must know which technology is the subject matter of property rights and who owns it in order to know who is entitled to authorize its use, so as to avoid infringement. The correct identification of the patent owner is therefore essential for ensuring legal security and predictability in legal relations involving patent rights. This is one of the most crucial aspects of patent law (as well as of property rights in general).[59]

In view of the above, it seems to follow that requiring compliance with procedures aiming to clearly identify the owner of the patent as well as other persons that may have proprietary interests in the patent is within the scope of 'reasonable procedures and formalities', under Article 62.1 of the TRIPS Agreement.

The same applies to requirements concerning the payment of procurement or maintenance fees, provided these are consistent with the provisions of the TRIPS Agreement – they may not discriminate, for example, against citizens of other WTO members. As explained above, both procurement and maintenance fees are accepted by the TRIPS Agreement, either as elements of WTO members' national legal systems and practices (Article 1.1) or as Paris Convention obligations (Article 2.1).

In conclusion, formal conditions that (1) have nothing to do with helping patent examiners to assess novelty, inventiveness and susceptibility of industrial application; (2) have no connection with inventorship and, consequently, ownership; and (3) are not aimed at evidencing the payment of fees are beyond the scope of the TRIPS Agreement and, ultimately, are TRIPS inconsistent.[60]

The need to implement Article 15 of the CBD does not make the Requirement 'reasonable' under Article 62.1 of the TRIPS Agreement, because Article 27.1 admits no exceptions other than those it specifically identifies.[61] Moreover, the CBD not being a WTO Agreement, Article XX(d) of GATT 1994 provides for no justification to discriminate against a field of technology in violation of the provisions of an annex to the WTO Agreement. Actually, the WTO being an Agreement about trade barriers, the WTO includes members that are not Contracting Parties to the CBD. It would not be reasonable to impose on those members an obligation they are not bound – and do not wish to be bound – to observe.

In conclusion, WTO members may adopt the Requirement if they so wish, but only if it does not constitute a condition for obtaining IP rights that depend on registration, and provided it is consistent with the provisions of the Agreement, including Articles 27.1 and 27.2.[62]

On the other hand, for those WTO members that are also members of the UPOV, the adoption of the requirement is barred as far as plant varieties are concerned. In fact, both the UPOV 1978 and 1991 texts provide that plant variety certificates may be annulled only when the varieties fail to meet the conditions of novelty and distinctness. Certificates may also be cancelled but only when the varieties fail to meet the conditions of uniformity or stability as well as a few formal requirements that are explicitly stated (and which do not include the Requirement). These are the *numerus clausus* grounds for annulment and cancellation under UPOV 1991, Articles 21 and 22. Article 10 of the 1978 version contains essentially the same provisions. More importantly, the grounds for annulling or cancelling plant variety certificates may not be expanded by UPOV members, under Article 10(4) of UPOV 1978, and Articles 21(2) and 22(2) of UPOV 1991. This means that a breeder that develops a variety based upon a plant genetic resource unlawfully collected shall not have the respective certificate annulled or cancelled by any UPOV member on the ground that he/she has failed to comply with national laws concerning access to genetic resources. This view was affirmed by the UPOV Secretariat in a communication addressed to the TRIPS Council (IP/C/W/347/Add.3, at 4).

Parties to the PCT may not impose the Requirement, either as a condition of patentability or not, on international applications. Article 27.1 of the PCT (on 'National requirements') bars national laws from requiring compliance with requirements relating to the form or contents of the international application *different from or additional to* those that are provided for in the PCT and the Regulations. Paragraph 8 of Article 27 contains exceptions to the provisions of paragraph 1, but those do not comprise the requirement to disclose the origin of genetic resources. It follows that the Requirement is not allowed under the PCT either as condition of patentability or as an additional requirement, during the international phase.[63]

According to Article 10.1 of the Patent Law Treaty, in conjunction with Article 6(1), formal conditions of patentability that are not provided either in the PCT or in the PLT itself are not allowed by the PLT. Given that the Requirement is, as shown, inconsistent with the PCT and that the PLT has no provision approving it,[64] the Requirement is also inconsistent with the PLT. Because the PLT is complementary to the PCT, in the sense that it applies to national and regional patent applications permitted under the PCT (PLT, Article 3.1), the conclusion is that the Requirement is inconsistent with the PLT (as a condition of patentability or not) both in the international and the national phases.

It is has been generally understood that the Requirement is necessary to help Contracting Parties to the CBD monitor compliance by bioprospectors and/or their successors with national legislation on access to genetic resources. It has also been assumed that the Requirement stems logically from the requirements of Articles 8(j) and 15.7 of the CBD. However, the Requirement, when adopted as a (formal) condition of patentability, is not only in violation of the TRIPS Agreement, the UPOV Convention and the PLT – and, eventually, if adopted in the international phase, of the PCT – the Requirement is, actually, also in violation of the CBD itself.

Where Article 15.7 of the CBD suggests that Contracting Parties should take legislative measures with the aim of sharing benefits arising from the commercial exploitation of genetic resources, it says that they should do so 'in accordance with Articles 16 and 19'.

The expression 'in accordance with Article 16' means two things. First, access to genetic resources in developing and least-developing countries may require technology that is in the hands of private companies in developed countries. Therefore, in order to obtain technology that will create the means for accessing their genetic resources, developing countries are to observe Article 16, which provides for measures that 'facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment'. (Article 16.1).

Second, the measures taken must be in accordance with paragraphs 2 and 3 of Article 16, which contain rules on technology transfer: 'such access and transfer' (and, under Article 15.7, all measures aiming at promoting benefit sharing) 'shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights' (Article 16.3) as well as 'in accordance with international law' (Article 16.5).

In other words, all measures aiming at implementing Article 15.7, including measures to monitor compliance with the obligation of benefit sharing, must respect Contracting Parties' international obligations under intellectual property agreements – which, as shown above, do not permit the adoption of the Requirement as a condition for obtaining rights.[65] Therefore, any measures aiming at monitoring compliance with benefit sharing obligations that are inconsistent with international intellectual property treaties are also inconsistent with the CBD itself. It is true that Article 16.5 invites Contracting Parties to make efforts to prevent patent and other intellectual property rights from creating obstacles to the implementation of CBD objectives. However, those efforts are to be made 'subject to national legislation and international law'. This means that, for Contracting Parties to be excused from observing current international obligations under intellectual property treaties, they must provide for the amendment of those treaties. But while that does not happen, they are obliged by the CBD itself to observe those treaties. The only conclusion possible is that countries that implement Article 15.7 through measures that are inconsistent with international treaties on intellectual property (such as adopting the Requirement as a condition of patentability) are in violation of the CBD itself.

Another argument that could be raised is that under Article 15.5, which conditions access to genetic resources upon prior informed consent, makes no reference to international treaties on intellectual property. Compliance with the obligation of obtaining prior informed consent, therefore, could be monitored regardless of international obligations in the area of intellectual property. To that extent, prior informed consent would give rise to different obligations under the CBD. Such an argument, however, would be flawed, as Article 15.4 subjects access to 'the provisions of this Article', which necessarily includes paragraph 7. In other words, measures aiming to implement the obligation to obtain prior informed consent are, like those concerning benefit sharing, subject to paragraphs 2 and 3 of Article 16.[66]

An alternative approach to the Requirement: The unclean hands doctrine

When TK is used, directly or indirectly, as a basis for creating inventive uses for genetic resources with which TK is associated, and where those inventions become the subject matter of patents, society has two ways to deal with the need to ensure the fair and equitable sharing of eventual benefits arising from those inventions with TK holders: one is to adopt the Requirement as a condition of patentability; the other is to adopt the Requirement as a condition of enforcement, based on the unclean hands doctrine.

The Requirement, as noted above, should not constitute a condition of patentability. That would undermine the value of patents as effective means of securing property rights in inventions. The ability to attack the validity of those rights because of factors concerning conditions that are intrinsic to raw materials used, and extrinsic to the invention itself or to inventorship, would create unpredictability. Patents would lose much of their accuracy as reliable meters of the invention's value, as their validity could depend on elements that have nothing to do with the invention. As said above, patents are certificates of *inventive* behaviour, and it is in that capacity that they perform their usefully social function. If transformed into certificates of *good* behaviour, patents cease being patents as such and become certificates of origin of genetic materials. Moreover, the Requirement, where established as a condition of patentability, does not promote benefit sharing: it simply generates information about the use of genetic resources and associated TK in the making of claimed inventions. Most patents fail to generate any economic revenue, particularly in the pharmaceutical industry, where patent applications are filed very early in the research process, and patent applicants are far away from obtaining a positive outcome. Thus, as a monitoring tool, the Requirement would give TK holders information about the existence of a patented invention only. It would not inform them about the commercial exploitation of that invention, let alone the financial gains of the patent owner.[67]

Governments can resort to the unclean hands doctrine as an alternative to adopting the Requirement as a condition of patentability.[68] The use of the unclean hands doctrine would have at least three advantages over the patentability approach.

First, as a rule on enforcement, it would be compatible with the different intellectual property international treaties mentioned above (namely the TRIPS Agreement, the UPOV Convention, the PCT and the PLT).

Second, it would not affect the patentability of an invention, thus avoiding transforming patents into certificates of origin. The idea proposed is not to use the inequitable conduct rule, because inequitable conduct can be alleged when the patent applicant fails to disclose to the patent office some material fact that may be (or probably is) material to patentability; therefore, inequitable conduct is linked to the conditions of patentability. Inequitable conduct may also lead to the partial or total unenforceability of the patent but, unlike unclean hands, it cannot be purged.[69]

And, third, the unclean hands doctrine does indeed promote benefit sharing because it surprises the patent owner at the moment he/she is using the court authority to collect revenue from an infringer (in the form of damages) and/or to maintain its position as exclusive user of the invention in the market by means of an injunction. Because the court will refuse to do so until the patent owner cleans his/her hands, the patent owner has no solution other than seeking a settlement with both the supplier of the genetic resources and the licensor of the associated TK.

The unclean hands doctrine has also advantages over the application of the inequitable conduct doctrine, which, like the Requirement (while a condition of patentability), destroys the economic incentive for the inventor and seriously reduces the possibility that the TK holder may share any benefits. Of course, it is not entirely because the patent will become unenforceable that the inventor will not benefit from its exploitation. A patent is not a *sine qua non* guarantee of commercial success. Nor once it is lost or expired, will the inventor necessarily refrain from commercially exploiting it. Nonetheless, the expiry of the patent (or the lapse of the rights to enforce it) reduces the patentee's capacity to reap the fruit of a commercially successful invention because nothing will prevent others from doing the same.

In short, the unclean hands doctrine approach has the advantage that it does not affect the enforceability of the patent – it just suspends it until the patent owner cleans his/her hands.

THE POSITIVE PROTECTION OF TRADITIONAL KNOWLEDGE

In order to claim enforceable rights in TK, creators may pursue two different avenues: in some countries, they may resort to traditional mechanisms, such as copyright, patents and trademarks, to protect those elements of their knowledge that meet legal requirements; in other countries, *sui generis* regimes are already available that purportedly are better adapted to the special characteristics of TK, particularly its holistic nature.

Existing IP systems as tools for protecting traditional knowledge

A number of committee members, such as Sweden and Switzerland, have indicated that IP mechanisms are, in general, available for the protection of TK, provided the conditions imposed by law are met. Other committee members have disclosed concrete experiences concerning the actual use of existing IP mechanisms.

For example, Indonesia, New Zealand, Qatar, Samoa, Uruguay and the EC indicate that copyright and related rights law could eventually protect some traditional creations. Australia mentioned a few court opinions that relied on copyright to protect Aboriginal creations. Canada noted that Aboriginal artists, composers and writers were using the Copyright Act to protect their creations (such as wood carvings, silver jewelry, songs and sound recordings, and sculptures).

Costa Rica, Hungary, Japan, the Republic of Korea, the Republic of Moldova, New Zealand and Romania said that patent law was generally available for protecting traditional inventions, provided the conditions of patentability were met. Kazakhstan, the Russian Federation and Vietnam provided concrete examples of patents granted.

New Zealand and Turkey noted that plant variety protection (plant breeders' rights) was also available for tradition-based creations.

Australia, Hungary, Indonesia, the Republic of Moldova, Uruguay and the EC informed the Committee that TK-based products could be identified and distinguished under trademarks and certification marks. Canada noted that trademarks, including certification marks, were often used by Aboriginal people to identify a wide range of traditional goods and services, such as traditional art and artwork, food products, clothing, tourist services and enterprises run by First Nations. Many Aboriginal businesses and organizations have registered trademarks relating to traditional symbols and names, but the number of unregistered trademarks used by Aboriginal businesses and organizations was considerably greater than those that are registered. In Costa Rica, indigenous peoples have marked cattle with distinctive signs. France, Mexico, Portugal and Vietnam mentioned concrete examples of trademarks, certification and collective marks in the field of traditional products and crafts.

Mexico disclosed the registration of two geographical indications that were particularly relevant to TK (*Olinalá* and *Tequila*).[70] France, Italy, the Republic of Moldova, Portugal, the Russian Federation, Tonga, Turkey, Venezuela and Vietnam also provided information and concrete examples of geographical indications designating indigenous handicrafts or agricultural products.[71]

Australia, Costa Rica, New Zealand and Toga stated that industrial designs were appropriate for the protection of TK. In Kazakhstan and the Russian Federation traditional crafts and textiles were already protected as industrial design subject matter.

Canada, Hungary, Indonesia and the US added that trade secret protection was particularly fit for protecting undisclosed TK. In Australia a court has already used the common law doctrine of confidential information to prevent the publication of a book containing culturally sensitive information (*Foster* v *Mountford* (1976) 29 FLR 233).[72]

The idea of a *sui generis* system for the protection of the contents of traditional knowledge databases[73]

Is a *sui generis* system really necessary for protecting TK? The US has insisted in the Committee that before embarking on such an exercise, it would be more convenient to explore first the experiences gained at the national level.[74]

But the need for a *sui generis* regime does not necessarily stem from the unsatisfactory experience of the use of existing IP regimes at the national level. When there is a clear incompatibility between those regimes and the characteristics of new subject matter, there is no need for obtaining frustrating experiences prior to moving towards the adoption of a *sui generis* regime. The approach of the US to protect layout-designs of integrated circuits, for example, could serve as a useful guideline: after enacting legislation to protect layout-designs under a *sui generis* regime at the national level, the US negotiated with its trading partners the extension (under a reciprocity regime) of that protection to their territories; and, regardless of the lack of national experience in other countries, multilateral negotiations on the IPIC were held in 1989.[75] Because those negotiations failed (on differences of opinion concerning compulsory licences) and the IPIC Treaty never entered into force, the *sui generis* regime was later incorporated (with modifications) into the TRIPS Agreement.[76,77]

Likewise, moving to international negotiations on the protection of TK under a *sui generis* regime would not be necessarily irresponsible, provided it became clear that traditional regimes are not entirely adequate to fit the special characteristics of TK. This point gives rise to two questions. Does TK have special characteristics that make it unfit for existing IP regimes? If yes, what characteristics are those?

A short fable may help illustrate the special characteristics of TK.[78] Let us imagine that a member of an Amazon tribe does not feel well and requests the *pajé*'s medical services (*pajé* is the tupi-guarani word for shaman). The shaman, after examining the patient, will go to his garden (many shamans in the Amazon rain forest are indeed plant breeders[79]) and collect some leaves, seeds and fruits from different plants. Mixing those materials according to a method only he knows, he prepares a potion according to a recipe of which he is the sole holder. While preparing the potion and, afterwards, while administering it to the patient (according to a dosage he will likewise prescribe), the *pajé* prays to the gods of the forest and performs a religious dance. He may also inhale the smoke of the leaves of a magical plant (the 'vine of the soul'[80]) that opens his way to contact with the gods.[81] The potion will be served and saved in a vase with symbolic designs and the *pajé* will wear his ceremonial garments for the healing.

The TK of the Amazon shaman is a combination of all those elements. If taken separately, existing IP mechanisms could protect most of, if not all, those elements. For example, the different plants from which the shaman has made the potion may be protected under a plant variety protection system, provide the plants are new, stable, distinct and uniform. The potion (or the formula thereof) can be the subject matter of a patent, provided it is new, inventive and susceptible of industrial application. If not yet disclosed and the shaman has taken measures to prevent others from learning it, the potion can be protected as undisclosed information. The use and the dosage of the potion can also be protected by a patent, under the laws of a few countries that make patents available for new uses of substances as well as for new and inventive therapeutic methods. The prayer, once fixed, could enjoy copyright protection, and under many countries' laws may also enjoy copyright protection in the absence of fixation. The performance, once fixed, can be protected by copyright-related rights, and the shaman – as performer – can be accorded the right to authorize the fixation of the performance. The vase containing the potion can be patented or protected under a utility model certificate if it has new and inventive functional features. If not, it can be protected under an industrial design system. And the designs on the vase and on the garments can be protected either by the copyright or by the industrial design systems.

However, the possibility of separately protecting TK elements does not necessarily correspond to its true nature. Traditional knowledge is not the mere sum of its separate components: it is the consistent and coherent combination of those elements in an indivisible piece of knowledge and culture. For the *pajé*, needless to say, the merit of the healing resides in the combination of the extract with the religious rituals, and not in the potion individually. The features of the several IP mechanisms mentioned above do not accept such a combination of elements of knowledge as a subject matter. It is necessary, therefore, to design a system that responds to the holistic nature of TK and takes a comprehensive approach to it. Patents, trademarks, designs, etc., may be effective in providing protection for individual elements of TK; but they do not attend to its holistic nature.

Traditional knowledge, in that holistic concept, has four unique characteristics: the spiritual and practical elements of TK are intertwined and thus are inseparable (it is in this sense that every element of TK serves as an inherent part of the cultural identification of its holders); since traditional communities generate knowledge as a response to a changing environment, TK is always evolving and being incrementally improved; TK covers different fields, in areas of cultural expression and in technical domains; finally, because its creation is not undertaken through a formal and systematic procedure, TK cannot be described with the same technical detail as required for patent specifications – the shaman may indeed be very knowledgeable about uses and properties of a given genetic resource, but he does not know its chemical or biological composition.

With those four characteristics in view, the only adequate way to document and formalize the protection of TK is through collections, or inventories, or databases[82] of TK. Through such a mechanism, a shaman could go to the patent office and file a general written description of his knowledge about the uses and properties of, say, the plants he employs in his daily activities in the tribe. Along with the description of the uses and properties, the shaman eventually would need to include recordings of the songs and the dances, and drawings of the symbols and the garments. Only an inventory of TK would permit such a collection of intertwined data without obliging the shaman to dismember his knowledge into separate elements.[83]

TK rights must cover the contents of such databases. Those contents are indeed the product of creative work, and in that sense they are *original*, because their origin can be attributed – frequently, the attribution falls upon a community, but in some cases it may designate an individual within a certain community.

Because TK *lato sensu* comprises ideas and expressions, the rights conferred should be those of excluding others from *using* the ideas, and/or of excluding others from *reproducing* the expressions (and/or *fixing* the performances). This is the second element of the *sui generis* regime: a regime that combines features of industrial property law with those of copyright and related rights. This distinction need not be made at the registration phase. Once vested in the title, the shaman would be able to go to a court and demand protection against a third party who has subsequently used his potion's formula to develop a product. In this event, the judge may not only order the payment of compensation but may also issue an injunction prohibiting the infringer to continue using the shaman's proprietary formula. Where a third party reproduces one of the shaman's songs or uses it as a basis for a new song, the judge may issue an injunction against the *reproduction* of that song.

The protection being formalized through a description of the different elements of the shaman's TK, makes it possible for him to come back to the patent office to expand the database with new or modified elements. A database – unlike patent specifications – is flexible enough to accept such improvements without the need for an entirely new registration procedure. Protection should be granted for every new element added to the original database. If the law establishes terms of protection from the date of the registration, then a new term would be applied to each new element added. This recognizes the fact that TK is not necessarily old, that is, it continues evolving. Therefore, TK creators should be given the possibility of reflecting the evolution of their knowledge in the documents that formalize their rights.

Finally, no one should expect that a shaman would be able to identify the chemical compositions of his potions or the scientific principles of their uses. A description would be necessary only for a third person to understand (and, eventually, to reproduce) the use given by the shaman to a determined genetic resource.[84] Such a simple (but minimally enabling) description would be, nonetheless, necessary for substantiating a claim of property rights, which is, by the way, the whole idea of TK databases as tools of positive protection. Property rights are essentially the right to prohibit others from trespassing. But for the prohibition to be enforceable, it is of the essence that the limits of the property be publicly announced so that others can be informed of those boundaries. The same concept applies in IP. Patented inventions must be disclosed so that others can be informed about their rights and obligations concerning the claimed and patented invention: if they cross the boundaries identified in the claims and can allege no exception to the patent rights conferred, they will be found to have infringed. A shaman may not allege biosquatting (or, once his rights are clearly identified, infringement) and request a court to rule accordingly if third parties have no way to clearly identify where the boundaries of TK rights are. TK databases, as simple as they might be, constitute the ultimate piece of evidence of the shaman's property rights.

The idea of a *sui generis* regime of protection of original contents of TK databases is not incompatible, as explained above, with measures enforcing rights in specific elements of TK. If a third party uses the formulation of the potion invented by the shaman, enforcement measures should be available to address such an act of infringement regardless of the absence of a reproduction of the prayer or the performance by the infringer. This 'minimalist' approach has an example in patent law: an infringer does not need to 'trespass' on all the claims of a patent to be liable as such. Infringement of one claim may be enough, as a matter of law. Similarly, it is possible to infringe copyright in a musical work by different acts (reproduction, broadcasting, making available to the public, etc.) without necessarily carrying out them all. The 'holistic' notion of TK calls for a simple mechanism for its recording and registration, but should not stand in the way of the enforcement of rights in each of its individual elements.

Protection of original contents of databases is not an entirely new idea, as it can be found in two international agreements. One is the TRIPS Agreement and its provision on protection of test data (Article 39.3) (WIPO/GRTKF/IC/3/8, paragraph 52). The other is the UNCCD and its provisions on the elaboration of inventories of TK and protection of their contents (Article 18.2(a) and (b)).[85]

FROM THE SHAMAN'S HUT TO FOREIGN PATENT OFFICES: EXPANDING TRADITIONAL KNOWLEDGE PROTECTION BEYOND NATIONAL BORDERS

Current multilateral provisions on the protection of traditional knowledge: the CBD, the FAO Treaty and the UNCCD

Under the CBD, protection of TK is not a separate value or objective per se.[86] Rather, it is ancillary to access to genetic resources. For that reason Article 8(j) refers to protection of TK in non-mandatory terms. Article 8 addresses *in situ* conservation of genetic resources – it is not concerned with protection of TK, as such. Protection of TK is the subject of a mere recommendation to contracting parties and as far as it is *relevant for the conservation and sustainable use of biological diversity*. TK (designated as 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles') that is associated with biodiversity but is not relevant for those two purposes is not within the scope of the CBD. Nor do the other CBD provisions that relate to TK contain any mandate to protect it as subject matter of enforceable rights.[87]

In short, the CBD is concerned with access to tangible resources and their preservation. It is indeed one of the major current misunderstandings in the debate on protection of TK (whether embodied in biological resources or not) to rely on the CBD as a conceptual framework for an IP mechanism. And it is no surprise that, more than ten years after its adoption in Rio de Janeiro, no substantive outcome or breakthrough has arisen from discussions in the CBD that could serve as guidance for countries wishing to enact IP protection for TK.

The same can be said in respect of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which has replaced the International Undertaking on Plant Genetic Resources for Food and Agriculture, of 1983.[88] Article 9 of the FAO Treaty deals with 'Farmers' Rights'. The first paragraph recognizes the contributions of farmers. The second paragraph, the language of which is inspired by Article 8(j) of the CBD, calls upon national governments to protect and promote farmers' rights. And the third paragraph calls for a kind of farmers' exemption that is different from any existing exception to intellectual property rights conferred, given that the existing exceptions (including those under UPOV 1978) do not permit third parties to engage in commercial activities (such as selling farm-saved seed/propagating material).[89]

This is not, of course, an affirmative intellectual property right, as the FAO representative stated at the second session of the WIPO Intergovernmental Committee.[90] On the contrary, once traditional landraces are integrated into the 'Multilateral System' (MS) established by the FAO Treaty, it will be impossible for traditional farmers to assert any rights in their traditional creations. The need for the creation of a new intellectual property regime that covers landraces (probably within the framework of a new, *sui generis* system of intellectual property rights in TK) becomes then more relevant and urgent, both at the national and international levels. The legal protection of landraces as intellectual creations in their own right will trigger the application of Article 12.3(f) of the FAO Treaty, thus avoiding the preemption of farmers' rights by the MS.

Unlike the CBD and the FAO Treaty, the UNCCD has several provisions that do call for IP protection of TK, albeit in the very narrow context of TK relevant to combat desertification and mitigate the effects of drought. It is also noteworthy that the UNCCD has language that suggests that the best manner to accomplish such protection is through (proprietary) protection of original contents of TK databases.

Those provisions can be found in three articles of the UNCCD. First, Article 16(g) recommends[91] two sorts of measures: on the one hand, parties shall ensure 'adequate protection for TK'; on the other, parties shall provide 'appropriate return for it'. That language seems to indicate that appropriate return (which theoretically could be obtained through a simple right to remuneration) shall be ensured *in addition* (and not alternatively) to protection. Although one can devise other possible meanings for 'protection' in Article 16(g), it makes sense to understand the word as comprising measures that may lead to appropriation of TK. But the UNCCD contains language that is even clearer.

The right to remuneration is also mentioned in Article 17(c), which provides for support of research activities that 'protect, integrate, enhance and validate traditional and local knowledge, know-how and practices, ensuring … that the owners of that knowledge will directly benefit on an equitable basis and on mutually agreed terms from any commercial utilization of it or from any technological development from that knowledge'.

Article 17(c), very importantly, says that the financial benefits (which, as in the CBD, may result both from commercial exploitation and from other types of exploitation, such as scientific research leading to 'any technological development') shall be attributed to *the owners* of TK. This language, therefore, clearly implies that TK holders are vested in *ownership*. Recognition of ownership goes beyond ensuring a right to remuneration, because, as owners, TK creators have the right to say 'no' to unauthorized use. Governments, therefore, must not only ensure that TK holders will benefit from the use of their knowledge: they must also seek their authorization for integrating TK into research and development initiatives. As owners, TK holders are entitled to manage their intangible assets – the UNCCD, therefore, shows a way that is quite different from the thrust of both the CBD and the FAO Treaty.

Article 18, which contains measures on the transfer, acquisition, adaptation and development of 'environmentally sound, economically viable and socially acceptable technologies relevant to combat desertification and/or mitigation of the effects of drought' (paragraph 1), calls for the protection of the original contents of TK databases in the following terms:

- TK (relevant for understanding the causes of and combating desertification and the effects of draught) should be collected into inventories (or databases);

- TK contained in those databases is the subject of ownership (Article 17(c)) and should be protected – in other words, the UNCCD calls upon the establishment of a legal regime that recognizes and protects ownership in (original) contents of TK databases.

It is worth noticing that protection of TK under the UNCCD has not only the static purpose of preserving it, but also the dynamic objective of promoting the creation of new TK and its dissemination.

It could be said that, to some extent, the UNCCD contains already the seed for a future harmonized *sui generis* regime of protection of TK. However, its provisions are not sufficient for that purpose because they are not only very limited in their scope, but also because they do not provide for national, that is non-discriminatory, treatment of foreign TK holders.

Some ideas for an international treaty on the protection of traditional knowledge

Intellectual property has the propensity for being guided by international and harmonized rules. Because it focuses on intangible assets as subject matter, these will flow from one country to another without physical constraints. If harmonized protection is not adopted in different territories, the flow of technology and ideas probably will be generated by unauthorized third parties only, for IP owners will be reluctant to invest in the commercialization of their assets in territories where, given the absence of IP protection, they will be the victims of free riding and other parasitic behaviour. The same goes for TK. The many denounced cases of biosquatting, even if most are not based on reality, reveal that there is a general perception that harmonized protection must be adopted in different territories.

It is nonetheless too early to envisage the possibility of having all 178 WIPO member states gather at a diplomatic conference to approve uniform *sui generis* standards of protection. There is a general conviction that TK is important and that it is also important to entertain discussions on what sort of features a *sui generis* regime for its protection should include. But there are different views on how to achieve that at the national level, let alone at the international level.

One main point of concern is the fact that several developed countries have enacted, or are in the process of drafting, their own national legislation dealing with relations with native tribes and indigenous peoples. Some of those relations have been established for centuries, and naturally those countries are worried that binding rules might interfere with and jeopardize those relations. However, the idea of an international treaty on the protection of TK would not be unrealistic if two preliminary points were established. First, the treaty should adopt a Paris Convention sort of national treatment, as opposed to the TRIPS Agreement type of national treatment. The difference is that Article 2 of the Paris Convention only requires that the rights of citizens of other member states be protected when the country in question protects the rights of its own citizens. If such protection is not accorded to nationals, the country in question does not have to grant protection to foreigners.[92] In contrast, Article 3.1 of the TRIPS Agreement provides that WTO members must accord nationals of other WTO members the minimum levels of protection established in the Agreement even if they do not accord such a protection to their own citizens.[93]

A Paris Convention-like approach would give members with different views on the urgency and criteria for protecting TK at the national level the possibility of coming together and joining a single treaty and yet preserving a certain level of flexibility. But, in order to avoid the treaty becoming an empty and irrelevant instrument, or that only a few countries agreeing to adhere to it, its scope – like the Paris Convention's – should be sufficiently broad as to attract countries with different interests in TK protection. The idea, then, could be to include not only *positive* standards of protection but also *defensive* ones, as described below. Therefore, countries which so far have shown an exclusively defensive concern with *sui generis* protection of TK, such as the US, could take their time and continue testing the applicability of traditional IP mechanisms – which, in any event, are available to foreign TK holders under the national treatment principles of the Paris Convention, the Berne Convention and the TRIPS Agreement.

Given the particular nature of TK, the principle of independence of rights would not apply. In fact, TK being a means of cultural identification, it may never be completely dissociated from its originators. Therefore, events that may affect the rights in TK at the national level, should also affect it in other jurisdictions.[94]

As to the principle of priority, its relevance depends on whether protection of TK is formal or informal. For those countries that are adopting a system of registration of inventories (a *sui generis* protection of original contents of databases) on a criterion of novelty, such as Peru and Portugal, priority may be important, but not for others. Thus, the principle of priority could be adopted on the understanding that it would apply only to those contracting parties that had adopted a system of national registration (either as a source of origin of a registration or as a recipient of a foreign request).

Under the flexible notion of a Paris-like national treatment, an initial treaty on *sui generis* protection of TK would contain minimum, mandatory standards[95] on: (1) acquisition of rights; and (2) enforcement; and it would leave countries free to define, at the national level, (1) the scope of protection and (2) the identification of the owners (attribution of rights).

On the acquisition of rights, one single mandatory provision would refer to recognition and protection of rights in TK, that is, ideas and expressions thereof developed by traditional communities and indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural environments and that serve as a means of cultural identification. The treaty could then identify a preferred manner of documenting and registering TK *stricto sensu* (that is, the ideas, as opposed to the expressions), through the submission of inventories of TK to the national competent authorities.[96] The conditions of protection (such as novelty and identification of TK holders) would be left for national law. The importance of setting some rules on registration and documentation is that contracting parties may make it mandatory as a condition of enforceability.

On the other hand, countries could be left free to decide on establishing exclusive rights as opposed to a right to remuneration (the latter solution was adopted by Peru for TK that was disclosed in the last 20 years). They should also decide on the rights to license and assign TK. Technical ideas, in principle, might be licensed and even assigned without harming the cultural identity of the community and the holistic integrity of the TK. But *expressions* and handicrafts should not be the subject matter of licences or assignment contracts because of their closer link to cultural identity. Once a handicraft is regularly made by a person who does not belong to a traditional community, it loses its cultural link, the *thread of Ariadne* that maintains TK connected to the community as an element of its identification and ceases *ipso facto* to be an element of TK.

The second mandatory provision should contain some rules on civil measures of enforcement, clarifying at least that compensation for damages and injunctions (including provisional measures) must be made available by contracting parties to protect separate elements of the registered databases. Where countries do accord informal protection (i.e. with no need for registration), it makes sense to require registration for the purposes of substantiating the filing of a law suit: TK, given its cultural background, is fluid and frequently difficult to identify; a registered inventory makes it easier for a judge or a jury to understand the real nature of the subject matter of the rights infringed. Whether criminal measures should also be included would be a matter for discussions: on the one hand, it might not be realistic, given the difficulties in assessing criminal intent in TK infringement, particularly when in so many cases the infringing product will be separated from the original TK by 10, 15 or more years of research, development and marketing efforts; on the other hand, delegates may wish to pay special attention to the nature of TK infringement, which generally implies a sort of cultural offence or human rights violation. For the same reason, border measures could be recommended, but not established as mandatory.

Contracting parties would be free to define the scope of protection (countries may prefer to narrow TK protection to biodiversity-associated knowledge; others may even narrow it further to TK associated with plant genetic resources; other countries may wish to use the system to protect expressions of TK or handicrafts). The importance of such a flexible provision would be not only to permit the articulation at the international level of different national approaches, but also to make it clear that TK is holistic and that in the end there is no incompatibility between ideas and *expressions* – while the enforcement measures will necessarily vary according to the specific element of TK infringed, but they are all elements of the same, holistic TK.

The treaty should also leave contracting parties free to determine the exceptions to rights conferred, including compulsory licences. As said above, because some elements of TK should not be licensed – otherwise they would lose their cultural identifying characteristic and purpose – those elements should be the subject of compulsory licences of exceptions to rights granted. But others can be: if a shaman has the knowledge of how to cure AIDS and refuses to transfer it, societal interests suggest that a compulsory licence should be granted. On the other hand, the CBD seems to provide that *all* benefits arising from *any* utilization given to the genetic resource should generate the right to a share of the benefits.[97] Therefore, it seems that there should be no exceptions to rights conferred for the private or non-commercial or the scientific use of genetic resources. Universities, botanical gardens and other research institutions should be obliged to pay in the event they extract *any* benefit from their research (benefits that can take either a commercial form, if the results are transferred to a commercial firm or exploited in a commercial fashion, or other forms, such as grants and awards). Customary uses of TK[98] as well as prior use by small firms and artisans[99] have been exempted from liability as exceptions to TK rights conferred.

Contracting parties should also be free to attribute rights in registered TK to communities or to individuals. The ultimate decision, as the laws of Panama[100] and Portugal make it clear, should stem from customary law (which could be the subject of a description in the inventory, so as to create certainty for third parties).

A provision could be added in order to clarify the relationship between *sui generis* protection and other IP mechanisms. *Sui generis* protection should co-exist with other forms of protection, not only as regards the databases per se (the selection and arrangement of whose contents are to be protected under copyright law, when original, to the benefit of the database makers) but also as regards their contents. TK holders would be capable, when the necessary conditions are met, of seeking protection under patent, trademark and industrial design laws, if they so wish. Such protection should supplement the *sui generis* regime. The shortcoming is that, once a patent expires, its subject matter would fall into the public domain, and it would not be possible to recapture and reintegrate it into the database.

On defensive measures, a treaty on *sui generis* protection of TK could include two mandatory rules, one concerning distinctive signs, the other concerning patents.

On distinctive signs, the treaty could include a provision establishing a system of notification of insignia and other spiritual symbols of indigenous peoples and traditional communities, so as to avoid their registration and use as distinctive signs in trade (in the form of trademarks or trade names). Those notifications, which should be made by governments (which would imply some sort of prior examination of the basis of the allegation made by the community as to the relevance of the insignia), would be registered by WIPO, which could draw inspiration from its database on official insignia and emblems, under Article 6*ter* of the Paris Convention – and which serves exactly the same purpose. Contracting parties could also be encouraged to adopt provisions, at the national level, permitting the invalidation of trademarks registered in bad faith, prior to the treaty's entry into force.

On patents, a provision would instruct patent applicants to identify the person or persons who have provided information about an element of TK from which the invention was derived, as well as a description of that element of TK, and how it was instrumental to the making of the claimed invention.[101] Where an applicant, who possesses or has reasons to be in possession of that information, fails to provide it in the patent specifications, he/she would not be entitled to enforce his/her patent rights against third parties until he/she obtained the required authorization from the TK[102] holder. In other words, third parties would be able to raise the *unclean hands* argument as a personal defence.

The treaty, finally, could include provisions on arbitration and mediation between contracting parties and between citizens of contracting parties.

CONCLUSION

This chapter has taken stock of the latest developments in the international discussions on the protection of TK, with a particular emphasis on a *sui generis* regime. The road seems to be definitely under construction so that the shaman can walk from his hut and knock on the patent office's door seeking formal recognition and title to his knowledge. The construction is far from complete, but it seems that work is advancing apace. Two major concerns should guide the construction work: one is the market response to the economic value of TK; the other is the need for legal security. Both concerns have an economic dimension, but experience shows that where the realities of market have been disregarded, legal measures tend to vanish in oblivion and discredit. Because the market has yet to express its recognition of TK, any legal measures should be simple enough so as not to create costly barriers and encumbrances to the effective transformation of TK into marketable goods and services; those measures should also be flexible, so as to permit their adaptation and enhancement, according to the actual response of the market. On the other hand, the interests of TK holders are to be carefully assessed along with those of industry. Both stakeholders must be aware of their rights and obligations. Therefore, a system for the protection of TK must be set in the form of clear and straightforward rules. Fortunately, there is no need to develop a *sui generis* regime from scratch, because the basic concepts – including those of a *sui generis* regime of protection for original contents of databases – have already been recognized in national and international law. A *sui generis* regime of TK protection based on existing and tested legal principles and practices would gain in security and enforceability.

Finally, the discussion about a regime for the protection of TK is based on the understanding that it must be adequate and effective. But the word 'effective' has two possible meanings: it means that something is 'adequate to accomplish a purpose; producing the intended or expected result'; and it also means 'in operation or in force; functioning; operative'.[103] If TK holders – who are or will be the users of any regime developed to protect their knowledge – are not involved in the discussions leading to the preparation of legislation with that purpose, they may not feel compelled to use the mechanism because of a failure to see the advantages or benefits they can extract from it. Therefore, in order to make whatever regime *effective*, it is essential to promote the participation of TK holders in national and/or international discussions.

NOTES

1 This chapter is a shortened version of a paper submitted to the Biodiversity, Biotechnology and the Legal Protection of Traditional Knowledge Conference, organized by the Law School of Washington University in St. Louis, on 4–6 April, 2003. The full version of this chapter has been published as 'From the Shaman's Hut to the Patent Office: In Search of a TRIPs-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent', *Washington University Journal of Law & Policy* vol 17, no 111 (2006). All views expressed in this chapter are the author's and not necessarily those of WIPO and/or its member states.

2 Traditional knowledge was included in the working programme of the TRIPS Council at the fourth session of the WTO Ministerial Conference, in Doha (WT/MIN(01)/DEC/1). WTO documents and legal texts are available on its website, at www.wto.org.

3 The CBD has established several bodies to address TK-related issues, such as the Working Group on Article 8(j) and the Ad Hoc Expert Group on Traditional Knowledge. CBD legal texts and documents can be found on its website, at www.biodiv.org.

4 Traditional knowledge was incorporated into the UNCTAD Plan of Action at its tenth session, held in Bangkok, on 12–19 February, 2000 (TD/386, paragraph 147). All UNCTAD documents and references to work on TK can be found on its website, at www.unctad.org.

5 Access to genetic resources for food and agriculture and protection of associated traditional knowledge are dealt with in the Commission on Genetic Resources for Food and Agriculture (CGRFA) of the FAO. The text of the International Treaty and information about the work of the CGRFA can be found at www.fao.org/ag/cgrfa/default.htm.

6 All WIPO documents as well as the texts of WIPO administered treaties can be found on the WIPO website, at www.wipo.int.

7 A more thorough examination of the Requirement can be found in Carvalho (2000). See also WIPO/GRTKG/IC/5/10.

8 The CBD opened for signature on 5 June, 1992, and entered into force on 23 December, 1993. Currently it has 187 parties. The text of the Treaty as well as an introductory guide to its provisions can be found on the CBD Secretariat's website, at www.biodiv.org.

9 The International Treaty on Plant Genetic Resources for Food and Agriculture was approved by the FAO Conference, at its thirty-first session (November 2001), through Resolution 3/2001. As of the date of this writing, the International Treaty had been signed by 78 countries and accepted (or ratified, approved or acceded to) by 14 countries (entry into force will require the ratification, approval, acceptance or accession by 40 countries). The text of the treaty is available at www.fao.org/legal.

10 The UNCCD was adopted in June 1994 and entered into force on 26 December, 1996. It has 186 contracting parties. The text of the Treaty and an explanatory guide prepared by the UNCCD Secretariat can be found at www.unccd.org.

11 WIPO/GRTKF/IC/4/8, paragraph 26.

12 WIPO/UNESCO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions, available at UNESCO's website, at www.unesco.org.

13 WIPO/GRTKF/IC/5/7, at paragraphs 6–10.
14 TRIPS Agreement, Article 25.2.
15 TRIPS Agreement, Article 10.1.
16 See e.g. Soma et al (1999) and Cohen and Lemley (2001).
17 Peru's Law No. 27,811 defines indigenous peoples as 'aboriginal peoples that existed prior to the formation of the Peruvian State, maintaining a culture of their own, occupying a specific territorial area and recognizing themselves as such' (Article 2(a)). The English version of Law No. 27,811, of Peru, as well as of the statutes on *sui generis* protection of TK of Brazil, Panama and Portugal, can be found in WIPO/GRTKF/IC/5/INF.2.
18 See Portuguese Decree-Law No. 118/2002, Article 3.1: 'Traditional knowledge is all the intangible elements associated to the commercial or industrial use of local varieties and other endogenous material developed by local communities, collectively or individually, in a non-systematic manner and that are inserted in the cultural and spiritual traditions of those communities'.
19 WIPO/GRTKF/IC/4/8, paragraph 27.
20 See Law No. 20, of 26 June, 2000, of Panama, Article 2. See Decree-Law 118/2002, of Portugal, Article 3.1.
21 Because of this crucial aspect, handicrafts that are being 'modernized' by some governments, eager to promote small and medium enterprises, through the introduction of modern designs or modern techniques of manufacture, may still be 'handicrafts' for some purposes, like tax law, customs tariffs and other financial incentives, but they are not TK as such.
22 'The structure of preliterate society renders conventional intellectual property protections ineffective. Typically, such cultures lack both written records and formal government. As a result, western-style patent and copyright laws, which require elaborate documentation and bureaucratic enforcement, are not feasible' (Suchman, 1989, p1272).
23 Actually, 'preliterate' societies are not the only social groups that have resorted to magic to establish some mechanism of appropriation of knowledge. Historically, before patent rights were made available to inventors, workers in the metallurgical industry would gather in secret societies; and so did the alchemists (Huygue and Bernard, 2000). In the absence of patent protection, and because, prior to the 19th century, protection of private trade secrets was not generally available, inventors would attempt to create some ritual protection around their technology, which would be accessible to those 'initiated' (that is, trustworthy) only.
24 In a remarkable book, Mark J. Plotkin describes several learning experiences with shamans in the Amazon rainforest (Plotkin, 1993).
25 Under Brazilian Provisional-Measure 2.186-16, protection is informal. Law No. 27,811 of Peru provides for registration, but rights can be enforced even in the absence of registration (Article 47(c)). In contrast, the laws of Panama, Portugal and Thailand make registration mandatory. In those three countries, therefore, unregistered TK is not enforceable.
26 Besides, 'old' does not necessarily mean 'in the public domain'. See note 39.
27 This chapter proposes the use of the word 'biosquatting' because it is more accurate than the word 'biopiracy'. The latter is generally used for qualifying the unwarranted private claiming of TK that could be deemed in the public domain as well as the unauthorized claiming of TK that is in control of indigenous peoples and local commu-

nities. But, unlike 'piracy', the first modality is not necessarily illegal – in many cases, actually, patent applicants benefit from a loophole or a particular feature in the law, such as the one that only accepts written disclosure of prior art for the purposes of patent novelty assessment. Such claims, which impinge on knowledge that otherwise would be in the public domain are similar to settling 'on public land in order to acquire title to the land', that is, squatting in the definition of the *Black's Law Dictionary* (1991). Squatting also means 'entering upon lands, not claiming in good faith the right to do so by virtue of any title of his own or by virtue of some agreement with another who [one] believes to hold the title' (ibid.), which corresponds to the misappropriation of TK that is in control of indigenous and local communities. This second meaning would be close to 'piracy', but not the first one. Besides, under international IP law, the word 'piracy' is linked to some practices of copyright infringement (TRIPS Agreement, footnote 14 to Article 51). Accordingly, the word 'cybersquatting' has been used to designate those cases of misappropriation of third parties' names and brands as domain names over the Internet. The term 'biosquatting' seems, therefore, more accurate to identify illegal or otherwise illegitimate IP practices related to genetic resources and associated TK.

28 Miller and Brewer (1992, p123) say that there exist three strategies for collecting plants for screening programmes: random, taxonomic and ethnobotanical. 'Random collecting is an attempt to sample as much taxonomic diversity as possible' (1992, p122). One limitation of random collecting 'is that it often yields samples that are often taxonomically biased by the geographical restriction of collecting' (ibid.). 'Taxonomic collecting is based on the general tendency ... for related taxa to contain related compounds' (ibid., p123). And ethnobotanical collecting consists of selecting the plants to be collected based on their use by traditional medicine (ibid., p123). The use of ethnobotanical data may be applied in the study of the use of plants in traditional medicine, followed by a testing of their effectiveness. It also may be used for random screening of plants 'used in traditional medicine on the assumption that they have a higher probability of yielding bioactive compounds' (ibid. p123).

29 Souté et al (1999) and Chabbert (2000).

30 WIPO (2001, pp186–187) (FFM to South America, Mission to Bolovia). See also Axt et al (1993, pp6–7), and Fernandes (2002, p14).

31 *Latin American Weekly Report* (2000, p316), and Cannell (1998). See also Fernandes (2002) on the economic prospects of exports of ayurvedic medicine.

32 On the application of the 'Coase theorem' as a primary rationale for the establishment of patent rights, see Carvalho (2002, pp20–22).

33 The relationship between the formalization of real estate belonging to poor communities and economic development is discussed in de Soto (2000).

34 WIPO/GRTKF/IC/4/8, paragraph 21.

35 Ibid., paragraphs 17 and 18.

36 The first alternative – obtaining trademark registrations not with the intent of putting them to a commercial use but of preventing others from acquiring rights in the registered signs – was the subject of information given by Canada to the Committee: in Canada, the Snuneymuxw First Nation has registered ten petroglyph with a special religious significance in order to stop the sale of commercial items, such as T-shirts, jewellery and postcards. The second alternative was followed in Colombia, New Zealand and the US. The Colombian Trademark Office has denied the registration of a trademark because it deemed that its use for commercial purposes would be offensive to the 'Tairona' culture (even if the 'Tairona' culture had already vanished). New Zealand

informed that a new Trade Marks Bill, currently being considered by Parliament, will if enacted allow the Commissioner of Trade Marks to refuse to register a trade mark where its use or registration would be likely to offend a significant section of the community, including Maori (WIPO/GRTKF/IC/5/7, Annex II). At the second session of the Committee, the delegation of the US informed that, 'on August 31, 2001 the USPTO began accepting requests for registration in the Database of Official Insignia of Native American Tribes. The Database would be included, for informational purposes, within the USPTO's database of material that was not registered but was searched to make determinations regarding the registrability of trademarks'. (WIPO/GRTKF/IC/2/16, paragraph 27).

37 35 U.S.C. 102.

38 Strasbourg Agreement Concerning the International Patent Classification (IPC), of 24 March, 1971, as amended on 28 September, 1979. The Strasbourg Agreement and the IPC Union are administered by WIPO. On the status of the development of special tools, under the IPC, that can apply to TK, see WIPO/GRTKF/IC/3/13.

39 This does not mean that disclosure will necessarily bar any kind of protection for TK. That is a matter of statutory definition. Portuguese Decree-Law No. 118/2002, for example, adopts a 'commercial novelty' concept, as opposed to a 'technical novelty' one (as Peru's Law 27,811 did).

40 Berne Convention (Article 2.5, referring to collections of literary or artistic works such as encyclopaedias and anthologies), the TRIPS Agreement (Article 10.2) and the WIPO Copyright Treaty (WCT), of 1996 (Article 5).

41 The EU is an exception. See Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases, 1996 O.J. (L77).

42 The following comments will focus on the intangible aspect of modified (domesticated or not) genetic resources, that is, on TK.

43 Article 8(j) provides:

Each Contracting Party shall, as far as possible and as appropriate: [...]

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practice of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices'. *(emphasis added)*

Article 15.7 of the CBD provides:

Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources *with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms'. (emphasis added)*

44 The anti-cancer properties of the rose periwinkle, from Madagascar, from which vinblastine and vincristine are produced, came as a surprise to researchers. Initially, the rose periwinkle called the attention because of its use by people in the Philippines and the Caribbean to lower blood sugar (Swerdlow, 2000). Another example can be found in Reissue Patent No. 18,667, which covered an extract of cube roots with vermifuge and insecticide properties. The inventor had learned about the active ingredient of that plant from observing Peruvian indigenous peoples using powder made of ground cube

roots for catching fish.

45 35 U.S.C. 282(2).

46 35 U.S.C. 121.

47 Patent offices generally do not examine the issue of inventorship, because their role is more a technical one, but some evidence is generally required that identifies those upon whom the law vests the patent rights (or their legitimate expectations).

48 Procurement fees are not referred to either in the TRIPS Agreement or in the Paris Convention, but they stem from customary administrative practices and are set as an obligation by the Patent Cooperation Treaty (PCT) (Articles 3(4)(iv) and 4(2), 39(1)) and its Regulations (see e.g. Rules 14, 15 and 16). The PCT and its Regulations are naturally concerned with fees due in the course of the international phase of patent applications. But Article 39(1)(a) of the PCT makes explicit reference to national fees. Article 1.1 of the TRIPS Agreement therefore, authorizes procurement fees ('Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice'). Maintenance fees, in contrast, are expressly mentioned by Article 5*bis* of the Paris Convention. Article 5*bis*(2) even obliges Paris Union Members 'to provide for the restoration of patents which have lapsed by reason of non-payment of fees', which, *a contrario*, means that Paris Union Members (as well as WTO members, in the light of Article 2.1 of the TRIPS Agreement) may indeed provide for the lapse of patents on grounds of non-payment of maintenance fees.

49 Carvalho (2002, pp159–160).

50 See *Moore* v *The Regents of the University of California*, 51 Cal. 3d 120 (Sup. Court of Cal., 1990), cert. denied, 499 U.S. 936 (1991) and *The Regents of the University of California* v *Synbiotics Corp.*, 849 F.Supp. 740 (S.D.C., 1994).

51 The Requirement has invariably been applied in the field of TK *stricto sensu* because, as it corresponds to the industrial property side of TK, the recognition of rights depends on a registration procedure. When it comes to expressions of TK, its protection being mostly informal, the granting of rights is not dependent on any formal requirement. Eventually, it would be possible to impose the Requirement as a condition of enforceability of rights in expressions of TK, as it has been previously suggested for TK *stricto sensu*.

52 The statutes of Brazil, the member states of the Andean Community of Nations (Bolivia, Colombia, Ecuador, Peru and Venezuela), Costa Rica, Egypt and India, make the Requirement a formal condition of patentability. In the People's Republic of China and the EC, the Requirement is imposed but not as a formal condition of patentability (in China, some administrative sanctions are applied; in the EC, the Requirement is the matter of a simple recommendation). Egypt, India, Peru and the EC have confined the Requirement to the field of patents. But the Andean Community, Brazil and Costa Rica have adopted legislation extending the Requirement to areas beyond patent law, such as plant breeders' rights and, where it applies, utility model protection.

53 The TRIPS provisions on substantive conditions of patentability are Article 27.1 and 70.8(b).

54 Article 29.1 of the TRIPS Agreement reads:
Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

55 Article 32 reads: 'An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available'.

56 Carvalho (2002, pp252–256). Section 66 of the Indian Patents Act, of 1970, reads:
Where the Central Government is of opinion that a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette and thereupon the patent shall be deemed to be revoked.
Section 66 was maintained by The Patents (Amendment) Act, 2002, of 25 June, 2002.

57 WT/DS50/R, paragraph 7.19.

58 This is evidence, as the Secretariat of WIPO has said, that patent law is not about protecting *inventors*, but about appropriating *inventions* (WIPO/GRTKF/IC/3/7, paragraph 34).

59 For that reason, the PCT establishes the identification of the applicant as one of the mandatory elements of the patent request (Article 4.1(iii)). Likewise, the draft Standard Patent Law Treaty (SPLT), in Article 4, says that the right to a patent shall belong to the inventor or to the successor in title of the inventor. The draft Substantive Patent Law Treaty (SPLT) is the subject matter of discussions in the WIPO Standing Committee on the Law of Patents, which held its eighth session 25–29 November, 2002. See, e.g. document SCP/8/2, of 16 October, 2002.

60 The conflict between the Requirement (as a condition of patentability) and the TRIPS Agreement was the subject of an exchange of views by WIPO Members at the Committee's third session. The US expressed the view that such a Requirement does not keep with the TRIPS Agreement (Report of the third session, document WIPO/GRTKF/IC/3/17, of 21 June, 2002, paragraph 71). The Dominican Republic (ibid., paragraph 70), Sri Lanka (ibid., paragraph 75), Egypt and Sudan (ibid., paragraph 76) expressed an opposed understanding.

61 As it will be explained below, it is actually CBD Contracting Parties that are under the obligation to respect international agreements on intellectual property, and not the other way around.

62 Under Article 27.1, WTO members may not restrict the Requirement to biotechnological inventions. It must be applicable in all fields of technology. Besides that, and under the principle established by Article 27.2 of the TRIPS Agreement, WTO members can apply the Requirement where genetic resources have been collected within national borders only. That is, members may not require evidence of legitimate access to genetic resources obtained in the territory of other members. The same territorial confinement of measures that restrain patent rights can be found in Article 31(f) of the TRIPS Agreement.

63 But nothing in the PCT and its regulations stands in the way of PCT members adopting additional formal requirements once the application enters the national phase. See, for example, 35 U.S.C. 371(c)(4), requesting an additional document containing an oath or declaration of the inventor (or other person authorized under chapter 11 of Title 35) complying with the requirements of section 115, once an international application enters the national phase in the US.

64 Additionally formal conditions of patentability, under the PLT, are that the contents of an application 'which correspond to the contents of the request of an international application under the Patent Cooperation Treaty be submitted under a special request form' (Article 6(2)); the payment of fees (Article 6(4)); evidence of priority (Article 6(5)); and the form and means of transmittal of communications (concerning the patent

application) to the Patent Offices (Article 8).

65 The UPOV Convention (1978) and the PCT were already in force when the CBD was negotiated and agreed, in 1992. The 1991 version of UPOV and the TRIPS Agreement, which was signed on 15 April, 1994, at Marrakesh, as an Annex of the Agreement Establishing the WTO, had their terms already negotiated.

66 The full version of this chapter discusses another requirement (the duty to disclose government funding under 35 U.S.C. 202). It concludes that, even if there are some similarities between the Requirement and the US duty of disclosure, the US is not in violation of its international obligations.

67 It should be noted, however, that under the CBD, the use of TK for scientific purposes also gives rise to an obligation of benefit sharing. Commercial gains, therefore, seem not necessary to trigger benefit sharing.

68 See Carvalho (2000, pp399–400).

69 An overview of recent cases on the inequitable conduct doctrine can be found in Dolak (2002).

70 Mexico noted that, because geographical indications, under Mexican law, belong to the government, the risk of certain indigenous individuals being excluded from their utilization was avoided. For this reason, geographical indications were seen as more appropriate than collective marks.

71 But some IP mechanisms are more adequate than others for protecting TK, because of the special nature of their respective subject matters. Geographical indications are one of those mechanisms. The reason for that is that most geographical indications are grounded on a certain reputation the establishment of which depends on traditional techniques (WIPO/GRTKF/IC/3/7, paragraph 40).

72 This information was extracted from WIPO/GRTKF/IC/5/7. This information concerns basically TK *stricto sensu*, as defined above. Factual information on national experiences in the use of intellectual property law for protecting expressions of TK can be found in WIPO/GRTKF/IC/3/10, of 25 March, 2002.

73 The full version of this chapter describes five statutes establishing *sui generis* regimes for the protection of TK (Brazil, Panama, Peru, Portugal and Thailand) and draws a brief comparison of those five statutes.

74 WIPO/GRTKF/IC/4/15, paragraph 136.

75 Treaty on Intellectual Property in Respect of Integrated Circuits (1989), adopted at Washington on 26 May, 1989.

76 TRIPS Agreement, Part II, Section 6.

77 An overview of the enactment of layout-design protection in the US can be found in McManis (1989).

78 The shaman's fable and the discussion that follows were originally addressed in Carvalho (1999, pp10–11), and was borrowed by WIPO/GRTKF/IC/3/8, 4/8, and 5/8, paragraphs 22 et seq., 38 et seq. and 64 and 65, respectively.

79 See in Plotkin (1993) a description of how rainforest shamans collect materials for their potions (pp200 et seq.).

80 Schultes and Raffaut (1992).

81 In certain cultures, the *pajé* is not seen as the healer, but as the instrument that conveys the healing from the gods to the patient.

82 As a matter of course, the word 'databases' does not necessarily refer to electronic databases: TK databases mean just collections of elements arranged in in an organized manner and/or in accordance with certain selection criteria. To that extent, existing

ethnobotanical or anthropological books describing medicinal plants and the uses certain communities give them are TK databases.

83 But there should be no need for maintaining a single sort of database as an instrument of entitlement. A certain indigenous community might wish to describe their medicinal, agricultural and other technical knowledge in separate inventories. Another community might prefer to describe the whole of its knowledge in a single document. A country might also decide to make a single, national TK database.

84 See Portugal's Decree-Law No. 118/2002, Article 3.2(b).

85 Protection of contents of databases under Article 39.3 is not dependent on their originality, however. The conditions for their protection are secrecy and substantial efforts in their collection. But the fact that those contents are secret implies that they are not publicly available – to some extent that amounts to originality.

86 The CBD has three objectives: the conservation of biological diversity; the sustainable use of biological diversity's components; and the fair and equitable sharing of benefits arising out of the utilization of genetic resources (Article 1).

87 Those provisions are Articles 10(c), 17.2 and 18.4. Actually, Article 8(j) does not even use the word 'protection'. Article 8(j) refers to 'respect', 'preservation' and 'maintenance'. None of these words implies a legal mechanism that permits the assertion of proprietary rights. Article 8(j) says also that measures should be taken to 'encourage the equitable sharing of benefits arising from the utilization of [TK]'. Sharing of benefits can be encouraged through bilateral agreements. A legal regime to implement Article 8(j) can be envisaged without the need for a system of proprietary rights: a simple right to remuneration would suffice.

88 Information about the International Undertaking and the negotiations for its review can be found on the FAO website, at www.fao.org/ag/cgrfa. Although overlapping as far as plant genetic resources that have an application in food and agriculture are concerned, the FAO Treaty and the CBD have different purposes: for the CBD, preservation of biodiversity is an *end*; for the FAO Treaty, agricultural diversity is a *means* to achieve food security.

89 Additionally, Part IV of the FAO Treaty establishes a Multilateral System (the 'MS') of access to plant genetic resources as well as of benefit sharing.

90 WIPO/GRTKF/IC/2/16, paragraph 15.

91 The UNCCD, like the CBD and the FAO Treaty, contains mere recommendations, because any measures are to be taken in accordance with national law and/or policy, and only 'as appropriate'. The reason for the CBD to ensure that national law shall prevail over its provisions was the wish of several negotiating Parties, in Rio de Janeiro, to preserve treaties negotiated with local tribes and subsequently enacted national legislation. Glowka et al (1994, p48).

92 For an explanation of Article 2 of the Paris Convention, see Bodenhausen (1991, pp27ff). For an explanation of the differences between the national treatment principle under the Paris Convention and the TRIPS Agreement, see Carvalho (2002, pp75ff).

93 The words 'nationals' and 'citizens' are not used here in their correct sense. The correct concept of 'nationals' is provided for by Articles 2 and 3 of the Paris Convention and footnote 1 of the TRIPS Agreement.

94 A parallel can be drawn with geographical indications, an IP mechanism that is almost exclusively dedicated to protecting TK. Under Article 24.9 of the TRIPS Agreement, WTO members have no obligation 'to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that

country'.

95 As under the Paris Convention, standards would be mandatory only to those countries that adopt protection at the national level. Under the Paris Convention, the provisions on compulsory licensing of patents (Article 5(A)) are mandatory only for those countries that have patent protection at the national level.

96 The Portuguese Decree-Law provides that the description of registered TK 'shall be made in a manner that allows for other persons to reproduce or use the traditional knowledge and obtain results that are identical to those obtained by the knowledge holder' (Article 3.2(b)). In other words, within some natural limitations, the description of registered TK must also be enabling.

97 CBD, Article 15.7:
with the aim of sharing in a fair and equitable way the results of research and development *and the benefits arising from the commercial* and other utilization *of genetic resources'*. (emphasis added)

98 Brazil's provisional Measure No. 2, 186-16, Article 8(III). Peru's Law No. 27,811, Article 4.

99 Panama's Law No. 20, Article 23.

100 Panama's Law No. 20, Article 15.

101 This aspect may be important for assessing the standing of the shaman: as a supplier of knowledge and materials, which were used just as leads for further research and development; or as an actual co-inventor.

102 Such TK should be registered or not, depending on whether the country in question would wish to make the registration of TK a constitutive or declaratory formality.

103 *Webster's College Dictionary* (1991).

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Chapter 19

Traditional Knowledge: Lessons from the Past, Lessons for the Future

Michael J. Balick

THE NATURE OF TRADITIONAL KNOWLEDGE AND ITS DEVOLUTION

Traditional knowledge, here considered as a body of information and set of skills developed by a group of people over time, is in a constant state of change. As each generation matures, skills perceived as immediately useful are gained while others with a lesser perception of immediate value may be lost. Thus the body of traditional knowledge is never static but rather dynamic in its shape and substance. In order to consider the 'preservation' of traditional knowledge, perhaps it would be useful first to explore the nature of this system, how it evolves over time, and to identify some of the forces involved in its destruction. This part of the current volume addresses the question of the composition of traditional knowledge and whether and how it might be protected.

Long ago, T. S. Eliot understood the task at hand; writing in *Tradition and the Individual Talent*, he noted that 'It [tradition] cannot be inherited, and if you want it you must obtain it by great labor'. In preparing this chapter, I have chosen to look at several site-specific examples, based on the notion that a study of the past may provide perspectives for the future.

In looking at the loss of information considered as traditional knowledge, Wolff and Medin (2001) suggested that 'with modernization, it may be that knowledge about living things has decreased, or as we say here, *devolved*'. The concept of devolution was derived from their study of undergraduate students at Northwestern University who were provided a list of 80 trees and asked to circle the species they 'had *heard* of before, regardless of whether they knew anything about them'. One result of the survey was that less than 50 per cent of the students recognized a group of trees that were frequently found in the area of their university, including alder, buckeye, catalpa, hawthorn, larch and others. The results were suggested to support the devolution hypothesis that linked modernization directly with loss of knowledge about living things. They suggested that this could be offset via 'cultural support', or, 'sufficient amounts of indirect experience with the natural world, through a culture's media, talk and values … the degree to which a society promotes a particular area of knowledge'. For example, adults can teach children about living things, and thus help offset devolution as it relates to knowledge about the natural world and its components.

The extinction of language is an excellent example of devolution, as related to cultural knowledge. Nettle and Romaine (2000) reported that of the 6600 languages spoken today, fewer than 9 per cent, or 600 have enough speakers to ensure their continuity into the next century. This loss of language includes 90 per cent of the 250 Aboriginal languages in Australia near extinction, with only 18 having at least 500 speakers each. The authors also point out that 'no young children are learning any of the nearly 100 native languages spoken in what is now the state of California'.

Concern for the loss of traditional knowledge is the driving force behind many of the ethnobotanical and culture-related projects now underway throughout the world. Workers in the ethno-sciences are collecting data, specimens and craft objects, and using modern technology to catalogue and study this information. In the realm of ethnobotany, this work is sometimes referred to as 'salvage ethnobotany', along the lines of the 'salvage botany' efforts that have been carried out for many years in endangered habitats of the tropics. These projects, for the most part, employ scientifically or technologically based approaches to recording information as their primary vehicle for the preservation of information. As I will discuss later in this paper, the scientific paradigm may be effective in documentation of information and data collection, but not as useful with regard to long-term preservation of the actual knowledge.

THE MICRONESIA ETHNOBOTANY PROJECT

In an attempt to quantify the rate of loss (or change) of information about traditional activities on Pohnpei, an island in the Federated States of Micronesia, Lee et al (2001) studied what they referred to as 'cultural dynamism and change'. For example, with the trade in different species and varieties of food plants between islands in Micronesia, *Alocasia macrorrhiza*, an edible taro that was once a pre-eminent food source, has been replaced by other taro species such as *Colocasia esculenta* and *Cyrtosperma chamissonis*. These latter introductions are considered more palatable, and thus more desirable, and as a consequence of their adoption as a major food crop, it is likely that the cultural knowledge associated with *Alocasia macrorrhiza* has diminished, even become extinct.

As part of the effort known as the Micronesia Ethnobotany Project, a great deal of formal and informal dialogue on the loss of cultural knowledge was held with traditional leaders and ordinary people on Pohnpei. Some of the results will be discussed further in this chapter. Lee et al (2001) reported that:

> *The traditional leaders we spoke to in Micronesia were concerned with a related, but qualitatively and quantitatively different phenomenon. Instead of their culture changing and evolving at a relatively slow 'background' rate, over the last two generations a large percentage of traditions and skills specific to Micronesia have not been passed on, and will become extinct if an active program is not put into place to keep them an active part of local life.*
>
> (Lee et al 2001, p9)

During an annual course on ethnobotanical techniques offered at the College of Micronesia (COM) in Pohnpei in 1999, we carried out an informal survey amongst the students. This involved a series of questions regarding how many students remembered seeing their grandparents and parents making canoes, and how many of the students had ever made a canoe. The results were extraordinary but not all that unexpected – not a single person on the course had experience in canoe making. One year later, during the next course we carried out a more formal survey about generational knowledge covering various components of Micronesian life: planting taro; using plants to stun and capture fish; fermenting breadfruit as a method to preserve it as a famine food; using marine plants as turtle bait; and constructing outrigger canoes. The results, presented in Lee et al (2001) (Figure 19.1) showed the predicted loss of information between generations on this island. In addition, this paper developed a linear regression for the survey results from each set of traditional knowledge (Figure 19.2) and made a series of very tentative predictions about the

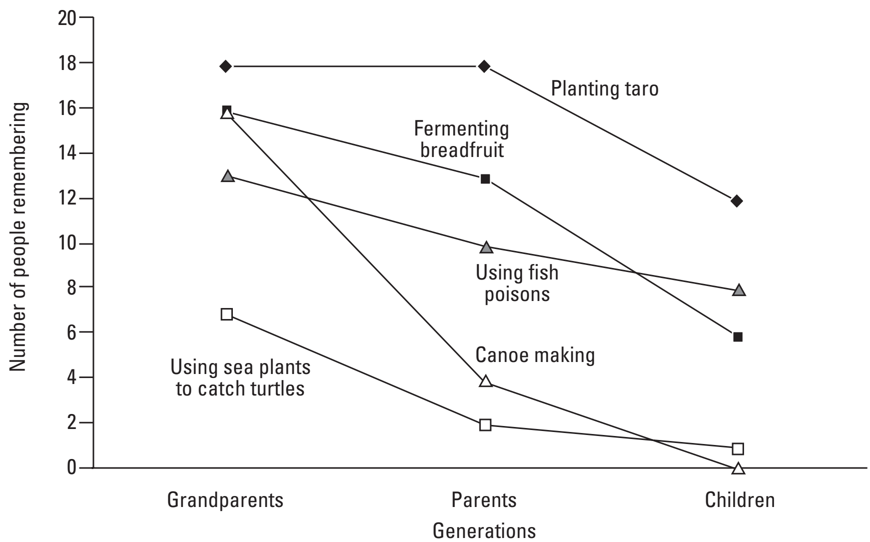
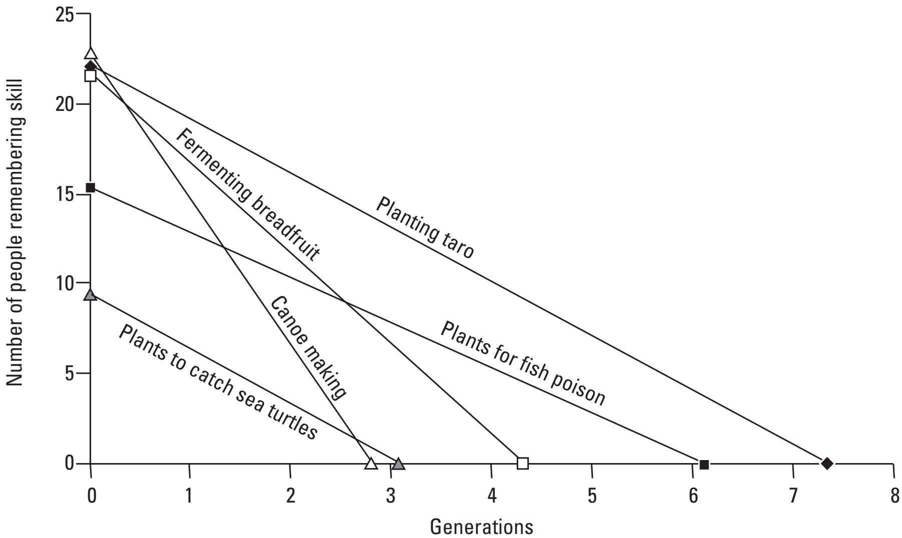


Figure 19.1 *Erosion of traditional knowledge on Pohnpei, FSM*



Generation 3 was the current group of students in the COM ethnobotany class.

Figure 19.2 *Predicted extinctions of traditional knowledge*

time (expressed in generations) that each of these skill sets might become extinct. This regression showed that the traditional knowledge involving canoe making and turtle catching were at greatest risk of extinction, predicted to disappear in the generation represented by the college students.

Because the small and biased (e.g. limited to a college class) sample yielded such tentative results, the following year we carried out a survey of traditional knowledge in Pohnpei, involving an instrument that contained 72 questions, in Pohnpean, administered by Pohnpeans, with a sample size of 160 people, approximately 0.5 per cent of the entire island's population. This survey included a significant focus on canoe making, patterns of sakau (*Piper methysticum*) consumption and quality of life questions. The results from this survey are currently being prepared for publication, and are consistent with the conclusions of the preliminary surveys – it is clear that there is a rapid rate of loss of traditional knowledge about canoe making, along with other skills on Pohnpei. Through their quantitative approach, these studies have also demonstrated that some skills and knowledge are more vulnerable than others, thus offering the possibility that priorities could be developed and evaluated for possible remediation of this loss, based on the rate at which the skill is being lost as well as its importance.

STUDYING TRADITIONAL HEALING IN BELIZE

From 1988 to the present, a group of traditional healers and conservationists in Belize has worked with the New York Botanical Garden on a project to inventory and catalogue the flora and ethnobotanical knowledge of that country. The objectives of the project include the preservation of cultural and traditional knowledge, natural products research through the National Cancer Institute, technology transfer, institutional development and training. The scope and flow of activities are illustrated in Figure 19.3, evolving from the establishment of an ethnobotanical inventory programme. Collaborators have included eight governmental and non-governmental organizations in Belize, with over 120 individuals active in the project. The most significant printed results of the project have been the production of a primary health care manual, a checklist of the flora of Belize, and a forthcoming encyclopedic treatment of the useful plants. From the standpoint of traditional knowledge, one of the most important results has been the establishment of an association of traditional healers, allowing the development of a community of individuals dedicated to this practice. During fieldwork, over 8000 plant specimens were collected, representing nearly 20 per cent of the holdings of the Forestry Department Herbarium in Belmopan, the capital of Belize. The project also promoted conservation of biodiversity, through various local initiatives including the establishment of an ethnobiomedical forest reserve, public displays, post-secondary classes, youth camps, school competitions, field trips and guest lectures. I will touch on some of the lessons learned during this project in this paper.

FACTORS CONTRIBUTING TO DEVOLUTION

Based on experience derived from several projects in various regions over the past two decades, we can identify some of the reasons for the loss of traditional knowledge, and the constraints to addressing this devolution. Modernization is probably one of the foremost issues involved in changing the focus of people's educational endeavours. Emerging generations in many locations around the world now have new career trajectories, based on opportunities derived from modernization and globalization that are the result of the information age. This modernization has been accompanied by the inability of people, particularly the young, to recognize value in traditional ways, as related to their daily lives. In many cases there do not seem to be perceived economic returns from engaging in traditional activities. For example, in the early 1990s, I was in a taxi in Belize, and the driver, a young man in his 20s asked the purpose of my visit. When I replied that I was a student of bush medicine, he enthusiastically launched into a monologue, laden with sentiment, about how his grandfather was a great bush doctor, who knew all of the uses of the plants in the forest, and would treat ill members of the family with great success. His father, the young man explained, knew much about the forest, and the uses of plants, but was not as skilled as his grandfather. The taxi driver himself had no interest in the forest, plants or traditional healing when he was growing up, and did not accompany either his grandfather or father in the forest when they went about their work. His goal, instead, was to have a vehicle, and a modern life filled with the most modern music, culture and food. Thus, as a result, at the point that his dream had been fulfilled, he felt trapped within it, as there were no longer options to learn family wisdom as both his grandfather and father had died without passing along their knowledge to family members. All too often, this is the case, and by the time young people begin to develop a passion for their roots, it can be too late.

In many places, the diffusion of the family as a unit has tended to reduce interest in traditional activities. As Hezel (2001) has pointed out in Micronesia, these changes have resulted in a complete reshaping of daily life in this region. On the island of Guam, the erosion of traditional culture has been linked to a rise in youth gang membership and criminal activity. Schmitz and Christopher (1997) noted that

> *within Micronesian cultures, family kinship, community cohesion, folk knowledge, and religious pageantry have long shaped the cultural life of the community. Courtesy, respect, deference to elders, cooperation, and community hospitality are cultural virtues. Traditional society hinges on family cohesion and community consciousness.*
>
> (Schmitz and Christopher, 1997)

In recent times, the ideology of modern Western society, individualism, leaves a vacuum in the lives of peoples accustomed to living as a community, and thus Schmitz and Christopher concluded:

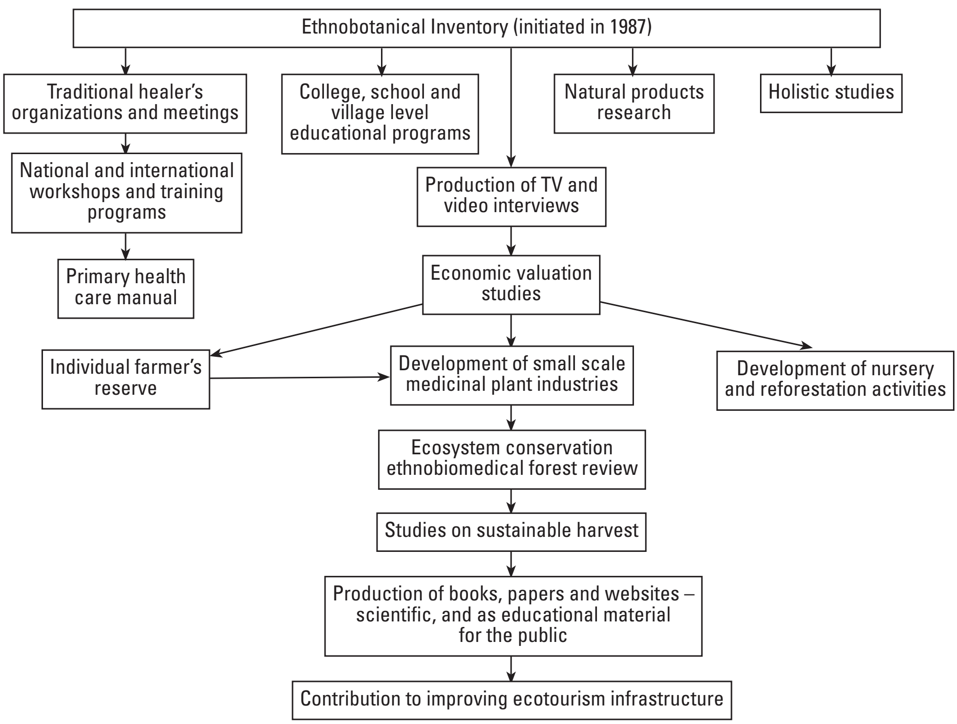


Figure 19.3 *Chart of activities that developed as part of the Belize Ethnobotany Project*

> *gang membership provides a perceived solution to disintegrating traditionalism and the unattractiveness, or unattainability, of modernism. Gang members ascribe to a moral vision based on traditional tribal warrior values.*
>
> (Schmitz and Christopher, 1997)

In many locations, the introduction of television has become a substitute for family and village storytelling and conversations during which traditional knowledge was formerly transmitted. In the early 1980s I worked with the Apinaje Indians of Northeastern Brazil, on a project involving the use of the babassu palm as an economic crop (Balick, 1988). We chose to go to these people because of their vast knowledge of the babassu, known as the tree of life in this region. The community would go into the forest surrounding their village at least 3 days a week, collecting babassu, Brazil nuts and jaborandi, the source of a leaf made into a pharmaceutical medication for glaucoma. As people sat in the forest and cracked the nuts, they would tell stories, transmit community information and gossip, and teach the younger members of the group about traditional life. This informal training would last for many hours during collection days, and continue around the fire at night. I was able to record stories, lore, songs and other information through my presence in the collection activity. Ten years later, in 1993, I returned for a brief visit to these people, to see how they had progressed now that a railway and highway were constructed near the reserve. Upon entering the village, the most striking new addition was the parabolic antenna, constructed next to the main communal palm thatched house. Inside, nearly all of the village's children were seated, facing a colour television, watching a blond haired, blue-eyed entertainer based in Rio dance and sing along with her audience of children. There were many complaints from the village leaders about the lack of interest in traditional values and activities now that television had arrived. The major role model for the children had become a series of television shows, rather than the traditional leaders.

There is also the fear that traditional knowledge will be used to the advantage of groups outside the culture, perhaps as a new drug or food plant, and thus there is often hesitation to collaborate on projects that might yield benefit to the community as far as preservation of knowledge is concerned. Over the past decade or two, this fear has been exacerbated by outside forces whose stated objectives are to protect, guide and council indigenous groups in order that they not be taken advantage of. While much of this guidance has been very useful in shaping local perspectives on the appropriate nature of the partnership and collaboration with outsiders, other efforts have resulted in the complete disenfranchisement of the cultures from potential opportunities that could rekindle interest in traditional knowledge and activities.

Finally, there is often the lack of a structure or support system for traditional knowledge and the activities related to its maintenance. For example, in many areas, people skilled in traditional activities cannot become part of a larger community of those with similar interests, nor are they supported by governmental or educational institutions. Prior to the development of the Belize Association of Traditional Healers and the Traditional Healers Foundation, people in Belize who were skilled in this aspect of their culture acted alone as individuals. They were belittled by their families and friends, criticized by local educational and religious institutions, and in the most severe cases, persecuted by the law. Once a community had been established, with standards for membership, and seminars and workshops developed, more and more prestige was given to this group of elders in Belizean society. Through a series of television shows, educational videos distributed to the schools, and related activities, children in Belize now accept the fact that traditional knowledge about medicinal plants is an important subject to learn, and there is presently much greater interest shown in ethnomedicine than ever before.

One way of strengthening the position of the traditional healer employed in the Belize project has been to consider these people as colleagues and teachers, rather than as informants. The more traditional way of giving healers an unknown identity can be an insult to them, as in most cases it is their knowledge or intellectual property that guided the research (H. O'Brien, pers. comm.). By including traditional healers who provided information for research as co-authors or providing acknowledgement using their names, all parties benefit.

An example of this is to be found in Glinski et al (1995), a pharmacological research project. After discussing the interest in identifying bioactive compounds with Belizean healer Don Elijio Panti, he suggested a group of plants for testing in various screens by the Glinski lab. One of these, *Psychotria acuminata*, was subsequently identified as a source of phenophorbide a, a green pigment that inactivates cell surface receptors. According to the resulting publication, 'our investigations suggest that the inactivation of cell surface receptors contributes not only to the antitumor effect of PDT [photodynamic therapy], but also to the systematic immunosuppression, a serious side effect of PDT'. It was found that an extract of this plant inhibited cytokinine and monoclonal antibody binding to cell surfaces, and this was attributed to the presence of phenophorbide a and pryophenophorbide a. This discovery was a contribution to the corpus of scientific information about natural products chemistry and bioactivity, but not relevant to the development of a new drug. Importantly, Don Elijio Panti was a co-author of this paper, published in *Photochemistry and Photobiology*, acknowledging, in the judgement of the research team and reviewers, that his discovery and utilization of the plant for many decades constituted a crucial and significant intellectual contribution to this paper. This is a standard that we, and increasingly more of our scientific colleagues, have attempted to adhere to in our ethnobotanical studies. Authorship of this paper was one of the achievements of which Don Elijio was quite proud, and the reprint was predominantly displayed on the wall of his home for many years. It was also extremely useful in dispelling the gossip from the teachers and religious leaders of the village that because this man believed in the Maya spirits, and practised ancient medicine, he was not deserving of people's respect. After collaborating with us for over a decade, he passed away in 1996, at the age of 103. Today, Don Elijio's house is a small museum and shrine to this master of traditional knowledge, and younger people in the village now practise Maya healing.

MOVING FORWARD AND LETTING GO

In the realm of traditional knowledge, what are the parameters for deciding what skills and data survive and what goes extinct? Who makes this decision and what should it be based upon? Perhaps it would be useful to disengage this part of the discussion from the legal issues of intellectual property rights, and learn from traditional perspectives. In 1999, I recorded a conversation with Ashok Ripoche, a Tibetan monk who came to the US as an emissary of the Dali Lama. He is the Director of the main library at Dharamsala, India and had recently been charged with a project to introduce Western science to Tibetan students, via the translation of significant textbooks and references. His group chose to concentrate on physics first, and biology second. We posed the question as to how a culture such as his can survive in the presence of another, more powerful culture that surrounds it. He replied:

> *Tibetan culture will never be the same as it used to be before. It is always changing… It will never be the same culture after 10 years, after 15, or 20 years … sometimes of course I am disturbed, but sometimes we know that this is a phenomenon. It will never be the same, it keeps changing, look at history ... and then whether we have any authority or the power to control the change or not – do we have it or not? Sometimes we think, yes we have some power or some control. And sometimes we find that there is no control. But if we could give some greater contribution – even though we know that it keeps changing – that includes the change of the culture from one point to the next … we can give a greater influence and the change will turn into favorable ways. And that way, maybe we can say we are preserving our culture… In many cases we have to say goodbye [to the past] but in many ways we have to cling on, hang on, and say, we give a good contribution so that the change will turn into a favorable way … the cultural aspect keeps changing in one form to another. Sometimes we see a loss. Another time we don't see a loss, we see an improvement, so we don't know exactly what's really improved and what's really lost – this is really difficult to see … before changing or losing whatever it is, we have to learn what it is – the heritage… At least we should have gotten the message from it, and then let it go. We cannot keep it.*

Ashok Ripoche then recounted the story of coming to Dharamsala in 1959, and having a greater respect at that time for Western medicine as compared with traditional Tibetan medicine, which he and others considered primitive. Gradually, however, he learned via the interest that Western physicians showed in traditional Tibetan medicine that the latter had value, and 40 years later now feels 'more comfortable taking a Tibetan pill everyday, rather than a Western chemical medicine'. His overall sense of the issue involved in the devolution of traditional knowledge was that people had to decide, on their own, or with outside help what subset of traditional knowledge to leave behind and what subset to move forward.

Back in Pohnpei, following the implementation of the various surveys, a group of Pohnpean elders and young people involved in the Micronesia Ethnobotany Project met to offer their perspectives on the importance of traditional information, includ-

Table 19.1 *Traditional skills on Pohnpei and their levels of importance**

1 Very important skills
- Wiahda ihmw en Pohnpei (making local house)
- Wiepen sapwasapw (traditional farming system)
- Wiahda wahr (making canoe)
- Wiahda koal (making grass skirt)
- Wiahda likoutei sang kilin mahi-likoumeimei (making breadfruit bark skirt)
- Preparing local medicine from native plants
- Pahda kahdeng sang ahlek (weaving curtain from ahlek plant)
- Pahda lirou ohng mehn didih ihmw (weaving lirau plant to be used in house construction)
- Wiahda pweten lihli (making local basket from coconut leaf for the preparation of uhmw en lihli [type of traditional breadfruit paste])
- Wiada kisin pwehl (making local rope from coconut husk)
- Wiahda kopwou sang idahnwel (weaving basket from idahnwel plant)
- Wiahda litopw sang wahn ahis oh pwehl (making local paint from the ahis tree and soil)
- Wiahda kopwou sang tehn nih (making basket or local purse from coconut leaf)
- Wiadha uhk en laid sang dipenihd (making fishing net from coconut husk)

2 Important skills
- Wiahda lohs sang mwatal (weaving mat from the mwatal plant)
- Wiahda pwili ohng wie mar (making the seashell for traditional preparation of mahr [breadfruit])
- Wiahda padil sang kolou (making paddle from hibiscus)
- Wiahda kpennok sang dipenihd (making broom from coconut husk)
- Wiahda kilahs en du sang tuken Pohnpei (making diving/fishing goggles from native trees)

3 Not as important skills
- Wiahda spoon sang poundal (making spoon and fork from coconut shell)
- Charcoal sang pohndal (making charcoal from coconut shell)
- Wiahda lisoarop sang deipw (making local hat from pandanus)
- Waiahda mehn limalim sang kelou (making canoe bailer scoop from hibiscus)

* This list was prepared by Pelihter Raynor, Ally Raynor, Robert Gallen, Elpiana Amor and Mark Kostka following discussions with various people in Pohnpei.

ing the development of a prioritized list of traditional skills (Table 19.1). It is interesting to note that many of the skills categorized as most important involve the construction of traditional structures such as houses and canoes, as well as the production of traditional dress, knowledge of traditional healing and fishing skills. Least important skills included items that were already made obsolete by the availability of inexpensive plastic and nylon substitutes on the island – spoons and forks, hats, and canoe bailers.

This series of exercises, including formal and informal surveys and grass-roots conversations and meetings, has helped Pohnpei to begin to set its priorities regarding the conservation of traditional knowledge. On other islands that are lacking in traditional leadership and interest, such knowledge is disappearing much more rapidly, a topic of concern that has been addressed by several recent conferences of Micronesian traditional leaders over the past few years.

Another factor often associated with traditional knowledge – particularly that concerning healing and medicinal plants – is the power that comes with its possession. In many cultures, including Western cultures, a person who can influence a person's health, whether by offering therapies or ameliorating the perceived cause of the condition holds respect and thus power in the community. Amongst certain practitioners of Ayurvedic medicine that I observed in Sri Lanka, the concern was that the source of their influence and power to heal depended on a series of secret cures that they possessed. Furthermore, if these were to be taught to their students, then the teacher would lose his/her power, become ineffective at their profession, thus they could no longer practise. In this type of setting, certain therapeutic regimens are expected, even obligated to become extinct following the death of the practitioner. In other systems and areas, this secret information is considered to be family or clan property, and is not taught outside of the group, but passed on to the younger generation as a valued inheritance. However, despite the expectation that family information will be preserved by the next generation, in many locations at present, there is often a lack of interest in carrying on the elder's work in healing, resulting in greater rates of disappearance of this type of information.

RETHINKING STRATEGIES FOR PROTECTING TRADITIONAL KNOWLEDGE IN ETHNOMEDICINE

In thinking about how best to 'protect' traditional knowledge, it might be useful to examine the qualities of traditional knowledge that make it somewhat unique. Each of our disciplines looks at this topic through its own set of lenses, which can offer different vistas of the same image. In many cases, projects to protect knowledge have involved significant components that involve documentation. Many of these projects are based in part in academic settings, and an important requirement for funding natural and social science research projects is the use of the scientific method, where hypotheses are put forward and tested as a major component of the project. These hypotheses involve data gathering, then imply that the activity or knowledge can be reduced to a discrete collection of data points, gathered by the scientists or assistants. Once entered into the database, it can be analysed, evaluated and preserved, and publications and websites produced. This is the operating model for much ethnobotanical work, where hypotheses are proposed, use information is gathered based on interviews and observations, and results are evaluated. This reductionist viewpoint assumes that, using modern scientific tools, a collection of individual pieces of data can be reconfigured into a reconstruction, and therefore an understanding of the whole.

As an object of scientific study, perhaps ethnomedical systems are equally, or even more complicated than, say, the remarkably diverse puzzle that is the DNA of a fruit fly. If so, other models of analysis need to be developed that involve a more holistic understanding of the system, rather than one that seeks to reduce it to a collection of parts. For example, when a healer treats a patient complaining of lower back pain, the observing ethnobotanists' response is usually to collect the plant being used, identify it and assign it to a use category, and write a few words about the preparation of the medication. Then it is entered into a database, and, with increasing frequency, the process of collection or even treatment may be filmed.

However, from a medical viewpoint, lower back pain is a symptom of many different conditions. First, it must be categorized as either acute, mechanical lower back pain, as with a lumbar strain, degenerative disc disease or fracture; non-mechanical lower back pain, as with a neoplasia, infection or inflammatory arthritis; or, lower back pain with neurologic signs, such as a herniated disc. A patient history is called for and the patient is asked how motion, posture and rest affect the pain, whether there is fever, weight loss or rash, and whether the presence of visceral disease – vascular, gastro-intestinal or kidney – is evident. The physician has a wide range of possible diagnoses to contend with including lumbar strain, spondylosis, fractures, congenital diseases, facet joint asymmetry, neoplasm, infection, renal diseases, infection, aortic aneurysm, pancreatitis, cholecystitis, penetrating ulcer and prostatitis to name a few. A plant that might be used for 'cough' might actually be used to treat seasonal allergies, upper respiratory illness, gastroesophageal reflux, lung cancer, tuberculosis, asthma or chronic obstructive lung disease (R. Lee, pers. comm.). The physician has a lot more at stake than the ethnobotanist – after all, the outcome of a poor ethnobotanical interview is at most the eventual rejection of a manuscript, while in medicine, it may be the loss of the patient! What, then, is the best way to preserve this practice?

This is not to argue against the value of ethnobotanical inventories. In the same way that in many regions of the Earth there exist no inventories of the native and introduced biodiversity, the case is also the same for an ethnobotanical understanding of the area and its people. Just as a checklist of the plants and animals of the regions is a tool for conservation and preservation – not an actual conservation unit in and of itself – an ethnobotanical inventory is also a tool, not an endpoint for preservation of traditional knowledge. Additional actions are required. It would seem appropriately humble, in the case of the preservation of traditional knowledge, to admit that an effective, science-based methodology for ensuring its indefinite preservation does not yet exist. In essence, a study involving the documentation of traditional knowledge or skills is a snapshot in time, freezing our concept of its framework, technologies and use of raw materials. It could be argued that, due to the way in which the body of traditional knowledge is formed – constant experimentation and change, as well as its complexity, the snapshot approach can never be effective in achieving the goal of preservation. For example, under the paradigm utilized by many ethnomedical systems, patients seen by a traditional healer are treated individually and often with different modalities or plant species, even though their conditions might be the same. In many cases, our present efforts comprise little more than producing a list of ingredients that bears little resemblance to the actual product. Each of the modern collection techniques has a place in capturing bits of data, and some of that cache may be appropriate to direct other scientific research, such as in pharmacology and drug discovery, and thus give it immediate value to Western society. From our perspective, we are often interested in saving what we need, and there is certainly benefit to this. It is clear, however, that the most effective way of saving traditional knowledge as a dynamic, living and vital system is to keep it in practice – to encourage its practitioners, to give economic and other importance to its end products, to incorporate its teaching into formal and informal curricula, and to incorporate its ethical values into everyday lives.

How can a scientist contribute to this goal? Perhaps it is time to dissect ethnobotanical methodologies, and see where strengths and weaknesses are found. At a superficial level, greater emphasis needs to be put on data capture using the most modern available tools – including digital videos. We have made films in Belize that chronicle traditional knowledge and beliefs of bush doctors, and these films continue to inspire young people who view them, long after the elders have passed on. Books in local languages, geared to primary health concerns are extremely important contributions and, again, help keep family lore alive. The creation of a cadre of local ethnobotanists is an extremely worthy goal. Outside scientists have the responsibility of being role models to people they interact with. This can include teaching people to gather data and appreciate the values found in their communities. Local institutions need to be supported as well, and initiated if they do not yet exist. Academic research projects should always leave something behind that has a perceived value to the community. Prior to the initiation of a project, thorough discussions with the community must be held, mutual expectations established and risks and benefits outlined.

In the arena of benefit sharing, there is a great deal of room for developing innovative strategies that go beyond what is considered the gold standard – a royalty sharing provision in the contract, along with up front benefits. Others write about about these mechanisms in this book, so I will not dwell on this topic. Cox (2001) outlines a novel benefit sharing programme that has resulted from his work with an antiviral phorbal isolated from *Homalanthus nutans* in Samoa. Prior to the production of a commercial compound from the plant, there has been over $480,000 supplied to the village of Falealupo, the home of the two traditional healers who taught Cox the use of the plant, as part of what he refers to as the 'Falealupo Covenant'. If a drug is to be developed from the plant extract, the government of Samoa will receive 12.5 per cent of the net profits of the Aids Research Alliance, with 6.7 per cent going to Falealupo village, and 0.4 per cent going to each of the families of the two healers.

Another unusual benefit sharing programme, resulting from the previously discussed ethnobotanical work in Belize, was derived from the publication and sale of a primary health care manual, *Rainforest Remedies: 100 Healing Herbs of Belize* (Arvigo and Balick, 1993). As outlined in Johnston (1998), a pension programme was devised for the 11 traditional healers that contributed knowledge to the book. Proceeds from the sale of the book are distributed twice per year to the healers – in July and December – through the Traditional Healers Foundation. As of early 2000, the total distributed was over US$20,000. The publisher, Lotus Press, also has contributed a portion of its profits from the sale of the book to the Traditional Healers Foundation.

The book has been adopted as a primary health care reference by many people in Belize.

However, as the example of Don Elijio Panti given previously shows, there is much more to benefit sharing than monetary value. The concept of cultural support, expressed by Wolff and Medin (2001) and discussed earlier in this chapter, becomes a very important part of benefit sharing. It is not limited by the financial resources of the investigator, but rather only by their level of cultural sensitivity, understanding and desire to make a difference.

Finally, I would like to offer an unusual example of how traditional knowledge is being saved – through export to other regions – as people immigrate to new islands, countries and continents. Most traditional cultures around the world have diseases or illnesses that are specific to their culture or region. Patients with these conditions seek treatments that are often traditional in their origins, but when symptoms become severe, also present at emergency rooms or to physicians in clinics. Such culture-bound diseases have received a great deal of attention, particularly in the field of psychiatry. The *DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders* published by the American Psychiatric Association (2002) contains an appendix, 'Outline for Cultural Formulation and Glossary of Culture-Bound Syndromes' on this topic. This document suggests that '[t]he term culture-bound syndrome denotes recurrent, locality-specific patterns of aberrant behavior and troubling experience that may or may not be linked to a particular DSM-IV diagnostic category'. It further suggests that:

> *many of these patterns are indigenously considered to be 'illnesses' or at least afflictions and most have local names. Although presentations conforming to the major DSM-IV categories can be found throughout the world, the particular symptoms, course and social responses are very often influenced by local cultural factors. In contrast, culture-bound syndromes are generally limited to specific societies or culture areas and are localized, folk, diagnostic categories that frame coherent meanings for certain repetitive, patterned and troubling sets of experiences and observations. There is seldom a one-to-one equivalence of any culture-bound syndrome with a DSM diagnostic entity.*
>
> (American Psychiatric Association, 2002, p898)

The manual lists 25 culture-bound syndromes, including *hwa-byung* from Korea, *koro* from South and East Asia, *locura* from Latin America, *mal de ojo* from Mediterranean cultures, *shenkui* from China and *taijin kyofusho* from Japan. Hwa-byung, describes a Korean 'anger syndrome' and includes symptoms such as panic, dysphoric effect and indigestion. *Locura*, refers to a severe form of chronic psychosis in which patients will exhibit incoherence, agitation and sometimes auditory and/or visual hallucinations. *Mal de oj*, or 'evil eye' in English, is a Mediterranean condition in which children are most vulnerable. It presents with symptoms of crying without apparent cause, insomnia, diarrhoea and/or vomiting.

It is interesting that the American Psychiatric Association has recognized the traditional disease concepts that characterize different cultures as a significant problem in contemporary Western society. Our work on urban ethnobotany in New York City has included much experience with traditional healers in the Dominican community, centred in Washington Heights. Thousands of miles away from their island homes, Dominican traditional healers are practising their trade, and providing an effective, parallel system of health care in the heart of the allopathic medical community. Ethnomedical systems continue to be carried out, and elders are teaching the younger generation. Stores such as *botanicas* are well stocked with plants that are collected in the Dominican Republic and sent to New York City, or grown in local farms on the east coast of the US. Far from being destroyed by the Dominican governmental programmes of past decades that minimized the value of traditional Dominican medicine, it is alive and well, both in the diaspora and at home. The same scenario is true for any number of ethnomedical systems of the multitude of cultures that flourish in the US and elsewhere in the world outside of their origins, a sort of 'reverse globalization' of which cultures can take great pride.

There are many actions that could contribute to the preservation of traditional knowledge, from a broad variety of disciplines. So far, top-down international mechanisms have been relatively ineffective. Grass-roots efforts seem to be working in some locations. Attempts aimed at preservation of traditional knowledge are constrained by the lack of significant funding, and the lack of agencies and institutions responsible for supporting this activity. The general nature of funding – for example short-term grants that need to be renewed every few years and contain an innovative 'twist' each time they are resubmitted for consideration – does not lend itself to addressing this problem. It is time for a sincere global commitment to the preservation of traditional knowledge, one that does not get caught up in layers of bio-political bureaucracy. Scientists must rethink how, if at all, their studies and other activities can contribute to keeping traditional practices alive. It is time to enlarge the group of disciplines typically involved in this topic, and identify new ways of approaching an age-old problem that is getting worse with time.

Traditional knowledge is rich in content and heritage, and an important legacy of those who have created it. We must also consider traditional knowledge the foundation on which to practise one's cultural belief system, and thus a basic human right – analogous to religious freedom – deserving of preservation and protection against the contemporary forces that seek to destroy it in so many parts of the world, as well as in our own backyards.

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Chapter 20

The Demise of 'Common Heritage' and Protection for Traditional Agricultural Knowledge

Stephen B. Brush

Until the end of the last century, crop genetic resources were managed as public domain goods according to a set of practices loosely labelled as 'common heritage'. The rise of intellectual property for plants, the commercialization of seed, increasing use of genetic resources in crop breeding, and declining availability of crop genetic resources have contributed to extensive revisions to the common heritage regime. Changes include specifying national ownership of genetic resources and the use of bioprospecting contracts in the movement of those resources between countries. The question addressed here is whether protection of traditional agricultural knowledge related to crop genetic resources is best accomplished through a form of bioprospecting that replaces common pool management by private ownership.

Vavilov Centers designate the geographic regions where a particular crop was domesticated and initially evolved under cultivation. Although the idea of 'centre' has been debated (e.g. Harlan, 1992) and crop centres are periodically redefined according to new data, the current consensus among crop scientists is that cradle areas of crop domestication are identifiable and reasonably well known. While genetic resources are found in all farming systems, they are particularly valuable and abundant in Vavilov Centers, and concern for conservation and protection of traditional knowledge associated with these resources appropriately focuses on these centres. Moreover, Vavilov Centers are critical repositories of genetic resources for the world's crops because of their role in ongoing processes of crop evolution, due to gene flow between wild relatives and cultivated types and decentralized selection by farmers.

Just as uneven distribution of genetic diversity suggests centres of crop domestication, so too does it evidence a diffusion of resources derived from Vavilov Centers accruing to the benefit of farmers and consumers located elsewhere. Thus, maize and cassava farmers in Africa and Asia rely on crop genetic resources that originated in MesoAmerica and the Amazon Basin, and New World farmers who grow rice, an Asian domesticate, or sorghum, from Africa, draw on resources from the Old World. Today, the flows of genetic resources in public breeding programmes and the diffusion of improved crops show a dependence on genetic resources from Vavilov Centers that is perhaps greater that in times when crop diffusion was informal (Fowler et al, 2001). Beginning in the 15th century, the global expansion of Europe changed the scale and nature of crop diffusion in two ways. First, the amount and rapidity of diffusion were greatly augmented by the Iberian linkage between Europe, Africa and the New World (Crosby, 1972). Second, crop exploration and diffusion were formalized and eventually institutionalized. Naturalists and plant explorers accompanied colonial expeditions, and diffusion of medicinal, industrial and food crops played a visible role in the European expansion of between the 16th and 20th centuries (Brockway, 1979). Indeed, plant collection and exchange was seen as a normal part of diplomatic and economic intercourse among nations (Ryerson, 1933), an idea that was immortalized in Thomas Jefferson's aphorism, '[t]he greatest service that can be rendered to any country is to add a useful plant to its culture' (Baron, 1987). Responding to the discovery of the principles of inheritance in genetics, national crop breeding programmes grew out of the foundations of informal plant exploration and introduction (Poehlman, 1995). The young science of genetics changed crop resources from a possible source of new production to a probable source. By 1970, an international framework for collection, conservation, utilization and exchange was in place (FAO, 1998). Diffusion had been transformed from an informal and decentralized process to a formal, institutionalized activity connected to crop improvement in public and private breeding programmes

THE COMMON HERITAGE REGIME

'Common heritage' has historically been the implicit system for managing the diffusion of crop genetic resources, from the informal movement of crops in prehistoric times to the formal national and international framework of crop exploration and conservation agencies. Common heritage refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest. Defining common heritage is similar to belated efforts to demarcate the public domain after the expansion of private property (Litman, 1990). The roots of common heritage are visible in the free exchange of seed among farmers, the long history of diffusion through informal and formal mechanisms, established scientific practices, and the application of the term to other resources in the international arena. Reference to crop genetic resources as a common heritage appeared in the 1980s in association with the establishment of the Commission of Plant Genetic Resources at the Food and Agricultural Organization of the United Nations (hereafter FAO Commission) and the launching of the International Undertaking of Plant Genetic Resources (Pistorius, 1997). The 1983 conference establishing the FAO Commission and International Undertaking affirmed a resolution stating that 'plant genetic resources are a heritage of mankind and consequently should be available without restriction' (FAO, 1987).

Common heritage for plant resources implies open access and non-exclusion with respect to seeds and plants from farmers' fields, with due recognition of prior informed consent and the importance of farmers' need for seed and undisturbed fields. Common heritage reflects common property regimes (Ostrom et al, 1994) with implied open access. Whereas common property regimes often imply 'club goods' (Cornes and Sandler, 1996) that are openly accessible only to members, common heritage for genetic resources appears to be less encumbered by membership rules than other common property assets. The logical foundation of common heritage is in the nature of crop genetic resources, the universal processes of diffusion and dispersal, and the historical practices of reciprocity. Crop genetic resources derive originally from the natural and amorphous processes of crop evolution: mutation, natural selection, exchange and decentralized selection. Likewise, the tangled history of diffusion and dispersal not only obscures points of origin but also suggests that all farmers benefit from fluid movement of seed.

The principle of reciprocity is inherent to common heritage of genetic resources: those taking seeds are expected to provide similar access to crop resources. Farmers who openly provide seed expect to receive it in the same manner, and the same is true for crop breeders. Reciprocity by plant collectors and breeders is evident in three ways. First, plant collectors who gather material that is freely exchanged within farming communities continue this free exchange with crop breeders everywhere (Shands and Stoner, 1997). Second, collectors and crop breeders have historically worked under the ethos of public sector research in which the free dissemination of improved crops and the availability of genetic resources from gene banks represent reciprocity to farmers and countries that provide genetic resources. The wide diffusion of modern crop varieties from international breeding programmes is one indication of the extent of reciprocity under common heritage (Byerlee, 1996). Third, plant variety protection, the most widely used form of Breeders' Rights, includes farmers' and research exemptions that allow farmers to replant and researchers to reuse certified seed without paying royalties to the certificate holder (Baenziger et al, 1993). Illustrating the reciprocity principle in practice, Shands and Stoner (1997), enumerate the multiple ways that the US National Germplasm System honours its obligations in the global flow of crop resources. These include donor support to other countries' and international conservation and crop improvement programmes, cooperative breeding programmes, access to USDA collections, repatriation of germplasm, training and scientific exchange.

Common heritage management for genetic material that is not claimed as intellectual property remains conspicuous at two extremes: in farming communities of Vavilov Centers and in the flow of germplasm through international gene banks. The exchange of crop material among farmers within and between communities appears to be ubiquitous (Zeven, 1999) and perhaps a necessary part of agriculture. Case studies of farmer seed management in traditional farming demonstrate that farmer-to-farmer exchange of seeds makes their crop germplasm an open system. Dennis (1987) found that average projected turnover time for upland rice in Thailand was 30–48 years, while the time for lowland, irrigated rice was 13 years. Similarly, Louette (1999) and Perales et al (2003) found that Mexican farmers regularly change the seed lots of their maize landraces and acquire seed of existing varieties and new varieties from outside their community. The same pattern is documented for traditional potato landraces found in Quechua farmers' fields in the Cusco area (Zimmerer, 1998). With better information about farmer seed management in traditional farming systems, we now think of landraces as meta-populations or networks of individual populations that are linked through seed flow among farmers and communities.

We also observe an open system in the flow of crop germplasm through international gene banks and crop breeding programmes. Very few countries or farming systems in the world today do not rely to some degree on the international system that moves crop germplasm, breeding lines, improved varieties, and commercial seed across international borders. Developing countries, including those within Vavilov Centers, are heavily dependent on international flows of germplasm and more dependent than developed countries (Fowler et al, 2001). Rejesus et al (1996) examined wheat breeding and found that in West Asia, the Vavilov Center for wheat, wheat breeders' use of their own landraces and advanced lines accounted for 41.6 per cent of the breeding material in their programmes compared to 45.6 per cent from international sources. Many countries in the region of origin and diversity of rice (e.g. India, Burma, Bangladesh, Nepal, Vietnam) depended on IRRI's international rice gene bank in their breeding programmes (Gollin, 1998).

Both farmer seed exchange and international crop germplasm flows evolved originally as common heritage regimes. Common heritage is logical within farming communities where land and other natural resources are communally owned, seed is exchanged or shared, invention is collective, provenance is ambiguous, and natural and artificial selection are intertwined. Because of the transaction costs of proprietary management of seed, common heritage arguably is the best way to satisfy the frequent necessity to change or acquire seed in non-market economies. Likewise, a common heritage approach for international exchange is sensible because it lowers transaction costs that are inherent in defining and defending property over genetic resources (Visser et al, 2000). These costs include negotiation costs, pre-distribution tracking costs, and post-distribution tracking costs (Visser et al, 2000) as well as the conventional transaction costs, for example exclusion, information and communication, as identified by economists.

An example of information costs associated with crop genetic resources is how to ascertain the true 'source' of collections. Plant explorers often cover large territories and reduce collection times by collecting in markets and other central places such as schools. Even if collections come directly from farmers, the seed may be a recent acquisition from another farmer or village. Assigning a territorial designation may also be problematic because of the frequency of migration and the transitory nature of political boundaries. Assuring that source information adheres to collections also incurs cost. Imposing transaction costs associated with privatization onto the international exchange crop genetic is defensible if outweighed by the benefits of privatization, such as compensation and conservation, but whether these benefits will indeed result is yet to be demonstrated. The US received germplasm from many sources, including missionaries, diplomats and plant explorers. The original collections that established the US national gene bank (National Seed Storage Laboratory) included material identified only by the country of origin (A. Damania, pers. comm.). These US collections were duplicated and distributed to other national and international gene banks (A. Damania, pers. comm.). Peeters and Williams (1984) report that passport data was wholly lacking for 65 per cent of the samples in the active international network of gene banks. This percentage has probably decreased as more systematic collection has added to inventories, but the FAO (1998) reports that only 37 per cent of the material in national collections has passport data.

TRADITIONAL AGRICULTURAL KNOWLEDGE

The interplay between biological variation and its control through selection makes crop and natural evolution similar to one another, but the two differ by virtue of the role of 'conscious' selection by humans in crop evolution. Conscious selection implies knowledge systems about the crop and its environment, which are subsets of the more general traditional knowledge and indigenous knowledge (e.g. Ellen et al, 2000).

While 'traditional knowledge' and 'indigenous knowledge' are not synonymous, they share many attributes, such as being unwritten, customary, pragmatic, experiential and holistic. The terms are frequently used in the same context to distinguish the knowledge of traditional and indigenous communities from other types of knowledge, such as the knowledge of scientific and industrial communities (Ellen et al, 2000). Indeed, the primary distinction between traditional and indigenous knowledge pertains to the holders rather than the knowledge per se. While Kongolo (2001, p357) observes that '[t]raditional knowledge is rarely defined within the national, regional and international frameworks', indigenous knowledge has been extensively analysed by ethnobotanists and others (e.g. Berlin, 1992), so it behoves us to utilize the analysis of indigenous knowledge to grapple with traditional knowledge. Traditional knowledge is a broader category that includes indigenous knowledge as a type of traditional knowledge held by indigenous communities (Mugabe, 1999). While traditional knowledge has recently emerged in international discourse on new legal mechanisms (Wendland, 2002), indigenous knowledge is a term long in use by anthropologists and other investigators of non-industrialized societies (Ellen et al, 2000), and because of this history, indigenous knowledge enjoys a more elaborated discussion and definition than the more inclusive term. Nevertheless, apart from the designation of the type of holder, the definitions applied to indigenous knowledge apply also to traditional knowledge.

Traditional knowledge is associated with folk nomenclatures and taxonomies of plants (Berlin, 1992), the environment (Ellen et al, 2000), practical domains such as disease aetiology (Berlin and Berlin, 1996), and agricultural practices (Brush, 1992). Distinguishing between indigenous knowledge and other knowledge systems has proven to be problematic (Agrawal, 1995), but anthropologists and others have argued that a number of criteria can be used to differentiate the two forms. Indigenous knowledge's distinguishing characteristics include (1) localness, (2) oral transmission, (3) origin in practical experience, (4) emphasis on the empirical rather than theoretical, (5) repetitiveness, (6) changeability, (7) being widely shared, (8) fragmentary distribution, (9) orientation to practical performance, and (10) holism (Ellen and Harris, 2000). However, these same characteristics apply to traditional knowledge.

While the existence of traditional knowledge and its accomplishments are unquestioned, its characteristics pose severe obstacles for its valuation and protection by indigenous people and outside interests such as conservationists, indigenous rights activists and rural development agencies. Indeed, outside efforts to value, promote and protect traditional knowledge appear inevitably to distort it and its social context (Dove, 1996). A severe obstacle to valuation and protection is the disarticulation of different types of knowledge when that information is local, orally transmitted, practical and fragmentary in distribution. Agricultural knowledge is comprised of numerous substantive domains – soil types, pests, pathogens, environmental conditions such as rainfall and temperature patterns, and crop genotypes – as well as management domains – irrigation techniques, soil amendments, planting patterns, pest control, weed control and crop selection, to name a few. Brookfield (2001) adds organization as a third domain that includes tenure arrangements, resource allocation and dependency on alternative production spheres. These domains are demarcated by distinct lexicons and nomenclatures such as crop variety names or terminology for management practices. Traditional knowledge is rife with 'covert categories' (Berlin, 1992) and unlabelled, intermediate domains (Brush, 1992) that may link substantive and management domains but require intensive research to understand.

The content of a single domain may be ordered taxonomically, but revealing taxonomy requires elaborate analysis similar to biological systematics to reduce noise of variation (Berlin, 1992). Unfortunately, the elaboration of folk nomenclature for crops is greatest at the variety (intra-specific) level that is often judged as having dubious value by botanists (e.g. Burtt, 1970) and ethnobotanists (Berlin, 1992). Since variety names are orally transmitted, repetitive, widely shared and fragmentary, name lists cannot be used directly to estimate genetic diversity or population structure above the farm level (Quiros et al, 1990). Synonyms may, in fact, be known to some farmers but not marked or widely recognized. Problems of over- and under-classification of genetic variation can only be resolved by careful agronomic and genetic characterization, a step that would seem to obviate the need to collect folk names. The fact that traditional knowledge is orally transmitted and changeable creates problems in identifying truly local and autochthonous knowledge (Agrawal, 1995). The fact that traditional knowledge is local, empirical and holistic suggests that indigenous people do not have to worry about consistency over wider areas, as plant collectors and geneticists must. Capturing the knowledge in a single domain by collecting its nomenclature, such as crop variety names, is relatively easy but of limited use. Linking nomenclatures of substantive domains to one another and to management domains is complicated by the inherent qualities of localness, oral transmission, and fragmented distribution. The best studies showing linkage between different domains (e.g. crop diversity and local ecological conditions) are executed in single communities or micro-regions (e.g. Bellon and Taylor, 1993). Linking multiple domains, such as crop type, soils and plant diseases, or showing how domains are linked across regions is daunting and generally not attempted in research on traditional agricultural systems.

CLOSING THE GENETIC COMMONS

Following the successful initiatives of the 1970s to organize an international framework for conserving crop genetic resources, the common heritage approach for managing access came under increasing, erosive pressure. Factors that combined to threaten the common heritage approach include the increasing value of genetic resources, the expansion of Breeders' Rights in industrial countries, liberal policy formulation for agricultural development, North/South political discourse and the rise of the environmental movement. These strands converged in the early 1990s to produce the Convention on Biological Diversity (CBD) and the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) that, when taken together, suggested the demise of common heritage. By the beginning of the 21st century, however, common heritage had regained status as the underlying principle of a new international framework for managing access to crop genetic resources.

Genetic resources gained value throughout the 20th century by virtue of increasing demand and decreasing supply. Systematic crop breeding both requires a supply of genetic material and threatens the supply of those resources (Harlan, 1975). The creation of an international network of over 1,300 formal collections in gene banks, breeding programmes and botanical gardens, in 103 countries, and with 6 million accessions is evidence of the increased value of genetic resources (FAO, 1998). The rise of crop breeding also contributed to the demise of common heritage by changing perceptions about crop breeders and the ownership of living matter. After 1900, crop breeders emerged as another type of inventor who manipulated common goods into novel and more useful ones (Fowler, 1994), so it is not surprising that intellectual property protection for plant breeders soon followed the rise of systematic crop improvement. A progression of different forms of Breeders' Rights followed the US Plant Patent Act in 1930, and since this act, Breeders' Rights have been expanded both in terms of what products are eligible for protection as intellectual property and the strength of protection afforded to breeders (Baenziger et al, 1993). Moreover, less developed countries have increasingly adopted Breeders' Rights to stimulate crop improvement and in response to international pressure. Perhaps most importantly, Breeders' Rights are included in the TRIPS Agreement as part of the package of national policies required for membership in the World Trade Organization (WTO). While the TRIPS agreement allows countries to fashion their own (*sui generis*) approach to Breeders' Rights, the need to conform to international standards encourages adoption of a system resembling the International Convention for the Protection of New Varieties of Plants (UPOV) approach.

The availability of Breeders' Rights in industrialized countries was seen by some as evidence of an imbalance in the stream of benefits flowing from genetic resources (Mooney, 1983). Breeders' were accorded the right to tangible, private benefits while farmers had to rely on indirect, public benefits. The critical ambiguity of whether common heritage should apply to all genetic resources or only to those in fields and farm stores became a political liability because the relatively low visibility of the reciprocity provided a basis for claims of exploitation under the label 'biopiracy' (Shiva, 1997). More generally, this reciprocity was undervalued by arguments that contractual collection arrangements are needed to ensure equitable returns and by movements to reduce government spending and those favouring participation in development activities. By 1992, conditions existed for a bold move against common heritage, and a potential *coup de grâce* was delivered in the CBD that defined genetic resources as belonging to nation states. The post-CBD system for managing crop genetic resources under national ownership overlies professional practices inherited from the pre-CBD (common heritage) period. The emphasis on sovereign ownership suggested a move to regulate access to national resources through bilateral contracting mechanisms that became known as bioprospecting agreements (ten Kate and Laird, 1999), although it also allows for a cooperative, 'soft law' approach (Roddick, 1997) based on voluntary mechanisms.

Reshaping access to genetic resources has varied according to whether pharmaceutical and natural product resources or crop resources are involved. Access to resources for pharmaceutical development has tended toward regulation by bilateral contracts while access to resources for crop development has tended toward open, multilateral mechanisms. Three differences between these two genetic resources explain this outcome. First, pharmaceutical resources tend to involve relatively discrete traits and are perhaps controlled by single genes, while crop resources involve quantitative traits that are controlled by multiple genes. Second, crop resources are dependent on human stewardship and have resulted from collective management and selection. Third, pharmaceutical resources lacked the international infrastructure of collection, conservation, public breeding and exchange that was developed for crop resources. The Merck/INBio contract (Reid et al, 1993) epitomized bioprospecting contracts for pharmaceutical and natural product development. No comparable agreements were negotiated for crop genetic resources. Rather, 'soft law' mechanisms, such as Material Transfer Agreements (MTAs; Barton and Siebeck, 1994), were developed for crop resources. These mechanisms are often informational rather than contractual. For instance, the instruments developed by the international gene banks of the Consultative Group on International Agricultural Research (CGIAR) system inform the recipient of germplasm that it is for research and breeding purposes only and inveighs him/her to forgo future claims of intellectual property. These mechanisms retain common heritage aspects of the pre-CBD era and avoid moving to more rigid contractual agreements that specify the sort of benefit flows that are found in bioprospecting agreements for pharmaceutical and natural products (ten Kate and Laird, 1999).

Civil society organizations, nations, regional coalitions and international agencies have responded to the closure of the biological commons with a variety of programmes and implements aimed at protecting the public domain. One programme is to register traditional knowledge practices and innovations, and thereby define them as prior art so that they cannot be directly appropriated as intellectual property. The American Association for the Advancement of Science has initiated the Traditional Ecological Prior Art Database where plant names and associated knowledge can be registered (AAAS, 2003). At the international level, the negotiation of the International Treaty for Plant Genetic Resources for Food and Agriculture represents the culmination of an enduring effort to maintain crop resources as common pool goods.

THE INTERNATIONAL TREATY FOR PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

In 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was completed and has now been signed by 98 countries, including the US (FAO, 2003). The ITPGRFA takes a multilateral approach that reaffirms common heritage for the crop genera that are included in the list of crops covered by the pact. States retain sovereign rights over their genetic resources, including the right to designate genetic material and whole plants as intellectual property. The core provisions of the ITPGRFA (Articles 10–12) place the resources of 36 genera of crops and 29 genera of forages in the public domain and guarantee access to these resources for breeding and research. Germplasm from the multilateral system will be available with an MTA that may include provisions for benefit sharing in the event of commercialization. The Treaty stipulates that:

> *Recipients shall not claim any intellectual property or other rights that limit the facilitated access to plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System.*
>
> (ITPGRFA Article 12.3 d)

The phrase 'in the form received' may be interpreted as allowing intellectual property once significant, inventive manipulation has occurred (CIPR, 2002). The FAO serves as the proprietor of the international crop collections that are held in trust by the CGIAR, and the CGIAR system has repeatedly confirmed its adherence to open access to these collections.

Article 13 of the ITPGRFA lays out a procedure for benefit sharing by stipulating that commercialization of a new plant variety will trigger a financial contribution to the multilateral system. Again, the approach is multilateral rather than contractual between the genetic resource provider and the person who commercialized a product using that resource. The level, form and conditions of payment (for instance whether small farmers are exempt) is not resolved in the treaty and will be subject to further negotiations within the Governing Body of the International Undertaking. The benefit sharing mechanism of the ITPGRFA faces a serious logistical difficulty because of the long lag time between access to genetic resources and commercialization. Moreover, identifying the contribution of a specific resource within the complex pedigree of an improved crop variety poses a major obstacle to negotiating benefit sharing. Nevertheless, the treaty provides a mechanism for negotiating these obstacles while access to crop resources remains open.

This treaty grew out of nearly two decades of negotiation at the FAO concerning an international system for managing crop genetic resources. While the CBD sovereignty clause invited the rise of bilateral agreements, four factors pushed treaty negotiation toward a multilateral framework. First, replacing the open system with one defined by bilateral contracts would entail steep transaction costs that might exceed the value of the resources. Second, the process of creating a new access regime based on bilateral contracts posed the threat of interrupting germplasm exchange because of an anti-commons (Heller and Eisenberg, 1998) resulting from the claims of different parties to control over access (Correa, 2000). Third, increasing evidence suggested heavy dependence by poor countries on outside germplasm resources (Fowler et al, 2001), contradicting the earlier conclusion (Kloppenburg and Kleinman, 1987) that industrial countries were more dependent on germplasm from developing countries. Fourth, accessions from large and valuable collections of the CGIAR network and industrial countries, such as the National Seed Storage Laboratory of the US, remained openly available to crop breeders.

Uncertainty over whether a new international order for crop genetic resources reconfirmed or undermined common heritage as plant breeders understood it had bogged down negotiations about the International Undertaking at the FAO (Fowler and Mooney, 1990). The ITPGRFA overcame the conflict by shifting the emphasis toward open access to crop resources and away from the issue of compensation. Avoiding the long-term disputes about patenting life forms and gene sequences also aided the agreement on the status of international collections. Finally, by separating the issue of gene bank access from Farmers' Rights and accepting the co-existence of Breeders' Rights and common-pool rights, the ITPGRFA gained acceptance from over 100 countries and avoided any specific national opposition.

FARMERS' RIGHTS AND INTERNATIONAL PROTECTION OF TRADITIONAL AGRICULTURAL KNOWLEDGE

The FAO Commission's International Undertaking on Plant Genetic Resources provided a forum to discuss equity interests of farmers in developing nations and gave rise to the Farmers' Rights movement. FAO Commission Resolution 8/83, which established the International Undertaking on Plant Genetic Resources in 1983, had stressed the common heritage principle that plant genetic resources should be available without restriction and provided a sweeping definition of genetic resources as incorporating not only wild and weedy crop relatives and farmers' varieties but also newly developed 'varieties' and 'special genetic stocks (including elite and current breeders' lines and mutants)' (FAO, 1987). Non-governmental organizations (NGOs) that presented the idea of Farmers' Rights to the FAO Commission in 1985 were antagonistic to Breeders' Rights (Mooney, 1996) and perhaps believed that international acceptance of Farmer's Rights would undermine individual rights (Fowler, 1994).

The gambit to undermine Breeders' Rights through a binding international resolution endorsing unrestricted access to all genetic material failed because of the opposition of states that provide for Breeders' Rights and the availability of large stocks of genetic resources in open collections that are linked to international agricultural development. FAO Resolution 5/89 resolved that the two types of rights were not incompatible and defined Farmers' Rights as:

> *rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.*
>
> (FAO 1998, p278)

Farmers' Rights differed from Breeders' Rights in that they were to be vested in the 'International Community' rather than with individuals. However, by not specifying what genetic materials were covered or who could claim ownership, the FAO definition created a problematic category. Farmers' Rights have remained an elusive goal. Their early association with the anti-Breeders' Rights agenda, and their ambiguities regarding materials and holders of the rights thwarted acceptance of Farmers' Rights as an international principle or programme. Following the ITPGRFA negotiation, the fate of Farmers' Rights will be determined at the national level.

The nature of Farmers' Rights hinges on the economic benefit provided in the past, but no estimate of value or widely accepted method to estimate value of crop genetic resources is available. Estimating the historic contribution of farmers' varieties ideally requires one to separate the economic contribution of germplasm from other factors such as the development of physical infrastructure and human capital. Likewise, estimating the cost of Farmers' Rights is hampered by the lack of a programme for how the stream of benefits to farmers might be used to achieve conservation goals.

Bipoprospecting contracts potentially offer a mechanism to provide equity and stimulate conservation by increasing the value of biological resources, but this mechanism is likely to be ineffective for addressing equity and conservation issues relating to crop germplasm. Because collecting genetic resources tends to be 'single shot' (Barrett and Lybbert, 2000), collecting fees are unlikely to have a long-term conservation effect. Contracts are likely to arbitrarily favour single communities or regions who have no special claim to crop germplasm, and Barrett and Lybbert (2000) argue that bioprospecting windfalls may be exclusionary or even regressive. The reaction of groups who were excluded from bioprospecting agreements confirms that exclusion is a liability (Nigh, 2002). If conceived as a market situation between community 'sellers' and seed company 'buyers', Farmers' Rights exist in a monopsony environment in which a multitude of farmers with genetic resources face an extremely limited set of potential 'buyers' for their resource. Mendelsohn (2000) observes that this situation leads to market failure and argues that a monopoly acting on behalf of farmers is necessary.

Possible titleholders of Farmers' Rights include farming communities and states (Correa, 2000). Inter-community exchange and seed flows make claims by one community for rights to a specific landrace or other crop resource open to challenge from other communities. The same may be true at the international level where informal seed movement also exists (e.g. Valdivia et al, 1998). Transaction costs to settle such disputes may be higher than the value of the right, and arbitrary allocation presents ethical problems of favouring one community over others. The possibility of international disputes or price competition has led some regions, such as the Andean nations, to initiate a consortium approach to providing biological resources (ten Kate and Laird, 1999), but the number of possible participants and other factors are likely to make the costs of a similar approach among communities prohibitive.

The subject matter of Farmers' Rights is equally ambiguous. Characterization of gene bank collections is limited, and much of the material is stored without adequate documentation to identify farmers who might be considered as the sources (Peeters and Williams, 1984). Defining knowledge rather than genetic resources as the subject matter of Farmers' Rights is equally problematic because farmers' knowledge is local, widely shared, changeable and orally transmitted. Lastly, the concept does not specify whether wild relatives of crops, which have provided valuable traits to crop improvement but are not always known or used by farmers, are covered by Farmers' Rights. The final criterion that distinguishes Farmers' Rights from intellectual property is their duration (Correa, 2000). The monopoly right of a grant of the intellectual property is made to be temporary as a way to balance the goal of increased invention over the goal of open competition. The unlimited duration of Farmers' Rights forgoes this balance, a policy of dubious merit if other communities or nations have valuable genetic resources or prove to be more effective conservationists.

The ITPGRFA moves away from a binding international resolution to create Farmers' Rights and assigns the realization of Farmers' Rights to national governments. The treaty inveighs on its Contracting Parties to provide for these rights in three ways: (1) protect traditional knowledge; (2) provide equitable participation in sharing benefits; and (3) allow participation in making decisions related to the conservation and use of plant genetic resources for food and agriculture (FAO, 2003). As in the *ex ante*, common heritage period, farmers are not granted the right to exclude others from using or benefiting from crop resources. Negotiating Farmers' Rights at the national level faces obstacles such as political weakness of the traditional farming sector, urban and consumer demand for low cost commodities, and the need to promote agricultural development that were not critical in the international arena. Although the CBD does not distinguish crop genes as a special category of biological resource, negotiations for Farmers' Rights will have to acknowledge the regime established by the ITPGRFA. Research on crop populations in traditional farming provides three lessons that will weigh on Farmers' Rights negotiations. First, crop genetic resources are collective inventions and meta-populations rather than assets that are privately derived and managed. Second, developing nations have benefited from adopting new technology, including new crop varieties, but landraces still exist in specific agricultural niches. Third, demand for crop genetic resources from outside sources is greatest in developing countries.

Experience gained in research and negotiation about possible mechanisms to protect farmers' knowledge offer four guidelines for crafting national Farmers' Rights programmes. First, the goals of Farmers' Rights are to balance Breeders' Rights and encourage farmers to continue as stewards and providers of crop genetic resources. Second, Farmers' Rights are held collectively rather than by individual farmers or communities. Third, Farmers' Rights are not exclusive or meant to limit access to genetic resources. Finally, mechanisms are needed to share benefits received by the international community from genetic material from farmers' fields or international collections.

FARMERS' RIGHTS AT THE NATIONAL LEVEL

India's Act No 123, 1999 for The Protection of Plant Varieties and Farmers' Rights recognizes (Article 16d) Farmers' Rights in four ways (India, 1999). First, farmers' roles as keepers of genetic resources and sustainers of crop evolution are to be recognized and rewarded through a National Gene Fund that will be financed by annual fees levied on breeders of registered varieties in proportion to the value of these varieties. Benefit sharing to communities that provided germplasm used in a registered variety will be determined according to the extent and nature of the use of genetic material in the registered variety [Article 26(5)]. Second, India's Act 123 establishes the farmers' exemption that was present in early plant variety protection regimes (Baenziger et al, 1993), allowing that farmers are entitled to 'save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act' (India, 1999, Article 39iv). Third, breeders are required to disclose in their application for registration information regarding tribal or rural families' use of genetic material used in the breeding programme. Failure to disclose this information is grounds for rejecting an application for variety registration. Fourth, any interested party may file a claim on behalf of a village or local community stating its contribution to the evolution of a registered variety. If this claim is substantiated, the breeder is required to pay compensation to the National Gene Fund.

The Organization of African Unity's African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (OAU, 2000) establishes Farmers' Rights in four ways. First, farmers can certify their varieties as intellectual property without meeting the criteria of distinction, uniformity and stability that breeders must meet. This certificate provides farmers with 'the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use' (OAU, 2000, Article 25). Second, farmers are given the right to 'obtain an equitable share of benefits arising from the use of plant and animal genetic resources' (OAU, 2000, Article 26). The African Model Law (Article 66) establishes a Community Gene Fund to accomplish benefit sharing and to be financed by royalties fixed to registered breeders' varieties. Third, farmers are guaranteed an exemption to Breeders' Rights restrictions, to 'collectively save, use, multiply and process farm-saved seed of protected varieties' (OAU, 2000, Article 26 (1e)). Fourth, farmers' varieties are to be certified as being derived from 'the sustainable use of a biological resource' (OAU, 2000 Article 27). This certificate does not imply financial reward.

The ITPGRFA, Indian Act 123, and the African Model Legislation accept the coexistence of Breeders' Rights along with Farmers' Rights and intend to accomplish benefit sharing through a centralized funding mechanism linked to Breeders' Rights. This same benefit sharing mechanism is present in the Genetic Resources Recognition Fund (GRRF) of the University of California, which imposes a licensing fee on the commercialization of patented plant material involving germplasm from Developing Countries (ten Kate and Laird, 1999). This mechanism is a generic tool for reciprocity rather than one to reward specific farmers or communities. The African Model Legislation goes furthest in signifying individual communities as the beneficiaries, and the Indian Act 123 combines both the generic and specific uses of compensation through the centralized gene fund. Farmers' Rights are also provided in farmers' exemptions to restrictions embedded in Breeders' Rights. Contradicting the view that Farmers' Rights are not a form of intellectual property (CIPR, 2002), the Model African Law goes beyond the ITPGRFA and the Indian Act 123 in granting exclusive rights to farmers over their varieties.

Two factors indicate that taxing certified crop varieties will offer meagre resources to finance Farmers' Rights. First, plant variety certificates in industrialized countries have relatively low or negligible value. Lesser (1994) determined that the price premium associated with soybean certified seed was only 2.3 per cent in New York State and concluded that this form of protection is too weak to be an incentive to breeders. Second, modern breeding programmes are increasingly dependent on the use of 'elite' breeding lines that are several generations removed from farmers' varieties and show increasingly complex pedigrees involving crop genetic resources from many sources (Smale et al, 2002). Although India is a net exporter of landraces as breeding material, foreign landraces are equally important to India's rice programme as are national landraces (Gollin, 1998). Because African agriculture is heavily dependent on crops originating in other regions, dependence on international germplasm is high. For instance, in Nigeria's rice breeding programme, 180 out of 195 landrace progenitors used in breeding were borrowed from other countries (Gollin, 1998). Estimating the contribution of a single landrace or collection to the value of a modern variety has not been accomplished and is likely to become more difficult as pedigrees become more complex.

In sum, Farmers' Rights are a moral but largely rhetorical recognition of the contribution of farmers to the world's stock of genetic resources, and they provide only a limited mechanism to share benefits from using crop genetic resources or to promote their conservation.

CONCLUSION

Mechanisms to protect traditional knowledge must account for the differences between biological resources of traditional agriculture and other sources. This chapter has argued that common heritage management of crop genetic resources are distinguished by a ubiquitous and necessary flow of genetic material among farming communities and over large regions that will undermine contracting or other market solutions for protection. Moreover, the *ex ante* system of collecting and using agricultural germplasm from traditional farming systems was characterized by the creation of national and international institutions that effectively used these resources to return benefits to developing countries in the form of modern crop varieties. The move to end common heritage as a management scheme for crop genetic resources is justified by liberal ideology to overcome the Tragedy of the Commons (Hardin, 1968) and as an anti-colonialist tool to stop uncompensated acquisition of resources from the South (Mooney, 1983). However, these justifications for closing the genetic commons in traditional agriculture are based on inaccurate caricatures of traditional resource managers and the international crop germplasm system. The Tragedy of the Commons overlooks the persistence of traditional crop varieties in centres of diversity (Brush, 1999), and the North/South dialogue overlooks incremental, collective invention, networks of interdependence among farming communities, and their links to a global flow of crop material. Moreover, the North/South dialogue understates the value of global public goods and international cooperation involving both North/South and South/South transfers.

Arguably, it is time to move beyond both the Tragedy of the Commons and North/South dialogue as bases for developing mechanisms to protect traditional agricultural knowledge and crop resources. This conclusion is embedded in the negotiated settlement of the ITPGRFA that returns to common heritage for the world's most important crops. The weakness of that treaty, however, is that it does not give proper emphasis to the obligations of industrial countries and developing countries alike to support conservation of crop resources beyond funds raised in connection with commercializing improved crop varieties. This mechanism faces the same limitations as the Indian and OAU gene funds and is likely to be inadequate in meeting conservation budgets that are already inadequate. Rather, benefit sharing must come from a more traditional transfer of international capital: development assistance focused on programmes to improve rural incomes in Vavilov Centers. An assortment of tools now exists to use those funds in a way that increases production and income without replacing traditional crop populations (Brush, 1999). Bilateral and multilateral development assistance that funds rural development activities and benefits the stewards of the world's crop resources can be justified as part of the reciprocal obligations of industrial nations to developing nations. Multilateral efforts such as the Global Environmental Facility's programme on Conservation and Sustainable Use of Biological Diversity Important to Agriculture (GEF, 2000) and the McKnight Foundation's Collaborative Crop Research Program (McKnight Foundation, 2002) embody reciprocity through international financial assistance. The irony of this conclusion is that it reverts to tools and principles that were established before the assault on common heritage.

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Chapter 21

Traditional Knowledge Protection in the African Region

Rabodo Andriantsiferana

Africa comprises 56 countries totaling 812 million inhabitants. The majority of this population is young: 43 per cent are less than 15 years old. People older than 65 years represent only 3 per cent of the population. Thirty-three per cent of African people are urban (Population Reference Bureau, 2001).

The World Conservation Monitoring Centre has designated various groupings of countries that are likely to be conservation priorities based upon the criteria of species richness and endemism (Caldecott et al, 1994):

- Group 1: The 25 most biodiverse countries in the world in terms of sheer number of species present;
- Group 2: The next 25 most diverse countries in the world in terms of sheer number species;
- Group 3: Islands or groups of islands that have fewer species in total, but which have a large proportion of native species that occur nowhere else (i.e. endemics). This group includes 20 countries.

There is also a 'hotspot' category consisting of countries that 'are geographically located in the areas of the world that have both high numbers of species and a great ecological risk because of human encroachment' (Mittermeier, 1997).

Sixteen African countries are listed among these groups. However, on the basis of both the gross domestic product rank per capita and the Human Development Index, African countries are the poorest in the world (Shea, 1997; USCIA, 1995). The African continent, however, is hardly allowed to complain. Natural resources, mineral as well as biological, overfow: diamonds, gems, ores, oil, a rich and dramatic flora and fauna, large varieties of landscapes (vast deserts, outspread rainforests, savannah and lakes). But 67 per cent of the population is rural (Population Reference Bureau, 2001), showing that the African economy is largely based on agriculture, breeding and fishing. Thus, the majority of African people still rely on natural resources for their needs, and so are tightly linked to their environment.

In spite of decades of European colonization, and the associated implementation of Christianity, the culture and way of life have little changed. Traditional social structures exist alongside the official modern management methods. Traditional knowledge deals with all aspects of life and the conception of the cosmos. For the Madagascan people, for example, human beings cannot be reduced to a physical body, but are also constituted of a soul and a spirit: immaterial elements, but very important. The soul makes them responsible for their acts, decisions and choices in their relations with other people and with all the universe (Andriantsiferana, 2002a). In general, however, traditional African societies are not aware of the financial value of their intellectual or manual work, or of the time spent in different activities (Andriantsiferana, 2002b).

The Convention on Biological Diversity (CBD, 1992) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS, 1994) opened a new era for peoples relying largely on natural resources. It is also a mercy that African populations are homogenous. The terms 'indigenous' or 'native' peoples are for the most part inapplicable in Africa. Heads of States and Governments are Africans.

INTELLECTUAL PROPERTY RIGHTS PROTECTION IN AFRICA

Some African countries have been endowed with tools for intellectual property rights (IPR) protection since the early 1960s. In 1962, French speaking countries created the Office Africain et Malgache de la Propriété Intellectuelle (OAMPI). For political reasons, Madagascar withdrew in 1976. Thereafter, this intergovernmental agreement was revised twice in Bangui (Central African Republic): in 1977 to become OAPI (Organisation Africaine de la Propriété Intellectuelle), and then in 1999 to implement TRIPS (OAPI Contact, 2002). For each of the16 member states, OAPI serves as a national office for industrial property. Likewise, the African Regional Intellectual Property Organization (ARIPO) serves 15 English speaking countries.

However, these institutions are only copied from northern models as applied to northern countries, and ignore problems related to traditional knowledge or technologies. In the OAPI 2000 Annual Report, among 367 applications recorded, only 28 (7.6 per cent) originated from OAPI Members: the majority came from the US and Europe.

Nevertheless, with the recovery of independence, nationalist Africans, convinced of the value of their natural resources, launched various research programmes on medicinal plants and traditional medicine including within:

- The Scientific and Technical Research Committee of the Organization of African Unity (OAU/STRC)

- the Conseil Africain et Malgache de l'Enseignement Supérieur (CAMES).

The following international or multilateral organizations followed their initiative:

- Agence de Coopération Culturelle et Technique de la Francophonie (ACCT)
- United Nations Industrial Development Organization (UNIDO)
- World Health Organization (WHO).

Also in African universities and in research institutions, individuals or team of researchers carried out investigations in different scientific disciplines. All these activities resulted in various publications (articles, theses, reports, books) such as the African Pharmacopoiea in two volumes by OAU/STRC, 'Médecine et pharmacopée traditionnelle' by ACCT, and many publications by national institutions. These works disclosed traditional knowledge which is only normally transmitted by word of mouth. Although writing down this information contributes to its value, and prevents it from being lost, the informants were not associated as authors, and felt exploited.

In the mean time, Western companies developed powerful medicines from African's natural resources, such as the periwinkle (*Catharanthus roseus*) from Madagascar, indicated for leukemia, and the african plum-tree (*Prunus africana*) used to treat benign prostatic hypertrophy. Benefits from the commercial use of these genetic resources have largely been enjoyed by companies and research institutes that developed marketable products and obtained intellectual property rights and patents. But neither the local first informants nor the countries where the resources originated received a share of these benefits (OECD, 2002).

TRADITIONAL KNOWLEDGE

Traditional knowledge concerns all aspects of life (food, health, housing, communications, etc.) and the environment (relations between biodiversity and ecological factors, identification criteria of biodiversity elements, etc.). Observations and experimentation in the environment have led to the selection of plant varieties as crops, medicines, timber, fuel and other uses. The use of animal products and minerals is also well known, as traditional knowledge is characterized by a holistic approach, relating every component of the environment to each other, and giving equal importance to rational thinking as well as to spiritual beliefs and social considerations (Andriantsiferana, 2002a). Taboos are often a way of expressing traditional knowledge, and as such may concern the appropriate way to achieve sustainable use of biodiversity or outlining effective management of community activities relative to agriculture. For example, at Ranomafana in Madagascar, basket work is forbidden during periods of peak activity in the rice fields to maximize the availability of female labour.

A large body of knowledge is transmitted through oral tradition, which makes this knowledge susceptible to loss and distortion. Much of the knowledge is locked up in shrines and sacred places and is therefore not available to researchers. Traditional knowledge often cannot constitute the intellectual property of an individual, as it is generally inherited and so is related to a lineage. Thus it is rather the property of one or more communities. Traditional knowledge generally does not fit the requirements for a patent application, which requires novelty, an inventive step and the capacity for industrial application.

THE AFRICAN REGION MOBILIZES TO PROTECT TRADITIONAL KNOWLEDGE

The CBD recognizes the importance of indigenous and local communities to the conservation and sustainable use of biological diversity. The key provisions are to be found in Article 8(j), which requires that the traditional knowledge of indigenous and local communities be respected, preserved and maintained; that the use of such knowledge be promoted for wider application with the approval and involvement of the holders of such knowledge; and that the benefits that arise from the use of their knowledge be shared equitably.

The CBD also requires, in Article 10(c), that the customary uses of biological resources in accordance with traditional cultural practices be protected and encouraged; in Article 17(2), that information concerning traditional knowledge and technologies be included amongst the information to be exchanged, and where feasible, repatriated; and in Article 18(4) that technological cooperation between contracting parties also includes cooperation regarding indigenous and traditional technologies (Lambrou, 1997).

Accordingly, Heads of States and Governments of the OAU drafted a model law during their Conference in Ouagadougou (1998). Its expanded version was adopted at the OAU Summit in Lusaka (Zambia), in July 2001 (OAU, 2001b). It is entitled ‘African model law for the protection of the rights of local communities, farmers and breeders , and for the regulation of access to biological resources’ (OAU, 2001a).

The WHO estimates that about 80 per cent of the population living in the African region depends on traditional medicine for their health care needs. In July 2001, African Heads of States at the OAU Summit held in Abuja (Nigeria), and in Lusaka (Zambia), declared respectively, that research on traditional medicine should be a priority and that the period 2001–2010 should be declared the ‘Decade for African Traditional Medicine’. In addition to this initiative, there is a need to institutionalize and strengthen the organizational aspects of traditional medicine in most countries of the African region. There is also a need to improve the political, economic and regulatory environment and to develop small-scale local production into large-scale manufacturing (OAU, 2001b).

In order to support member states, WHO/AFRO (World Health Organization Regional Office for Africa) developed a comprehensive Regional Strategy on Promoting the Role of Traditional Medicine in Health Systems. For its implementation, the WHO Regional Director, Dr Ebrahim M. Samba, established in 2001 the WHO Regional Expert Committee on Traditional Medicine (REC/TRM). The REC held its first meeting in Harare (Zimbabwe), 19–23 November 2001. The REC reviewed the technical documents developed by the Regional Office as tools to assist countries to institutionalize and integrate traditional medicine into their national health systems and made recommendations to the WHO Regional Director for Africa (WHO/REC, 2001). Following the Declaration of the OAU Summit of July 2001, designating the period 2001–2010 as the Decade for Traditional Medicine, the OAPI adopted for the celebration of its 40th Anniversary (September 2002), as its focus topic: 'The protection and valorization of African inventions in the field of medicines'. This decision expresses the will to coordinate actions carried out in Africa, to assure more efficiency.

As a member of the REC, I participated in the Experts Committee Meeting, for the elaboration of the document to be submitted to the Conference of the Ministers in charge of Industry and Health within OAPI member states (OAPI, 2002b). The final document was entitled *Initiative pour la protection et la valorisation des inventions africaines en matière de médicaments* (OAPI, 2002b). The main ideas expressed in this document were reported to the second REC/TRM meeting held in Libreville (Gabon) in November 2002, where another document, prepared by the WHO Regional Office was presented: 'A regulatory framework for the implementation of the protection of traditional knowledge and intellectual property rights related to medicines derived from traditional medicine in the African Region' (WHO/REC, 2002).

Among REC/TRM meetings results, the classification of traditional medicines must be mentioned. There are three categories of traditional medicines in Africa:

- Category 1: Medicine(s) prepared by a traditional health practitioner for a patient;
- Category 2: Medicine(s) originating from the community but having commercial applications;
- Category 3: Products originating from research and academic institutions.

The First Africa-China forum on Traditional Medicine convened 20–22 October 2002 in Beijing. Twenty-one African Health Ministers and a high-level WHO delegation, led by Dr Samba, Regional Director of WHO, adopted a plan of action for cooperation and the development of traditional medicine. This action plan covered *inter alia* intellectual property rights related to traditional medicines. Under the action plan, specific projects will be formulated by individual countries and implemented through the signing of bilateral agreements based on the principles of equality, mutual respect, partnership, mutually beneficial relations and the sharing of results (Special Communication, 2002).

SYNTHESIZING THE PREVIOUS DOCUMENTS

In general, the following comments are required:

- The appropriate protection of the various aspects of African traditional knowledge should be applied under the laws existing in a member state.
- The intellectual property rights protection of a country should be consistent with existing international agreements. For example, any country that is a signatory to the following conventions must develop its laws and regulations to meet their requirements: WIPO, ARIPO, OAPI, UPOV, CBD, TRIPS and the OAU Model Law.
- Globalization is not a reversible phenomenon. Thus any method of protection of traditional knowledge must find ways to avoid widening the economic gap between the different parts of the world.

In addition, with reference to all the activities and meetings carried out across Africa after the CBD, particular emphasis should be focused on the following points:

- a regulatory system for access to biological resources;
- community rights;
- equitable benefit sharing;
- sustainable use of biodiversity;
- fair management of databases.

A regulatory system for access to biological resources

- Any access to any biological resources and knowledge or technologies of local communities in any part of the country shall require the application of the prior informed consent and written permission.
- All applications shall be directed to the National Competent Authority: consultation and prior informed consent of the concerned local communities (including women) is also required.
- Any access permit shall be granted through a signed written agreement between the National Competent Authority and the concerned local community(ies) on the one hand, and the applicant or collector on the other hand.
- The Agreement shall include:
  - a limit on the quantity and a specification of the quality of the biological resource that the collector may obtain and/or export;
  - the guarantee to deposit duplicates of specimens of the biological resource, with accompanying field information, or records of community innovation, practice, knowledge or technologies with the duly designated governmental agencies and, if so required, with local community organizations;

  - a commitment to the feeding back of all findings from research and development on the resource to the National Competent Authority and local partners;
  - a provision that permits no material transfer without the authorization of the National Competent Authority and the concerned local community(ies);
  - a provision that prevents the application for any form of intellectual property protection without the prior informed consent of the original providers;
  - a provision for the sharing of benefits;
  - a committment to the efforts of the regeneration and conservation of the biological resource, and the maintainance of the innovation, practice, knowledge or technology to which access is sought;
  - a committment to provide a regular status report of research and development on the resource concerned.
- Applications for academic purposes as well as for bioprospecting with commercial partners should be treated equally.

Community rights

- Community intellectual rights, including those of traditional professional groups, particularly traditional healers, shall at times remain inalienable, and shall be protected.
- An item of community innovation, practice, knowledge or technology, or a particular use of a natural resource shall be identified, interpreted and ascertained by the local communities concerned under their customary practice and law, whether such law is written or not.
- Here, the situation of traditional healers is complicated but very important, considering their contribution to community health care all over the continent.

The strategy to protect and promote their knowledge and practices should include:

- the official recognition of traditional medicine by governments;
- the formulation and implementation of a national policy on traditional medicine.

In addition the following activities are required:

- the production of technical guidelines, and a legal and regulatory framework for the practice of traditional medicine;
- the promotion of research;
- the local production of traditional medicines;
- the registration of traditional medicines.

To achieve these goals, traditional healers should be organized in formal associations so that they constitute an identified interlocutor. In such groups, it will be easier for them to determine specific objectives, to implement collaboration between themselves and to find out what and how they intend to cooperate with researchers, physicians or economic operators, in order to promote or deepen their knowledge or practices, and thereafter to profit by the results of such multidisciplinary enterprise. Obviously, a signed agreement will govern such a collaboration, including a confidentiality clause and a provision for a benefits sharing schedule.

The registration of traditional medicines is another tool for protecting traditional healers' knowledge. The Minister of Health should establish a National Committee of Experts, which has the role, *inter alia*, to examine applications for authorization to market medicines (AMM), for medicines originating in the community but having commercial applications.

An association of traditional healers also has the opportunity to issue their knowledge in a collective work, which profits from an author's right. The publication of a written or oral description of a biological resource and its associate knowledge and information, or the presence of these resources in a gene bank or any other collection, or its local use, shall not preclude the local community from exercising its community intellectual rights in relation to those resources.

Farmers' rights

Farmers' rights are recognized as stemming from the enormous contributions that local farming communities have made in the conservation, development and sustainable use of plant and animal genetic resources that constitute the basis of breeding programmes. Farmers' varieties and breeds are to be recognized and shall be protected under the rules of practice as found in, and recognized by, the customary practices and laws of the concerned local farming communities, whether such laws are written or not. A variety with specific attributes identified by a community shall be granted intellectual protection through a Variety Certificate, which does not have to meet the criteria of distinctiveness, uniformity and stability. This variety certificate entitles the community to have the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use without prejudice to the Farmers' Rights. Any product derived from the sustainable use of a biological resource shall be granted a certificate or label recognizing this fact.

Database protection

There are many databases in Africa, and more are developing. Some are related to biological resources, their components or their derivatives. Others concern the local community knowledge and the natural resources that they use.These elements could be material or immaterial. In the development of these collections, it is particularly important to make the capture of information concerning traditional knowledge relative to natural resources a priority, because this information is highly vulnerable in societies where oral transmission prevails and where older people represent a thin sector of the population:

- The author of the database is the group of persons who contribute to the constitution of the database.

- The author has the right to dispose of the exclusive *sui generis* right in the database.
- The author profits by the exclusive right to authorize the reproduction of all or part of the database and to define the form in which its information is shared.

Various types of legal management could be included in the authorial constitutive charter including:

- free access;
- access associated with a material transfer agreement (MTA);
- access reserved to the adherent members of the charter;
- access subject to scientific evaluation.

CONCLUSION

The new millennium offers opportunities for the African region to implement efficient systems for the protection of intellectual property rights related to traditional knowledge. Success relies on the political will of the decision makers within each country. However, scientists and technicians also have a huge responsibility towards rural communities, who need information, sensitization, awareness and confidence. Rural communities are ignorant of the economic value of their knowledge or of their environment. They have a different scale of values in which human relations and good communication with supranatural forces have first priority. Globalization should not eclipse cultural identity. Traditional communities need to be aware that their knowledge is as important and useful to mankind as modern science. With such awareness, their confidence will increase. High ethical standards are required from all stakeholders: decision makers, scientists, technicians and economic operators. Everyone should focus on the same goal: the reduction of poverty in Africa by restoring the dignity of those who, for too long, have not received the esteem they deserve from the modern world. African citizens are facing a difficult but fascinating challenge. With firm desire, honesty and national and international solidarity, we will meet this challenge.

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Chapter 22

The Conundrum of Creativity, Compensation and Conservation in India: How Can Intellectual Property Rights Help Grass-roots Innovators and Traditional Knowledge Holders?

Anil K. Gupta

The conservation of biodiversity and the associated knowledge systems both need incentives tailored to specific social, ecological and economic conditions in different parts of the world. These incentives can be endogenously generated or exogenously provided. They can be in material or non-material form, and aimed at individuals or communities. The incentives can also be graduated or constant and provided singly or in the form of a portfolio. It is obvious that incentives must be substantial to act as a motivator for influencing behaviour in a particular manner. Too small an incentive may not be an incentive at all. But a combination of various material and non-material incentives can produce much more powerful synergistic effects than any one of these incentives singly.

Intellectual property rights (IPRs) constitute only a small subset of individual material incentives. Without accompanying support and mediation by other institutions and initiatives, IPRs may not bring about any significant change in the livelihood or prospects of communities and/or individuals at the grass-roots level. In the first part of this chapter, I look at different kinds of creativity for conserving biodiversity or solving the problems of everyday life, through inventions or innovations or use of traditional knowledge. In the second part of the chapter, I describe different ways of conceptualizing incentives and identify the interface of natural, social, ethical and intellectual capital and within that, the role of intellectual property rights. I also discuss the interplay among different kinds of knowledge systems such as individual, community based or public domain. In fact every knowledge system includes different proportions of all three. It is very seldom that knowledge will have only public domain or only individual/private aspects. In the final part of this chapter, I discuss the implications for intellectual property policy, institutions, and movement at the global level to ensure that future debate on this subject is better informed. I strongly decry the tendency to assume in the intellectual property rights debate that it is always the North that has strength, and has to give, whereas it is South that has weakness and therefore has to be seen to be on the receiving end. I will demonstrate that in the future, whether in the field of health or poverty alleviation, or sustainable development, grass-roots innovations from the developing world will provide important solutions for problems even in the North. The knowledge economy is going to change the current polarity of discourse and power that is biased against the South.

CREATIVITY AT THE GRASS ROOTS

When does the curiosity of an individual transcend the limits or constraints of a given situation? Instead of amplifying creativity to cope with the constraints, when does curiosity result in generating an innovation or invention? Out of millions of pigeon pea crop plants in a field, when a class IV educated farmer, Dhulabhai, picks up two plants that have pink and red flowers instead of yellow flowers, curiosity has taken over from an individual's acceptance of conventional limits of knowledge. He develops a new variety that gives a better yield, does not attract as many pests because of the red coloured flowers and therefore requires very low or no pesticide consumption. However, the inherent economic disadvantage of a small farmer becomes a modifying influence on the generation of technological advantage in the new innovation. When this farmer shares the seeds with other farmers who grow it and make enormous profits from it, he has contributed to the economic well-being of others. Soon a company might select it and develop it as a commercial plant variety without any reciprocity towards Dhulabhai. Interestingly enough, Dhulabhai may treat it as a normal occurernce and continue to struggle. Opportunity for higher income generation for his unemployed graduate son may elude him. He is not aware of the notion of intellectual property rights. The prevailing ethics generate no responsibility among the beneficiaries of the technology to share part of their gains with the provider of an innovative solution. Dhulabhai remains poor.

Teenaged Remya Jose travels for two hours one way on three different buses to reach her school. She is extremely good in academic studies as well as in extra curricular activities. Last year her mother was not well and her father has been a cancer patient for several years. She was forced to handle greater responsibility and household chores. One of the tasks that consumed much time was washing clothes for herself and also for her two sisters and parents. An ordinary person with a moderate standard of living would cope with the problem and adjust or adapt. Remya was not an ordinary person.

She decided to make a sketch of a washing machine that is also an exercise machine, (as she discovered as an afterthought), and asked her father to contact a local mechanic to fabricate that machine according to her design. She collected some old parts and her father contacted the mechanic. The mechanic faced some problems and she once had to meet with him. Otherwise her father would visit now and then and act as a link between his daughter and the mechanic. In the prevailing conservative cultural conditions, teenaged girls are generally not encouraged to mix with males. After a while, the washing machine was ready and Remya could sit on the machine, pedal it and wash the clothes and of course, at the same time, maintain her figure. A low-cost washing machine had become available. Even poor people could dream of such utilities that could reduce their drudgery and allow more time for doing other value adding jobs or just relaxing. The technology is so simple that it might seem obvious now, but the fact remains, it did not happen for a long time.

Did Remya talk about it to anyone? Most of her classmates did not know about it because she was afraid they might laugh at her. They might make fun of her and even call her 'Edison' (not as a compliment but as an attempt to mock an ordinary person claiming to be an extraordinary inventor like Edison). Nobody in the village including her neighbours knew much about what she had done. Why would they know of it until she sent an entry to the National Innovation Foundation (NIF) (www.nifindia.org) and the representatives of the foundation visited her. Slowly, recognition started coming her way. In the meanwhile, she has found some limitations in the existing design and she has started working on them. For instance, the inner drum in which clothes were kept for washing, if not used for several days, would develop rust. It needed to be either of a different material or painted with a rust proof material. NIF, through its regional collaborator, extended a US$100 grant to develop a $30 washing machine. The purpose was also to give her some money for developing the next dream of Remya's – a $50 vacuum cleaner. Perhaps with intellectual property rights protection some company would license these technological innovations and help Remya to get better medical treatment for her parents and for her go to a good college to study cardiology, a subject that she wants to pursue. She might also help her other sisters to study further. Will her dreams of being an inventor and also a technologist be fulfilled? Will IPRs help her to cross-finance her studies?

Amrutbhai, an artisan, repairs and makes small farm implements in the Pikhor village of Junagadh, district Gujarat. He lost his father at an early age, studied only up to 4th class and his mother brought him up after working as a hired labourer. By and by, Amrutbhai developed a small workshop and started fabricating a few new devices depending upon the feedback and the feed forward from farmers. During a survey of innovations in farm machinery, he was scouted as an innovative artisan. Later, during one of the research advisory committee meetings of the Society for Research and Initiatives for Sustainable Technology and Institutions (SRISTI) (www.sristi.org/cms/) in 1995, he was asked to put forward his proposals for new innovative implements or devices so that he could be given risk capital if his ideas were found feasible and attractive by the committee. He mentioned a tilting bullock cart to enable farmers to spread manure directly into the furrows before sowing crops. Normally, farmers transport the manure to the field and empty the cart in one place. With the help of baskets, farm labourers – particularly women – scatter the manure in the field manually during the heat of summer. The idea was found to be quite attractive by the committee and a small risk capital grant was given to him to develop this cart. Subsequently a patent was filed in the Indian Patent Office. The state government agreed to provide a subsidy on this cart and promote its usage. Patents in India take a long time to be granted – generally 6–7 years. In the meantime, three entrepreneurs came forward to take the technology on licence.

The Grassroots Innovation Augmentation Network (GIAN) (see http://north.gian.org/node/326) was set up in 1997 as an incubator to convert innovations into enterprises by mobilizing or providing investments. It was set up after the participants of an International Conference on Creativity and Innovation at Grassroots, organized at the Indian Institute of Management, Ahmedabad (IIMA) in January 1997, resolved that one of the most important types of institutional support needed by grass-roots innovators was support for intellectual property protection, incubation, micro-venture capital, etc. GIAN located three entrepreneurs who agreed to license the technology for five districts for five years and pay the licence fee of about $2000. This was the first time a technology had been licensed on a district basis for which a patent had only been filed (not yet granted) and it was easy to copy, and yet entrepreneurs agreed to license the technologies. Among other things, it also showed that a new ethic was emerging in the market place where respect for the intellectual property of an innovator was beginning to be articulated.

Recently GIAN put together a portfolio of about 12 sprayers of various kinds and sizes for licensing to entrepreneurs. Many of the sprayers received awards from the NIF, which was set up by Department of Science and Technology in March 2000. The NIF builds upon the previous 15-year struggle of the Honey Bee Network (http://knownetgrin.honeybee.org/honeybee.html) to give respect, recognition and reward to unsung heroes and heroines of our society who have solved technological problems without any outside aid from formal institutions or prominent individuals. The portfolio of these sprayers was publicized among various potential entrepreneurs. In August 2003, an entrepreneur came forward to license four sprayers on a non-exclusive basis by paying a licence fee of $5,000 and a royalty of 2.5 per cent on sales for five years. If the entrepreneur desires to renew the licence for another five years he has to pay 15 per cent of licence fee paid now as a renewal fee. The patents for these four sprayers are still being filed. The individual cost of these sprayers varies from $5–50 apiece. They are easy to copy and if the entrepreneur had copied these, there would be hardly any legal recourse to prevent him from doing so. Why did this entrepreneur pay fees when patents are yet to be granted and when he could have easily copied the designs without legal liability? Perhaps he wishes to use the recognition given by SRISTI and NIF to these innovators as a sale promotion strategy. He may also wish to share the potential benefits with the innovators, plus he respects the intellectual property rights of the innovators. He has promised a goodwill payment to SRISTI from the proceeds of the marketed products. Yet another example of increasing respect for intellectual property rights in a society where imitation and not innovation has been the rule for a long time.

Arvindbhai has developed an auto-kick pump. It helps by filling air in the tubes of two-wheelers, when punctured in use, by utilizing the engine as the air compressor. The device is very handy and costs only $5. Frequently, when people experience punctures in two-wheelers, while driving long distances, they get stranded on the way. They either have to drag the two-wheeler to the next repair shop because they do not have a spare wheel or they have to hire another means of transport to carry the two-wheeler to the nearest puncture repair shop. A patent for this device has been filed in India as well as the US. The innovator received an award at the hands of the President of India at the Second National Award Function award organized by NIF in December 2002. An entrepreneur in Mumbai has licensed this technology (although a patent is yet to be granted) and paid a licence fee of $1000 and agreed to pay a royalty of 2.5 per cent of sales after he has sold 10,000 pieces. In India half a million two-wheelers are sold every year. This product obviously has a global market and the rights for licensing the technology abroad are assigned to SRISTI.

Likewise there are 35 other cases where patent applications have been filed in India for herbal, mechanical and other technologies (see Appendix 1) and five patent applications have been filed in the US, one of which was granted on 8 April, 2003 to Mansukhbhai for developing an innovative cotton stripper. All these patents have been filed through *pro bono* help from intellectual property rights firms in India and the US through GIAN.

In addition to the above, several other incentives have been provided to the conservators of biodiversity, as well as other inventors, primarily to promote creativity and innovation at the grass roots and conserve resources in the process.

INCENTIVES FOR CONSERVATION, CREATIVITY AND INNOVATION

In a paper entitled 'Why the poor do not cooperate', (Gupta, 1987) I argued that a change not monitored is a change not desired. If a society does not monitor and reward creativity and innovation at the grass roots, it obviously does not desire the same. This may be a strong statement and may not be liked by many but the fact remains that most developing countries see intellectual property rights as an instrument of control and manipulation by the developed countries and within them by large multinational corporations. They do not see intellectual property rights as the instruments for rewarding creativity and innovations in their own society so as to make that society innovative and competitive in emerging global markets. It is not my contention that stronger protection of intellectual property rights alone will make societies innovative. I would not even argue that intellectual property rights can be a major instrument in achieving that goal. But respect for intellectual property rights can certainly bring about a change in the ethical barometer of a society as has been shown in the first part of this chapter. It does not matter too much what kind of disputes arise so long as the basic ethics and humanitarian concern lie at the core of consciousness of various actors in the value chain and a framework for ethical resolution is created. Initially, many people will not respect the intellectual property rights of others and some people will misuse their own rights. However, the experience of the Honey Bee Network over the last 15 years shows that recognition and reward, even in non-monetary forms, can be a great motivator for the people and therefore spur creativity.

In this section, after recounting stories illustrating perennial efforts throughout history to protect what we would call intellectual property, I describe the experience of the Honey Bee Network in promoting creativity and innovation. The interface between public, private and common domain knowledge and resources is discussed next and the interface between natural, social, ethical and intellectual capital is described. I also highlight the need for tailoring incentives according to the contingent interface between different kinds of capital and different domains of knowledge. Brief examples will be given of four kinds of incentives, that is material individual, material collective, non-material individual and non-material collective. The argument will be that a portfolio of incentives will always be more rewarding and sustainable than any one incentive alone.

I have demonstrated in earlier studies that almost every society around the world has attempted segmentation of the knowledge market from time immemorial (Gupta, 1999b, 2000). For instance, communities have tried to draw boundaries around knowledge such that not every kind of knowledge was considered to be in the public domain. Asymmetry in knowledge production and distribution was essentially responsible for some people becoming better known than others for specific skills. Stories abound in which skilled people preferred to suffer ignominy rather than reveal their secrets. Any number of examples are available in which traditional knowledge holders did not disclose their knowledge even to close kith and kin. Many of them believed that knowledge would lose its effectiveness if shared with others. At the same time most of them did not charge for their services for healing humans or animals. Still, it is not the case that the concept of intellectual property protection is a construct developed in post-industrial societies. However, it is true that modern forms of intellectual property protection, which are managed through legal instruments rather than societal norms, are indeed developments of the last few centuries.

Societies evolved various means to protect intellectual property and some of these means were extremely coercive. The world famous monument of Agra known as Taj Mahal was built in white marble by a Mughal King, Shahjahan, in memory of his wife Mumtaj. Large numbers of artisans worked on it for several years to create the eighth wonder of the world. However, few people know that the right hand of all these workers was cut off so that they could never build another Taj Mahal. A monument of love actually became a monument of torture in order to protect the king's creative design. In Manusmruti if scheduled caste people (lower caste untouchable people) were to hear vedic hymns, it was prescribed that molten lead should be put in the ears of such people. They were not supposed to learn and acquire the vedic knowledge, a preserve of Brahmins.

There is also a famous epic in India called Mahabharat. It describes the extraordinary reputation Dronacharya had for teaching students, among other things, the skill of archery. He was a famous teacher who had an ashram, a kind of elite school for the children of royal families. Once a tribal student called Eklavya came to seek admission in his ashram. Dronacharya refused him admission because Eklavya was not a royal scion. Eklavya was very determined to learn archery only from him. He made an idol of his assumed guru, Dronacharya, and put it before him in the forest. He started practising every day to hone his skill in archery. One day Dronacharya was moving in the forest along with his disciples, including Arjun, whom Dronacharya wanted to become the best archer in the world. Suddenly a dog started barking and disturbing their conversation among themselves. Then, they saw that the mouth of the dog was so filled with arrows that it could not bark anymore. Dronacharya told his disciples that someone who could aim arrows by hearing a sound from a long distance would be an extraordinary archer. They went in search of this person. After a while they discovered Eklavya who bent on his knees to pay respect to Dronacharya. Dronacharya asked him from whom he had learnt such fine archery skills. Eklavya confessed that it was Dronacharya himself who had taught him. The teacher was flabbergasted. When questioned further, Eklavya showed him the idol that he had worshiped as he practised all these years. Dronacharya asked him to pay gurudakshina, that is, a kind of fee, if he indeed had learned from Dronacharya. Eklavya agreed and immediately offered to pay whatever Dronacharya wanted. Dronacharya asked him to offer the thumb of his right hand, which Eklavya immediately did. He was incapacitated for life, and thus the career of an outstanding archer was nipped in the bud.

This tale is narrated in the Indian subcontinent to reinforce devotion to teachers and to show what can one achieve by persistence and perseverance. Historically, the attempt Dronacharya made to protect his proprietary business methods by sharing them only with those in whom he had faith was never considered obviously bad.

Likewise, any number of healers and herbalists believe that their particular formulations would lose their effectiveness if revealed to anyone else. Frequently, the knowledge of such formulations dies with these healers. Moreover, many healers reveal the knowledge of the particular healing technology only to their closest kith or kin. In Patan there is an old traditional technology of dyeing and weaving patola silk sarees in such a manner that the same design appears on both side of the sarees. This is a 750-year-old tradition involving the use of vegetable dyes and it is considered one of the most complex manual weaving technologies in the world. Only three families are continuing this tradition. Now, however, fake imitations of Patola sarees are known to flood the markets. If additional protection is not provided for this rapidly vanishing traditional technology, these few families will have little or no incentive to carry on this tradition. It is said to have been customary among families to teach the skill only to their daughters-in-law not their daughters, as daughters customarily shift their domicle after their marriage to their husband's family, that is to the son-in-law's family. Parents wanted to protect their intellectual property rights and keep the technology within the family.

There is another story about a community in Murshidabad, in the northern part of West Bengal, which was known for a very exquisite variety of mangoes, endemic to the region. It was customary to send a basket of these mangoes to the king and later to the British viceroy. But the people were clever. They took a very thin needle and punctured the seed of each mango before sending it to the king. The idea was that this variety should not be grown elsewhere – a kind of plant variety protection through indigenous *terminator* technology.

There are numerous other examples where communities have tried to assert their rights over intellectual property in the past and wish to continue asserting them in the present. In a famous case in Australia, the Federal Bank of Australia used a painting made by a particular aboriginal artist on a $5 bill. The community of the artist came to know about this and protested. The community leaders believed that the artist had no right to license his art to the Federal Bank because he had made the painting after following certain rituals sanctified by the community. The painting could not have been what it was, they argued, without the community cultural codes and rituals. Therefore, only the community had the right, they claimed, to license or not the work of their members to any outside agency. The court did not accept this particular argument but was sympathetic.

The entire debate on biopiracy rests on the assumption that property rights of some sort exist in biodiversity, and associated traditional knowledge. Whether these rights exist at the level of nation states, communities or individual farmers or tribal healers, is a matter of debate and the recent FAO Treaty and the CBD (see Chapter 1) provide a framework for dealing with that question. A safe conclusion is that neither the resources nor the knowledge associated with these resources can be considered a public domain resource. Otherwise the entire case for compensation and benefit sharing falls.

Intellectual property rights in creativity and innovation at the grass roots

Let us look at the issue of intellectual property rights creativity and innovation at the grass roots, which may or may not involve traditional knowledge. Generally when we deal with the issue of traditional knowledge three aspects should be kept in mind:

1 Traditional knowledge is evolved by people to cope with various stresses and challenges around them. In many cases, institutional norms, ethical values and cultural codes also evolve along with traditional knowledge. While some of the bits of knowledge perform very specific functions, such as solving health, conservation or production problems, others help in shaping the broader worldview. With the passage of time, some of this knowledge, innovation and practice survives in functional form and some as part of belief systems, even as superstitions. Not everything in the tradition is necessarily functional or even morally desirable. A healthy sceptical approach provides answers to the constant struggle that takes place between traditional technologies and contemporary consumer needs. Not everything, rejected by the consumers, is necessarily wasteful and

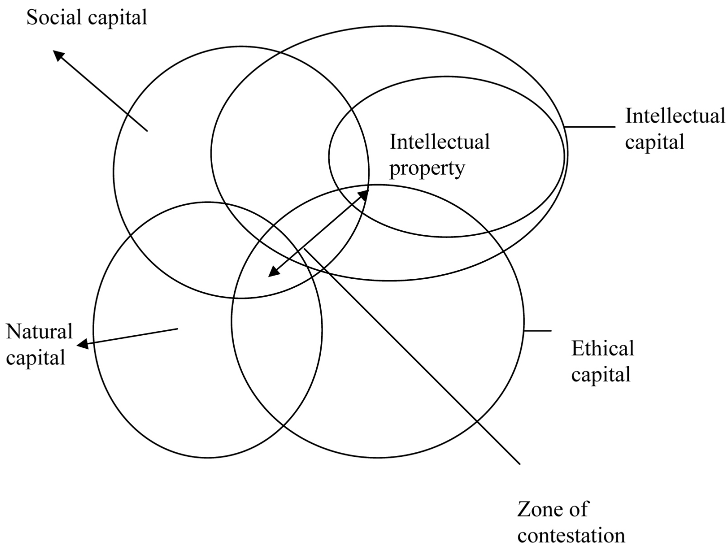
likewise not every part of tradition carried forward by community members is necessarily synergistic with the demands of a modern rational and communitarian society.

2 Traditional ways of solving problems will always remain a powerful means of generating grass-roots innovations and improvised traditional knowledge. Trial and error, keen observation, experiments and an eye for detail contribute to many innovations at the individual or community level. The tradition of invention is a continuing one, although given the colonial history and defeatist mentality it might have spawned in developing countries, many people may not recognize this tradition. The problem thus arises when many of these innovations developed recently or a long time ago at the grass-roots level are not recognized or rewarded. Diffusion of such innovations may not take place and people may struggle with the same problems that might have been solved in another part of the society. Farmers, men or women, might select an odd plant that eventually generates a new plant variety, or develop a new machine, or develop a new drug or use the fat of fish for killing pests, etc. These solutions might even be seen as contemporary grass-roots innovations.

3 Traditional technologies many times involve modern materials, scientific concepts and tools. In many ways these innovations are quite similar to the innovations generated in the formal scientific and technological systems, except for the process by which these solutions are evolved. A fishing community develops a new use of dynamite for catching fish (a non-sustainable means), farmers use a soap solution (soap made of new chemicals and different from old natural oil soaps) for controlling pests, or a potter uses concrete to make tiles for a roof, etc.

The values guiding these solutions also differ from some of the dominant values in the modern system. For example, most innovators generously share their knowledge, innovations and practices whether based on local resources, traditional technologies and tools or modern materials or tools. Because of this sharing, the users may benefit but the producers of knowledge do not, except in a spiritual sense. However, that may be the reason why many of them remain poor. Children do not want to pursue the knowledge path, erosion of traditional knowledge takes place, and society loses a very valuable source of local solutions. Giving creative people their due could restore respect for traditional knowledge and help in blending it with modern science and technology and produce valuable intellectual property.

Historically, natural capital was the first to be created when the domestication of species began. Humankind used several approaches to define property rights in natural resources: (1) marking territories within which one group claimed rights for hunting food, gathering or fishing, etc.; (2) evolving norms, values and rituals restricting the use of various species over time, space and social categories; (3) developing technologies for harvesting, storing, distributing or exchanging natural produce to extract economic and social rent; (4) cultivation of crops, rearing of animals or managing fishing grounds through common property institutions or



Source: Gupta (2001)

Figure 22.1 *Relationship between natural, social, ethical and intellectual capital and intellectual property*

common poor resources; (5) privatization of rights in land, or water or biological species reared on common property or open access territories; (6) private assignment of rights in land and water and the natural resources found or grown in them; (7) multiple layers of rights over the same resource varying over time and/or space,[1] etc. Given various ways of generating natural capital, some of it may overlap with social and ethical capital. Social capital involves evolution of norms, trust and reciprocities such that the private transaction costs of using resources or internalizing the externalities go down. Ethical capital is a subset of social capital where institutional norms govern the way natural and social capital are used within the ethical framework evolved by the communities. Intellectual capital is the sum total of knowledge produced while generating natural, social and ethical capital. Only a small part of intellectual capital is governed by intellectual property norms, whether formal or informal or customary in nature.

The evolution of intellectual capital can be understood through the interface of the private or individual driven production of knowledge, community-based knowledge systems and pubic domain knowledge systems. Contestation emerges when the producers and users of knowledge have unequal access, ability and assurance about the resources and the benefits emerging from commercial or non-commercial usage of those resources with or without value addition (Gupta, 1999a).

One of the issues to be explored is the relationship between property right regimes governing resources vis-à-vis the knowledge associated with these resources (see Table 22.1)

Table 22.1 *Resource right regime*

Knowledge right regimes	*Private*	*Community*	*Quasi public*	*Public*
Private	PKPR	PKCR	PKQPR	PKPUBR
Community	CKPR	CKCR	CKQPR	CKPUBR
Public	PUBKPR	PUBKCR	PUBKQPR	PUBKPUBR

PKPR: Private resource and private knowledge right: if an individual has proprietary knowledge about the use or application of a particular plant or variety found only in her land, then the right to exclude from the physical property and intellectual property are privatized. Such a case will be rare because single plant varieties are unlikely to exist in one habitat alone. However, in Latin America and Africa there may be individuals who own large tracts of land or water bodies having endemic biodiversity around which proprietary knowledge might be developed.
PKCR: Private knowledge concerning community resource: a healer may develop specific knowledge about the use of a plant or a fish or any other natural resource found on common property. The right to disclose, dispense or disseminate the knowledge developed by this individual may be governed by customary knowledge rights or contemporary protection under intellectual property rights laws. The community may or may not demand rent from the income generated by the concerned individual through use of the resource. It is also possible the concerned individual may not disclose the knowledge but dispense the medicine or other services associated with community resource free of cost.
PKQPR and PKPUBR: Individuals may likewise produce private knowledge about resources governed by quasi public (neighbourhood resources) or public resources such as public forests, lakes or grazing land. The nature of the right and its legal derivations may not vary much from PKPR except where public authorities may control the right of extracting resources from public properties. In such cases the right to use proprietary knowledge may be circumscribed by the access to a public resource.
Likewise, the community and the public may generate knowledge concerning private, community and public resources.

NATIONAL AND INTERNATIONAL INNOVATION POLICY DEVELOPMENT

In the final part of this chapter, I suggest various national and international policies that would help promote conservation, creativity and innovation at the grass roots.

National innovation policy

1 National technological innovation acquisition fund

There are inevitably a few inventions and innovations that the concerned innovator (in the private, public or informal sector) may not have the wherewithal to scale up. Some of these innovations may need to be diffused for the larger social good. For instance, improvements in design of a kerosene stove that saves energy may be vital for national interest but the concerned innovator (as is indeed the case with some of the innovators with NIF who have improved stove design) may have neither the incentive, nor the capacity, to diffuse the design among large numbers of small-scale manufacturers. But then who will invest in the diffusion of such technologies and why? A National Technological Innovation Acquisition Fund may be created to acquire the licensing rights to such innovations and inventions for eventual out licensing at low or no cost to small-scale manufacturers under a technological upgrading programme.

2 Protection of traditional knowledge

Traditional knowledge systems help a very large section of our society not only survive against all odds but also generate products that might have national and global markets if properly developed. Within traditional knowledge systems are innovations and improvements by individuals and communities that need protection so that potential investors can have incentives to invest and recover the cost of investment. It has to be appreciated that if traditional knowledge is assumed to be in the public domain, then no exploiter of this knowledge within or outside the country will be obligated to compensate or reward the knowledge provider. However, traditional knowledge systems in many cases, when blended with modern science and technology, can generate immensely valuable solutions for societal problems and opportunities for improving livelihood opportunities for knowledge holders. Another very important ethical, moral and institutional issue is why traditional knowledge holders should be expected to disclose their knowledge with the National Innovation Foundation if NIF cannot protect their rights?

A system of protection may require that any community or individual disclosing their knowledge for posting on a National Register for Grassroots Innovations and Outstanding Traditional Knowledge may get provisional protection for say, ten years with a maximum of five claims per innovation or traditional knowledge, subject to the following conditions:

1 If any other community also claims similar knowledge, then that community will be considered the co-holder of the rights. (The system should not encourage inter-community fights about ownership.) The assumption will be that unless the knowledge is unique (i.e. patentable), it is quite possible for similar solutions to emerge across communities over time and space for similar problems particularly when base resources, for example the same plants, exist in those regions.
2 The duration of protection may be extended if any further improvements have been made and disclosed.
3 Possibly a small tax on every herbal and ayurvedic product and forest product import, as well as domestic trade above a particular scale, could be levied to collect revenue for conservation, reward and information dissemination to traditional knowledge holders.
4 Local language databases of such disclosed innovations and traditional knowledge as well as of patents issued on herbal knowledge should be developed and made available at the district level for scrutiny by the traditional knowledge holders and tribal communities. Such a database must be insisted upon at the international level also.

5 All university and research institute scientists working on traditional knowledge must be advised to use a prior informed consent form (Appendix 2) to ensure that they do not publish the results of their research without (a) sharing with the knowledge holders and providers; (b) obtaining the consent of the traditional knowledge holders; and (c) ascertaining the uniqueness of their research so that intellectual property rights protection opportunities are not missed. They must be obliged to share part of their pecuniary gains, if any, with specific communities or a national fund. This fund may be managed a by non-bureaucratic body responsible for sharing it fairly and without undue transaction costs with traditional knowledge holders.
6 All commercial organizations must be obliged to share part of their profits with the National Biodiversity Conservation Fund where they draw upon wild biodiversity (on which local communities depend and survive) without any reciprocity or responsibility for conservation. This is important because traditional knowledge systems cannot survive and grow if the resource base on which they rest itself does not survive.
7 A national fund needs to be set up to promote the filing of patents by grass-roots innovators and TK holders internationally. NIF has facilitated five patents for innovators in the US, of which one has already been granted with the help of SRISTI and the *pro bono* services of a Boston-based law firm.

3 Disclosure requirement in patent applications

This suggestion needs to be pursued at the international level also. Every patent applicant should be obliged to disclose whether the resource and/or knowledge obtained from third parties for developing the patent claims have been obtained lawfully and rightfully. Evidence of 'lawful' access would establish that whatever laws exist in the source countries have been complied with. Evidence of 'rightful' access would establish that the prior informed consent of the knowledge providers has been obtained. It is obvious that India can argue for this change only if it brings it about within its own territory.

India should consider developing laws requiring such consent and disclosure by any domestic or international party proposing to work on traditional knowledge.

4 Product patents

Product patents are essential if traditional herbal knowledge systems are to be valorized for generating new products and services that increase social welfare, and providing a new knowledge-intensive model for poverty alleviation and employment generation. It may be mentioned here that in a study of herbal patents done a few years ago, I found that China had about a 45 per cent share of the total herbal patents, followed by Japan, at about 20 per cent, and Russia at about 16 per cent. Most of the inventors were individuals not corporations. The concentration of patents was very low and most people had sought protection in only one or two countries. Two other observations make this point even more important. One in five Americans uses Chinese medicine, and in China, herbal medicine finds a place of honour in the chemist's shop, unlike India where such medicines are generally kept in an obscure corner. Without a product patent, we cannot protect herbal knowledge in any significant manner. The Indian Traditional Knowledge Database Law (TKDL) provides only defensive protection through disclosure so that patents on public domain Indian traditional knowledge are not issued by various patent offices in the world. This serves a very useful purpose, but it obviously answers only a limited but important problem. The larger problem of protecting the rights of traditional knowledge holders remains unadressed by TKDL.

International innovation policy

1 International registry of sustainable technological innovations and traditional knowledge

The Society for Research and Initiatives for Sustainable Technologies and Institutions (SRISTI) made a proposal for developing an International Network for Sustainable Technology Applications and Registration (INSTAR) in 1993. The purpose is to provide a low-transaction-cost system for innovators and traditional knowledge holders to obtain worldwide protection and thus have an incentive to disclose. Traditional knowledge holders in many developing countries that do not have any capacity to set up such systems in the next decade or two will suffer if such a registry is not established.[2] In TRIPS there is a provision for an international registry to be negotiated for wines and spirits. There is no reason why such a negotiation should only concern itself with the interests of a particular European country, at whose behest this clause was incorporated in the TRIPS.

2 Geographical indications and service marks

Collective marks could also be utilized by associations of healers, seed producers and others to guarantee the quality as well as authenticity of products. Accordingly these could improve the prospect of market returns and consequent benefit sharing. These provisions can go a long way in safeguarding traditional habitats and lifestyles. It is obvious that if a particular production process or output does not derive any specific advantage from a given region, it might move to locations where it is cheaper and more profitable to make it. Accordingly, local producers might have to emigrate to these regions where production now takes place or may have to become unskilled labourers in the other urban and rural regions. Patan silk is a good example, as only three families are left in north Gujarat and one on Baroda who pursue the authentic 750-year old patan silk tradition.

Much of traditional knowledge and products have disappeared precisely through such erosion of opportunities associated with geographical regions. Most developing countries have not yet taken steps to provide protection to distinct localities and characteristic products and processes utilizing local knowledge and biodiversity.

3 Sacred marks registry at international level

In many cases, sacred signs and marks of one culture have been used by another culture in an irreverent manner causing hurt and disrespect to other cultures. India should argue strongly for an international registry of such marks and also a general agreement that names and signs associated with God and goddesses venerated by any culture would not be allowed to be used in a disrespectful manner (some years ago, a US company put such pictures on toilet seats). Of course, such respect should be shown domestically also.

4 Intellectual property information system

The ability of the local communities to avail themselves of existing intellectual property instruments depends on their ability to access existing IP information in their own language and in a manner that is readily accessible to them. Granting that much traditional knowledge is available in the ecologically rich regions where market forces and administrative support systems are weak, one has to recognize the complexity of providing IP information systems in a widely accessible manner.

The essential elements of IP an information system would include the following institutional and technological arrangements:

1 A very wide information technology-based communication network in remote regions, enabling community leaders and educational research institutions to scan prior existing IP on plants, animal products or other associated knowledge or innovations developed by these communities. In the absence of prior experience and training many of these communities would find it difficult to make sense of the IP information even if it were available in local languages.

2 Capacity building among local educational, research, community and public service agencies for providing support to local communities in searching and interpreting existing IP on biodiversity, genetic resources and associated knowledge systems.

3 It is to be expected that there would be many cases where traditional knowledge and/or genetic resources have been obtained without prior informed consent, or developing mechanisms for sharing of intellectual property or any kind of benefits. Many such cases could relate to periods before CBD came into being and also before national sovereignty on biodiversity was recognized. It will be difficult for local communities to recognize and appreciate that they cannot object to the violation of their ethical and intellectual property rights simply because the legal system was not in place to defend their claims. There could also be cases where an opposition could not be filed even if the patents being applied for used prior known TK of specific communities, as was the case with the US ayahuasca (*Banisteriopsis caapi*) patent. The conventional legal constraints on the period within which opposition can be filed may need to be reviewed so far as it relates to knowledge of communities.

4 Legal help to local communities to file objections in cases where intellectual property has been obtained on prior traditional knowledge could pose two

problems: (1) if local community knowledge is considered prior art then it might facilitate questioning of some of the existing patents but it might also prevent the seeking of new intellectual property on the unclaimed intellectual property of local communities; (2) it will be difficult to make the case that a plant found in many places could not have been identified as a source of a particular compound or use independently for which a particular local community had found a use. Therefore this issue of prior art is very complex. My own belief in the matter is that communities have more to gain by accepting that much local knowledge is considered outside the prior art definitions unless it is well known and is in public domain through widespread practice. For all other cases where knowledge is restricted to a small localized community and otherwise inaccessible to outside scholars or corporations, it should be considered patentable subject matter, subject to an obligation to share benefits.

5 The information system will need to have a national and international hub, enabling national and international IP support organizations to play a role in educating as well as empowering local communities to deal with a whole range of issues affecting their rights. In other words IP help desks capable of handling queries from local communities in local languages would need to be created to provide support.

6 It is obvious that the current capacity of neither international nor national IP systems is sufficient compared to the need of large numbers of communities around the world. This has led to the widespread feeling of rights violations among these communities. Many communities that do not support the concept of IP on their community knowledge would also like to ensure that others not authorized by them do not seek private individual IP rights on their knowledge. An IP information system administered by WIPO should take care of the needs of such communities as well.

7 Pilot projects for providing access to IP information systems with the help of NGOs and willing national agencies need to be started to learn first-hand the various complexities involved in the task.

Adoption of national and international innovation policies such as the foregoing should go a long way toward responding to the conundrum of creativity, compensation and conservation in India and elsewhere.

APPENDIX 1

List of Patent Applications Filed by NIF IPR Division/GIANs (December 2002–July 2003)

Serial no. & competition	*Innovation and innovator*	*Country*	*Status*
1, 2nd	Single wheel weed remover. Gopal Malhari Bhise	India	Filed (with provisional specification)
2 1st	Improved multicrop thresher. Madanlal Kumawat	India	Filed (with provisional specification)
3, 2nd	Portable power generating device N. V. Satyanaryana	India	Filed
4, 1st	Sprinkling apparatus with multiple nozzles. Annasaheb Udgavi	India	Filed (with provisional specification)
5, 3rd	Double acting liquid discharger. Manubha Jadeja	India	Filed (with provisional specification)
6, 2nd	Pathfinding android. Prem Singh Saini	India	Filed (with provisional specification)
7, 1st	Multicylinder reciprocating pump. Shakun Das	India	Filed
8, 1st	Coconut harvesting device. P. Karuppiah	India	Filed
9, 3rd	Dishwashing apparatus. Anil K. Makkanwar	India	Filed (with provisional specification)
10, 2nd	Self-propelled weeder. Ramkumar Patel	India	Filed
11, 2nd	Leaf mat-making apparatus. P. Marthandan	India	Filed
12, 1st	Cardamom drier. P. J. Abraham	India	Filed
13, 1st	Water level indicator. Eldose Markose	India	Filed
14, 3rd	Mobile charger. Manoharan	India	Filed
15, 1st	Moped LPG kit. Ram Kumar	India	Filed
16, 3rd	Manual washing machine. Ramya Jose	India	Filed
17, 2nd	Improved bicycle. Kanak Das	India	Filed through (GIAN-NE)
18, 2nd	Process … Mooga silk. Dulal Chaudhary	India	Filed through (GIAN-NE)
19, 3rd	Power disc. Deb Gupta	India	Filed through (GIAN-NE)
20, 3rd	Anti-locking device. G. C. Gogoi	India	Filed through (GIAN-NE)
21, 3rd	Process … for treating bone fractures. Pushpalata Saikia	India	Filed through(GIAN-NE)
22, 3rd	Beauty care umbrella. Dulal Chaudhary	India	Filed through (GIAN-NE)
23, 3rd	Process … Mosquito repellent. Leena Talukadar et al	India	Filed through (GIAN-NE)
24, 3rd	Combating termites with Ipomea Carnea. Jacq Upasana Talukdar	India	Filed through (GIAN-NE)
25, 1st	Power saving pump. Ram Naresh Yadav	India	Filed through GIAN-N
26, 2nd	Process … medicine for kidney-stone.	India	Filed through GIAN-N
27, 2nd	Tooth extraction machine.	India	Filed through GIAN-N
28, 1st	Oil expeller. Kalpesh Gajjar	US	Filed through GIAN West
29, 2nd	Cotton stripper. Mansukhbhai Patel	US (Granted) US 6543091, 8 April 2003	Filed through GIAN West

Serial no. & competition	*Innovation and innovator*	*Country*	*Status*
30, 1st	Adaptive agricultural machine. Mansukhbhai Jagani	US	Filed through GIAN West
31, 2nd	Convertible 3-wheel tractor. Bhanjibhai Mathukia	US	Filed through GIAN West
32, 1st	Fibre optic cable. Anand Gogte	US	Filed through GIAN West
33, 2nd	Auto air-kick pump. Aravindbhai Patel	US	Filed through GIAN West
34, 1st	Aruni tilting bullockcart. Amritbhai Agravat	India	Filed through GIAN West
35, 1st	Natural water-cooler. Arvindbhai Patel	India	Filed through GIAN West

Please note that last two applications were filed by GIAN West before the existence of NIF. The entries from the third competition have been taken up for IP protection on the basis of *prima facie* evaluation. The formal screening and evaluation for possible awards is yet to be completed.

For further information, contact info@nifindia.org; also visit nifindia.org and sristi.org gian.org.

APPENDIX 2

National Innovation Foundation, Ahmedabad

Explanatory Note for PRIOR INFORMED CONSENT

NIF is extremely happy that you have shared Innovation/Traditional Knowledge developed/communicated by you based on your own and independent effort or drawn from community knowledge. It has been included in the National Register of Grassroots Innovations and Traditional Knowledge. We need your informed consent before we decide to share this with any third party, or on the web or in any publication, or with any prospective entrepreneur or potential investor, or other individuals or communities requiring that knowledge for their own livelihood needs, with or without any restriction as per your instructions.

The objective is to balance the twin goals, partly in conflict, of dissemination and protection of your innovation/traditional knowledge. Dissemination will benefit communities and individuals directly without any cost where as the protection and potential commercialization of the same through contractual arrangements may also help them but at some cost. If we had an intellectual property rights system in our country that granted the rights quickly, we could have got you the protection for new and non-obvious innovations/localized traditional knowledge with industrial applications. We could have then shared the innovation/traditional knowledge with others without causing any trade off. It is because of the absence of such a system that we need your PIC so that we do what you think proper under the circumstances. PIC is also needed to fulfil ethical responsibility that NIF has towards knowledge providers (individuals or communities) and grassroots innovators.

NIF is duty bound to follow your instruction and keep complete confidentiality if that is advised. The purpose is to make you aware of your rights as a knowledge provider and as a contestant in the National Competition for scouting green grassroots innovations and traditional knowledge. It is not required as yet by law but NIF has decided to take your PIC so as to follow an ethical practice. This will help generate an environment of trust among various stakeholders who may provide innovation or add value to it or may have interest in commercial or non-commercial diffusion of the same. However, if the knowledge, innovation or practice provided by you is already well-known and is in public domain, then the restrictions on its diffusion or application will not apply.

Consent of community for sharing traditional knowledge with NIF

Community knowledge, innovation and practices may sometimes be communicated by individuals who may or may not have improved it significantly. In general, we will appreciate if any communicator of community Innovation or traditional knowledge would ensure the following conditions:

A Knowledge of a community, as it exists, is shared with NIF preferably after obtaining the informed consent of the concerned community leaders, with the understanding that individual improvements in the same can indeed be communicated after informing the community.

B The degree to which a given traditional knowledge is known and/or practised within or among communities may be disclosed in the submission.

C In the case of community traditional knowledge, any individual may share the same with NIF as stated above, but the right if any (that is if the traditional knowledge is not in the public domain already) would belong to the community represented by its leaders or customary institutions except in the cases where (i) improvements are brought about by individuals or (ii) only an individual practises or specializes in that knowledge. In the latter two cases, the benefits if any would be shared between the individual and the community.

It is obvious that each individual communicator or community representative submitting entry to NIF will have to ensure compliance with these conditions. NIF will act in good faith and without negligence and hope that this will eventually become a general practice in the country. NIF will have no machinery of its own to ensure that this has indeed been the case in each entry. What we hope is that as the awareness increases in society about ethical ways of accessing people's knowledge, more and more people will comply with these conditions.

The process of seeking consent by NIF provides the Innovator/Traditional Knowledge Holder/s with complete information on the basis of which to make an informed decision. In case of incomplete information provided by you, we will be bound only by the columns ticked or instructions provided. Wherever possible, if your innovation or traditional knowledge has been scouted by some third party, he/she will also try to explain to you the implications of PIC.

Definitions:

Unaided technological innovation refers to any technological improvement in an existing method, use or material involved in solving a problem or producing a product or service; or a new invention or application of existing technologies without taking the help from any outside agency or institution in the formal or informal sector. Innovations or inventions/traditional knowledge, which may cause any adverse consequence to the environment or cause any moral hazard, will be excluded from the purview of NIF.

Traditional Knowledge is any knowledge, innovation or practice produced by individual knowledge experts, healers, crafts persons, etc., alone or in groups or as a community a long time ago or several generations ago.

There are three implications of '*Informed Consent*': (1) that the innovators/knowledge providers have been fully informed of all information relevant to the activity for which the consent is sought, in the native language or other mode of communication; (2) the innovators/traditional knowledge holders understand and agree in writing to the carrying out of the activity for which the consent is sought, and the consent describes that activity and lists the records/innovations or traditional knowledge that will be released to third party; and (3) the innovators/traditional knowledge holders understand that the consent is voluntary and may be revoked by them.

It is true however, that even after you sign the form, you are free to change your mind and decide not to participate in the value chain or technology transfer process. But such a change may not be binding on the agreements already entered into by then by NIF or anybody assigned with the responsibility. NIF is duty bound to keep you informed of the progress in the development, if any, of your idea or innovation. You can change your views at that stage also.

There are a number of implications for each of the conditions:

Sharing of addresses with a third party

Quite often people interested in an idea or innovation or traditional knowledge are keen to find out more about the same, just for curiosity's sake, or for adding value or doing further research or for exploring commercial opportunities of using the same.

Advantages of providing your address:

- The third party may directly contact you and thus his/her transaction cost of seeking information will be reduced.
- You may be able to assess the terms of possible agreement directly without any influence or suggestion by NIF.
- Dissemination of your ideas may take place directly through you without any chance of distortion or loss of information.

Disadvantages of giving your address:

- While dealing with a third party, you may or may not be able to (a) ascertain the genuineness of the information seeker; (b) negotiate a favourable deal; (c) or draw up a proper agreement safeguarding your interests.

In case you do not provide your full address, we offer to mediate and help in the process of negotiation and try to protect you from unscrupulous parties. However, even if you wish to deal directly with the third party and at some stage seek our help in negotiation, you are always welcome to contact NIF.

Sharing of the innovation/idea on the web site or through publication in *Honey Bee* or other media such as film: with or without full disclosure

Nature of disclosure:

- We can show only the summary
- We can show the entry in detail

Partial disclosure or disclosure in summary form only

Advantages of partial disclosure:

- Potential entrepreneurs, investors or other collaborators including researchers in private or public sector may show an interest in joining hands in improving the technology or TK or disseminating it on a commercial or non-commercial basis in society. The summary statement for a herbal technology may mean, for instance, ‘a herbal solution to treat diabetes developed and based on local available raw materials’. Likewise, in the case of a machine it may be, ‘a motorcycle based ploughing machine’.
- Appreciation may follow from others within and outside of one’s community when others with similar problems read or hear about your innovation. This recognition may prove to be more valuable for some people than any monetary reward.
- The media (press, radio, television, etc.) may approach you for wider sharing of your innovation/traditional knowledge if they find the summary of your information interesting

Disadvantages of partial disclosure:

- Potential investors, entrepreneurs or scientists may not contact you for development/commercialization of product if they can make it with the help of disclosed information on their own.

Full disclosure

Advantages of full disclosure:

- Any third party can contact you directly regarding your innovation/traditional knowledge with their queries.
- Your innovation/traditional knowledge may gain recognition, publicity and respect among the readers/viewers/listeners.
- Horizontal dissemination among peers or other members of the local or wider community may encourage experimentation and possible utilization of the disclosed knowledge, thus increasing opportunities for self-employment, poverty alleviation, environmental conservation and improvement in productivity.
- Copyright in the knowledge/innovation/practice is protected.
- Disclosure may, by itself, generate demand for the products among consumers or potential partners in the value chain. In some cases, the method of practising the traditional knowledge or the process of using the innovation is complicated or all the materials are not available locally, such that users cannot practise it or develop it on their own. In such a case they may like to buy it from the innovators and thus demand may be generated.
- Potential investors, entrepreneurs or scientists may contact you for further development/commercialization of the product.

Disadvantages of full disclosure:

- The information will be in the public domain, anybody will be able to use the disclosed information.
- Once the information is disclosed, a patent cannot be granted on the disclosed information. Any specific part of the technology not disclosed can still be protected.
- Potential investors, entrepreneurs or scientists may not contact you for the development/commercialization of the product if they can make it with the help of disclosed information on their own.
- Other people may benefit from it without giving you any credit for the same.

Sharing of information

There are a number of ways in which information may be shared:

- with restrictions imposed;
- on a commercial basis;
- on a no-cost basis for personal application or household use only;
- with further research or value addition in it;
- any other.

With restrictions imposed

The knowledge provider may like to be consulted before taking up any value addition or licensing discussions with third party. Some innovators/traditional knowledge holders would like non-monetary benefits such as attachment (appellation) of their name to any product that is developed and diffused, or credit to them in the product package or on a label. Likewise, they could put any other restriction, which NIF is expected to follow.

On a commercial basis

The right to use the technology is granted to a third party only on the basis of benefit sharing. The terms may vary from one commercial deal to another. In some cases, the entrepreneur may agree to offer a small amount as an up-front licence fee, but may share a given proportion of gross sales (generally 2–3 per cent) as a royalty for a given period of time. However, the ability of a technology to generate commercial demand may depend upon its uniqueness, its commercial viability, whether the technology is in a usable form or requires further research and development to convert an innovation or idea into a product. Thus, even if somebody chooses this option, it may be appreciated that NIF may not be able to immediately generate commercial options for everybody submitting entries to the National Register. We will share synoptic information on the web and in our databases, and then potential entrepreneurs may show interest in a specific technology or product.

The disadvantage in marking this option is that only those users may get the advantage of your innovation or traditional knowledge who have capacity to pay for the right to license the technology. Further, in the absence of sharing full details with others, those interested in developing this technology further may not be able to do so.

No-cost for individual use, but permission necessary for commercial use

The implication is that if an individual small farmer or artisan wants to use your innovation or traditional knowledge for personal application at his/her own small farm or in a small workshop only, he/she can do so without any obligation to share benefits.

The disadvantage is that somebody may claim that it is for personal use but may later end up generating a commercial advantage. This will require a carefully drafted licensing agreement.

With further research and value addition

The innovation or traditional knowledge can be shared only after it is made more effective or efficient by pursuing further research by the innovator herself/himself or by another research organization. The innovation/traditional knowledge will not be shared with any third party without further research on it, if this condition is chosen.

The disadvantage is that if NIF or the innovator is unable for some time to take it up for value addition, because of a lack of priority or lack of resources, the innovation will remain undisclosed to the rest of the society. Further, in the absence of disclosure, some independent researchers may also not be able to come forward to join hands for value addition.

Any other

If you want to specify any other condition to NIF for enabling sharing of your information, you can do so under this option.

Mediation by NIF for technology transfer

The assignment of technology or right to NIF to mediate implies that NIF can intervene on the behalf of the innovator/traditional knowledge holder/s, communicator/community for various purposes such as the development of a business plan, products, protection of intellectual property rights (IPR) in the cases where applicable.

1 Consent for business plan preparation implies that NIF might engage students, GIAN team, or others to explore the business prospects of an idea or innovation or traditional technology.
2 The consent for product development may require NIF to engage institutions such as IITs, NID or other technological colleges or private entrepreneurs, or research and development centres for value addition.
3 The consent for IPR would enable NIF to pursue possible protection of the intellectual property rights through its own team or by engaging private attorneys.

The cost of these activities may be recovered from the possible licensing fee or royalty income that might be generated from the commercialization of the technology or shared by the innovators/traditional knowledge holders wherever applicable and possible. NIF reserves the right to include only some of the award winning or priority technologies accepted in the national register for pursuing the above. Criteria may include any potential social impact, uniqueness, possible positive impact on the environment or poverty alleviation or on jobs, or just the wider consumer applicability in reducing drudgery of women, or increasing efficiency or the development of dryland regions, etc.

Technology transfer

Assignment to NIF or authorization to mediate

By assigning rights to NIF or authorizing it to mediate, an innovator/traditional knowledge holder enables NIF to negotiate on its behalf with the potential entrepreneurs and investors. In the case of any dispute regarding transfer of technology to a third party, NIF will provide legal support in deserving cases to innovators/traditional knowledge holders to enforce the agreements with the concerned party.

Advantages:

- You will receive guidance about when, on what terms and to whom the technology should be transferred.
- NIF will contact the concerned persons/institutions for further development.
- This will avoid the possibility of some third party taking advantage of the ignorance or lack of familiarity with the negotiation process on the part of the innovator/knowledge provider.
- The know-how or tacit knowledge may remain undisclosed and thus provide an opportunity to negotiate separate agreements for the same.

Disadvantages:

- The assumed benefits in the licensing agreement may not actually fructify.
- Given social expectations, the licensing terms may try to balance the interests of small entrepreneurs and thereby prevent the innovator/traditional knowledge holder from maximizing his/her gains.

In the absence of the disclosure of tacit knowledge, the technology users may have difficulty in exploiting the full potential of the technology.

Technology transfer on one's own
Advantages:

- Complete control over the process of negotiation.
- No obligation to share benefits or economic gains with other innovators, or innovation fund or community (although the innovator may decide to do so voluntarily).
- The know-how or tacit knowledge may remain undisclosed and thus provide an opportunity to negotiate separate agreements for the same.

Benefit sharing arrangements

Benefits can be of four kinds, monetary–individual (MI), monetary–collective (MC), non-monetary–individual (NMI) and non-monetary–collective (NMC). The first category includes monetary awards, licence fees or royalties from any commercial exploitation of technology or traditional knowledge, or any other monetary gain by entrepreneurial process. The incentives in this case go to individuals. However, as per the benefit-sharing clause given in the Consent Form, one can share part of the individual monetary gain with the community, innovation promotion fund and institutions helping the value chain. The second kind of incentive is for communities or groups but in monetary form. It could include trust funds, a micro-venture fund, common property infrastructure for use by individuals as well as communities (for instance, a workshop to fabricate tools, machines to process herbs, make medicines, etc.). In this category also, individuals can be supported by the collective fund. The third kind of benefits deals with non-monetary reward to individuals such as recognition, a citation in a public function, dissemination of one's creativity through media or in workshops or other public functions. Naming of streets or some other infrastructure or any other landmark after the innovator, etc. The fourth kind of benefit is for collectives/communities and is non-monetary in nature. For instance, the changes in policies and pedagogies for education at different levels so that respect for informal innovators/traditional knowledge holders increases in society.

Monetary benefits

The campaign for making India innovative will succeed in the long run only if the innovators and traditional knowledge holders and other stakeholders take on the responsibility of running it in a self-reliant manner. The self-reliance of the entire value chain will require that some part of the benefits that innovators may get from possible commercialization is shared with various actors and institutions. Those involved in the conservation of resources, the process of adding value, sharing information or generating commercial opportunity, need to have incentives to join the value chain. The community of which an innovator is a member is an important stakeholder because it helps in conserving resources, provides the general knowledge pool by drawing on which of many innovations or traditional knowledge evolve and are improvised. Thus the share of the community is generally essential to maintaining knowledge systems in a vibrant form.

Likewise, the shares of the various stakeholders have been suggested in the proposed ratio of benefit sharing. But you are free to decide what proportions you feel proper. That may have a bearing on the motivation of the various stakeholders. For instance, suppose you say that 90 per cent of benefits should come to you, the innovator, and the remaining 10 per cent may go to those who add value, or the community or innovation fund. In that case, it is possible that many scientists or private entrepreneurs may not agree to commercialize the innovation or traditional knowledge. The Innovation Fund will make it possible to help those innovators or traditional knowledge holders whose ideas or innovations may not attract private parties for value addition or dissemination. NIF has limited funds and the ability of NIF to help a larger number of innovators will depend upon the resources we can raise for the Innovation Promotion Fund.

Non-monetary benefits

NIF has shared several non-monetary benefits so far, such as recognition in national award functions (this also includes a monetary benefit for some), dissemination of innovations/traditional knowledge through exhibitions, Shodh Yatra (walk through the villages every summer and winter in different parts of the country), multi-media and multi-language database, workshop of the innovators to promote lateral learning, workshops with experts for product development, or other feedback, and visit to each others' place. The diffusion of non-commercializable innovations/traditional knowledge and consequent recognition is one of the major non-monetary benefits. There are cases when these benefits count for much more in motivating one to innovate or share one's knowledge with others.

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NOTES

1 For instance if radioactive minerals such as uranium or precious metals are found underneath private property then the state has a right to claim property rights on those resources in certain countries such as India, with or without compensation. Likewise, an individual has a right to grow sandalwood trees on private land but does not have a right to cut them down without government permission. In Bhutan individuals have right to kill an animal if it strays into a field and damages crops but they do not have the right to kill animals in the wild. Problems arise when an animal moves onto the public land after having been wounded on private land. Some communities allow private rights in trees growing on community lands and vice versa. In Rajasthan, individuals having private water wells cannot refuse to give water to someone for drinking purposes. A private well becomes common property or open access for drinking water purposes.

2 National and international registry systems have been proposed to incorporate elements of an innovation patent system so as to provide incentives to local communities, herbalists and developers of plant varieties to share their knowledge without foregoing the benefits possible through intellectual property protection. The issue remains as to whether knowledge produced over a long period of time through cumulative contribution of communities in a given region should get only a short duration of protection with limited claims. There are several reasons why a registry may help the innovators and TK holders and even if with a short duration of protection:

(a) the possibility for potential investors, entrepreneurs and R&D partners seeking collaboration with innovators and TK holders would be very low if they did not have access to a registry that would reduce transaction costs (TC) in the process;

(b) the possibility of willing partners filing joint IPRs for longer duration may also be low in the absence of a registry;

(c) the technological obsolescence factor being high, many leads might not have much value if not explored within ten years;

(d) the possibility of learning from one another might increase if there were a registry. Many times this goal gets neglected in the debate and to those involved in the Honey Bee Network (see www.sristi.org/honeybee.html) lateral learning among the local innovators and communities is a central concern. Surviving collectively is some thing that a registry can facilitate.

The cost of filing a patent can be very high. For example, a US patent application in the 1990s was around US$20,000 while in the EU, it could cost twice that amount. However, this cost varies a great deal and in 32 countries it was found to vary from US$355 to $4772 in the 1990s (Helfgott, 1993). We need to devise ways of reducing these costs for small innovators and traditional communities. INSTAR, an international registry, might offer one way.

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Chapter 23

Holder and User Perspectives in the Traditional Knowledge Debate: A European View

Geertrui Van Overwalle

The present chapter offers a European view of the conceptual issues and intellectual property problems in the traditional (medicinal) knowledge debate, and comments on the presentations made at the April 2003 conference on Biodiversity, Biotechnology, and Traditional Knowledge Protection, with particular reference to the other chapters included in this volume.

TRADITIONAL KNOWLEDGE? CONCEPT AND CLASSIFICATION

Traditional knowledge *sensu lato* and *sensu stricto*

The scope of the term 'traditional knowledge' has been the subject of many debates. According to Andriantsiferana traditional knowledge concerns 'all aspects of life (food, health, housing, communications) and the environment (relations between biodiversity and ecological factors, identification criteria of biodiversity elements)' (Chapter 21). In his view, traditional knowledge is characterized by a holistic approach relating to every component of the environment and giving an equal importance to rational thinking and to spiritual beliefs and social considerations. Balick argues that traditional knowledge is to be considered as 'a body of information and set of skills developed by a group of people over time' (Chapter 19). By way of example he refers to canoe making, use of fish poisons, use of sea plants and planting taro. Brush for his part takes the view that traditional knowledge is associated with 'folk nomenclatures, taxonomies of plants, the environment, practical domains such as disease aetiology and agricultural practices' (Chapter 20; Brush, 2005). He argues that a number of criteria can be used to differentiate traditional knowledge: localness, oral transmission, origin in practical experience, emphasis on the empirical rather than the theoretical, repetitiveness, changeability, being widely shared, fragmentary distribution, orientation to practical performance and holism. Lewis and Ramani describe traditional knowledge as a body of knowledge built by a group of people living in close contact with nature, which includes a system of classification, a set of empirical observations and a system of self-management that governs resource use (Chapter 25). Carvalho, from his side argues that, given the vast scope and vague boundaries of traditional knowledge, it is not very meaningful to look for a final and complete definition (Chapter 18; Carvalho, 2005). He prefers to adopt a practical approach of finding statutory characteristics that traditional knowledge must present in order to be eligible for legal protection.

For now, one interpretation seems to be commonly accepted. The term traditional knowledge is understood to comprise both aesthetic and useful elements, as well as literary, artistic or scientific creations. Consequently, categories of traditional knowledge include, amongst other things, expressions of folklore in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of language; agricultural knowledge; medicinal knowledge (WIPO, 2001). Carvalho introduces an interesting distinction in this regard: 'traditional knowledge *stricto sensu*', encompassing the knowledge itself and 'traditional knowledge *lato sensu*', encompassing the former plus expressions of traditional knowledge (Chapter 18; Carvalho, 2005).

Holders and users of traditional knowledge

The scope of the terms 'traditional knowledge holder' and 'user' has also been widely discussed. According to the World Property Organization (WIPO), traditional knowledge *holders* are 'all persons who create, originate, develop and practice traditional knowledge in a traditional setting and context. Indigenous communities, peoples and nations are traditional knowledge holders, but not all traditional knowledge holders are indigenous' (WIPO, 2001). According to Barber and Tobin '*users* of genetic resources' are defined as those individuals or entities that actually import and utilize genetic resources, whether for commercial or purely scientific purposes. Examples include: botanic gardens that collect, display and conduct research on plant species from other countries; pharmaceutical and biotechnology firms engaged in drug discovery and product development based on genetic resources accessed from another country; and cosmetic and nutritional companies that import, process and sell a wide variety of consumer goods that are based on natural products (Barber and Tobin, 2003). By analogy 'users of traditional knowledge' might be defined as individuals or institutions making use of traditional knowledge for commercial or scientific purposes.

Many countries are both 'holders' or 'providers' and 'users' of genetic resources and traditional knowledge. However, there has been a tendency in the international debate to view developing countries as primarily providers, while more industrialized developed countries have been portrayed as users. Barber and Tobin correctly underline the inaccuracy of such generalizations and argue that in many cases industrialized countries, such as Australia or Brazil, are also important providers, while some developing countries, such as Brazil, have highly developed biotechnology and agro-industrial capacities (Barber and Tobin, 2003).

Classification of traditional knowledge

Efforts have also been made to classify the various types of traditional knowledge. In international discourse it is agreed that the term 'traditional knowledge' refers to tangible as well as to non-tangible components (WIPO, 2001). The *tangible* component of traditional knowledge mainly refers to genetic resources. Brush correctly underlines that genetic resources encompass pharmaceutical as well as natural product resources and crop genetic resources (Chapter 20; Brush, 2005). The *intangible* component of traditional knowledge has been subdivided into three classes: traditional medicinal knowledge (TMK), traditional agricultural knowledge (TAK) and traditional ecological knowledge (TEK) (WIPO, 2001). According to Andriantsiferana the class of traditional medicinal knowledge can be subdivided in three categories: category 1 deals with medicine(s) prepared by a traditional health practitioner for a patient; category 2 encompasses medicine(s) originating from the community but having commercial applications; and category 3 relates to products originating from research and academic institutions (Chapter 21). Brush rightly says that the class of traditional agricultural knowledge relates to knowledge leading to crop improvement (Chapter 20; Brush, 2005). Balick adds another class to the trinomial classification, namely traditional cultural knowledge (TCK). Language is an excellent example within this category (Chapter 19).The present survey mainly focuses on traditional medicinal knowledge.

HOLDER PERSPECTIVES: POSITIVE PROTECTION SYSTEMS

There is a growing consensus that indigenous communities that are involved in the identification of therapeutic properties of native plants should be compensated for the exploitation of their traditional medicinal knowledge. However, there seems to be a lot of obscurity and uncertainty as to the appropriate legal instruments that should be used to give shape to the right to compensation. Overlooking past and presents efforts to establish an appropriate model that fits the contribution of indigenous communities, we can observe two approaches (Wendland, 2002a, b).

A first approach, the so-called 'positive protection' route, is based on the assumption that protection of indigenous knowledge is important to safeguard the rights of knowledge holders in view of commercial exploitation and benefit.

Various existing IP systems have been suggested as a protection system for traditional *medicinal* knowledge: patent law, copyright protection, database protection, utility models (Petty patents, *Gebrauchsmuster*) and geographical indications (Van

Overwalle, 2002). In their conference presentations, Andriantsiferana (Chapter 21), Otten and Jones focused on pre- and post-grant problems when applying for patents. Balick (Chapter 19) stresses the importance of copyright protection: one-way of strengthening the position of traditional healers is to consider these people as colleagues and teachers, rather than as informants. By including traditional healers who have provided information for research as co-authors or providing acknowledgement using their names, all parties benefit. Both Andriantsiferana (Chapter 21) and Balick (Chapter 19) underline the need for database protection: workers in the ethnosciences are collecting data and are using modern technology to catalogue and study this information. Although data gathering may not be as useful with regard to long-term preservation of the actual knowledge, IP protection of the data collections might still be worthwhile. According to Andriantsiferana, various types of database management can be established: free access, access associated with a material transfer agreement, access subject to scientific evaluation, etc.

On top of existing IP systems, a new IP tool has been suggested to fit the needs of indigenous peoples: the adjudication to knowledge holder countries of a special form of IP protection for traditional medicinal knowledge, a so-called *sui generis* solution. Such an approach could find a legal basis in Article 27 (3) (b) of the TRIPS Agreement,[1] which provides for an effective *sui generis* system for plant variety protection and which would offer an opportunity to introduce an alternative protection system modelled along the needs of indigenous peoples.[2] In their conference presentations, Otten and Carvalho (Chapter 18; Carvalho, 2005) and others critically explore this route. (Cottier and Pannizzon, 2004; Leistner, 2004)

Another route to provide protection for traditional knowledge is the establishment of appropriate, national access and benefit sharing (ABS) measures. As Lewis and Ramani (Chapter 25) rightly point out, such measures place the burden upon the government and can only be successful in practice if the national government involved is willing to espouse the interest of the indigenous peoples involved and protect such rights *for* them.

Still another attempt to give shape to the expectations and needs of indigenous peoples is the voluntary concluding of contractual arrangements between a variety of institutions from provider and user countries. Andriantsiferana (Chapter 21), Balick (Chapter 19), Benbrook (Chapter 11), Gámez (Chapter 7), Miller (Chapter 5) and Otten all extensively examine this option. Last but not least, Andriantsiferana suggests the establishment of 'Community Intellectual Rights'.

There is a well-established IP tool, which offers adequate legal protection for traditional *agricultural* knowledge: the plant breeders' rights system. This system will not be further discussed here.[3] Hamilton (2005) has addressed some of the recent developments.

Patents

The suggestion has been made that indigenous communities that are involved in the identification of the therapeutic properties of native plants, should be compensated for the exploitation of their medicinal knowledge by way of patents. The premises, concepts, interpretation and requirements of patent laws, however, have largely been dictated by the industrial and technological circumstances in Western economies (Blakeney, 1997; Moufang, 1998). In this context it is questionable whether the contribution of traditional knowledge from which a pharmaceutical product has been developed, can be the sort of contribution that will meet patentability standards. (Posey and Dutfield, 1998)

Intrinsic thresholds

A first problem in analysing traditional knowledge in conventional patent terms is the observation that indigenous peoples do not view their heritage in terms of property at all, but in terms of community and individual responsibility. Possessing medicinal knowledge carries with it certain responsibilities such as how to show respect and maintain a reciprocal relationship with the human beings, animals, plants and places with which the medicine is connected (Daes, 1993; Wells, 1995). There are two catches in this observation, however. First, there is most probably not one, monolithic indigenous view on property, but a diversity of views on how to regulate property internally. Second, not much is known about internal protocols. (WIPO, 2001)

A second problem relates to the final goal of patent law. The principal rationale of patent law is to provide an incentive for inventiveness and creativity, commercialization and distribution, by offering the patent holder a period of time during which his rights are immunized from competition. Indigenous peoples have been reported to be not primarily concerned with the commercial exploitation of their knowledge and market economic values. As Balick (Chapter 19) points out, knowledge may have its greatest value to indigenous peoples because of its ties with cultural identity or its sacred significance (cf. Blakeney, 1997; Posey and Duffield, 1998). This observation should probably be put in perspective because such a point of view would imply a monolithic indigenous view and because there might well be diverging views on the value of knowledge in indigenous communities.

A third impediment is the novelty requirement. Two difficulties can be observed in this regard. First and foremost it is often said (Lewis and Ramani, Chapter 25; Lewis, 1991), that indigenous knowledge is transgenerational, communally shared and considered to be in the public domain and, therefore, unprotectable (cf. Posey and Dutfield, 1998). Recent investigations, however, have shown that not all indigenous knowledge is communally shared, and not all of it is considered to be in the public domain (WIPO, 2001). Various healing methods have been reported to have been held under a secrecy regime. Second, it is often argued that a problem with the patent claims of indigenous peoples in relation to traditional medicinal knowledge is that ethnobotanists and ethnopharmacologists often publish accounts of the uses of plants by indigenous peoples (Blakeney, 1997; Huft, 1995). This may have the effect of destroying the novelty of therapeutic claims, especially in a European patent setting. The US, however, handles prior art and publication from foreign locations differently from Europeans. Moreover, the patents applied for often do not concern the precise use undertaken by the indigenous community. The rosy periwinkle case (Kadidal, 1993) might serve as a good example of this issue. The indigenous knowledge provided the lead and it is unacceptable that this was not recognized, but the patent was not on the particular use revealed by the indigenous community.

A fourth obstacle is the notion in contemporary patent law of the inventor as an individual, solitary and original creator, or a group of individuals (so-called joined inventorship), not collective entities (Blakeney, 1997; Posey and Dutfield, 1998). It is often claimed that, for indigenous peoples, knowledge and determination of the use of resources are collective. As Lewis and Ramani (Chapter 25) correctly observe, custodians of traditional medicinal knowledge and indigenous peoples in general, do not fit the individuality model and might therefore be denied patent protection (cf. Blakeney, 1997; Posey and Dutfield, 1998; Wells, 1995). Once again, this observation should be put in perspective, since knowledge and determination of use are not necessarily collective. Diverging views exist within indigenous communities on this issue (WIPO, 2001).

The concept of joint inventorship is only helpful at times, because it requires that each of the joint inventors must have contributed to the inventive conception, working on the same subject matter and making the same contribution to the inventive thought and to the final result (Janssens, 2005; Singer and Singer, 1989). One does not become a joint inventor by being the first to observe a useful property or effect of an invention. In order to claim joint inventorship, some demonstrable role in the final conception needs to be established. As Carvalho (Chapter 18; Carvalho, 2005) points out, in case of collaboration with indigenous peoples or shamans, the problem is that their cooperation with ethnopharmacologists may be considered to be too indirect to the process of joint invention. However, Lewis and Ramani (Chapter 25) and Rosenthal (Chapter 24) have observed some successful events in this context, more in particular in the Peruvian ICBG project. In case of collaboration with scientific institutions, joint inventorship might be exacted, as Gámez' experience with regard to INBio clearly shows (Chapter 7; Tamayo et al, 2004). Another nice example came about in the context of the Belgian-Vietnamese *Saponin* project.[4]

Practical impediments

A first practical problem, mentioned by Lewis and Ramani (Chapter 25) and others, is that patents are expensive: next to the cost of patenting, which is high, the costs of opposition proceedings and infringement actions should be added, which can also be very high (cf. Blakeney, 1997; Posey and Dutfield, 1998). Acquiring and defending patent protection requires substantial financial resources. These actions tend to be complex and time-consuming and well beyond the means of indigenous peoples. The securing and enforcement of patents will therefore often be prohibitively expensive for indigenous peoples. However, costs associated with the use of the patent system have been argued not to make the system inherently unjust, particularly if ways can be found to lower costs or to assist indigent persons and communities to use the system (WIPO, 2001).

A second practical impediment relates to the lack of intellectual property expertise of traditional knowledge holders. Gollin (Chapter 28; Gollin, 2005) takes the view that fairness dictates that when poor and excluded people are confronted with the very complicated issues involving intellectual property, they should have access to expert advice and representation. In order to provide such advice, he took the laudable initiative to establish an independent international service and referral organization, the Public Interest Intellectual Property Advisors (PIIPA).

Contracts

Another attempt to give shape to the rights of knowledge holders is the voluntary concluding of contracts between a variety of communities and institutions from provider and from user countries.

Monetary and non-monetary benefits

Experience shows that contractual arrangements first and foremost deal with tangible aspects, monetary benefits. They focus on what – quite significantly – has been termed by Balick (Chapter 19) 'the gold standard' and has been experienced in an ICBG-setting by Lewis and Ramani (Chapter 25): the user countries agree to pay a lump sum for the right to analyse indigenous material from plant and animal origin, complemented by a royalty for the benefits derived from this material. Balick (Chapter 19) and Gámez (Chapter 7) testify that in various cases substantial research budgets have been acquired on top of that.

However, it has been repeatedly argued that contracts and partnerships can only be successful in the long term if both monetary and non-monetary benefits are shared. Various innovative strategies have been developed that go beyond the gold standard and include both tangible and non-tangible elements. Gámez (Chapter 7) correctly says that scientific and technological capacity building is a very important non-tangible asset that can contribute directly and significantly to the formulation of proper national policy and legislation regulating the access to, and benefit sharing derived from, biodiversity resources. Similarly, Benbrook (Chapter 11) states that leveraging local knowledge is of major importance. Miller (Chapter 5) equally underlines that activities that improve research capacity through institutional support, training, and technology transfer, can have significant impact in developing countries. Balick (Chapter 19) in turn argues that the concept of cultural support is a very important aspect of non-monetary benefit sharing. This support is not limited by the financial resources of the investigator, but only by their level of cultural sensitivity, understanding and desire to make a difference.

Informed consent and disclosure procedures

In general, agreements should be based, as Andriantsiferana (Chapter 21) rightly brings to mind, on the principles of equality, mutual respect, partnership, mutually beneficial relations and the sharing of results. The concluding of contracts might require intense 'grass-roots efforts', speaking in Balick's language (Chapter 19).

In particular, contracts should pay special attention to *prior informed consent* procedures. Prior informed consent in the context of genetic resources is defined by the World Conservation Union (IUCN) guide to the Convention on Biodiversity (CBD) as ‘consent of the contracting party which is the genetic resource provider, based on full and complete information provided by the potential genetic resource user prior to consent for access being granted’ (Glowka et al, 1994). Miller (Chapter 5) argues that informed consent has to be obtained from the party providing access to genetic resources. However difficult and expensive obtaining informed consent may very well be, it has led to a very positive re-examination of collaborative research, which has fostered short-term benefits that have greatly supported the development of biological research capacity in source countries. As Lewis and Ramani (Chapter 25) rightly point out, informed consent should also be obtained from the concerned local community for the use of traditional knowledge. In this context, Rosenthal (Chapter 24; Rosenthal, 2006) offers a very interesting analysis of two landmark projects and draws some lessons about the role of culture, politics and local governance as they influenced the differing outcomes. In particular, he points to the role of pre-existing and broadly representative indigenous governance as a key factor in determining the feasibility and integrity of prior informed consent for the use of traditional knowledge. In the same vein, Lewis and Ramani (Chapter 25) and McManis (2003) focus extensively on one of those cases, the successful Peruvian ICBG project.

According to Otten, it is questionable whether contracts should also deal with the *disclosure* requirement.

Bilateral or multilateral scope

Another aspect to be considered is the scope of the agreements: do bilateral agreements suffice or should multilateral contracts be negotiated? According to Vogel (Chapter 9), the greatest threat to sustainability is no longer biopiracy per se but something far more insidious: the biofraud inherent to all bilateral contracts between a corporation and only one supplier. These contracts fuel a price war denying everyone the possibility of garnering an economic rent (Chapter 9; Vogel, 2000). Vogel proposes a cartel as a solution. In such a cartel, the price of access is fixed and the benefits are distributed among all who could have supplied the same resource or knowledge. Negotiating multilateral contracts between knowledge holders and bioentrepreneurs on an international level is definitely a step in the right direction.

As a closing remark, one can point to Lewis and Ramani (Chapter 25), who offer an overview of the various CBD and WIPO reports that contain model clauses that the parties to a contractual agreement could use taking into account both the concerns of knowledge holders and users.

HOLDER PERSPECTIVES: DEFENSIVE PROTECTION SYSTEMS

A second approach, the so-called 'defensive approach' route, aims at protecting indigenous knowledge against acquisition and exploitation by third parties. The major route to protecting indigenous knowledge against the unauthorized use and unauthorized acquisition of patents over traditional knowledge by third parties, is the documenting of traditional knowledge (WIPO, 2001). In this context, Carvalho (Chapter 18; Carvalho, 2005) points to two possible alternatives. First, knowledge holders may apply for patent rights with the single purpose of preventing others acquiring rights in their knowledge. Second, traditional knowledge holders may publish the information and, as a result of publication, the knowledge becomes part of the state of the art and is novelty destroying for future patent applications based on or related to this knowledge.

Another – informal – effective way of protecting knowledge against unauthorized use is secrecy. A secrecy regime is usually maintained with regard to a formula for a chemical compound, a process of manufacturing, a pattern for a machine or other device, but it could also be applied to the field of traditional medicine, for example with regard to healing methods or techniques for using certain ingredients of particular plants in well-balanced amounts. Some traditional knowledge holders have pointed out that it is sometimes difficult to maintain secrecy within small communities, where close-range interaction and collaboration constrains the innovator's ability to conceal his innovation. Innovators often rely on modifications of traditional techniques, which have been passed on in the community from one generation to another. Therefore, minimal observation might suffice for would-be infringers to imitate the innovation (WIPO, 2001).

It has been reported that yet another – informal – way of protecting knowledge, is the use of ritual or magical components that form part of traditional medicine. Those rituals often allow traditional healers to control the use of their innovations in spite of full disclosure of their techniques and methods within the local community (WIPO, 2001). Some people have pointed out that rituals operate as a barrier against reverse engineering; in other words, rituals function as a mechanism that prevents the use and development of technologies based on imitation. Apparently, ritual regimes can create exclusive rights similar in strength to patents, at least in the local context and within supportive cultural frameworks (Golvan, 1992; WIPO, 2001).

USER PERSPECTIVES

Since the entry into force of the CBD, attention on the regulation of access and benefit sharing has tended to focus on measures taken by provider countries to implement adequate measures. Recently, however, greater attention has been given to the promotion of a range of measures countries, particularly developed countries, could take in their role as users of genetic resources and traditional knowledge accessed from provider countries.

Patent law

Various attempts are being made to modify patent law in developed countries in order to meet various objections and public concerns relating to the patenting of traditional knowledge by user countries and to adapt the patent system in a way that the expectations and needs of source countries and indigenous peoples can be better accommodated.

This can be achieved in a number of ways. First, one can think of a number of options that are available for user countries in the pre-grant phase: the reassessment of the current novelty regime and the introduction of additional requirements for the grant of a patent, in particular the incorporation of a disclosure of origin and a prior informed consent requirement. Secondly, some routes are also available in the post-grant phase, notably with regard to tempering the effects of a granted patent, through the introduction of responsible governance of patent rights.

Pre-grant options: Disclosure of origin requirement

The introduction of a disclosure of origin requirement in patent law is a possibility for the production of evidence in respect of access and benefit sharing rules.

In Europe, the origin requirement was implemented in the European Union Biotechnology Directive of 6 July 1998,[5] in particular in Recital 27.[6] Recital 27 requires that 'whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents'. Although Recital 27 contains a praiseworthy principle, the wording of Recital 27 is so noncommittal, that one can wonder if the recital will have any effect at all.

So far, Belgium and Denmark are two member states to have taken Recital 27 seriously: both Belgium and Denmark recently implemented the origin requirement in their patent act. The current Danish Patent Act stipulates that where an invention involves or uses a biological material of vegetable or animal origin, the patent application shall contain information about the geographical origin of the material, if the applicant for the patent has knowledge about this. If the applicant for the patent has no knowledge about the geographical origin of the material, this shall be indicated in the application. A lack of information about the geographical origin of the material or the applicant's lack of knowledge about this does not affect the manner in which the patent application is treated or the validity of the rights that follow from the patent issued.[7]

In the initial Belgian proposal, non-compliance with the disclosure requirement was severely sanctioned (Van Overwalle, 2006). The proposal stipulated that the exploitation of an invention is contrary to *ordre public* and morality, when the invention is developed on the basis of biological material that was collected or exported in breach of Articles 3, 8j, 15 and 16 CBD. Consequently, an invention using plant or animal material imported in violation of the law of the country of origin, would run counter to Belgian *ordre public* and morality and the relating patent could be nullified.[8] A great deal of protest was raised against this severe approach. The finally voted text softens the origin requirement to a great extent: the origin should be mentioned *if known* and if the origin is not communicated, no sanction is provided (Van Overwalle, 2006).

Otten and Carvalho (Chapter 18; Carvalho, 2000; Carvalho, 2005) are critical with regard to systems equivalent to the Belgian initial proposal, aiming at including the origin requirement as a substantial rather than just a formal requirement. They argue that the obligation to disclose the origin of genetic resources and/or traditional knowledge as a substantial requirement for granting a patent could infringe Article 27 of the TRIPS Agreement. This obligation might be taken up as a procedural requirement, within the meaning of 'reasonable procedures' of Article 62 TRIPS. Tobin and Barber share this concern, with regard to Article 27 TRIPS but take the view that if the implementation of benefit sharing under the CBD framework is a matter of vital importance to countries both from an economic and a technological perspective, an origin requirement in patent law might not be contrary to TRIPS (Barber and Tobin, 2003).

On 12 September 2002 the European Commission announced that it welcomed disclosure of origin requirement, production of evidence in respect of access and benefit sharing rules as long as this requirement does not constitute an additional formal or substantial patentability criterion and as long as it has no bearing on the patentability of the invention or the validity of the patent.[9] It is clear that the Belgian legislator finally aligned himself with the Danish approach and the European Commission's declaration.

Pre-grant options: Informed consent requirement

Next to the addition of an origin requirement in patent law, a suggestion has been made to introduce an informed consent principle in patent law as well. This principle, laid down in Article 15.5 CBD, would imply that every patent applicant has to show evidence that he obtained consent from the government or local communities where the material originated. Andriansiferana (Chapter 21) repeats in this respect that prior informed consent should not only be obtained in case of access to biological resources, knowledge or technologies, but also in case of application for any form of intellectual property protection. In their conference presentation, Hunter and Jones underlined that inserting the prior informed consent in patent law is a way of integrating human rights in IPR law.

Initially the European Commission did not make any reference to the prior informed consent requirement for the use of biological material: the EU Biotechnology Directive of 1998 does not mention informed consent for the use of biological material. An informed consent requirement has been taken up in the

Danish patent act, but has not been foreseen in the Belgian proposal. The Danish patent act stipulates that where an invention involves or uses a biological material of human origin, the patent application shall indicate whether the person from whom the biological material originates has given consent for the application to be submitted. The information concerning consent does not affect the manner in which the patent application is treated or the validity of the rights that follow from the patent issued.[10]

Meanwhile the EU has underlined its desire to take into account the principles embedded in the CBD. The EC recently stated that it welcomes the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing, agreed by the Conference of the Parties (COP) in The Hague on 19 April 2002,[11] which sets out practical ways and means of implementing the principles of prior informed consent and of mutually agreed terms enshrined in Article 15 of the CBD at national level.[12]

Post-grant options: Humanitarian use restriction

Regulation of some post-grant issues might contribute to achieving a better balance between the rights of inventors/investors and traditional knowledge holders. In this respect Khush (Chapter 14) advocates the implementation of humanitarian use restrictions in licences. Humanitarian use has been defined as use in developing countries (according to an FAO definition) by resource poor farmers who make less than US$10,000 per year, leaving the company free to explore commercial prospects for the technology (Potrykus, 2001). To date licences have been given to five major rice-growing countries, namely the Philippines, India, China, Vietnam and Indonesia.

Alternative measures

Self-standing regulations

Ethical concerns regarding the patenting of inventions based on biological material of plant origin and local traditional knowledge can be taken care of within patent law, but can also be cured in other laws by introducing a supplementary provision, prescribing that the origin of the plant material must have been disclosed and that the knowledge holder must have had an opportunity of expressing prior, free and informed consent to access, use and patenting. Such a provision can be issued by a government and carries an obligation to comply. This approach has been advocated by Carvalho (Chapter 18; Carvalho, 2005) and has also been suggested by the EC.[13] However, it remains to be seen what type of information will be requested and what the legal consequence will be of failure to disclose. To have any effect, non-compliance, in cases of the non-existence of a disclosure of origin and informed consent, should probably result in a regulatory penalty.

'Doctrine of unclean hands'

As should be clear from the above, there are differing opinions with regard to the question of whether requiring disclosure of origin and legal provenance of genetic resources and traditional knowledge is in fact in conformity with TRIPS. Barber and Tobin (2003) and Carvalho (Chapter 18; Carvalho, 2005), however, point to an area of the debate about which there appears to be more widespread agreement. This relates to the principle that the holder of a patent, which has been obtained following an illegal act, should not be entitled to benefit from his illegal act, through exercise of the rights obtained in the grant of the IPR. This is generally referred to as the application of the 'doctrine of unclean hands'. On the basis of Article 8.2 of TRIPS, which authorizes WTO members to adopt appropriate measures to prevent the abuse of IPRs, Tobin and Barber argue that if genetic resources are directly or indirectly used in making a patented invention and have been obtained in a country that has adopted legislation requiring prior informed consent, then failure to obtain that consent would amount to fraud (Barber and Tobin, 2003).

CONCLUSIONS

The legal protection of traditional knowledge and the equitable sharing of its benefits have gained wide concern in civil society and have triggered stakeholders, government officials, politicians and scholars to develop new lines of thought.

For traditional knowledge providers, protection within existing IPR systems remains problematic, but various alternative initiatives have been established or are underway that take into account their expectations and needs. For user countries in the Western world, establishing sharing mechanisms offers a unique chance to rebalance North–South relations in a spirit of corporate social responsibility. However difficult it may seem from a TRIPS point of view, the disclosure of origin and prior informed consent requirements need to be implemented as substantial patentability requirements, or at least as self-standing regulations with substantial regulatory penalties. Doing so will reduce the public reserve with regard to the current use of patents by the bioindustry and restore trust in bioentrepreneurship and in the patent system. Also in contracts, efforts should be made to establish monetary standards and non-monetary requirements on a multilateral or international level, avoiding time-consuming recurrent discussions in bilateral negotiations.

NOTES

1 Agreement on Trade-Related Aspects of Intellectual Property Rights (Annex IC of the Marrakech Agreement Establishing the World Trade Organization signed in Marrakech, Morocco on 15 April 1994), see www.wto.org/english/tratop_e/trips_e/t_agm()_e.htm. For a critical review of article 27 TRIPs, see Correa and Yusuf, 1998.

2 The relationship between TRIPs and the CBD is the subject of intense discussion. See, *Study on the Relationship between the Agreement on TRIPs and Biodiversity Related Issues, Final Report* for DG I European Commission, 2000, see http://trade.ec.europa.eu/doclib/docs/2003/september/tradoc_111143.pdf

3 An impressive quantity of literature exists on plant breeders' rights. See Van Overwalle, 1999 and the references cited there.

4 Saponins are natural surfactants found in many plants, but they are most abundant in the desert plants. Extracts from these plants are commonly used. A Belgian invention was developed, closely related to the use of antiprotozoal saponins. A European patent, entitled 'Antiprotozoal Saponins', was granted to the pharmaceutical company Janssen Pharmaceutica on 16 June 2004 (EP 1.140.127-B1). A group of Belgian scientists were named as the inventors, as well as two Vietnamese collaborators (Van Tri Mai and NgocNinh Tran) who are working at the National Centre for Science and Technology in Hanoi.

5 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Invention, 213 *Official Journal EC-L*, 30 July 1998, p13.

6 For more information on the history of the development of Recital 27, see Blakeney, 1998–1999; Straus, 1998: 'Genetic resources have become an issue of high priority to scientists, industry, politicians and even the public at large. … they form a warehouse of enormous use potentials for plant – and animal breeding, food, chemical and environmental industries, pharmaceuticals and medicine'.

7 Order no 1086 of 11 December, 2000, entering into force 20 December, 2000, amending Order no 374 of 19 June, 1998 on patents and supplementary protection certificates.

8 Article 49 §1 (1) 1984 BPA stipulates that a patent may be revoked by court if the subject matter of the patent falls within articles 3 or 4, or does not meet the requirements of articles 2, 5, 6 and 7. Cf. article 138 (1) (a) EPC that stipulates that a European patent may be revoked if the subject matter of the European patent is not patentable within the terms of articles 52–57.

9 Communication by the European Communities and their member states to the TRIPs Council on the Review of Article 27.3(b) of the TRIPs Agreement, and the Relationship between the TRIPs Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore – A Concept Paper, Brussels, European Commission – Directorate General for Trade (12 September 2002). Also see: Submission by the European Community and its Member States on Traditional and Intellectual Property Rights – 3rd Session of the WIPO Intergovernmental Committee on IP and Genetic Resources, Traditional Knowledge and Folklore (13–21 June 2002) Also see: Review of Article 27.3(B) of the TRIPs Agreement and the relationship between the TRIPs Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge and Folklore – A Concept Paper, submitted by the European Communities under Paragraph 32 (ii) to the WTO (14 February 2003).

10 Order no 1086 of 11 December 2000, entering into force 20 December 2000, amending Order no 374 of 19 June, 1998 on patents and supplementary protection certificates.

11 COP 6 Decision VI/24, see www.biodiv.org/decisions/default.asp?1g=0&dec=V1/24.

12 Communication by the European Communities, Brussels, 12 September 2002 (see note 8). Also see the Submission by the European Community and its member states on Traditional and Intellectual Property Rights, Brussels, 14 June 2002.

13 Communication by the EU to the TRIPS Council, 12 September 2002.

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PART IV

Ethnobotany and Bioprospecting: Thinking Globally, Acting Locally

Chapter 24

Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities

Joshua Rosenthal

Why did an early effort to build an ethical bioprospecting relationship with indigenous people in Peru survive, when a more sophisticated approach with arguably better opportunities for indigenous communities in Mexico later foundered in a sea of criticism? Two projects funded under the International Cooperative Biodiversity Groups (ICBG), one working with Aguaruna people in Peru and another working with Maya people in Chiapas, Mexico, have both struggled with identification of appropriate representation of community interests, and with concerted campaigns by NGOs to halt their efforts, despite broad interest among indigenous communities they contacted. The Peru ICBG ultimately succeeded in developing credible, working partnerships, and carrying the project through to completion, while the Maya (Mexico) ICBG became mired in defence of its approach to prior informed consent (PIC) and ultimately was terminated early. In this chapter I summarize relevant aspects of the history of these two landmark projects and draw some lessons about the role of culture, politics and local governance as they influenced the differing outcomes of their efforts. In particular, I point to the role of pre-existing and broadly representative indigenous governance as a key factor in determining the feasibility and integrity of PIC for use of traditional knowledge. This conclusion is important because it suggests a concerted movement away from the traditional model of individually oriented ethnobotany studies for bioprospecting involving indigenous communities, and towards one that is structured around institutional relationships.

The central thesis of the ICBGs is that carefully constructed and equitably managed research and development projects designed to discover new pharmaceuticals from biodiversity in developing countries can produce benefits to health, conservation and sustainable development. Since 1993, several agencies of the US

Government – the National Institutes of Health (NIH), the National Science Foundation (NSF), the Department of Agriculture (USDA) – have supported 12 projects working in 16 countries in Asia, Africa and Latin America that have striven to accomplish this ambitious programme. A critical component of the ICBG programme is the development of ethically sound partnerships among diverse organizations, including those indigenous communities involved in or significantly affected by a project (Rosenthal, 1997; Rosenthal et al, 1999).

In this paper I aim to analyse, from the perspective of a scientist administrator, the context, basic approaches and results of efforts by the Peru and Maya ICBGs to develop PIC and to negotiate access and benefit sharing (ABS) agreements with the Aguaruna and Maya indigenous communities in 1995–1996 and 1998–2000, respectively. Chapter 25 in this volume by Lewis and Ramani describes the Peru ICBG agreements in some depth, therefore I make only brief comments about those agreements.

In the past decade there has been an important debate on the potential cultural costs that may accrue to indigenous groups, such as the Maya, by participating in modern scientific projects such as the ICBGs (Nigh, 2002 and responses therein and Anderson, 2002). Similarly, there is a range of views on the benefits that may accrue to indigenous groups from such projects (for reviews see Barsh, 2001; Guerin-McManus et al, 2001; Laird, 2002; Moran et al, 2001; and this volume). I do not attempt to treat these important questions in any depth here. Rather, I begin with the significant assumption that, *if prior informed consent is properly developed, indigenous people make will intelligent decisions about the costs and benefits of participation and that, generally speaking, the opportunity to enhance resource use and material quality of life through modern science is positive*. My aim is to identify major contextual issues that facilitate or inhibit the development of cooperative research projects with indigenous peoples, including the elaboration of equitable agreements for access and benefit sharing.

CULTURE, GOVERNANCE AND POLITICS IN PRIOR INFORMED CONSENT

Prior informed consent in the context of genetic resources is defined by the World Conservation Union (IUCN) guide to the United Nations Convention on Biological Diversity (CBD) as '(1) consent of the contracting party which is the genetic resource provider, (2) based on full and complete information provided by the potential genetic resource user (3) prior to consent for access being granted' (Glowka et al, 1994).[1] In bioprospecting arrangements with indigenous peoples there are several important dimensions to the context that regulates PIC, beyond legal requirements and the basic issues of transparency and language. These dimensions can be denoted very generally under the headings of culture, governance and politics.

Much has been written about the role of culture in maintaining traditional knowledge. While there is likely to be significant variation among indigenous peoples regarding the degree of sharing/secrecy of knowledge and the role of specialist healers (shamans), it is clear that in most cases a significant portion of traditional knowledge relevant to drug discovery is communally held (Berlin and Berlin, 1994; Posey and Dutfield, 1996) (see Berlin and Berlin, 1996; Reyes-Garcia et al, 2003 for analytical examples). If we recognize communal origins and stewardship of knowledge of healing practices, then for many uses by outsiders such knowledge may be treated as a communal resource.

Nevertheless, arriving at a consensus on what constitutes the relevant 'community' that can legitimately make decisions regarding sharing of knowledge is a significant challenge. Is it the village, clan, entire language group or all those who share a bioregion? Ethnographic studies that help determine the degree to which relevant knowledge is held in common across these groups (e.g. Reyes-Garcia et al, 2003) could be a useful starting point in some cases. However, this conceptually appealing academic approach to defining 'community' is unlikely to be practical to implement for many potential partnerships because of the time and expense involved. Moreover, as I will outline below, it is unlikely to be satisfying to many stakeholders and outside commentators because of governance and political issues that may impinge on the definition of the relevant unit of 'community'.

Historically, PIC has been used to ensure that medical research subjects understand the risks of potential harm they may be exposed to in participating in a clinical research project (NCPHS, 1979; CIOMS, 1993). In more recent years PIC, or its parallel, PIA (prior informed approval) has become a part of environmental impact assessments relating to land use or other development projects that involve communities (Hardison, 2000). The risks that are most relevant to biodiscovery research projects that make use of knowledge and genetic resources are generally identified in relation to intellectual property, and sometimes cultural or political issues (see Rosenthal et al, 1999 and references therein). Adequately identifying and communicating the types and degrees of such risk for a given project is extremely difficult for both scientists and community laypersons.

The ICBG programme approaches PIC on the basis of three points. First, it recognizes the above-described implications of communal origin and stewardship of traditional knowledge. Second, it recognizes the possibility, however remote, of harm to community interests. Third, PIC, in some cases, has become an important means of outreach to communities to raise awareness regarding potential global values of their knowledge, as well as the importance of biodiversity and the need for conservation. In this context, the programme strongly recommends that PIC be obtained at the 'community' level prior to seeking it from individuals (NIH, NSF, USAID, 1998).

The legal authority to give PIC for genetic resources is defined in the CBD at the minimal level of the nation state (CBD Article 15). For some nations, such as Argentina, significant authorities for resource management are identified in the constitution at the province/department/state or lower level, but for the most part the implications for genetic resources are not yet articulated in regulations. Legal assignment of PIC authority by the government to indigenous communities has been slow in many countries because of pre-existing disputes over land ownership or use rights between indigenous peoples and the governments. However, the CBD (Article 8j; COP Decision VI/24) strongly encourages, and most countries recognize at some level, the principle that PIC must be obtained from indigenous and local communities for use of traditional knowledge associated with biodiversity. Frequently, this principle is extended to cover rights to use the associated genetic resources.

Even where PIC is not legally required, most scientists wishing to use traditional knowledge today are willing, and often eager, to go through culturally appropriate channels to obtain PIC at the level that it is required by an indigenous society. However, their ability to do so is greatly influenced by the degree to which the process is clearly defined and communicated to them, and possible to achieve with reasonable effort. A number of both general and community-specific models for the process of PIC are emerging (see Laird, 2002 for examples). The principle problem for the research community is the absence of a clearly delineated governance hierarchy in many indigenous societies that formally establishes, *for the outside world*, what level of an indigenous community or nation has the authority to give consent. Moreover, the self-defined authorities of some indigenous groups overlap and may change over time (Brown, 1993; Greene, 2004; Posey and Dutfield, 1996). Frequently, overlap occurs because self-defined 'communities' may share language, knowledge traditions and land use rights with other such communities. The temporal fluidity of some authorities may derive from strong traditions of family and village or clan autonomy (Brown, 1993), and sometimes nomadism. Finally, indigenous governance systems are rarely acknowledged formally in national laws. Consequently, a research scientist is rarely secure that the PIC conferred by an indigenous society through the locally identified mechanism is authoritative or enduring.

In addition to the broad areas of culture and governance is politics at local, national and international levels. Tensions among indigenous communities, between those communities and national governments, and among national governments in discussions around the CBD and the World Intellectual Property Organization (WIPO) make it difficult to achieve clear and reasonable dialogue between the scientific and indigenous communities on issues such as intellectual property rights and benefit sharing. Emotionally charged issues related to human rights, land tenure, the ability of poor communities to exploit the patent system and the morality of patenting inventions derived from the study of living organisms ('Patenting life') frequently inject themselves into the debate. All of these levels of political turmoil enter both public and private discussions around high-profile projects such as the ICBGs. The result is an extraordinarily politicized planning process.

These tensions are frequently at play even where culturally well-defined community governance systems exist, and may be overwhelming to a partnership that depends on participation of communities where such governance systems are lacking or poorly integrated with western legal systems. In such situations, global or national politics that might be considered external to local questions of stewardship and collaboration easily inflame the discussion.

PRIOR INFORMED CONSENT IN THE PERU ICBG (1994–1999)

The Peru ICBG began to navigate these complex issues in 1994, when there was very little formal guidance on PIC from the CBD, national governments or indigenous societies. The Peru ICBG was a partnership among Washington University, the Universidad Peruana Cayetano Heredia of Peru, the Universidad San Marcos of Peru, and the Searle-Monsanto Company. Their project aimed to integrate biodiversity conservation and community development with development of new therapeutic agents against a wide range of infectious and chronic diseases of relevance to both Peru and the US through tropical plants research using modern bioassays and ethnomedical knowledge from traditional healers among the Aguaruna peoples of the Alto Maranon region of Northern Peru.

The principles of the ICBG programme at that time required funded projects to address the principles of informed consent at both national and other levels that were relevant to indigenous societies, but left it to the groups to define what that meant in a given situation (NIH, NSF, USAID, 1992). Existing definitions in 1994 for the term, '*informed consent*', and models for its conduct were primarily based on the protection of individual human subjects involved in biomedical research from physical harm (see for example CIOMS, 1993; NCPHS, 1979).

The following account represents my understanding of the history of the initial events of the Peru ICBG based on our records, site visits, communications with a number of the parties as the events unfolded, and my recollections. It is both important and instructive to point out that different players in the ICBG have different recollections about some of the specifics.

The initial plan of the Peru ICBG was to work with a small clan-based Aguaruna organization called Organizacion Central de Comunidades Aguarunas del Alto Maranon (OCCAAM) that Dr Lewis had encountered in previous fieldwork. The ICBG funding agencies, NIH, NSF and USAID, required that agreements and permits be in place before the grant could be awarded. A short time frame (four months) was imposed because the government budget calendar required that NIH make the award by the end of the fiscal year. Under this time pressure and with logistical and linguistic difficulties in communication between OCCAAM and the universities, the investigators chose to make an arrangement with another NGO, the Consejo Aguaruna y Huambisa (CAH), that appeared to be larger, more organized and easier to communicate with than OCCAAM. A Letter of Intent was signed between the CAH and the three university partners. Within a few months of establishing this partnership a formal complaint was sent by representatives of the CAH to the lead funding agency, the Fogarty International Center of the NIH, asserting that PIC had not been properly obtained. The principle complaint of the CAH was that they were not informed in an appropriate and timely manner of the development of a linked licence option agreement developed between Washington University and Searle-Monsanto to test and develop any discoveries using Peruvian samples and associated knowledge. Furthermore, they were unhappy with the terms of that agreement. The funding agencies responded by imposing a temporary moratorium on drug discovery activities in the project, conducting an investigation into the matter, and calling on the investigators to resolve the conflict involving the Peruvian government and outside expertise.

The funding agencies concluded that mistakes were made on all sides, that there was insufficient stakeholder involvement, and that the narrow timeline allowed for the establishment of the agreements was a significant contributor to the problems. The agencies provided the Peru ICBG limited financial support and a more flexible timeline to rebuild the project, starting with a rigorous PIC process, and encouraged the investigators to be as inclusive as possible both in this process and in inviting multiple Aguaruna organizations involved in the project. The project was also advised that all parties should have competent and independent legal counsel to represent their interests during the negotiation process. In the year and a half that followed, three clan-based Aguaruna federations (OCCAAM, Federación Aguaruna Domingusa (FAD), Federación de Comunidades Nativas del Rio Nieva (FECONARIN)) under the leadership of their national umbrella organization Confederacion de Nacionalidades Amazonicas del Peru (CONAP) participated in a series of workshops and meetings in Lima, provincial cities and villages in Peru, as well as in St Louis. Other participants in the meetings included representatives from other indigenous organizations, Aguaruna community leaders, the Peruvian Society for Environmental Law (SPDA), the Peruvian government, the US government, the participating universities and Searle-Monsanto, among others.

Lewis and Ramani (Chapter 25, this volume) and Greene (2004) provide more details of the PIC and negotiation process. Of note here is that it was an iterative, redundant process representing multiple layers of Aguaruna society. This was necessary in order to obtain prior informed consent from a 'community', as it could best be defined in the context of Aguaruna culture and governance at that time. Notably, individuals from all three universities and Searle-Monsanto were very committed to making the process work. However, even so, resolution of the problems would not have been possible in the absence of credible leadership by the umbrella federation, CONAP and a pre-existing collective decision-making process of the Aguaruna, called '*Ipaamamu*', for arriving at demonstrable consensus on matters of shared concern among communities. Ultimately, 55 communities represented by three local federations were represented in the process, and later a fourth federation, Organización Aguaruna del Alto Mayo (OAAM), joined the collaboration. The rival CAH was not invited to rejoin; I will return to this point below.

While important in setting the stage, once the PIC process began in earnest, external organizations, including international NGOs as well as Peruvian and US government agencies became primarily observers that provided advice and reference points in existing regulations. Consent authority for the project boiled down to the affiliated federations under CONAP, and applied to the geographically restricted areas for which these organizations could demonstrate legitimacy to the Aguaruna, the Peruvian government, the ICBG partners and the global community.

While the PIC process and its outcome was a landmark event for the ICBG that is held by some to be exemplary (see for example, Barsh, 2001) it did not achieve at least one outcome seen as desirable by the funding agencies and others. A significant number of Aguaruna clans are not included (Greene, 2004), nor are the other related Jivaro tribes with whom they share some traditions. This includes those communities that continued to ascribe to the CAH. The loss of trust between the Peru ICBG and CAH leadership that occurred because of the initial missteps was never regained between the individuals representing these parties. According to several reports, the omission of the CAH and some of the events of the first year fomented pre-existing discord among the CAH and the federations associated with CONAP, and continues to be a source of tension eight years later (Greene, 2004).

NEGOTIATING AGREEMENTS IN THE PERU ICBG

The two stage history described above of the Peru ICBG produced a complex web of agreements that evolved from a series of direct and formal negotiations between organized indigenous NGOs, the US and Peruvian universities and the industrial partner. Lewis and Ramani outline these agreements elsewhere in this volume, and so I will not go into these in great detail. However, several features of these agreements and the process that led to them were significant for the funding agencies.

First, all parties had representation of legal counsel at some point in the process. The Aguaruna (CONAP) not only had their own staff counsel, but additional advice and participation in negotiations from knowledgeable counsel from the Peruvian Society for Environmental Law (SPDA). The largest and most organized indigenous groups such as the Kuna Yala of Panama, the Maori of New Zealand and the larger North American tribes, typically have access to such independent counsel, but it is still uncommon in the developing world.

Second, the Aguaruna organizational representatives and their counsel negotiated directly with the companies and the universities, rather than through mediating NGOs. Even today this is relatively uncommon (Barsh, 2001). It is generally assumed that indigenous groups will be at a disadvantage in this situation, and that pharmaceutical companies do not wish to engage directly with these non-traditional partners. In fact, both are often true. However, there are a number of advantages to achieving this direct communication, and when the table can be levelled somewhat, it can yield powerful results.

Next, the application of a know-how licence model to traditional knowledge was a novel and useful innovation that is likely to be emulated elsewhere. This arrangement allowed for non-patentable information to be protected contractually and valued separately from the material resources, that is, plants and their chemical constituents (genetic resources). Thus this innovation allowed for the Aguaruna to establish the principle of ownership of their traditional knowledge and negotiate terms under which it could be transferred and used by others. This was particularly important because in Peru and many other countries the claim of legal rights over genetic resources by indigenous peoples is more likely to be in conflict with other property right laws and the CBDs assignment of rights to nation states.

The basic breakdown of benefits among the non-industrial partners seemed fair to most involved and to well-informed non-partisan commentators on the outside. The financial benefits (advances, milestones, royalties from the industrial partner were divided evenly among the four organizations, recognizing the contributions of stewardship and knowledge (Aguaruna), taxonomy and field work (San Marcos), extractions and initial testing (Cayetano Heredia), and leadership, project management, taxonomy and further testing (Washington University).

Several concessions important to the Aguaruna and their advisors were obtained from the company, including a prohibition on developing pesticides and genetically modified organisms. The company agreed in principle to joint inventorship on patents where relevant. The company also agreed not to develop or claim intellectual property rights in a manner that would interfere with 'traditional uses' of the materials or knowledge provided. Further, they agreed to provide access to pharmaceuticals developed under the agreements to indigenous populations of the Peruvian Amazon on 'most favourable, and where possible, preferential terms'. However, several 'grant back' provisions, such as a royalty free licence to market products in Peru, were sought by the Peruvians without success.

On the whole, these agreements were seen as groundbreaking (Barsh, 2001) and were carefully studied in Peru and elsewhere (e.g. WIPO, 2000), and used in the subsequent development of national laws on genetic resources and traditional knowledge (Ruiz, 1997).

PRIOR INFORMED CONSENT IN THE MAYA ICBG (1998–2001)

When the Maya ICBG was awarded an ICBG grant in 1998, four years after the Peru ICBG had begun its efforts, the regulatory environment for access and benefit sharing (ABS) under the CBD had changed relatively little in most of the world, but the political tenor of the debate was significantly more charged. Mexico was one of a handful of countries that had enacted formal legislation to regulate access to genetic resources, with a very general law on collecting for scientific purposes (Article 87 of the Ecological Equilibrium and Environmental Protection General Act – EEEPGA) and collections for 'biotechnological' [commercial] purposes (Article 87 BIS) (Larson-Guerra et al, 2004). The law indicates that 'biotechnological' collections need a special permit, and that such permit will only be issued when the requestor has obtained PIC and negotiated ABS agreements with the owner or legal possessor of the land on which the samples are collected. Unfortunately, no further guidance for PIC had been developed in formal policies and no process to obtain such a permit existed.

The Maya ICBG proposed to build upon almost 30 years of work by the principal investigators, Brent and Elois Ann Berlin, with a diverse group of Mayan communities from two language groups, Tzeltal and Tzotzil, in the Central Highlands of Chiapas. The Maya ICBG was a partnership of the University of Georgia (UGA), El Colegio de La Frontera Sur (ECOSUR) in Chiapas, and Molecular Nature Ltd (MNL), a small natural products pharmaceutical and botanical company in Britain. The project proposed to develop an 'Asociacion Civil' (NGO) to incorporate Maya community participants and manage a trust fund that would distribute any earnings. The aims of the project were multiple, but centred on drug discovery from the plants and macrofungi most widely used by the Highland Maya. Rather than work with specialist healers, the investigators chose to focus on those species most often cited by community members as useful medicinally. A substantial amount of the ethnomedical information was already in the public domain in one form or another, and a large number of the plants of interest were cosmopolitan weedy species.

The funding agencies considered the project a challenging one because of the continuing tensions, including armed conflicts, stemming from the 1994 Zapatista rebellion in Chiapas. However, the proposal was ranked as outstanding because of the qualifications of the research and development teams from all three institutions, a very sophisticated research and development plan that integrated drug discovery with needs-driven agro-ecology, ethnobotanical knowledge documentation and dissemination in local languages, extensive training and technology transfer, and a progressive benefit sharing plan. The rates of loss of biodiversity and ethnobotanical knowledge in the region denoted urgency. The extensive experience and anthropological training of the principal investigators in the communities and the strength and commitment of the local institution (ECOSUR) to community development inspired confidence that the project would manage to overcome the political challenges.

The Highland communities of Chiapas include approximately 8000 villages representing 900,000 Maya-speaking people. They are a society deeply stressed by poverty, a deteriorating natural resource base and extraordinary population growth. Communities are further riven by religious conflicts, successive attempts at agrarian reform, and divergent loyalties to the Zapatistas and the national government of Mexico (Larson-Guerra et al, 2004). These pressures profoundly challenge the ability of the traditionally loose-knit indigenous governance systems to find consensus on many topics.

The concept of a 'community' in Chiapas today is the subject of intense debate (Anderson, 2002; Berlin and Berlin, 2005; Nigh, 2002). The most generally recognized 'community' is the village, or 'paraje' in Spanish. Villages are legally organized under Mexican national law into Municipalities. But the Maya traditions of village autonomy challenge the authority of Municipalities as appropriate entities for bioprospecting-related PIC. As is the case for many indigenous societies, a tradition of general communal assembly exists for decisions of generalized import, but the participants of such assemblies are self-identified and the representational authority of those assemblies for the rest of the community is a subject of debate. Unlike the situation in Peru, there are no indigenous political organizations that exist continuously and are authorized to speak on behalf of communities in relation to local or national resource issues (Berlin and Berlin, 2005).

The Maya ICBG began the development of an elaborate PIC protocol under ECOSUR's leadership, concurrent with the non-drug discovery portions of their work in 1999. The early work included training of Maya participants and ECOSUR students, establishing a laboratory at ECOSUR, establishing local horticultural projects (non-timber forest products and botanical gardens), translating, analysing and disseminating ethnobotanical knowledge to communities, collecting plant specimens for taxonomic research, and experimenting in a variety of agro-ecological projects focused on pest control and crop productivity. Recognizing the national stage on which they were working, the project members began the PIC process by organizing a national forum on Mexican experiences with bioprospecting to draw lessons from other projects. They followed with an invited general information assembly of Maya community members, flyers in native languages and radio items. In addition, they put much of their proposal as well as their progress reports on the project website at the University of Georgia, and invited comments to improve their plans.

The heart of their PIC process was a one-act play in native languages enacted by a group of about 20 Mayan ethnobotanical apprentices. The play depicted the aims and methods of the project, the proposed near- and long-term elements of the benefit sharing plan, the low probabilities of a commercially successful drug discovery, and the more likely concrete benefits from other parts of the project (e.g. agro-ecology research, community gardens, etc.). They did not attempt to articulate the debate about patents and traditional knowledge nor the related risks of participation, such as acculturation or loss of potential value to other current and future bioprospecting ventures. The play was performed at ECOSUR for Municipal Presidents and other community representatives who responded to general and specific invitations from the group. These representatives were then given a tour of the laboratory and ICBG projects at ECOSUR and invited to ask questions. Project members then offered to visit villages and municipal centres to re-enact their play and answer questions for the entire community, and where invited, did so. In the three-month period in which this play was enacted, 46 of the 47 communities in 15 municipalities they visited signed up.

What the project did not anticipate was a concerted campaign to halt it. Several other high-profile bioprospecting projects in Mexico (Larson-Guerra et al, 2004) had begun to receive significant criticism from academics, NGOs and the press. A confederation of local healers organizations (Consejo de Medicos y Parteras Indigenas Traditionales de Chiapas – COMPITCH) in concert with international advocacy NGOs (principally RAFI) launched an aggressive media, internet and word-of-mouth campaign that highlighted a variety of local, national and international concerns including 'patenting of traditional knowledge and biodiversity', and linked these to US colonialism and the ongoing occupation of Chiapas by Mexican national troops. The project's critics asserted that the PIC process was invalid, and hence the expressed interest of the participating communities should be, in effect, overruled. Their basic critique was that leveled at all bioprospecting projects – that there is insufficient legal protection of indigenous rights over genetic and intellectual resources at the national and global levels. Their more specific criticisms of the Maya ICBG consent process were: (1) that the informative play omitted information on the global policy debate about patents and traditional knowledge; (2) that the signatures on many of the community memoranda of understanding did not reflect the percentage of community members required by customary law; and (3) that until all Maya-speaking communities in Mexico and Guatemala (over 2 million people) were engaged, valid consent could not be achieved (RAFI, 2000)

In the suspicious environment that surrounds bioprospecting globally, the complex history of Mexico–US relations, and the long-simmering conflict in Chiapas, the objections of COMPITCH received considerable attention. The emotional appeal of their charges were greatly strengthened by media-wise advisers from international NGOs, as well as their ability to mount websites and present articulate spokespersons for national and international media. The campaign reignited a national and international debate on bioprospecting, the patent system and the plight of the Maya of Chiapas.[2]

The most substantive questions about the project (what constitutes PIC? Who can legitimately provide it?) were lost in the media-fuelled war of words that enveloped the project. Unfortunately, the 46 relatively remote communities that signed onto the project did not have a profile in this debate. Community participants were rarely presented by the press, they did not have their own websites or list serves, and were not invited to the NGO seminar in Mexico City that publicly evaluated and 'rejected' the project (RAFI, 2000). Lacking organizational structure, these basic but distributed stakeholders did not have a visible representative body, a credible biopolitically versed indigenous leader to speak on their behalf, nor a medium to express their opinions on the national and international stage.

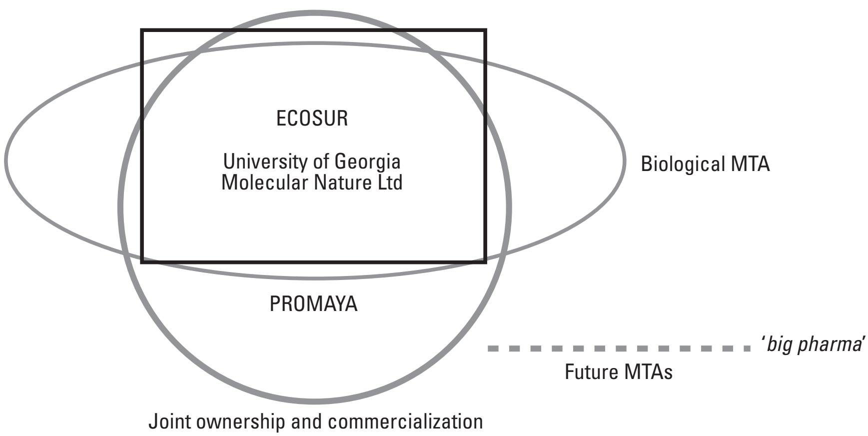
While there were differences of opinion in the relevant Mexican government agencies, these were largely supportive of the project in discussions with ICBG personnel in the beginning. Several officials indicated that the Maya ICBG represented a transparent and commendable opportunity to develop a working model with national significance on which to build a permit process for collection-based 'biotechnology' projects. Unfortunately, but not surprisingly, as the debate enflamed the national media, the government became more and more circumspect. In addition to pressure from the media and NGOs, Mexican officials were concerned about widening their already significant credibility gap related to the Zapatista movement. ECOSUR applied for the first 'biotechology' permit in the history of the country, and after months of back and forth negotiations attempting to define the requirements of the permit during this very public debate, ECOSUR decided to withdraw their application. The principal investigators of the Maya ICBG subsequently proposed that the duration of the project focus exclusively on a large-scale experiment and analysis to define PIC in this context, and the proposal was tentatively accepted by the funding agencies. However, a year and half of exhausting debate and continued harassment of ECOSUR personnel, including those unrelated to the project, had taken its toll. In 2001, ECOSUR reluctantly withdrew from the project. Without a host country institution in a leadership role, the project did not satisfy one of the minimum criteria for continued support (NIH, NSF, USDA, 1998) and the Maya ICBG was terminated.

NEGOTIATING AGREEMENTS IN THE MAYA ICBG

The draft contracts in various stages of development by the Maya ICBG when it terminated represented a coherent framework (Figure 24.1) among scientific partners with an allocated space and leverage assigned to the non-profit organization being formed to represent the Highland Maya (PROMAYA).

The *Benefit Sharing and Protection of Intellectual Property Agreement* was a general agreement that outlined the objectives and responsibilities of the scientific organizations, including recognition of the CBD conferred sovereign rights of Mexico over the genetic resources and committed them to sharing benefits among the partners and establishing PROMAYA and an associated trust fund to distribute any financial benefits that emerged. The *Biological Material Transfer Agreement* was modelled on the NIH Uniform Biological Materials Transfer Agreement. It established the basic terms under which the Mexican University ECOSUR would transfer samples to University of Georgia and Molecular Nature Ltd and tie any materials and derivatives that could enter the commercial research stream to the Joint Ownership and Commercialization agreement described below. PROMAYA was to be party to the *Joint Ownership Agreement*, which gave each organization an ownership stake in any intellectual property that emerged from the project.

PROMAYA was conceived of as a legally established civil association with an advisory board of local and national representatives that would eventually be controlled primarily by representatives of the communities that joined the ICBG project. PROMAYA was also identified as the entity that would initially receive benefits and distribute them to highland Maya communities after developing an appropriate trust fund to do so.



Conceptual map of three interwoven agreements that the MAYA ICBG participants drafted but did not finalize due to early termination of the project. Each box/circle denotes a draft contract among the parties enclosed within it. The dotted line indicates how future material transfer agreements (MTAs) for bioassay and potential commercial development by pharmaceutical or dietary supplement companies would have been linked to the ICBG partnership.

Figure 24.1 *Maya ICBG intellectual property and benefit sharing agreement framework*

The conceptualization of PROMAYA was a means of establishing formal rights for Maya participants in the project, including mechanisms to exert substantial control over the intellectual property. This approach was necessary because, as mentioned above, there was no pre-existing widely representative organization that could take on this role. A variety of special interest NGOs, such as healers' unions, conservation groups, church organizations and growers' associations were in existence, but each lacked critical elements that would have provided for broad representation of indigenous communities in the region. PROMAYA would be dedicated to the interests of all Highland Maya communities, initially under the leadership of a handful of widely respected Mexican national academics, with the step-by-step addition of community representatives and other Mayan leaders as they emerged.

Among the provisions that provided Maya participants with control over the project, beyond that which derived automatically from joint ownership (assignment) of patents, included terms that allowed Maya partners to hold up publication or patent applications where they felt these would be injurious to economic or cultural objectives, and a voice in every licence agreement that the partnership might want to sign for screening or development (e.g. with major pharmaceutical companies).

Another value of the partnership construction was afforded by a business model utilized by Molecular Nature that would allow limited rights to companies that wanted to screen the numerous novel purified compounds isolated from individual plants through their proprietary profiling methods. Molecular Nature had agreed in principle that the contributions of all four partners to the process were such that this licensing income should also be split equally. Based on their current earnings and surprising discovery rates with relatively well-studied English plants, it was probable that a reasonable income stream could be generated for PROMAYA in the near term, whether or not a commercially successful drug was developed.

Despite a great deal of goodwill and dedication, the strengths of the partnership design, and the careful and creative thought by the participants of the Maya ICBG, the agreements were not concluded because of the controversy that enveloped the project. The termination of the ICBG represented the loss of a unique opportunity to attempt integrated and scientifically sophisticated ethnobotanical, biomedical and biodiversity research and development that would be responsive to and dependent upon the participation of Chiapas Maya communities. In hindsight, the political, cultural and governance context in which the members of the Maya ICBG chose to erect the project may have doomed it from the beginning.

WESTERN-STYLE GOVERNANCE AS AN ENABLING CONDITION

While these two ICBGs differed in many ways, including their approaches to PIC, and the cultural and political context in which they worked, one factor seems preeminent as fundamental in determining their different outcomes. That factor is the existence of an established, credible and broadly representative governance system of the indigenous communities involved. The pre-existing federations of Aguaruna, despite internal differences, provided a foundation that gave the participating communities in Peru at least three key advantages unavailable to the participating Maya communities of Chiapas: increased autonomy, stronger ownership claims for the resources involved, reduced transaction costs to forming a partnership, and greater project stability. Below I describe these three advantages and briefly consider how relevant they may be beyond these two ICBGs.

First, if indigenous communities are to find the space to negotiate on their own behalf with outsiders, rather than through national governments, universities or external NGOs, they will need the authority that western organizational and accountability systems provide. Otherwise they will be susceptible to paternalistic efforts to exploit or protect their interests by those organizations they depend upon, as well as those that self-identify as their protectors. While an important part of the development community today, most NGOs represent special interests and are not generally accountable directly to communities. Similarly, universities often attempt to negotiate on behalf of indigenous communities with which they work and, while less prone to political agendas, may have a significant conflict of interest, especially if they are simultaneously negotiating with the same communities.

Because a key element in these partnerships is a culturally defined and maintained resource, traditional medical knowledge, there are both principled and practical reasons to look for autonomous indigenous representational authorities rather than working through nationally defined institutions. Autonomy is a central concern of indigenous societies around the world and was a major component of the Zapatista rebellion and associated conflicts in Chiapas. Municipalities in Mexico and elsewhere in Latin America are experimenting with more participatory and deliberative municipal governance systems that share decision making with local and indigenous groups. However, these experiments still tend to be 'low-intensity', transient or co-opted by national parties (Selee and Santin, 2005). As a result, the representational authorities claimed by local and national governments for indigenous societies in much of Latin America still lack credibility. While credibility is, by definition, in the eye of the beholder, credible representative governance systems tend to have participatory processes that can be observed, have representatives that are accountable to community members and persist over time. The semiautonomous political status of the Aguaruna federations provided them the flexibility under Peruvian law to enter into partnerships with international groups of their choosing, despite poorly defined legal rights to the land and genetic resources.

Second, organizations with networks of geographically contiguous communities represented in hierarchical governance systems are likely to be in a better position to represent the interests of the large number of people with valid claims over shared genetic and intellectual resources. Although there is some fluidity of community membership between them, the smaller federations of the Aguaruna (OCCAAM, FAD, FECONARIN, OAAM) are essentially geographically bounded, clan-based clusters of communities. While neither their knowledge of medicinal plants nor the plants themselves are completely restricted to the federation's zones of influence, such federations may have more politically defensible rights to develop these resources with outside partners than do individual communities. When smaller federations band together for common interests, as these Aguaruna federations have done under CONAP, the case for representational authority becomes stronger still. The representational vacuum of the indigenous people in Chiapas put the Maya ICBG in the difficult position of having to work with widely separated communities that responded individually to invitations from the university participants.

Third, the existence of a coherent system to assess and document the interests and concerns of community members, resolve differences internally, and authorize a leader to negotiate on their behalf reduces the transaction costs of a biodiscovery partnership. Because of the experimental nature of the ICBGs and the programme's intent to explore models of ethical research, both projects were able to undertake expensive, multi-year efforts to assess prior informed consent and negotiate agreements. However, the flexibility to invest so much time and effort in these developmental steps of a research project is still rare in the vast majority of programmes sponsored by government, academic or industrial organizations. An attempt to negotiate formal agreements with each of 40–100 communities for a single project would quickly raise the transaction costs beyond that which most outside organizations are willing to support. Furthermore, when founded upon the formalized processes above, a partnership is more likely to be able to negotiate with outside partners from a position of strength and withstand challenges from within or without.

It would be unwise to leap from these two experiences to a general policy statement about how scientists should relate to indigenous communities around the world. The enormous diversity of indigenous cultures in the world and their diverse relationships to the western society and national governments would suggest that the thesis presented above should be treated as a hypothesis, and will probably be wrong in many situations. However, it is fair to say that the involvement of a pre-existing and broadly representative indigenous organization will often be important to achieving sustainable collaborative projects of mutual benefit. This hypothesis is primarily directed to the research and development committees regarding their identification of indigenous partners.

I do not wish to suggest that indigenous societies should compromise traditional governance systems in favour of corporate style systems in order to participate in research projects on genetic resources. Few, if any, bioprospecting projects can offer the sorts of reliable and sustainable benefits that would justify consideration of governance changes unless they are already desirable to the communities themselves for other reasons. In any case, debate about such significant social changes must take place fundamentally and broadly within the indigenous society, rather than be dominated by advocates of one side or the other outside that society (Sen, 1999).

IMPLICATIONS FOR ETHNOBOTANY, BIOPROSPECTING AND DEVELOPMENT

An important challenge then is – how do global development and research organizations respond appropriately to the enormous needs, and the scientific opportunities presented by indigenous communities that are not organized into larger governance units that facilitate ethical and stable interactions with the corporate world? Perhaps the best answer today is that we have a responsibility to help build their capacity to choose development paths that enhance their goals (Sen, 1999). Practically oriented projects and publications such as the AAAS Project on Traditional Knowledge (Hansen and VanFleet, 2003), WIPO's Project on Traditional Knowledge and Cultural Expressions (www.wipo.org/globalissues/index.html), and Sarah Laird's handbook on biodiversity partnerships (Laird, 2002) are among a diversity of significant resources that have emerged recently in this regard. However, in order to take advantage of such resources the global community will need to invest in culturally informed on-the-ground training and other capacity-building efforts with specific indigenous groups that express clear interest in receiving this kind of support. To the extent that the resources involved are communal and the potential for exploitation, real or perceived, is significant, researchers and their funders are functioning in an ethical and political minefield. Navigating it will require extraordinary efforts to develop prior informed consent that is based on broad participation and can rely on visible, credible indigenous representation in some form. It will also require that the benefits available to local participants are broad-based and address important local needs that are highlighted by the communities themselves. In some cases preserving local knowledge, strengthening biodiversity-based health care systems, forming partnerships with local universities, and defining a potential monetary benefit may meet these criteria. In other cases they may not.

As academic and industrial research have become more entangled in the past 20 years, ethnobotanists frequently have seized the opportunity to broaden their work from a largely scholarly pursuit to one that might have a more direct impact on human health through development of new pharmaceuticals and *in situ* conservation of culture and biodiversity through economic valuation. The ICBGs that utilize ethnobotany have embraced this principle. The costs of this highly publicized trend in academic ethnobotany have been substantial. Today, ethnobotanists are viewed by many indigenous communities, particularly in Latin America, with a mixture of both suspicion and unrealistic expectations as pipelines to drug companies. As a result, the field is in a state of crisis (Brown, 2003). Although not as dependent on indigenous knowledge, the situation may be as difficult for classical natural products chemistry (pharmacognosy) because of the difficulty in drawing a line between academic studies that identify novel chemistry and the path to industrial drug development. To a lesser extent, the suspicion interferes with basic biological inventory and taxonomic research as well.

To address this issue, some government sponsors and academic institutions, including botanical gardens, have begun to formalize and publicize policies that clearly separate academic and commercial research. One means of doing so, applying the lessons outlined in this paper, would be to declare that any collections that anticipate the possibility of developing a commercial product using genetic or intellectual resources from indigenous societies would be limited to working with societies that have formal systems of accountability and authorization and the resources that can reasonably be ascribed to their authority. The complement to this approach is for purely academic projects to formally declare their research objectives as strictly for basic knowledge and publication. Ethnobotanists, natural products chemists and their institutions should evaluate carefully whether or not they can do this effectively and ethically in today's politicized climate, and their conclusions may vary a great deal between projects. Formalizing this intent may require some sort of agreement, and several models for this are described in Sarah Laird's recent compendium (Laird, 2002). Critical to this approach is thoughtful discussion between researchers and communities about the implications of publication and what to do if intentions change during the course of a project.

It may also be useful to consider a two-phase approach to preserve elements of both the freedom of academic research and the flexibility to pursue industrial development of potential discoveries, while offering security to providers. In this approach both provider and collector would agree formally that all research is considered basic and academic until one decides to transfer materials to a company or to pursue a patent. If and when an academic researcher approaches one of these 'trigger points' he or she must return to the community to develop an agreement that establishes the potential commercial terms of the relationship.

THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE HISTORY OF HUMAN SUBJECTS' PROTECTIONS

In the past ten years the negotiations at the UN Convention on Biodiversity, and more recently the WIPO, as well as policy discussions within dozens of national governments, have struggled with the very complex policy questions relating to ABS associated with genetic resources and traditional knowledge of indigenous peoples. A substantial portion of the discussion aims to achieve a policy environment that facilitates more equitable interactions between indigenous peoples and the scientific and industrial organizations of the world. The trend is toward construction of complex regimes empowered to make judgements regarding specific standards for prior informed consent, partnership make-up, benefit sharing and related matters.

The somewhat analogous history of the human subjects' research protection regime offers some insights. Over the past 30 years, the US has evolved a system of research oversight mechanisms that are increasingly rigid, detailed and legalistic to prevent unnecessary harm to research subjects. Yet this system has proven frequently to be inadequate to protect patients (Moreno, 2001). Moreno has pointed out that this system has promoted a mentality and practice that encourages researchers to adopt minimum standards of compliance, rather than promote a sense of responsibility and thoughtful evaluation by the individuals and groups involved. He argues that the latter is often more important than the regulatory environment because of the difficult judgements involved. For example, deciding whether a patient understands the potential risks and benefits in an experimental medical treatment, and is therefore able to provide *informed consent*, is a complex judgement that depends on many situation-specific parameters. Standardizing the information received and the manner in which it is transmitted clarifies the rules of engagement, but it doesn't necessarily enhance understanding or ameliorate the underlying inequities in researcher–subject relationships (Joffe et al, 2001). Lavery has very cogently argued that no matter how clearly we define the rules of ethical research, international collaborations that involve human subjects in developing countries must be viewed in the context of development. In this context, it is critical to build a culture of ethical research within those countries, including the social, technical and institutional capacity for appropriate local evaluation (Lavery, 2000) and a culture of responsibility among the global research community.

Access and benefit sharing (ABS) is at least as complicated technically, politically and ethically as is biomedical research with human subjects. Adding the linguistic, cultural and political layers necessitated by work with indigenous peoples and communal rights produces an extraordinarily complex package that requires tailored approaches to most situations, and thoughtful consideration by all involved. There is a need for generally accepted principles, such as those embodied in the Bonn Guidelines (CBD COP Decision VI/24), and national interpretations of those principles in policy measures. Clear and effective ABS policy measures are important to give resource 'providers' sufficient confidence to seek out international collaborations, and to give 'users' clarity on how to approach the issues, as well as confidence that they are operating within recognized principles and law. However, it seems likely that unless much more is done to develop enabling conditions, such as capable authorizing institutions and a culture of responsible research, few of these regimes will be able to provide the protections that many in the global community seek or to facilitate the ability of indigenous and scientific communities to derive benefits.

The Peru and Maya ICBGs have struggled very publicly with the definition and implementation of prior informed consent (PIC) in attempts to build equitable and ethical research collaborations. Both projects have done a great deal to inform us regarding the requirements of PIC for research involving genetic resources and traditional knowledge of indigenous peoples. An analysis of the contrasting political, cultural and governance environments and the differential outcomes between the two projects suggests that governance of potentially collaborating indigenous societies is a key ingredient to developing ethical and sustainable projects. The generality of this conclusion remains to be seen. Ultimately, conducting ethical research involving indigenous societies will depend a great deal on our ability to help create an enabling environment that includes appropriate local governance systems, well-defined national and international policies, and a culture of responsible research. In such environments we are most likely to achieve that which most of us seek – research collaborations that advance science and promote human rights and improved health and well-being of indigenous peoples and the global community.

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NOTES

1 The recent Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (COP V1/24 2002) do not define PIC, but outline principles and suggested procedures in more detail for current and future projects.

2 In addition to a barrage of press releases from RAFI and other NGO websites and a few responses by the Maya ICBG, numerous other articles and commentaries appeared in Mexico in the daily newspaper, *La Jornada*, the Mexican weekly, *Milenio*, and in the US on National Public Radio, in the *Texas Observer*, *Time* magazine, *Nature* magazine and elsewhere. Michael Brown describes the dynamics of this media and NGO commentary very clearly in *Who Owns Native Culture* (Brown, 2003).

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Chapter 25

Ethics and Practice in Ethnobiology: Analysis of the International Cooperative Biodiversity Group Project in Peru

Walter H. Lewis and Veena Ramani

The aim of this chapter is to discuss the various ways in which traditional knowledge can be adequately protected. The first part examines the means of protection that exist in the current legal system, and discusses whether these modes of protection are adequate given the characteristics of traditional knowledge. The next part discusses how the International Cooperative Biodiversity Group (ICBG) at Washington University in St Louis used a combination of various methods of protection to effectively protect the traditional knowledge obtained during an ethnobotanical project in Peru. The chapter concludes by discussing alternative modes of protection.

Anthropologist Johnson (1992) defines traditional knowledge as a body of knowledge built by a group of people living in close contact with nature. It includes a system of classification, a set of empirical observations about the local environment and a system of self-management that governs resource use. The characteristics of traditional knowledge include:

- creation over a long period of time in which it has been passed down from generation to generation;
- constant improvements as new knowledge is integrated to the existing;
- both creation and improvement of knowledge is a group effort.

Yet the individual's role can not be underestimated in this group effort. For instance, an Achuar (Jivaro) man bitten by a snake in an isolated area of the Peruvian rainforest was provided a snakebite remedy by a bicultural Candoshi-Achuar man who knew of this remedy from his mother's tribe, but one unknown to the Achuar. On drinking the preparation the man felt relief from pain around the puncture site, perhaps due to reduced inflammation. On return to his community he expounded the virtues of this 'new' antivenomous plant, and on a return visit in six months we discovered that this treatment had become generally adopted as part of the Achuar traditional pharmacopeia, all as a consequence of one man's experience (Lewis et al, 1991).

In recent years traditional knowledge has grown tremendously in significance in view of its value to biotechnology, particularly the pharmaceutical, phytomedicinal, nutriceutical and herbal sectors. Three quarters of the biologically active plant-derived compounds currently in use have been discovered through follow-up research to verify authenticity of data derived from traditional sources (Farnsworth et al, 1985). More recent research continues to validate the importance of an ethnobotanically targeted approach to the initial discovery of therapeutics (Lewis et al, 1999; Schuster, 2001). Such research draws on the traditional knowledge of local and indigenous communities who have custody of such resources, thereby allowing a targeted testing of specific plants for specific purposes.

Assessing the worth of drugs obtained from traditional sources both now and in the past is difficult. A few recent examples, however, provide a commonality of independent estimates in the billions. In the last decade, Japanese or Kampo traditional drug sales reached $56 billion annually (Okada, 1996). Others estimate that only one eighth of the pharmaceutically important drugs have been discovered in the rainforests globally. If, as described above, as many as three quarters of plant-derived drugs used today are of traditional origin, then in this single ecosystem, such discoveries could generate a total value of $110 billion (Mendelsohn and Balick, 1995). In still another example of a single discovery dating from 1630, Peruvian indigenous people provided Jesuit priests with their traditional knowledge of *Cinchona* bark to treat intermittent fever or malaria. Since that time, crude bark, quinine (isolated in1820) and its synthetic derivatives, and also quinidine (isolated in 1833) for treating arrhythmia, have generated untold wealth, relief from suffering and saved millions of lives. Further, the use of antimalarial drugs led to the successful habitation of vast areas of tropical and warm temperate regions of the world by all peoples, making possible new opportunities for progress and riches. Sales and other such direct and indirect benefits of these drugs over the centuries to the present are estimated at tens, if not hundreds, of billions of dollars (Lewis and Elvin-Lewis, 2003). These examples of only a modest fraction of plants used traditionally by peoples worldwide provide some measure of their enormous value when coupled to traditional knowledge.

Thus, considering its significance to the global economy and health, it is clear that traditional knowledge should be protected, and a part of the value generated from its protection should be transferred back to the authors of this knowledge, that is the indigenous people.

EXISTING METHODS OF PROTECTING TRADITIONAL KNOWLEDGE

The following legal frameworks can be adapted to protect traditional knowledge:

- international protection through treaties and conventions;
- national protection through national legislation controlling access to genetic material enacted in various countries, and national intellectual property legislations;
- local protection through private contractual measures.

International protection

The Convention on Biological Diversity (CBD) was drafted at the end of the UN Conference on Environment and Development held in Rio de Janeiro in 1992. It deals with issues relating to environmental law and policy making in the context of sustainable development. The objectives of the CBD are the *conservation* of biological diversity, the *sustainable use* of its components, the *fair and equitable sharing of the benefits* arising out of the utilization of genetic resources including appropriate *access to genetic resources*, the appropriate *transfer of relevant technologies*, the consideration of all rights over these resources and technologies, and the availability of appropriate funding to develop these issues.

Article 8(j) of the CBD calls on the signatories of the Convention to respect, preserve and maintain the knowledge, innovations and practices of the indigenous communities. Read with other provisions of the Convention, Article 8(j) implies that researchers should pay for the traditional knowledge made available to them, and that they have to maintain the confidentiality of such knowledge if so required. Article 8(j) is supported by Article 18.4 that encourages countries to develop models of cooperation for the development and use of technology, particularly indigenous or traditional technology.

However, the CBD has no enforcement mechanisms of any sort. The principles espoused by the CBD can be enforced only when they are incorporated into the national access legislation of the signatory countries, should they choose to institute them.

Other newly drafted instruments have begun to supplement the CBD treatment of traditional knowledge. Article 9(a) of the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture of 2001 (available at www.fao.org/AG/cgrfa/itpgr.htm) deals with the need to protect traditional knowledge. Article 29 of the Draft UN Declaration on the Rights of Indigenous People (available at www.unhchr.ch/indigenous/main.htm) is more elaborate in its protection of traditional knowledge and other traditional resources of the people. It states that indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. Special measures should be developed to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual and performing arts. Chapter 26 of Agenda 21 is focused on indigenous people and is targeted towards empowering them. Paragraph 4(a) of Chapter 26 calls on the relevant national governments to adopt policies or legal instruments that would protect the cultural and intellectual property of such people. The aim of this provision is to provide some protection over the traditional knowledge and folklore of such persons.

Therefore, the scope of international measures that have been developed merely recognizes the rights of indigenous people to their traditional knowledge. None of these instruments specify a regime to protect such knowledge. Also, none of the instruments specify mechanisms to enforce this recognition of the rights of indigenous peoples to their traditional knowledge – they are merely persuasive in nature.

Regional and national measures

There are many regional initiatives that govern the access to genetic resources of countries. Further, many countries – particularly developing countries – are in the process of initiating national access legislation to declare their sovereignty over the natural resources within their jurisdiction and to control access to these resources. Frequently such legislation covers the protection of traditional knowledge.

ten Kate and Laird (2002) used a system of classification that divides national access legislation into five categories:

1 Environmental framework laws that simply charge a national government to provide specific guidelines on access and benefit sharing (Gambia, Kenya, Malawi, Korea and Uganda).
2 Sustainable development or biodiversity laws provide more details than the first group. These laws also establish the principles for prior informed consent and mutually agreed terms (Costa Rica, Eritrea, Fiji and India).
3 Dedicated laws on access to genetic resources (Philippines and Brazil).
4 Modifications of existing laws and regulations (Nigeria, US and Malaysia).
5 Regional measures.

National access legislation has attempted to protect traditional knowledge in two ways. Some countries attempt to protect traditional knowledge as a form of property in itself. The biodiversity laws of Peru and Costa Rica protect the rubric of community intellectual property rights, practices and innovations of indigenous people and local communities related to the use of biodiversity and associated components. Costa Rica has created a national database where such traditional knowledge can be recorded. It also recognizes the right of indigenous people to benefit from the use of traditional knowledge. Concerned local communities are also guaranteed a share of the benefits arising from access to genetic resources. Other countries attempt to protect traditional knowledge of communities in practice. For example, Brazil's national access legislation establishes certain disclosures that have to be made by the researcher in the application to the government using material transfer agreements (MTAs). Such legislation places the burden on the government to protect traditional knowledge of the communities in each case.

However, national legislation in relation to traditional knowledge protection is successful in practice only if the national government involved is willing to espouse the interest of the indigenous people involved and protect such rights *for* them. This is often not the case: indigenous people may be far removed from the mainstream population or in conflict with and not usually represented in their national governments.

Another way in which indigenous people could use the national legal system to protect their traditional knowledge is by making use of the existing national intellectual property (IP) laws. However, strict IP laws are said to be ill-suited to protect traditional knowledge (Dutfield, 2001). The requirements of patent and copyright laws set forth certain measurable criteria under which intellectual property is evaluated. Traditional knowledge is said not to conform to the criteria in the following ways:

- Both patent and copyright laws require a definite inventor or author of the work being protected. Traditional knowledge is created through a process of evolution that sometimes spans generations. However, on occasion, traditional knowledge is the demonstrable result of an individual's innovation/invention.
- Both patents and copyrights have a time limit, which may not be appropriate to the protection of traditional knowledge.
- Copyright requires 'fixation' of the work, and does not recognize the frequently oral tradition through which traditional knowledge is recorded.
- Patents are granted for a single act of invention, while traditional knowledge, in most cases, is assumed to be a dynamic ongoing process, although cases of individual innovation do exist.
- Finally the act of obtaining, maintaining and enforcing patents and copyrights is expensive.

On the other hand, McManis (2004) argues that existing intellectual property regimes can provide far more comprehensive legal protection for the traditional knowledge of indigenous peoples than critics generally acknowledge. Thus, national measures as they currently exist may or may not be adequate for protecting traditional knowledge.

Private contractual measures

Contractual arrangements have traditionally been used as a means to arrive at a consensus in transactions involving the access to genetic resources and benefit sharing therefrom. They catapulted into importance following the much publicized Merck–INBio agreement (Coughlin, 1993), and have since continually been cited as a mechanism that can be used to resolve the contentious positions adopted by the developed nations on one hand and the biodiversity-rich nations on the other hand regarding the protection of traditional knowledge among other questions (Janke, 1998). Various committees, including the expert panels of the CBD and the World Intellectual Property Organization (WIPO) have released several reports that comment on the importance of such contractual arrangements. These reports also contain model clauses that the parties to the agreement could use, so that the interests of the provider of biodiversity and/or traditional knowledge, the recipient of the same, and the local community involved are all protected.

The CBDs intersessional working group on Article 8(j), and other related provisions of the CBD (CBD Report 1999, 2000), reported on contractual agreements that may be used during the transfer of traditional knowledge. The report states that concerns of local communities involved that need to be addressed by the MTA include access to community land and territories (e.g. sacred spaces, etc.), confidentiality agreements to protect the knowledge being transacted, rights either to authorize public dissemination of results or to protect such information through IP laws, rights to repatriation, that is to receive research results based on the use of their knowledge, and joint ownership of IP that results from such transfers. The report also recognizes the peculiar nature of traditional knowledge and attempts to incorporate clauses in MTAs that protect the local communities involved, that is, clauses recognizing that the traditional knowledge being transferred is community owned, and therefore that benefits resulting from such knowledge transfer should be equitably distributed throughout the community, and that the transfer of such knowledge will not detract from the right of the local community to continue to use the knowledge. However, the report makes the assumption that traditional knowledge is community owned and developed, and does not make provisions for individual invention and innovation. Nor does it consider that the IP of the indigenous peoples may need protection during research and development phases leading to pharmaceutical commercialization, for if the information is in the public domain it is unlikely that major new therapeutic products will ever be developed and marketed.

Also relevant is the report of the second session of the intergovernmental committee of the WIPO on intellectual property and genetic resources, traditional knowledge and folklore (WIPO, 2001). This document focuses exclusively on determining what the contents of a model MTA would be, taking into account both the concerns espoused by the CBD and the need to protect intellectual property.

Where the MTA involves the transfer of traditional knowledge, it should involve a ‘provider’ of material, a ‘recipient’ of material and a local community. The agreement should provide that the expressed informed consent of the concerned local community has been obtained prior to entering this agreement. Prior informed consent involves holding discussions with the local communities in their local language. Such agreements normally provide that the transfer of materials will in no way detract from the right of the local communities involved to continue to use knowledge and material as per traditional practices.

Apart from the specific benefits that depend on the parties to the agreement, MTAs typically provide for certain general types of consideration to the provider for the transfer of material, on the assumption that traditional knowledge has been created by the community as a whole.[1] One type of payment is through royalties, either a lump sum for the material being transferred or a share of net profits that result from the commercialization of either the material being transferred or the derivatives thereof. Another type of compensation involves shared ownership rights of the intellectual property rights (IPRs) that accrue from the transfer of material. Alternatively, the MTA could leave the question of joint ownership of IPRs open and condition the right of the recipient to commercially use or patent an invention without the authorization of the provider or the local community. This allows another opportunity at negotiating an equitable solution.

However, as these regulations of CBD and WIPO are not mandatory, MTAs cannot be the sole means for protecting traditional knowledge on account of the differences in bargaining power between the research organization and/or corporation on one hand and the indigenous community on the other.

PROTECTION OF TRADITIONAL KNOWLEDGE AND INDIGENOUS RIGHTS IN THE ICBG–PERU PROJECT

Within the International Cooperative Biodiversity Group (ICBG) programme there exists a harmonious interdependence between biotechnology and biodiversity in which the practice of bioprospecting encompasses a three-fold goal to promote human health, economic development and conservation of diversity (Rosenthal, 1999 [2000]). Indeed, the success of this goal depends on the existence of and ready access to biodiversity, but many countries are currently making unsustainable use of their natural resources, and it has been estimated that up to 10 per cent of the world's species will be extinct within 25 years (McManis, 2002).

The ICBG is a grant programme administered by the Fogarty International Center and financed by the US National Institutes of Health, National Science Foundation and Department of Agriculture. The theme underlying the ICBG programme is the concept that the discovery and development of pharmaceutical and other useful agents from natural products can promote economic opportunities and enhanced research capacity in developing countries while conserving the biological resources from which these products are derived. Thus, the intent of these grants is to promote the conservation of biological diversity through the discovery of bioactive agents from natural products, and to ensure that benefits accruing from both the research process and any discoveries are shared with the country of origin (RFA, 2002).

Sharing benefits from the research process and from drug discoveries that could be made in the future create incentives for conservation and provide alternatives to destructive use. Therefore, these projects involve all aspects of the CBD: increasing access to the biological resources and traditional knowledge of developing countries, providing for sustainable use of such biodiversity, and entering into fair and equitable benefit sharing arrangements with developing countries and concerned institutions in such countries.

Washington University (WU) in St Louis was awarded an ICBG grant in July 1994 to conduct research on ‘Peruvian Medicinal Plant Sources of New Pharmaceuticals’. Two universities in Lima, Peru, Universidad Peruana Cayetano Heredia (UPCH) and Universidad Nacional Mayor de San Marcos, Museo de Historia Natural (USM), and the corporation G.D. Searle and Co. were the original partners who submitted the application. A Letter of Intent had been signed between these partners and the Consejo Aguaruna y Huambisa (CAH), representing one Aguaruna Federation and only those Huambisa living along the Río Santiago. A formal agreement between the CAH and the partners proved impossible, and lengthy discussions were terminated in January 1995. However, in February 1995, negotiations began with the Organización Central de Comunidades Aguarunas del Alto Marañón (OCCAAM), an organization with a good reputation in Peru and the one originally cited in the grant application. At the end of October 1996, agreements were signed in St Louis with the indigenous organization Confederación de Nacionalidades Amazónicas del Perú (CONAP) who represented three (and later four) Aguaruna Federations (including OCCAAM) in the Departments of Amazonas and San Martín, all of whom became collaborators in the project and partners of equal standing with each of the three universities. A strong relationship continues today with members of these federations.

CONAP is an administrative and facilitating organization for about 18 indigenous groups in north-central Amazonian Peru. Its president is elected by these groups for terms of six years. César Sarasara was president in 1996 and he continues in that office today. Each federation (clan) is headed by a leader elected for a three-year term. Communities within each federation who wish to participate in the ICBG produce an Acta signed by the *apu* (chief) and those persons who wish to voluntarily participate (a majority and usually all). The collaborating federations are: OCCAAM, Federación Aguaruna del Río Domingusa (FAD), Federación de Cominidades Nativas Aguarunas del Río Nieva (FECONARIN), and later Organización Aguaruna del Alto Mayo (OAAM).

The grant was funded for 1994–1999 (extended to 2000) to identify new pharmaceuticals based on ethnobotanical prescreenings while concomitantly conserving biodiversity in northern Peru by enhancing economic growth among collaborating Aguaruna people. The project was to serve both globally important diseases as well as those of serious concern in Peru. Field research with full collaboration of the Aguaruna federations was achieved from 1996 through 1999. G.D. Searle & Co withdrew as a partner from the ICBG in 1999. The company was no longer conducting pharmaceutical research with plants (only micro-organisms), and even their research in nutriceutical supplements was terminated that year. However, Searle did continue to provide up-front payments to the Aguaruna Fund as agreed through 1999.

The project was ethnobotanical in nature, that is it involved the use of the knowledge of the Aguaruna people about plants used in their traditional medicine to conduct assays focused on specific diseases and syndromes. Ethnomedicinal data provided details of what and how plants were used, their parts and under what circumstances. Most bioprospecting is random in nature and involves the collecting of plants without regard to ethnobotanical data, and the poor level of bioactivity usually obtained reflects this randomized approach (Lewis et al, 1999 [2002]; Lewis and Elvin-Lewis, 1995; Schuster, 2001).

The ICBG–Peru project involved all possible combinations of stakeholders, that is the academic researcher represented by WU, UPCH and USM, the commercial prospector, represented by G.D. Searle, a division of Monsanto Co., the indigenous community groups represented by CONAP, and the government of Peru through the Ministry of Agriculture.

The project is particularly notable in that it used each form of protection mentioned in the first part of this chapter in addressing the various aspects of traditional knowledge protection. Thus, the project incorporated each of the principles laid down in the various international instruments, as well as the documents brought out by organizations, such as the CBD and, to some extent, WIPO.

Negotiations

The prior informed consent (PIC) procedure was divided into two phases. In the first phase, research collectors mainly talked with leaders of the stakeholders to acquaint them with the project, obtain their consent to talk with members of the indigenous communities, and to attend the Aguruana Congress (IPAAMAMU). The meetings also tried to map out the broad conditions for agreements being reached between the universities and the corporate partner and the stakeholders. A series of meetings were held in order to acquaint everyone with the ICBG–Peru project: its goals, aims and nuances. Two rounds of meetings and workshops were held in order to introduce the project with representatives of WU, UPCH, USM, Searle and representatives of the Aguaruna people consisting of CONAP and two lawyers, leaders and staffs of the four regional federations, and significantly the annual Aguaruna IPAAMAMU meeting, which included most players of the four federations and representatives of other groups.

Apart from introducing the project, these meetings also established the nature of the benefit sharing arrangement that would be instituted between the indigenous people and the commercial partner in particular. The following benefits (among others) were agreed to:

- A flat collection payment for plant samples collected annually over four years.
- A licence fee paid as long as Searle continued to make use in assays of plant extracts accompanied by traditional medicinal intellectual property.
- Milestone payment during the development of new products.
- A shared royalty payment based on net sales of products.
- Favourable terms of supply and distribution of products in Peru.
- Intellectual property rights, such as sharing in patent ownership.

Obtaining prior informed consent from indigenous communities

From indigenous communities, consent was obtained through a detailed system of local administration. A field coordinator was appointed who was a member of an Aguaruna community and who had long-term contacts throughout the regional federations. He knew members personally in many communities and was well respected, and he spoke both Aguaruna and Spanish. The coordinator travelled to the communities that had agreed to participate in the project and also to those whose members were interested in learning more about the project. He held town meetings with men and women and provided them with the following information:

- What the project was about in some detail: collecting, research and what might be produced.
- What rights the people would have and how their knowledge would be protected.
- The concept of informed consent: he would explain the PIC document in Aguaruna, emphasizing the fact that it was voluntary, and that anyone could withdraw from the agreement at any time.
- He explained the benefits that the federation, community and individual would obtain from the project: payments to assistants and informants, payments for food and lodging, payments for plant samples collected and used in research, and potential long-term benefits. He outlined the Aguaruna Fund that would be established with earnings from collecting and user fees. This income would be divided equally between the three (and later four) federations, the Fund monies being dispersed through grant applications and low interest loans. Confidentially and protection of their knowledge through the issuing of patents would provide long-term benefits and the recognition of intellectual property of Aguaruna individuals and communities in patents issued by the US Patent and Trademark Office.

Discussions moderated by the community chief were lively events with opinions being expressed by most members present, men and women alike. When requested the coordinator would withdraw, further discussions would occur, and if the results were positive, a community Acta would be drawn up and members of the village would provide a signature or mark by his or her name in agreement. This was followed at that time or at a later date by the signing of the PIC document by those who were willing to participate. The terms of the document included that:

- consent was voluntary;
- the purpose of the project was to obtain plants and information of their use in traditional medicine, the material and information being used in research that could lead to the development of new pharmaceuticals;
- participation would involve plant collecting and providing information, such as the common name of plants, use of plants, plant part used, methods of preparation and use, storage and preference compared to other plants to treat particular diseases or conditions;

- the participant could withdraw from activity without prejudice;
- the intellectual property rights (IPR) of the participants were to be protected. If the participation of an informant leads to a discovery or an invention, the informant and community will be acknowledged and if a product is commercialized the federations, and hence all communities and members, will be compensated through the Aguaruna Fund – special recognition of the community and informant who provided the data would also be included in, for example, patents;
- reasonable measures would be taken to protect the confidentiality of information provided.

Once the PIC was obtained, access to the genetic resources would begin. This was a process that was ecologically and economically sustainable, and involved the stakeholders in the process. The coordinator would lead the community through a workshop in which the following were explained: how to collect plant herbarium vouchers and their purpose, how to collect samples for drying to be used for extraction, how extraction proceeded using their wide use of decoctions as a model, and what to provide in field notebooks for each collection that would receive a unique field number. Notebook data would be more fully explained to show the need for many aspects of the plants to be included, although focusing on the informant who would lead the discussion regarding its use. The informant's name and age would also be recorded.

Each community would select two individuals, a man and woman, who would act as field assistants to the coordinator and researchers when they arrived at the community. The assistants would be paid a daily stipend from the grant negotiated by the coordinator. They were usually young, knew Spanish, and were thus able to communicate with the older, more knowledgeable members in Aguaruna so that full field data could be recorded in Spanish or English. They would also assist the coordinator in handling community details, such as costs of room and board per person and the per diem fee for each informant to be paid from the Aguaruna Fund. Assistants also helped with the processing of vouchers and preparing and drying samples for extraction.

During the town meeting the community also selected about five informants consisting of the most informed men and women healers. The informants would accompany the researchers on day-long expeditions into the surrounding forest and as interesting medicinal plants were found they would provide details about the plants. The name of the informant would be noted along with the information given for eventually assigning IPR. Such visits lasted about one week, and repeat trips were often made.

Agreements

Before collecting began, researchers and stakeholders entered into a series of detailed discussions that recorded their agreement on all pertinent issues. The agreements were (Lewis 2000a) (Figure 25.1):

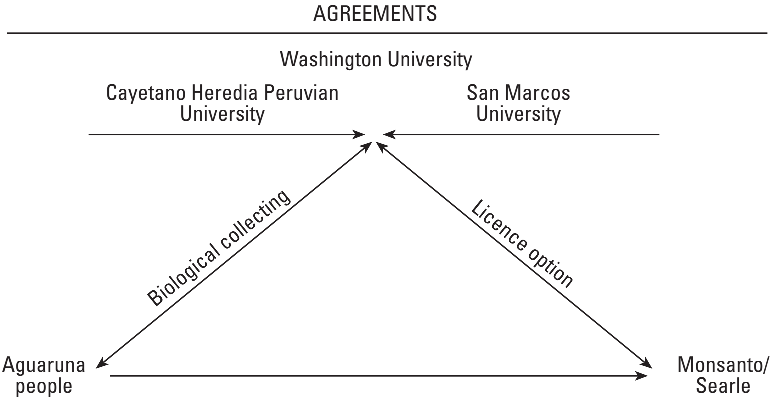

Figure 25.1 *Know-how licence*

- *Licence Option Agreement and the Amendment thereto*: this provided the royalty rates for pharmaceutical products, established how they would be shared and provided the basis of interaction between the researchers and the commercial partner.
- *Biological Collection Agreement*: which outlined who would be involved in collecting, where collecting could occur and under what circumstances, and what annual collecting fees would be provided. This is the agreement between the researchers, the source country institutions and the indigenous people.
- *Know-how Licence Agreement*: which described annual licence fees to be paid by the corporate partner to collaborating Aguaruna federations while their knowledge was being used in extraction and screening programmes, and also milestone payments at different times during the discovery and development phases prior to drug commercialization. This agreement is one of its kind between an American corporation and an indigenous group.
- *Subcontract Agreements* with the two Peruvian universities described the field collection programme with USM and the plant extraction programme and functional assays of specific diseases to be conducted by UPCH.

Each agreement recognizes that the traditional knowledge of the indigenous people is their cultural legacy and that the people have a right for such knowledge to be protected *from* the public domain. They state that such knowledge is being provided voluntarily and is being retained in confidence. Should such information prove valuable, then the original IPR of the indigenous people over such knowledge would be preserved through the filing of appropriate patents, and by the inventors assigning shared ownership of the patents to the indigenous federations. The agreements also recognize the ownership and patrimony of the Peruvian state over certain tangible resources (whole plants) collected by the researchers in Peru for scientific purposes and for making extracts, fractions and isolating compounds of potential commercial use as new pharmaceuticals. The agreements assure that collecting activities do not endanger natural populations of the plant species or their habitats and that a programme of restoration to help conserve medicinal and other plants would be initiated.

Conservation and education

Initial conservation aims were achieved by training the Aguaruna to raise plants in nurseries and to plant seedlings in secondary forest areas. Seedlings of cedrela and sangre de drago, for example, were planted in up to 15 hectares of secondary forest areas near several communities in two federation regions. Antimalarial plants, which had been depleted due to over-exploitation by the Aguaruna, were replanted in plantations in a third federation area.

The ICBG–Peru project also trained members of the Aguaruna community in assisting with the project and for those persons interested in general principles of botanical field collection in both parataxonomy and paraethnobiology. Graduate students from Washington University and/or USM participated in every field expedition, and these students as well as technical staffs were trained in laboratories of UPCH and WU, and for biodiversity studies at the herbaria of USM and the Missouri Botanical Garden (MO).

Confidentiality

The ICBG–Peru project developed various steps to protect the confidentiality of traditional knowledge that had been entrusted to it. All in-house researchers and collaborating laboratories signed confidentiality agreements. All plant dried samples destined for extraction were assigned random codes, none of which were associated with original field collecting numbers, nor gave clues to a plant's taxonomic identity. Databases created as a result of the research were password protected and encrypted. Biodirected assaying of extracts, their fractions, and compounds isolated therefrom were all coded using the code suffixed with appropriate additional identifiers.

As part of repatriation, complete CD databases with research results were provided in strict confidence to CONAP, UPCH and USM to share, and the Ministry of Agriculture's INRENA (redacted). These will be updated periodically as additional taxonomic determinations are made.

Benefit sharing and capacity building

The project ensured that source-country participants received adequate benefits as a result of their participation in the project and in respect of their rights over knowledge. The benefits that were provided are summarized below:

- *Peruvian Ministry of Agriculture.* In pre-grant award discussions with the Vice-Minister of Agriculture to consider government participation and appropriate capacity building, we were advised not to partnership with a government agency, but rather to consider in exchange for our use of genetic resources of the country assisting major universities in teaching and research by enhancing their abilities to conduct and fulfil their educational missions. In the Vice-Minister's opinion, helping them and thus by enhancing education we would be providing an important service to the country as a whole. Thus, payments and fees were made only to the Ministry's INRENA for obtaining permits to collect and export material, for renovations and furniture at the Imazita agricultural field-station used by the field researchers during the grant and left for their use, and for seeds and seedlings of potentially useful crops provided to both indigenous people, mestizos and agricultural researchers.

- *Two Source-Country Universities, UPCH and USM.* As subcontractors under the ICBG–Peru grant, the universities each received a portion of grant funds to support their specific research responsibilities outlined in the proposal. These funds supported salaries, purchases of supplies and equipment, and travel costs as needed for the participating researchers and training of technical staffs and students in both the field and laboratory. One or more sets of plant and animal collections were provided to the Museum of Natural History at USM, and a complete set of dried plant materials was supplied to UPCH for extraction. These institutions were provided, in confidence, databases of field collections for all material obtained during four collecting years and subsequently researched using mostly biodirected assays. Infrastructural support included a field vehicle, metal specimen cabinets, computers, printers, a wide range of laboratory equipment and many used items from Searle to assist in their overall programmes. Attendance at scientific meetings, research institutions and enhanced publications were all part of university capacity building.
- *Four Affiliated Aguaruna Federations.* Payments from Searle of collection and licence fees were made annually to the Aguaruna Fund established and operated by the three and later four federation leaders together. Sums were paid to the fund at the beginning of the year and kept in a US dollar account until needed. CONAP was provided 18.5 per cent of the funds as overhead in compensation for its administration of the programme in Lima. The remainder of the Fund was dispersed for community efforts, like building wells, purchasing engines and developing radio communications and plantations for sustainable products, all based on individual or community applications to the federation leaders. Part of this money was set aside for women as low interest loans to develop cottage industries, such as weaving, planting of marketable foods, art work, etc. to be sold in mestizo communities and coastal cities mostly to tourists. Funds were also kept aside for educational purposes for students to attend grammar school or university in regular or remedial programmes. Payments were provided for books, tuition, clothing, hostel room and board and transportation. The Aguaruna Fund also reimbursed each informant who participated in the field research programme.

Payments from the ICBG-Peru budget were used to assist CONAP with equipping its office in Lima, limited travel and communication costs, and legal obligations associated with the grant. Salaries of the Aguaruna field coordinator (full-time) and his assistants (part-time) were also paid from the ICBG budget, as were payments to the two field assistants from each community assisting with collecting, and for food, lodging and transportation costs in and between communities.

Some members of the Aguaruna communities were trained in collecting and determining of plants to Latin families. All were constantly reminded of the importance of their traditional medical knowledge and language, and the naming and classifying of their plants. Toward the end of the field research, the Aguaruna field coordinator and his assistant directed two of their own field expeditions. The results were spectacular.

A provisional patent submitted to the US Patent and Trademark Office on 31 January, 2002 was followed by an updated non-provisional utility application dated 1 January 2003. Submissions were based on the plant antimalarial know-how of the collaborating Aguaruna with subsequent research by the inventors who showed those compounds responsible for activity individually and in combination against the malarial-causing organism in vitro and in vivo. In the patent it was noted that informants signed prior informed consent documents and all information was obtained voluntarily. Informants and their communities were named individually for each of the three plants involved in the application. The inventors assigned equally (25 per cent) shared ownership of the US patent to the four partners of the ICBG–Peru programme, that is WU, UPCH, USM and CONAP on behalf of the four federations, and the assignments have been accepted. To our knowledge this is the first example of joint ownership of a US patent by an indigenous group, at least in Latin America.

Further basic research may be conducted with these antimalarials, or alternately the IP may be licensed following an appropriate agreement and up-front fee payment to a company willing to develop and eventually commercialize the protected compounds, and also provide appropriate milestone and royalty payments to be divided equally to the four partners. The plan is to conduct most clinical trials in South America to provide efficacy and low toxicity data, and possibly also to manufacture the product in South America for use largely in tropical countries. By so doing, together with hoped for supplements from WHO and other global organizations, the cost will be within reach of those needing antimalarial products the most.

CONCLUSIONS AND RECOMMENDATIONS

The description of the ICBG–Peru project makes it clear that it succeeded in part by making use of each of the available modes of protection described in the opening part of the chapter. The project incorporated the goals of the CBD by accessing genetic material and traditional knowledge with the PIC of the people involved. It recognized the rights of the indigenous people to their traditional knowledge and compensated them fairly. It also recognized the sovereign rights of the government of Peru, provided them with benefits, particularly by involving source country institutions and transferring back knowledge and technology to the country. The project has also attempted to fulfil the mandate of conservation and sustainable harvesting.

The project harnessed the US national IP laws by filing a patent based on the traditional knowledge obtained from the Aguaruna and by transferring benefits of the patent back to the indigenous people.

Finally, negotiations with the indigenous communities followed each of the recommendations put forth by the expert committees of the CBD and, to some extent, the WIPO.

The ICBG–Peru project succeeded in its mandate to protect the traditional knowledge of indigenous people as it was uncompromisingly fair on three principles: communication, confidentiality and compensation (Lewis, 2000b).

However, the project was not without its share of controversies. That with the Consejo Aguaruna y Huambisa at the beginning of the project highlights the fragmented nature of most indigenous communities and the difficulty of treating them as a composite whole for the purpose of identifying 'authors' of the knowledge as well as for distributing benefits. One commentator pointed out the unrealistic and heightened economic expectations of the Aguaruna people as a result of the project and their disappointment when Searle withdrew from the project in its final year (Greene, 2002).

Another important question to consider is how many researchers would be willing to go through the process taken by the ICBG–Peru project in order to obtain the consent of the indigenous community and to protect the traditional knowledge so obtained. Research institutions like the Missouri Botanical Garden are in the process of framing institutional codes of conduct that incorporate the principles of the CBD and other instruments. It remains to be seen if other institutions will follow this lead.

We propose that certain changes in international law are needed to incorporate these principles into normal research practice. Considering the value being generated by traditional knowledge to the global economy, world trade organizations with their enforcement mechanisms seem appropriate fora to target. Since strict IP law will not adequately protect traditional knowledge, an adaptation of the same seems called for. Developing countries have frequently proposed the Agreement on Trade Related Intellectual Property Rights (TRIPS Agreement). They have proposed that the rights of the collective holders of traditional knowledge be recognized, and that the source of the traditional knowledge be specified (Quinn, 2001). Once the rights of communities to the knowledge are recognized, and/or their individuals, such communities will be automatically compensated for the exploitation of their rights. Until then we recognize that the best specific protection is through the filing of utility patents.

At the same time, governments need to be encouraged to enhance the capacity of indigenous people to negotiate with interested parties, as well as to strengthen their bargaining power. This can be accomplished by affirming the rights of indigenous people to their traditional knowledge in national legislation. Governments should also assist them during the negotiation process to develop agreements that ensure that principles established by international organizations are followed.

In Peru (WIPO Fact-finding Missions to Peru, 2000) and also elsewhere (Rosenthal, this volume, Chapter 24) the ICBG agreements were seen as groundbreaking and as such were carefully studied for subsequent development of new Peruvian *sui generis* laws. Their use was further extended to regional legislation of the Andean Pact/Community of Nations of which Peru is a leading member. Thus, Peru Law 27811 (2002) incorporated those parts of the ICBG agreements that: (1) promote respect for and recognition, preservation, application and development of TK; (2) promote fair and equitable distribution of benefits from the use of TK in license agreements, royalties and other compensations; (3) promote the use of TK for benefiting indigenous people and mankind; (4) ensure that obtaining and using TK takes place with prior informed consent; (5) develop means of sharing and distributing benefits, for example, the forming of the Aguaruna Fund; and (6) consider TK as prior art when developing patents. Without the basic ICBG agreements as early models and subsequent collaborative research between the three Peruvian and American universities and the Aguaruna people that showed viable and productive partnerships, it is unlikely that Peru would have produced timely and comprehensive legislation represented by Law 27811. The law is by no means perfect, and in our opinion parts should be amended or even excluded, but nevertheless it provides a foundation for protecting, rewarding and using IP and TK to the benefit of all signatories and to others worldwide.

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NOTE

1 The document does not specify this – the assumption is that traditional knowledge has been created by the community and the benefits should go out to the community as a whole.

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Chapter 26

Ethics and Practice in Ethnobiology: The Experience of the San Peoples of Southern Africa

Roger Chennells

The San of Southern Africa,[1] well known as one of the world's 'first peoples', have over the past centuries been decimated to the point of virtual extinction. Those who survived successive invasions of their traditional lands were evicted or otherwise deprived of control of their natural resources, and were forced to exist in subservience alongside dominant pastoralists and colonial landowners. Within the past decade, the San have formed their own networking and umbrella organization, known as Working Group of Indigenous Minorities in Southern Africa (WIMSA), in order to articulate and protect their rights and interests. Apart from the right to land and resources, the value of traditional knowledge systems, and the need to protect the rights to such knowledge, have become increasingly important. This chapter examines the controversial case of the patenting of an extract of the Hoodia succulent, which is traditionally used by the San as a thirst and appetite suppressant. Issues of intellectual property, prior informed consent and benefit sharing in the appropriation of indigenous knowledge are raised, and selected aspects of the benefit sharing agreement concluded on 24 March 2003 are discussed in the light of the general principles underlying the Convention on Biological Diversity (CBD 1992).

The perspective in this chapter is that of a lawyer[2] working for the San peoples of Southern Africa, who have latterly begun to engage in the debate on the protection of heritage, including traditional and indigenous knowledge systems.

As the acknowledged 'First Peoples' of the African subcontinent, the San peoples need little introduction, although as a powerless minority grouping their present status, whereabouts and rights are of little consequence to the dominant political groupings.

The debate on ethics and law in the field of bioresearch, intellectual property and bioprospecting rages to a large extent over the heads of many of the world's indigenous peoples, who have only in the latter decades begun to assert an opposing view to that prevailing in the industrialized North. This chapter will first describe 'indigenous peoples' as an interest grouping that includes the San peoples of Southern African and will thereafter address issues related to 'biopiracy' or 'bioprospecting' as the general field in which biological resources and products are identified and protected by intellectual property systems for commercial gain. It will then describe some of the ethical and moral issues that have arisen whilst negotiating the San rights to the Hoodia family of patents. Finally some suggestions are offered with regard to the laws and protocols required in order to ensure that trade in or appropriation of traditional knowledge of indigenous peoples is equitable and in line with the CBD.

INDIGENOUS PEOPLES AND KNOWLEDGE

The term 'indigenous' is frequently contested, and is open to different interpretations. In its most simple form, the word means 'belonging to the earth'. In that broad sense virtually every person could be said to be indigenous.

In the most commonly understood sociological context, subject to various definitions, the word describes peoples belonging to regions or countries, usually subject to colonial predation at some prior stage. The word is also used to mean 'local', 'native' or 'non-european' (Saugestad, 2000). In this sense, all of the peoples indigenous to Africa, for example, are termed 'indigenous', and are potential holders of indigenous knowledge systems, or traditional knowledge systems. This broader meaning would include all major groups in Africa such as Kikuyu, Swahili, Tswana, Zulu and Xhosa.

Many indigenous peoples, or local communities embodying traditional lifestyles, live in circumstances where they are under economic siege by their own national governments. They are truly marginalized and dispossessed, despite their indigenous or 'First Peoples' status and are all too often denigrated by narrow governments as 'primitives', in dire need of civilizing and modernizing.[3] The Native American Indians, Canadian Innus and Innuits, Maoris of New Zealand, Aborigines of Australia and San of Southern Africa all share not only a recent history of the most ruthless and despicable persecution, but in addition a similar holistic cosmology or approach towards the natural world and hence towards development.

The legal meaning of the word is more problematic. Various peoples have emerged to claim 'indigenous' status, and numerous attempts have been made to arrive at a definition encompassing the narrow meaning of the word, as intended in the United Nations decade of indigenous peoples ending in 2004.

The widely accepted definition of 'indigenousness' proposed by Erica-Irene Daes, Chairperson-Rapporteur of the United Nations Working Group on Indigenous Peoples, highlights the following elements:

- a priority in time;
- the voluntary perpetuation of cultural distinctiveness;
- an experience of subjugation, marginalization and dispossession; and
- self-identification.

Although the term ‘indigenous’ is thus of necessity ‘relational’, in that it only has meaning in relation to another (dominant) group, it is capable of providing binding rights under international conventions such as the International Labour Organization (ILO) Convention 169 (Convention on the rights of Indigenous and Tribal Peoples[4]) and the Draft Declaration on the Rights of Indigenous Peoples.

In addition, it is submitted that the meaning of ‘indigenous’ in this more legally restricted context is the one referred to *inter alia* in the CBD,[5] the World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and in the World Intellectual Property Organization (WIPO) round of consultations on intellectual property rights.

Indigenous knowledge systems (IKS) in turn, are complex bodies of knowledge collectively held by indigenous peoples, and passed down over the generations in a traditional context, invariably embodying a sophisticated knowledge of biodiversity and its use to mankind.

THE INDIGENOUS PEOPLES MOVEMENT

Since the commencement of negotiations towards the Draft Declaration on the Rights of Indigenous Peoples, at the United Nations Working Group on Indigenous Populations in July 1992, a wave of revisionist thinking by indigenous peoples has swept across international law, challenging some of the prevailing assumptions hitherto accepted as given in the western developed countries.

The dominant paradigm, propounded in various forms in the meetings of the WTO by adherents or proponents of western knowledge systems, is that civilization is a continuum originating with hunter-gatherer societies and striving towards the ultimate destination of modern and western industrialized society. This paradigm sees the ancient ways, knowledge and the world view of indigenous ‘savages’ as largely irrelevant, if existent, and in any event an inconvenient impediment to progress and development.

The declaration of the Decade for Indigenous Peoples by the United Nations in 1993 (from 1994 to 2004) was the culmination of 20 years of activism by a new force on the international stage, namely the growing collective of peoples that identified themselves as ‘indigenous peoples’. In the early 1970s the World Council of Indigenous Peoples was formed. This lead to the formation of the Working Group on Indigenous Populations, which met in Geneva every year under the auspices of the UN Commission for Human Rights, and took on the twin tasks of drafting the Draft Declaration on the Rights of Indigenous Peoples, and negotiating the formation of the first Permanent Forum on Indigenous Issues in 2002.

After years of lobbying at international fora, and despite sustained objections by many states, the 2002 World Summit on Sustainable Development (WSSD) included the term 'indigenous peoples' in its formal final statement, with the following sentence. 'we reaffirm the vital role of indigenous peoples in sustainable development' (Deer, 2002).

THE APPROACH OF INDIGENOUS PEOPLES TO WESTERN INTELLECTUAL PROPERTY RIGHTS AND KNOWLEDGE SYSTEMS

The indigenous peoples movement has an ethical problem with patents in principle, whilst the patenting of life forms is essentially regarded as abhorrent.

The history of the world is written by the conquerors, who proceed to proclaim their rules over the conquered. Indigenous peoples share the generally critical view articulated by developing world countries relating to the world's recent history of conquest, where the 'Western' or 'Northern' powers dominated the world and successfully instituted the economic and legal systems required for their continued economic comfort and succour. Patents are closely related to this history of conquest and colonization. Christopher Columbus was, for example, issued with a common form of charter or 'letter patent' for the discovery and conquest of foreign lands, in accordance with which he was entitled on behalf of his principals to conquer and own the lands and indigenous peoples of America.[6] The arrogance of the 'discovery' of America (as with Australasia and numerous other colonized countries) lies in its naïve implication that the land was terra nullius, or empty land, that is not inhabited by white Europeans. The letters patent were the means to convert empty land, into 'property'.

Just as these letters patent were issued to justify conquest over territory, so modern patents strive to justify conquest of economies. Patents in the global patent system are viewed by a largely developing world coalition, including the indigenous peoples' movement, as effective tools of recolonization. Arguments supporting this recolonization revolve around the relatively new battlefield, namely knowledge, or 'intellectual property', in which the steadily advancing scope of modern patents is seen as the attempt to harness and convert valuable knowledge of life forms and processes, into 'property'. This position is powerfully expressed in the book 'Protect or Plunder' by Vandana Shiva, who states,

> *The 'enclosure' of biodiversity and knowledge is the final step in a series of enclosures that began with the rise of colonialism. Land and forests were the first resources to be 'enclosed' and converted from commons to commodities. Later, water resources were 'enclosed' through dams, groundwater mining and privatisation schemes. Now it is the turn of biodiversity and knowledge to be 'enclosed' by IPRs.*
>
> (Shiva, 2001, p13)

This corporate enclosure of biodiversity happens in two ways, first by the IPR systems that allow the enclosure of biodiversity and knowledge, and second by treating the 'corporation' as the only form of association with legal personality (Shiva, 2001).[7] Thus, it is argued, this process is designed to and does take knowledge and power away from indigenous communities, placing it in the hands of the corporate western world.[8]

Indigenous cosmologies, and the indigenous knowledge systems that they support, are receiving unprecedented recognition in international fora. The struggles of indigenous peoples for land, recognition, international legal and cultural rights, as well as in many cases self-determination, underpin a general resistance to globalization and centralization of power and wealth in the West. As stated by Victoria Tauli-Corpuz, Chairperson of the Indigenous Peoples' Caucus, 'the recognition of these rights by governments and broader society is crucial to saving what is left of the cultural and biological diversity in the world today' (Tauli-Corpuz, 2001).

The debate over patenting of life forms and modifications thereof, genetic resources and IKS has raged at the WTO/GATT meetings. The arguments take various forms, and it is not intended to traverse them all here. In essence, the indigenous peoples' argument is that patents over life forms reflect human arrogance, presenting the scientist as the 'creator' of the living organism that he/she seeks to patent. The deadlock between nations at the TRIPS meetings is evidence of a crisis of legitimacy, which strikes at the root of the very purpose of the WTO.[9]

The heavily contested Article 27.3.b of the TRIPS agreement of the WTO[10] legitimizes private property rights in the form of intellectual property over life and processes entailed in modifying life forms.[11]

The following statement, made by the Indigenous Peoples Caucus at the WTO meeting in Seattle in 1999 sets out the public position held by this group;

> *The theft and patenting of our biogenetic resources is facilitated by the TRIPS of the WTO. Some plants which Indigenous Peoples have discovered, cultivated, and used for food, medicine and for sacred rituals are already patented in the United States, Japan and Europe. A few examples of these are ayahuasca,*[12] *quinoa,*[13] *and sangre de drago in forests of South America; kava in the Pacific, turmeric*[14] *and bitter melon in Asia. Our access and control over our biological diversity and control over our traditional knowledge and intellectual heritage are threatened by the TRIPS agreement.*
>
> (Deer, 2002, p1)

In essence, indigenous peoples claim that there is ongoing and systematic piracy of their traditional knowledge. The fact that existing intellectual property law (namely patent, copyright and trademark law) does not address or protect the appropriation of traditional knowledge, is the common cause and on the agenda for change.

SOME IPR ISSUES IN INTERNATIONAL LAW

Article 6 of ILO Convention 169, the most binding international agreement for the protection of indigenous peoples' rights, requires parties to consult with indigenous peoples 'whenever consideration is being given to legislative or administrative measures which might affect them directly':

> *In addition the convention requires member states to 'recognize and protect their social, cultural, religious and spiritual values and practices' (Article 5.1), 'and to respect the special importance for the cultures and spiritual values of the peoples concerned of their relationship with the lands or territories they occupy or otherwise use, and in particular the collective aspects of this relationship'.*
>
> (ILO Convention 169, Article 8.2)

Article 29 of the UN Draft Declaration on the Rights of Indigenous Peoples states that

> *Indigenous Peoples have the right to own and control their cultural and intellectual property.*
> *They have the right to special measures to control and develop their sciences, technologies, seeds, medicines, knowledge of flora and fauna, oral traditions, designs, art and performances.*
>
> (UN Draft Declaration on the Rights of Indigenous Peoples, Article 29)

In a similar vein, Article 8(j) of the CBD calls on governments to 'respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity'. It is regarded as implicit in this article that such indigenous communities have the right to equitable compensation for sharing their knowledge with bioprospectors (Posey, 1996).

WIPO and the state parties of the WTO thus find themselves at the centre of an ideological conflict between those advocating collective or *sui generis* ownership of intellectual property rights on the one hand, and the powerful national and multinational forces that rely upon the current legal paradigm. WIPO has been called upon to make recommendations on 'the most appropriate means of recognizing and protecting traditional knowledge, medicinal plants, seeds, and expressions of folklore of indigenous peoples and local communities'.

The statement made by the Indigenous Peoples' caucus to the Johannesburg WSSD contained *inter alia*, the following demands:

- We demand the establishment of an international code of ethics on bioprospecting to avoid biopiracy and to ensure the respect of our cultural and intellectual heritage.
- We will oppose biopiracy and the patenting of all life forms.

- We call for constitutional and legislative recognition of our conservation and management of biodiversity, as inherent to the sovereignty of Indigenous Peoples.[15]

PRIOR INFORMED CONSENT

A golden thread running through attempts to protect weak, 'local', traditional or indigenous peoples from exploitation, is the insistence that 'prior informed consent' is to be afforded them in all cases. This implies that in all situations where an indigenous people or local community is involved in a transaction encompassing intellectual property rights, biological resources or traditional knowledge, there will be full consultation, and complete exchange of information, leading to full and explicit consent *prior to* any appropriation of information.

The World Bank has adopted policies on indigenous peoples, binding on all loans to countries and international consortiums, which in essence require full consultation leading to such prior informed consent with such peoples with regard to any development affecting their land or heritage rights.

Most states have or are about to comply with the requirements of the CBD by entrenching the need for such prior informed consent into their local biodiversity legislation. Article 15.5[16] of the CBD attempts to protect states themselves from plunder of their own biological resources, and to secure the sovereign right of states to their own biodiversity. The danger of plunder or piracy is presented by the powerful hunger for valuable knowledge driving the bioprospecting initiatives of pharmaceutical and research entities, and this clause recognizes that many states need protection from this threat. Most states have yet to enact legislation to ensure that the same right of prior informed consent is provided internally to their own indigenous or local communities whose knowledge systems are often intricately interwoven with the sought-after biological resources. In order for this protection to become effective, states are entitled to know who the applicants for genetic resources are, what resources are being collected, the uses for which the resources are to be put and the potential products to be developed. This requires a bioprospecting permit application, which should also set out:

1 whether traditional indigenous ecological knowledge relating to the indigenous genetic resources is sought or to be used;
2 whether the traditional use of the indigenous genetic resources is sought or to be used;
3 whether the indigenous genetic resource is endemic to land owned or occupied by any local indigenous community or associated with land rights;
4 whether prior informed consent of local indigenous communities has been given.[17]

Prior informed consent as a principled requirement is based upon a central tenet of common law, namely that any party contracting or entering into an agreement with legal consequences must be capable of understanding the implications of the transaction at hand. Ancient treaties in which the representative of an indigenous tribe was not aware of the consequences of the contract proffered, have been proven vulnerable to legal challenge on that principle alone.

Regrettably, prior informed consent, like transparency in government, is all too often agreed to in principle, yet in practice is highly unpopular in the eyes of those engaged in the drive to acquire commercially valuable knowledge. The race to secure a competitive advantage, in practice secured by patents or plant breeders' rights, is characterized by the desire to use such advantage as they can in secrecy and without limitation, in order to maximize such advantage and consequent profits.

In essence, prior informed consent is about transparency and respect. Indigenous peoples are finally demanding respect for their knowledge, despite the fact that their knowledge systems are so far removed from the ethos and laboratories of the West. Few of their number are able to engage in the discourse of bioprospecting, chemical trials, genetic manipulation, drug development and commercial risk. A process unequivocally designed first to convey all the appropriate knowledge and implications relating to the genetic/biological resources and the knowledge related thereto, prior to eliciting consent, is thus an emerging *sine qua non* for the constructive engagement of indigenous peoples in bioprospecting.

THE CASE OF THE P57 PATENT

The case study of the Hoodia succulent (Stephenson, 2003) is instructive, although in many ways unique. San traditional knowledge on the use of the succulent, freely conveyed to anthropologists and researchers many decades ago, provided the crucial lead guiding scientific tests towards crucial 'discoveries' and the eventual registration in 1996 of an international family of patents codenamed 'P57' by the South African Council for Scientific and Industrial Research (CSIR). The San healers had advised what was and still is commonly known by them, namely that the 'Xhoba' or Hoodia succulent had been used by them since time immemorial to reduce their hunger and thirst, in times of hardship and also whilst hunting. The rights to further research, clinical trials and eventual commercially exploitation of the patent were licensed by the CSIR first to Phytopharm in the UK, and thence to Pfizer Inc in the US.

By the time the research findings were about to be patented in mid-1990, consultation with the San, early providers of the original lead knowledge, was simply not on the agenda. The CSIR had understandably focused its efforts on advancing the research, and on negotiating the complex licensing and development path that would hopefully and eventually lead, if clinical trials proved successful, to the US Food and Drug Administration (FDA) approval and eventual commercial release of an appetite suppressant drug by a target date of 2008.

During May 2001, and as a result of groundwork by a local activist NGO[18] and uncompromising investigative journalism, the facts of the registration and prospects of this exciting future product were exposed to the world. Possible future sales of many billions of dollars of a derived 'blockbuster drug' were confidently predicted. When asked whether the San peoples, from whom the traditional knowledge on the product had been derived, had been properly consulted with or were to be financially compensated, the head of Phytopharm was quoted as saying that to the best of his knowledge, the San tribe that had provided this knowledge was unfortunately extinct, the implication being that no form of benefit sharing agreement was appropriate![19] This unfortunate comment was later placed in more acceptable context, but at the time the San were far from amused. The San peoples, numbering about 100,000 in Southern Africa, had since 1996 begun to organize themselves with the formation of WIMSA (Working Group of Indigenous Minorities in Southern Africa), and the scattered populations of San had become progressively united under a collective leadership. Current estimates of San populations are 55,000 in Botswana, 35,000 in Namibia, 7,000 in South Africa, and a further approximately 8,000 in Angola, Zimbabwe and Zambia.

The CSIR was immediately challenged by the San organization WIMSA, which demanded an explanation and an explicit recognition of the San rights as a precondition to further talks. The threat of a legal challenge to the entire family of patents was never explicitly made, but existed as an obvious possibility in the event the parties did not reach an early understanding. To its credit, and unlike numerous examples involving other large pharmaceutical and research organizations, the CSIR urgently commenced a process designed make amends for the failure to consult earlier, and to negotiate a fair benefit sharing agreement with the San. The position taken was that the San had no direct recourse to Phytopharm or Pfizer Inc, as the holders of the patents and licensor of the rights was CSIR, which had negotiated and was bound by the terms of their licensing agreements.

The San demanded transparency with regard to the entire process, which was initially uncomfortable for a scientific research organization accustomed to privacy, but transparency was provided to a significant degree. The negotiation process resulted first in a critical Memorandum of Understanding signed in early 2002 in which the CSIR acknowledged the ancient traditional knowledge of the San (that had lead to the identification of the novel molecule (NCE) that formed the basis of the P57 patent) and in which the parties mutually acknowledged the crucial role and contribution of the other towards the success of the ongoing project. In effect, the CSIR as the legal holder of the intellectual property rights, undertook irrevocably to enter into a benefit sharing agreement with the San, in recognition of their collective rights in and to the fruits of the P57 patents.

The negotiations pursued in terms of this agreement have now been concluded, and the benefit sharing agreement was formally signed on 24 March 2003.[20] The core terms of the agreement are that: The San will form a 'San Hoodia Benefit-Sharing Trust' that will, in the event of the continued success of the clinical trials and commercial release, receive:

1 8 per cent of all milestone payments paid to the CSIR over the next three years, (which amount to about R12,000 or US$1.5 million), and
2 6 per cent of all royalty payments received by CSIR for the duration of the patents.

Some of the interesting questions that engaged the minds of the San[21] during negotiations, aside from the aforementioned obligation to secure prior informed consent, were the following:

1 At what stage in the highly risky, expensive, sensitive research process should the CSIR have ideally consulted with the San? Their research had been ongoing for at least 20 years prior to the filing of the patent in 1996. According to all codes of best practice, they should theoretically have at the very least kept the San informed about progress. However, these codes do not provide sufficient credence to the practical difficulties such as the communication gap and power mismatch between the parties, the fact that groundbreaking scientific research is inevitably carried out in a regime of high secrecy, and to the fact that meaningful scientific feedback to an illiterate indigenous community is a daunting task.
2 Would the San have been in a stronger negotiating position had they been approached for consent prior to the filing of the patent? This was a difficult question to answer. Many have suggested that the San in 1995 would not have known about the phenomenal 'blockbuster' potential of the proposed drug, nor would they have had the capacity to understand the complex research and development protocols prior to FDA drug approval, nor the complex IPR and financial implications of the transaction. The CSIR would have negotiated with extreme caution, and would perhaps have strategically made much of the financial risks and lack of guaranteed outcome. The San might thus well have been satisfied with far less than they eventually settled upon. In 2002, supported by a powerful network of local and international NGOs, and armed with crucial knowledge about the provisional successes of the P57 trials, the San were well placed to evaluate the likely outcome, and pitch their request for a royalty at an appropriate level.
3 How should the San share the benefits amongst themselves? There are many species of Hoodia in Southern Africa, many of them used for similar medicinal purposes, yet one species growing largely in the Northern Cape[22] has been selected and identified in the P57 patents. One group of San[23] live in the area, and could conceivably have made out a case for a priority share of the benefits. In addition, the South African San, living within the boundaries of the South African State, could have opportunistically claimed the entire amount for themselves, based upon the fact that both the CSIR and the Hoodia in question are within the legal jurisdiction of South Africa. However the San have repeatedly confirmed the principle that their heritage is collective, and not to be privately appropriated by individuals or groups. It was decided as early as 2001[24] that any benefits derived from their shared heritage are to be shared amongst all

San peoples. The royalties and other benefits are thus to be shared amongst 100,000 San, rather than amongst a mere 1500 Khomani San or 7000 South African San.

What other non-financial benefits were appropriate to be included in the agreement? A recently published checklist[25] for 'best practice' in bioprospecting lists numerous other benefits that should be included where possible. Research and development benefits, technology transfer, education and training, institutional capacity building, as well as aspects that should protect the broader interests of the nation are recommended. The San acknowledged that they were not in a position to demand many of the other benefits listed, and both they and the CSIR were hasty to finalize the entire benefit sharing agreement. A mutual commitment towards a joint CSIR/San bioprospecting partnership, in which the San will contribute their traditional knowledge of plants in exchange for a yet to be determined benefit share, is a soft potential benefit that will require further negotiation to realize. In practice, the alternative benefits seemed less important than negotiating the highest possible royalty share, which became and remained the focus of the San during the process.

4 Was 6 per cent of CSIR royalties sufficient? Did the San 'sell out' in accepting such crumbs of this pie? The CSIR based their initial offers on a benchmark of 4 per cent of their royalty, which was demonstrably in line with many similar benefit sharing arrangements. In addition the CSIR initially demanded and expected an initial compensation for the millions disbursed over the past years in testing and developing the family of patents, which was not acceded to by the San. Whilst the figure of 6 per cent of royalties admittedly represents a minute fraction of the gross sales that will be made in the West, as stated by Weinberg in an article, 'Sharing the crumbs with the San', this figure is claimed to represent a mere .003 per cent of gross sales.[26] Critics of the agreement might with commendable hindsight aver that the San could have done better. At the end of the day the negotiations reached an uncomfortable compromise acceptable to all parties, and if the sales are successful, the money received will be considerable by any standards.

5 To what extent could the San allow themselves to be influenced or controlled from outside with regard to how they disburse the money? Did the CSIR, or the South African Government, have a legitimate interest in or right to deciding what controls, audits, checks and balances will prevent corruption or manipulation on the benefit sharing trust? Is such meddling or control not an insult towards the San's right to distribute without undue interference? An indigenous grouping faces unprecedented challenges when a new institution is created to manage and control an amount of money far beyond any previous imaginings. The San Hoodia Benefit Sharing Trust, which will be registered in accordance with the South African Trust Laws, contains specific objectives that will bind the trustees. In addition it has various mechanisms that will hopefully ensure that all disbursements are properly applied for, accounted for and audited. Managing this process will entail immense challenges for a San leadership largely foreign to the notions

> of strict budgets and financial controls, but no alternative exists but to develop a democratic yet stable institution capable of responding fairly and openly to the challenge. Trustees will be drawn from the San leadership, with a number of institutional appointments designed to ensure a balanced board.[27]

Negotiations were informed by some of the guidelines and ethical codes in circulation that have been drafted with full collaboration of indigenous peoples. One such code is that of the International Society of Ethnobotanists,[28] which provides a valuable matrix of best practice and principles in the field and which will be referred to further below.

Interesting to some observers, and annoying to others, was the fact that the San peoples, traditional supporters of the indigenous peoples' 'anti-patenting of life' lobby referred to above, elected when presented with the ethical dilemma, not to consider any form of legal challenge on the Hoodia patents. Faced with the choice of joining in with an effective partnership with the CSIR in the P57 patents, they unashamedly chose the path of self-interest. This decision underscored the truism that noble principles come at a price, and when presented with an opportunity to benefit meaningfully in a manner that could well assist in addressing centuries of discrimination and disempowerment, the San chose to join forces with the patent team, and thereby to empower themselves financially (Stephenson, 2003).

CONCLUSION

The Hoodia case study provides a potent example of the commercial power of a patent, based upon scientific 'discoveries' made after crucial leads from traditional knowledge sources. It is clear that the process was initially flawed. Few will begrudge, however, and most will celebrate the San's negotiated share of sales of the Hoodia drug in the pharmacies and clinics of the West. The need for more appropriate checks and balances in bioprospecting, and in particular the balance of power between the seekers of the knowledge, have not been answered. The greatest challenge for the San lies ahead, namely to ensure that the fruits of their freely given knowledge provide true 'benefit' for their peoples, and encourage more appropriate management of their intellectual property and traditional knowledge in the future.

NOTES

1 Numbering approximately 100,000 in the Southern African countries of Angola, Botswana, Namibia and South Africa.

2 Roger Chennells (B Comm, LlM London) is a lawyer with the human rights law firm Chennells Albertyn, in Stellenbosch. He acts for the San NGO WIMSA (Working Group of Indigenous Minorities in Southern Africa) and its support organization SASI, (the South African San Institute), in representing the various San peoples in Southern Africa.

3 The Botswana Government, under international pressure for its recent forced eviction of San peoples from the Central Kalahari Game Reserve, is on record as stating that they should not live 'like animals' and should, despite their resistance, be forced to live like the other 'civilized peoples' of Botswana.

4 Adopted by the International Labour Conference in June 1989, available at www.ilo.org/public/english/region/ampro/mdtsanjose/indigenouse/derecho.htm.

5 Available at www.unhchr.ch/indigenous/main/html.

6 Columbus' voyage was supposed to be to India, but he landed in the Americas by mistake, hence his terming of the indigenous peoples as 'indians'.

7 Shiva (2001, p45)

8 Egziabher, T. B. G. (2001) *The Inappropriateness of the Patent System for Life Forms and Processes*, Third World Network, Penang, Malaysia. The author concludes 'society knows the distinction between discovery and invention. It is greed that makes individuals distort these meanings so that, in the name of invention, they can monopolize discoveries. But discoveries should be rewarded. A system for such rewards should be developed. However, distorting the meaning of patenting in order to make it applicable to life only serves to attract the rejection of the whole system. Who ever worried about the legitimacy of patenting before the 1990s, before it became known that the USA was allowing the patenting of living things? But now, opposition is growing all the time, opposition not only to the legitimacy, but also to the legality, of patenting.'

9 *TRIPS on Trial* (Action Aid 2001): 'It (TRIPS) is the first international agreement that converted "intellectual property" to include patents on life (article 27.3) (b)) and established monopoly IPRs within the WTO, a multilateral body whose purpose it is to reduce trade barriers rather than protect a few industries of a few countries' (Action Aid, 2001, p1).

10 General agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, 15 April 1994, Annex 1C.

11 Article 27 '(3) Members may also exclude from patentability: … (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.'

12 This ceremonial drink used for centuries by the indigenous tribes of the Amazon basin to treat illnesses was successfully patented by a US citizen claiming his 'invention' to be a new and unique plant variety. The US PTO rejected the patent claim when leaders of the Amazon filed for re-examination on the basis that such plant variety was not novel (Quinn, 2001).

13 Bolivian quinoa was successfully patented by two scientists at Colorado State University. This vegetable is a staple food crop of indigenous peoples in Chile, Bolivia, Peru and Ecuador. The patent was later abandoned after indigenous groups exerted pressure on the university. (Quinn, 2001)

14 A US patent was granted to two expatriate Indians for the method of administering turmeric to wounds for healing purposes. The Indian Council for Scientific and Industrial Research challenged the patent in re-examination proceedings, claiming that such use had been utilized by the public for thousands of years. As a result, the US PTO cancelled the patent.

15 Indigenous Peoples' Caucus statement at the World Summit on Sustainable

Development, by Victoria Tauli-Corpuz, Johannesburg, 4 September 2002.

16 Article 15.5 'Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party'.

17 Legal Resources Centre (2003).

18 Biowatch, based in Cape Town, South Africa.

19 *Observer* (2001).

20 A copy of the agreement can be provided on request via the South African San Institute, sasi@iafrica.com

21 WIMSA and its negotiating arm, the South African San Council.

22 Hoodia Gordonii.

23 The Khomani San, living in the Askham area about two hours north of Upington, North Cape.

24 WIMSA Annual General Meeting: Report on Activities April 2001 to March 2002 (p60).

25 Weinberg (2003a).

26 Weinberg (2003b).

27 The Board of Trustees will be comprised as follows: representing the three San clans of South Africa, three trustees; representing the San clans of Botswana, Namibia and Angola, three trustees; representing the CSIR, one trustee; representing WIMSA, one trustee; representing the Department of Culture, Arts, Science and Technology, one trustee; professional lawyer or accountant, one trustee.

28 http://guallart.dac.uga.edu/ISE.

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Chapter 27

Commentary on Biodiversity, Biotechnology and Traditional Knowledge Protection: A Private-sector Perspective

Steven R. King

The chapter presented by Dr Nuno Pires de Carvalho (Chapter 18; see also Carvalho, 2005) is quite remarkable in its scope, depth, breadth and compassion on this complex and challenging issue. In reading this chapter and listening to Dr Carvalho, I found elements of the chapters by Peter Raven (Chapter 2), Ursula Goodenough (Chapter 3), Michael Balick (Chapter 19), and the presentations of John Hunter and Chris Jones, Maui Solomon, Metro Leach and Alejandro Argumedo (see http://law.wustl.edu/centeris/index.asp?id=1772). This is most notable because, Dr Carvalho is a lawyer working at the World Intellectual Property Organization (WIPO) and all the other people mentioned with the exception of Mr Solomon are biologists or social scientists. Here, we see an illustration of the concept of 'trialogue' (see Chapter 1) in action.

THE SPIRITUAL FOUNDATION OF TRADITIONAL KNOWLEDGE: THE CIRCLE AROUND THE TRIALOGUE

Specifically Dr Carvalho stated that (1) 'Traditional Knowledge (TK) is "holistic" in the sense that both its spiritual and practical elements have the same purpose of integrating the community with its environment'; (2) 'There must be an unbreakable link that connects TK to its creators, a sort of a subtle (but spiritually significant) thread of Ariadne that does not permit that link to be broken and thus lost'; (3) '[o]nce it is admitted that the concept of TK cannot be dissociated from its 'holistic' nature, one could expect that only a holistic, that is broadly inclusive legal approach could satisfy such a nature'. In fact the holders of traditional knowledge are, in many cases, working to ensure the biological and spiritual survival of ancient traditions. This ethic was expressed with elegance and reverence by John Hunter, Chris Jones, Maui Solomon and Meto Leach in this session. A similar reverence for the people, nature and the mystery of life was expressed by Peter Raven, Michael Balick and Ursula Goodenough in their presentations.

DISCLOSURE OF ORIGIN AND PRIOR INFORMED CONSENT: THE STARTING POINT FOR TRIALOGUE

In many ways the chapter by Carvalho is also a state of the art analysis and guide for how the above mentioned values may potentially be integrated within the existing international intellectual property rights system. It is obvious that he and the WIPO section on Genetic Resources, Biotechnology and Associated Traditional Knowledge, in the Traditional Knowledge Division, have been learning a great deal about the multiple levels of people and cultures that have created and manage traditional knowledge. The chapter sets a framework by defining traditional knowledge, identifying both its economic and non-economic importance, which should gain the attention of governments. An extensive discussion on the possible requirement of disclosure of origin of genetic resources and prior informed consent of TK holders within patent applications as a condition for enforcing otherwise valid patents is presented. My comment on his chapter is that it is only a matter of time and that a disclosure of origin in patent applications as a condition for enforcing a patent should become a requirement of the world intellectual property system now.

DEFENSIVE PROTECTION OF TRADITIONAL KNOWLEDGE

One focus of this chapter is the protection of traditional knowledge, using a defensive approach, developing legal measures to prevent third parties from claiming rights to traditional knowledge. Carvalho decribes the first possibility of the collection and organization of elements of TK in databases that would allow patent examiners to take TK into consideration as prior art or as bars to registration when examining patent applications. A number of initiatives are discussed that relate to this topic, a few of which will be discussed below. My comment on this method or area of protecting traditional knowledge is that the United States Patent Office (USPTO) and European Patent Office (EPO) have been especially lethargic in this area. One question might be why are these two agencies so slow to adapt?

The EPO and the USPTO have been briefed and informed about the existence of a number of excellent and easily accessible electronic databases that can be utilized via the Internet or leased out as an in-house electronic version to search for prior art that should and could be invoked to avoid granting a patent that is not novel. I have personally provided detailed information on such databases to representatives of the EPO on several occasions in the past three years. These are collections of existing scientific publications that are already part of the public domain. One of the best examples is the University of Illinois at Chicago database known as NAPRALERT. This database was developed by Dr Norman R. Farnsworth in the late 1970s as a worldwide database that compiles scientific literature on medicinal plants, microbes, marine organisms and fungi. This database is continually updated and can be searched by indigenous and local names of plants (i.e. traditional plant names), by plant species or genus and contains extensive data on published indigenous use, biological and chemical information on thousands of well- and lesser-known plant species. One of the best ways to protect access and inappropriate granting of intellectual property is to increase the ability of patent examiners to quickly review and cite existing 'prior art'. Another example of a database that seeks to help reduce the number of inappropriate grants of patents on traditional knowledge, is 'The Traditional Ecological Knowledge Prior Art Database (T.E.K*P.A.D.), which has over 40,000 entries of data already in the public domain. It can be accessed via the web at http://ip.aaas.org/tekpad. Carvalho also describes a number of emerging TK databases that are being developed in India, Venezuela and several other countries in order to 'protect TK', but some cautionary comments need to be provided to this 'national level approach'.

PROPRIETARY DATABASES AS AN AFFIRMATIVE METHOD OF TRADITIONAL KNOWLEDGE PROTECTION

A number of very dynamic and progressive national level digital/database projects seek to catalogue TK in order to ensure that interested companies or organizations work through legal channels when seeking TK or biological diversity as material for research and development. One notable example is the Venezuelan 'BioZulua' database, a project of an NGO and the Venezuelan Government (Johnson, 2002). The TK contained in this database is 'the intellectual property of the indigenous communities' and it is reported that WIPO and the Brazilian Government, among others, are exploring this approach as a model for other nations. This is indeed one innovative way that governments could (and likely will) require that any patent application based on this TK disclose the legal origin and negotiate appropriate access and benefit sharing agreements. The note of caution on this approach is that the indigenous communities and holders of TK need to be fully aware and informed of what is being negotiated on their behalf with seekers of this knowledge. As of late 2002 there were significant concerns among indigenous communities in Venezuela about the process of prior informed consent (PIC) utilized for the creation of this 'BioZulua' database. There is also concern about the inclusion of sacred or spiritual knowledge within the database. It will be important for any national government that develops such an approach to ask for the appropriate PIC everywhere that data is collected and if indigenous or local communities say no, for whatever reason, that their wishes be respected. In fact the focus on the protection of TK is intimately linked to another point in the trialogue, the actual users of TK who would seek out such databases as part of a PIC process. Carvalho points to this in his conclusion, stating that 'experience shows that where the realities of the market have been disregarded, legal measures tend to vanish in oblivion and discredit'. Fortunately, segments of the private sector are working to address, understand and respect the holders of TK and their world view.

COMPANIES AS A PART OF THE TRIALOGUE

The World Business Council for Sustainable Development (WBCSD) is a worldwide business organization with approximately 140 member companies. The WBCSD recently completed and published a stakeholder dialogue focusing on 'Intellectual Property Rights in Biotechnology and Health Care', which is available at www.wbcsd.org. One portion of this multi-year process of debate and discussion focused specifically on the 'protection of traditional knowledge'. The concerns and perspective of NGOs, indigenous peoples and corporations are expressed and this document may be useful to local communities, indigenous peoples, governments and NGOs as a template for working with international corporations who are interested in collaborating with a broad cross section of stakeholders involved with biological diversity, biotechnology and the protection of traditional knowledge.

TRADITIONAL MEDICINE, BIODIVERSITY, PATENTS AND PUBLIC HEALTH: LINKING THE TRIALOGUE

Carvalho also points out that the 'The relevance of TK as useful source of information for researchers in the pharmaceutical field who seek to identify chemical and biological agents, as well as new approaches to disease treatments, is generally undisputed'. This is especially true in a few important development-stage pharmaceutical projects. Research on the anti-HIV compound Prostratin, discovered through collaboration with traditional healers in Samoa, is demonstrating the ability to inhibit HIV 1 and to also induce latent virus out of cells so that it can be eradicated (Gulakowski et al, 1997; Gustafson et al, 1992; Kulkowsky et al, 2001).

Chennells' discussion (Chapter 26) of the benefits of sharing negotiation process between Phytopharm plc, the Council for Scientific and Industrial Research (CSIR) and the San Bushman of Southern Africa highlights another potentially important pharmaceutical development candidate. The focus of this agreement is the anti-obesity compound P57. This compound was discovered through research focused on the Hoodia cactus utilized by the San Bushman of Southern Africa to stave off hunger during periodic famine conditions. The South African government research organization CSIR did approach Shaman Pharmaceuticals Inc. in the mid-1990s and sought advice on how to initiate and maintain collaborative relationships with indigenous peoples in South Africa. It is surprising then that CSIR did not choose to negotiate and put in place a benefit sharing agreement at the time of initial licence of P57 to Phytopharm plc. The problems with the timing of the benefit sharing process will no doubt be discussed at length in this volume but the discovery process provides abundant examples of the effectiveness of collaborating with the holders of traditional knowledge.

One other example of an emerging therapeutic based on collaboration with indigenous people and traditional knowledge is the anti-diarrhoea compound crofelemer. This compound, like the others described above, was isolated from a plant that is utilized by indigenous people in the northwestern Amazon basin of South America to treat diarrhoea and other gastro-intestinal problems (Carlson and King, 2000). In this case the compound is working via a novel mechanism of action that inhibits the secretion of chloride ions without causing constipation or other side effects associated with opiate-derived anti-motility drugs (Gabriel et al, 1999; Holodniy et al, 1999). This compound is well suited to treating cholera and has been provided for free, as a dietary supplement, to 26 countries in Latin America, Africa and South East Asia. There are several therapeutic areas for which this compound is being developed for international utilization. Three of the traditional pharmaceutical development applications for this compound are irritable bowel syndrome diarrhoea, HIV associated diarrhoea and travellers' diarrhoea. Two of the other important therapeutic areas of focus are the treatment of cholera and paediatric diarrhoea. A phase II clinical trial with crofelemer for treating cholera was intiated in 2006 at the International Diarrhea Research Center in Daka, Bangladesh. One other appliction for this compound is for paediatric diarrhoea, a global health problem that kills more then 2 million each year.

These examples need to be considered within the larger context of traditional knowledge as a fundamental part of the health care system in biodiversity-rich developing nations. Carvalho notes that 'TK is also used by traditional communities and poor populations as an alternative to non-existent or inaccessible public health systems in developing countries'. He cites a study by WIPO (2001), which reports that indigenous communities in Bolivia would like to have traditional medicine integrated into the national health care system. There have been similar calls and movements to do this in many biodiversity-rich nations that have extensive traditional medical systems. The World Health Organization is focusing on evaluating the safety and efficacy of traditional plant medicines so that more practitioners can and will utilize plant medicines as part of public health systems.

Many of the most devastating global diseases, however, continue to kill millions of people. Diseases such as HIV/AIDS, tuberculosis and malaria are among the best publicized, but many lesser-known tropical diseases such as leishmaniasis, chagas disease and trypanosomiasis also cause massive suffering in tropical countries. Fortunately, a number of international efforts are targeting these lesser-known neglected tropical diseases. One example is the non-profit pharmaceutical company OneWorld Health Institute in San Fransicso, California (www.OneWorldHealth.org). This organization is focusing on developing new medicines for neglected diseases, with an initial focus on parasitic diseases. The organization has identified anti-parasitic compounds that have been isolated and patented, but not developed by pharmaceutical companies and individual scientists around the world. They request and negotiate licences to develop these compounds with little or no licence cost or royalties. The work of groups such as One World Health can benefit greatly from public interest *pro bono* (see Gollin, 2005) legal assistance, which is elegantly described in Michael Gollin's chapter.

Michael Gollin's (2005) paper 'Answering the call: Public interest intellectual property advisors', addresses the need for intellectual property-related legal assistance in developing countries. His organization (PIIPA) provides opportunities for lawyers to become proactively involved with the protection and positive utilization of traditional knowledge and biological diversity. This need is especially critical in the area of public–private health care initiatives and access to essential medicines, for one of the most critical IP issues Gollin highlights in his paper is that of compulsory licensing of drugs for the treatment of HIV/AIDS. As we all know, for people dying of HIV/AIDS in biodiversity-rich countries, access to life-saving medications is a matter of life or death. As Gollin notes 'Developing countries need professional assistance to develop strategies to cope with the restrictions of TRIPS and the Doha declaration. For example, invoking compulsory licensing laws might require input from intellectual property professionals.' I can think of no area of greater importance for legal assistance to developing countries then to help nations, communities and individuals gain access to essential medicines for HIV/AIDS.

One related area that may be worthy of pursuit by lawyers, scientists, governments, drug development companies and the holders of traditional knowledge on medicinal plants would be a more focused exchange of knowledge and essential medicines. I am suggesting that large pharmaceutical research organizations create agreements with communities and countries that provide for access to essential medicines in exchange for access to targeted traditional knowledge and biological diversity as an explicit exchange. A number of innovative reciprocal exchanges have been conducted in the past ten years but to my knowledge large-scale access to essential medicines has not been part of such agreements. At this time there is a diminished interest in natural products and traditional knowledge in the pharmaceutical industry in general. I believe that will change in the next 3–6 years.

MAINTAINING SYMMETRY IN THE TRIALOGUE AS IMPERATIVE FOR ITS UTILITY

The conclusion of Carvalho's extensive paper contains several key suggestions and observations: (1) 'There is no need to develop a *sui generis* regime from scratch, because the basic concepts – including those of a *sui generis* regime of protection of original contents of databases – have already been recognized in national and international law'. (2) 'If TK holders – who are or will be the users of any regime developed to protect knowledge – are not involved in the discussions leading to the preparation of legislation with that purpose, they may not feel compelled to use the mechanism because of failure to see the advantage or benefits they can extract from it. Therefore in order to make whatever regime *effective*, it is essential to promote the participation of TK holders in national and/or international discussions'.

The first point is well defended in Carvalho's extremely well-researched and constructed chapter, but the conclusion that there is no need for a *sui generis* regime may well not be widely accepted by the diverse universe of traditional knowledge stakeholders. I say this simply because the existence of the world intellectual property rights system clearly did not involve the 'participation of the TK holders in national and/or international discussions'. Instead, highly skilled and committed individuals such as Carvalho are now trying to overlay this part of the trialogue onto traditional knowledge holders who are concerned about many issues other than ownership, profit, wealth or the protection of intellectual property rights. This is not to say that this process is not constructive or useful. I have seen in the past ten years enormous advances in cultural sensitivity to these complex issues among international multilateral agencies and the legal profession. This volume is strong evidence of the opening of the legal mind to the spiritual and sacred dimensions of traditional knowledge.

The second point is of course absolutely critical and in fact traditional knowledge holders have been absent or intensively under-represented in discussions of the use, conservation or protection of traditional knowledge. I would like to provide two examples to illustrate this point.

In September of 2001 I had the pleasure of meeting the organizer of this conference, Charles McManis, in Manaus, Brazil at an international seminar organized and funded by the European Commission (EC) and the Brazilian National Institute of Industrial Property (INPI). The title of the Seminar was 'The Role of Intellectual Property Protection in the fields of Biodiversity and Traditional Knowledge'. Lawyers, government officials and NGO experts were flown to Brazil from all over the world for this meeting. Manaus, Brazil is located in the heart of the Amazon rainforest in a country with an extensive diversity of indigenous peoples, major stakeholders in discussions about traditional knowledge. One of the reasons often cited for not having formal participation of traditional knowledge holders and indigenous people is the logistical difficulty of bringing people from remote communities to the US, Europe or other regions of the world. This was clearly not an obstacle in Manaus. In fact a well-known indigenous leader of Brazilian indigenous peoples did come to the meeting and wished to participate by giving a presentation on the views of Brazilian indigenous peoples. He was not added to the programme but he did gain access to the president of INPI who was participating in the meeting. To the credit of INPI it was announced at the meeting that INPI was aware of the importance of hearing the opinions and concerns of Brazilian shamans regarding the focus the seminar and that they, INPI, would convene a meeting of shamans in a few months to listen to their concerns and their issues would be taken directly to WIPO as the voice of the Brazilian Amazonian shamans and traditional knowledge holders. That meeting did take place and their statements and concerns were directly communicated to WIPO in a formal process. While this is quite important, it would have been, in my opinion, even more effective to have the participation of these stakeholders at the EC/INPI meeting as well.

A second more recent example occurred in November 2002 in Peru. I was asked to give a presentation at a Workshop on Access to Genetic Resources, Traditional Knowledge and Intellectual Property to the Group of Like Minded Megadiverse Countries (Bolivia, Brazil, China, Costa Rica, Colombia, Ecuador, India, Indonesia, Kenya, Malaysia, Mexico, Peru, South Africa, the Philippines and Venezuela). It was an honour to be asked to make a presentation to this group of lawyers, government officials and experts from these countries. The collective traditional knowledge holders of these megadiverse nations is a large percentage of the planet's cultural diversity. However, there were no participants from indigenous or traditional communities at the meeting. As in the case of Brazil, there are many, many indigenous people's organizations in the mountains and rainforests of Peru who could have participated in this meeting. I should point out, however, that all of the meeting participants were invited and most did go to visit a group of traditional Andean communities who have created an integrated *in situ* food and medicinal plant conservation and management programme. Many important community created initiatives were presented to two large bus loads of people from the Megadiverse Countries. Again, however, as Carvalho indicated 'it is essential to promote the participation of TK holders in national and/or international discussions'. Clearly more participation TK holders is needed in this process.

TRIALOGUE ON THE GROUND

The chapters written by Rosenthal and Lewis provide actual examples of governments, scientists, ethnobiologists, traditional knowledge holders and non-governmental organizations working together (or against each other as the case may be) in pursuit of the protection and development of traditional knowledge and biological diversity. The overall scope and accomplishments of the International Cooperative Biodiversity Groups (ICBG) was presented by Rosenthal, with a focus on natural products drug discovery, economic development and biodiversity conservation in 12 countries. The details of the accomplishments of this programme over the past ten years is impressive. In addition to the bioactive compounds isolated, scientists trained and research conducted, the programme has been the most transparent government-sponsored international experiment conducted to date, testing the process and methods of working to implement the guiding principles of the CBD. The focus of the talk on prior informed consent is a key issue for the protection of traditional knowledge, as is the focus on the requirement for the disclosure of origin and prior informed consent of TK holders in patent applications as a condition for enforcing otherwise valid patents.

Rosenthal did echo the comment of Ana Sittenfeld and Ana Espinoza of Costa Rica (Chapter 12) that none of these programmes, which are focused on drug discovery as well as conservation, has yielded any pharmaceutical products after more then ten years of work. My comment on this observation is that patience is a virtue. The actual estimated cost of identifying and developing a new pharmaceutical product is estimated to be in excess of US$500 million by the pharmaceutical industry. This figure of course takes into account all the failures and high costs of pharmaceutical R&D. The actual amount of money invested in the ICBG and INBio Costa Rica programmes is nowhere near US$500 million and there are still drug discovery candidates under study in many laboratories. The investment in Shaman Pharmaceuticals Inc. was approximately US$200 million and a drug development candidate reached a US FDA fast track Phase III clinical trial prior to the financial problems that ultimately led to the demise of Shaman's business. The compound SP-303, which was purchased in a US government bankruptcy auction, is still in development. It is quite possible that a New Drug Application approval for crofelemer will be achieved with a great deal less total investment then US$500 million dollars.

Rosenthal's chapter clearly demonstrates that large challenges remain in gaining 'appropriate' prior informed consent from cultural groups that consist of 20–30 thousand people living in dozens of communities spread out over large geographic areas. In the ICBG–Peru project, described by Walter Lewis, a great deal of time and effort was expended to identify the appropriate indigenous federations that represented segments of the Aguaruna cultural groups. Despite extensive efforts, a formal agreement between the Consejo Aguarauna y Huambisa (CAH), which represented a confederation of the Aguaruna and Huambisa living along the Rio Santiago, was terminated in 1995. The ICBG–Peru programme did establish a successful long-term collaborative relationship with several other Aguaruna federations in the region. My comment on this is that rarely will all the political organizations representing large cultural groups make the same choices. The important lesson in this case is that individual confederations can and will make their own choices as they wish, based on prior informed consent. My experience working in Peru and many other countries on such agreements is that many communities and cultural groups are quite interested in opportunities to collaborate with R&D projects that focus on traditional knowledge. The effort to establish such relationships takes time, patience, transparency and a large amount cultural and institutional sensitivity.

Novel and important contract provisions were negotiated in this Peru–ICBG, as a result of the efforts of Lewis, the indigenous leaders and the lawyer Brendan

Tobin, who made an excellent conference presentation on this topic. This precedent-setting *Know-how License Agreement* provided for 'annual license fees to be paid by the corporate partner to the collaborating Aguaruna federations while their knowledge was being used in the extraction and screening program'. These licence fees were in addition to any milestone payments that may have become due, based on research accomplishments in the R&D process. A specific know-how licence agreement had not been established with a large pharmaceutical partner prior to this agreement.

One of the other important outcomes of the ICBG–Peru project was the identification and isolation of antimalarial compounds. As noted in my strong endorsement of PIIPA, the organization that Michaal Gollin has founded, for research, development and access to therapeutics for malaria, tuberculosis, HIV/AIDS and diarrhoeal diseases, is of critical importance to local and indigenous peoples throughout the developing world. One of the other long-term ICBG projects has been especially focused and effective at identifying compounds for tropical parasitic diseases (Schuster et al, 1999).

The other ICBG project described by Rosenthal was the Maya–ICBG project, led by Brent and Elois Berlin and their highly skilled and dedicated Mayan colleagues in State of Chiapas in Mexico. In this case the Maya–ICBG collaborative team conducted an extensive prior informed consent process in the region of Chiapas and in other parts of Mexico. A very enthusiastic prior informed consent was granted by a wide diversity of communities, many of whom had collaborated on previous projects with the ICBG–Maya team members. In this case, as in the ICBG–Peru project, the Maya cultural groups were represented by numerous political organizations, spread over a large area involving many thousands of people and dozens of communities. The political climate of Chiapas and Mexico is very distinct from the northern Peruvian Amazon region where the Aguaruna live. More importantly, however, a North American NGO (ETC, formerly RAFI) became intensely involved in a campaign to stop the Maya–ICBG project and aggressively courted cultural organizations that have had historical conflicts with the Maya organizations that were working as full partners in the Maya–ICBG. I fully support cultural groups making the choice to not participate in research focused on traditional knowledge. I do not support, however, the sabotage of very well-constructed international collaborations between groups that have chosen to create programmes that will provide multiple short-, medium- and long-term benefits to local Maya communities. Sadly, a successful media campaign managed to make the Maya–ICBG a national and international focal point for concerns about the potential inappropriate exploitation of traditional knowledge. The specific details and process of the collapse of the Maya–ICBG are extremely complex. The halt of this particular ICBG project in Mexico has not and cannot alter the tremendous collaborative research achievements of all the parties who created the Maya–ICBG and who continue to work together.

INTELLECTUAL CREDIT AS A FORM OF RESPECT FOR THE TRIALOGUE

Carvalho (Chapter 18), Balick (Chapter 19), and Hunter and Jones have all noted the contribution of traditional medicine in the development of a great number of western medicines that have saved and helped millions of people each year. In the opportunities that I have had over the past 20 years to work with the holders of traditional knowledge I have heard a consistent message from many healers, leaders and mothers. I have been asked to make certain that the people and cultures who led scientists to plants that have yielded modern medicines be accorded the proper intellectual credit for their traditional knowledge and contribution. In fact most pharmacy or medical school textbooks do not provide credit to traditional knowledge as the origin of many wonder drugs. Nor do high school or lower grade schoolbooks identify the tremendous contributions that traditional knowledge has provided to the western pharmacopoeia. Michael Balick illustrated the rapid disappearance of traditional knowledge and correctly reminded the conference that if it traditional knowledge disappears at the current rate these discussions of how to protect it become moot exercises. One of the ways that younger generations of traditional knowledge holders decide to celebrate and maintain their cultural legacy is to see respect and tribute paid their elders, their culture, and their contribution to the world. Contractural provisions, PIC, benefit sharing, and ethical focus are all important but credit for the contributions of traditional knowledge to modern medicine is critical. Such recognition can also enhance the integration of traditional medical systems with national public health programmes where 80 per cent of the populations rely on traditional health care practitioners.

RECONNECTING THE CIRCLE AROUND THE TRIALOGUE

In the talk at the conferences by lawyer Maui Solomon I was especially struck by his metaphor of the fruits of traditional knowledge. He expressed profound concern about our nearly obsessive focus on the codification of traditional knowledge. He asked if we really were intent on 'squeezing all the juice of the fruit' as he closed his fist on an imaginary fruit. His and many other peoples' concern is that the profound spiritual linkage of traditional people to the Earth and their holistic cosmology is being crushed and destroyed by so many market and materialistic forces. This is in many ways the most profound issue in this conference and the largest challenge to lawyers, scientists, companies and the public. How can we show proper homage and respect and contribute to the protection of thousands of years of sacred cultural and spiritual development?

The presentation of the painting by John Hunter and the ten years of training he has received to be able to create and understand it was an oral and visual introduction to the next and greatest challenge to the lawyers of the future. Hunter's presentation with his colleague, Chris Jones, provides a more familiar, but equally important invitation to this challenge. How can IPR and the practitioners of the law begin to reconnect, even in the highly structured field of intellectual property law, a long overdue respect and reverence for the cultures, people and spiritual values embodied in traditional knowledge? One of the answers is in the words of Raven: love, compassion and respect for all creatures on this planet. Before the road from the shamans hut to the patent office can be completed, it may be that patent officers and attorneys will need to paddle a canoe to a shaman's village and spend some time learning about the values of the culture in order for the shaman to invite them in to discuss the protection of his or her traditional knowledge.

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Chapter 28

Answering the Call: Public Interest Intellectual Property Advisors (PIIPA)

Michael A. Gollin

Despite the growing debate about the complex global role of intellectual property over the past decade, and the diversity of policy initiatives and academic studies spawned by (and contributing to) this debate, little has been done to meet the practical demands of developing countries and public interest organizations for access to intellectual property expertise on a case-by-case basis. Wealthier organizations and private industry have access to such expertise, by paying for the services of the intellectual property professionals that are concentrated in developed countries. In contrast, in developing countries, there are few intellectual property professionals and many organizations cannot afford to pay for their services. Moreover, many intellectual property professionals are ill-equipped to meet the needs of public interest clients. Society benefits when all people have access to good information and competent advice, and fairness dictates that when poor and excluded people are confronted with the very complicated issues involving intellectual property, they should have access to expert advice and representation.

Public Interest Intellectual Property Advisors (PIIPA) was established as an independent international service and referral organization that can help fill the need for assistance by making the know-how of intellectual property professionals available in developing countries. PIIPA's services are practical, not policy-oriented. PIIPA's goal is to provide balance and information that may help harness the power of informed debate to solve problems, and combat the fear and ignorance that make solutions impossible and lead to protracted disputes. PIIPA's beneficiaries are finding new ways to solve problems in such contentious and difficult fields as traditional knowledge, biodiversity, health and agriculture.

In recent years, the impact of intellectual property laws and practices on developing countries has increased dramatically. Globalization has increased the contacts between developing countries and governments and organizations within countries with well-developed intellectual property legal regimes (mostly, the industrialized nations of the northern hemisphere, especially the EU and the US). Numerous international conventions and trade agreements that affect developing countries expand or involve intellectual property rights. These include the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS, 1994), the United Nations Convention on Biological Diversity (CBD, 1992), and the International Convention for the Protection of New Varieties of Plants (UPOV, 1991). As these treaties have multiplied, their secretariats have dealt continuously with issues involving the impact of intellectual property on developing countries and other public organizations (Gollin, 1999). In addition, international organizations, such as the World Intellectual Property Organization (WIPO), have begun to examine in-depth the role of intellectual property in issues of particular concern for developing nations, such as traditional knowledge, cultural heritage and communal rights.[1]

Despite these rapid changes and their effects on developing countries, most developing countries do not have access to qualified intellectual property professionals who are willing and able to help them address the myriad issues they now face. Rather, most of the participants on the global and national stage have been economists, academics, anthropologists, scientists and policy specialists, but not intellectual property professionals. In response to this need, in 2002, an international association of concerned individuals, including the author of this chapter, decided to establish a new public interest organization. The new organization was named Public Interest Intellectual Property Advisors (PIIPA), and was incorporated as a non-profit, tax-exempt global *pro bono* initiative to provide intellectual property-related services for governments, agencies and research institutions in developing countries and other public interest organizations.

This chapter describes the genesis and development of PIIPA, focusing on the need for services of the type PIIPA offers and plans to offer as well as the logistical, legal, ethical and political hurdles that public interest organizations working in the area of intellectual property must overcome. The first part describes the growing need for intellectual property-related legal and professional assistance for developing countries, and in the public interest. The next part discusses how PIIPA was founded and organized to address these needs. The third part addresses the work of PIIPA, including illustrative cases, planned growth and future directions.

THE NEED FOR INTELLECTUAL PROPERTY-RELATED LEGAL ASSISTANCE IN DEVELOPING COUNTRIES

The expansion of international intellectual property law to date has been based on the argument that it brings benefits to innovators in all countries, but it has proceeded primarily at the insistence of industrialized, technology-exporting nations that have sought to obtain the same intellectual property protection for their inventions and creations in developing countries that they benefit from in industrialized countries (Syverson, 1992). Opponents of intellectual property expansion include some non-industrialized, technology-importing countries that have historically opposed or sought to limit the expansion of intellectual property rights (Commission on Intellectual Property Rights, 2002) seeking to retain access to the technologies of the wealthier countries, and discounting the significance of incentives for innovation in their own countries. Others oppose particular kinds of intellectual property such as 'life patents' and Internet patents. At the same time one movement has sought to assert new types of intellectual property rights, such as sovereign rights over genetic resources previously understood to be the common heritage of humankind (Asbey and Kempenaar, 1995) and rights to traditional knowledge.

As a result, the international laws relating to intellectual property developed in recent years have been met with wariness and opposition to the widespread implementation of western-style intellectual property laws. Is the current regime being applied fairly and equitably to people in developing countries? On at least one level the answer is no. Given that expertise in intellectual property laws, strategies and management is currently limited primarily to professionals in industrialized countries and in the private sector, there exists a great gap in access to such expertise for developing countries.

Expertise in intellectual property can help advance the public interest in a wide range of endeavours. These include: health care (e.g. obtaining access to patented medicines); agriculture (e.g. licensing of improved crop varieties); biodiversity (e.g. entering into biodiversity prospecting agreements and challenging misappropriation of biological resources); environmental protection (e.g. entering into contracts for technology transfer for renewable energy sources); traditional/indigenous knowledge (e.g. agricultural and health practices, and protecting traditional designs, handiwork, art, music, etc.); scientific research (e.g. obtaining patents or other protection on inventions); and software and technology licensing (e.g. dealing with internet access and related issues/disputes).

A consensus should support the benefits of providing intellectual property expertise to developing country and public interest clients. Intellectual property expansionists would recognize the need for expert assistance to realize the promise of intellectual property in innovation in health, agriculture, the environment and industry. Opponents of intellectual property expansion, or of particular types of intellectual property, should support access to intellectual property professionals who may mitigate or avoid negative impacts of intellectual property, balance the unfair advantage of wealthier organizations, which may be collaborators or opponents, and find specific policy/legal initiatives that may be workable and therefore viable alternatives in international policy discussions.

A small, informal survey conducted in the summer of 2002 confirmed the need of developing countries for intellectual property-related legal assistance. The survey polled professionals working in a variety of technical sectors (e.g. biodiversity, environment, health) and geographical regions (e.g. both industrialized and non-industrialized nations) about their knowledge of the need for legal assistance for public interest intellectual property-related projects in developing countries. In response to a question regarding how many potential clients would seek out professional assistance on intellectual property-related legal issues, the majority of the respondents indicated that more than 100 such clients exist worldwide, with over one quarter indicating that more than 500 such clients may exist. In addition, the majority of the respondents indicated that such clients would have needs that arise on a continuous basis. In response to a question regarding the fields in which such intellectual property related projects would arise, the respondents listed a variety of fields, including health, agriculture, biodiversity, environmental technology, cultural/art and information technology. Similarly, the survey responses suggest that developing nations may need assistance in many different areas of intellectual property law, including: patents, copyright, trade secrets, licensing, litigation and legislation.

As the survey suggests, there is an acute need for public interest intellectual property-related legal assistance. However, as noted above, many people and organizations in developing countries are either unaware of, or unable to deal with, the impact of intellectual property rights either in their favour or against them. In addition, in most of these countries, there are few qualified legal professionals who can represent the rights and interests of such people or organizations – even for those who could afford such services. Furthermore, most of the non-industrialized countries in the world have very limited resources to expend on acquiring knowledge, training or professional assistance for the types of intellectual property-related projects enumerated above. Many of the organizations in this field lack intellectual property professionals on staff, and existing organizations focus on policy formation, or generalized training and capacity building regarding intellectual property management, not practical case-by-case representation. Thus, there is a gap to be filled for many developing countries and public interest organizations that need access to *pro bono publico* intellectual property services (literally 'for the good of the public').

Conversely, among intellectual property professionals in industrialized nations (including lawyers, agents and licensing specialists), there is a need for information regarding the types of public interest projects for which their education, skills and experience are uniquely suited. While many organizations admirably perform this service in other areas of the law, such as poor criminal defendants, immigrants seeking asylum and the formation of small non-profit corporations by artists, few organizations attempt to inform legal professionals about the opportunities for intellectual property-related public interest work. Many intellectual property professionals in industrialized countries, especially law students and recent graduates, have expressed a desire to use their skills and experience to improve the role that intellectual property plays in the developing world and would relish the chance to share their expertise with disadvantaged public interest clients. However, as noted above, intellectual property professionals have no regular reliable sources of information about how they can help developing countries cope with the plethora of intellectual property issues they face. If developing countries are to gain access to useful intellectual property expertise, this information deficiency must be remedied.

In particular, competent professional legal advice is needed to address the following specific intellectual property related issues that affect developing nations.

Agricultural technology

The protection of agricultural technology, and biotechnology in particular, is an important and contentious area of intellectual property. Agricultural biotechnology, in its broadest interpretation, refers to the application of biotechnology to agricultural problems in order to increase crop yields, open up new growing environments, use less chemical pesticides, improve nutritional content and decrease energy consumption in growing and processing (Gollin, 1996). Generally, these activities involve research and breeding to produce improved crops, and the innovators charge a premium price for such improved varieties, in order to recover the investment in making the improvements. A key component of commercial innovative breeding is the ability to ensure that farmers must buy the improved seed each year, and not keep and replant seed from the past season.

The highly touted benefits of agricultural biotechnology are not readily accepted by everyone, though, and many have raised concerns ranging from possible increased use of herbicides to unintended effects stemming from the planting, use and consumption of genetically modified organisms. Along with the rapid pace of technology innovation, a host of legal mechanisms for protecting the intellectual property rights in these agricultural biotechnology advances have developed (Hamilton, 1993).

Major changes in the legal regime surrounding agricultural biotechnology have occurred in recent decades, ranging from UPOV's requirement that '[e]ach Contracting Party grant and protect breeders' rights' (UPOV Art. 2) to the US Supreme Court's decision in *Diamond* v *Chakrabarty*, 447 U.S. 303 (1980), that genetically modified bacteria are 'compositions of matter' or 'manufacture' subject to patenting. This legal regime continues to evolve – for example, the Canadian Supreme Court recently held that a genetically modified mouse, the so-called Harvard mouse or oncomouse, is not patentable subject matter; and in so holding noted that: 'The patenting of all plants and animals, and not just human beings, raises several concerns that are not appropriately dealt with in the [Canadian] Patent Act'.[2] The impact of this decision on the Canadian agriculture market, on the international legal regime and other countries' laws remains to be seen, but it illustrates that determining how intellectual property laws apply to agricultural biotechnology innovations relating to plants and animals presents high impact issues whose resolution requires significant professional expertise.

The enforcement of intellectual property licensing strategies by agricultural biotechnology companies has also led to high profile court challenges against farmers, for example in the case of *Monsanto* v *Percy Schmeiser* in Canada.[3] Intellectual property concerns pervade even technical, non-legal measures to prevent farmers from reusing seed from past growing seasons, such as the so-called genetic use restriction ('Terminator') technology. Recently, a body of the CBD (described in the following section) notified WIPO and UPOV that there is a need to examine 'the specific intellectual property implications of genetic use restriction technologies, particularly in respect of indigenous and local communities'.[4] This communication notes that the potential impact of genetic use restrictions on smallholder farmers, indigenous and local communities and on farmers' rights needs to be explored with an emphasis on the development of new legal mechanisms to cope with such restrictions.[5] In addition, the World Trade Organization's TRIPS Council is currently reviewing Article 27.3(b), regarding patent protection for plant and animal inventions.[6]

New intellectual property management strategies have been developed recently. The case of golden rice[7] involved the negotiation of a complex web of licences to provide freedom to use the technology for humanitarian purposes. The Collaborative Crop Research Programme of the McKnight Foundation is requiring grantees to adopt intellectual property terms facilitating technology transfer to poor countries.[8]

The rapid changes that have been seen in agricultural biotechnology in recent years are likely to continue as genetic manipulation techniques open up new avenues for scientific research and new corporate business strategies confront farmers with the need to understand intellectual property rights. Developing countries and farmers, therefore, have a need to understand how these new technologies will impact them and how the decisions regarding the management of intellectual property rights in these new technologies will affect them.

Biodiversity

In 1992, the UN Conference on Environment and Development convened in Rio de Janeiro and created two international agreements – the climate change framework, and the CBD (Rio Declaration, 1992). Generally, the CBD 'established sovereign national rights over biological resources and committed member countries to conserve them, develop them sustainably, and share the benefits resulting from their use' (Gollin, 1999). Although the CBD has now been signed by at least 187 countries,[9] significant debate surrounded its passage and still plagues the implementation of the CBD (Laird and ten Kate, 2002).

Over the centuries, many samples of unique genetic resources have been taken from their original country of origin to collections in industrialized nations. Many unique biological resources have yet to be catalogued or even discovered. These resources, which are concentrated in developing countries of high biodiversity, remain in demand as sources of leads for new products, or for scientific collections (Laird and ten Kate, 2002). This demand has led many biodiversity-rich developing countries to exercise their rights over biological resources established by the CBD by enacting national laws and rules to protect their resources (Gollin, 1999). The extension of developing country national laws to require informed consent and benefit sharing as preconditions to access to biological resources has resulted in contractual arrangements between biodiversity source countries and biotechnology and pharmaceutical corporations seeking access to the biological resources. These agreements are variously referred to as either biodiversity prospecting agreements or access and benefit sharing agreements.

While this national legislation relating to biological resources and biodiversity prospecting agreements is intended to protect these countries' rights to their biological resources, it has also added new legal complexities with which developing countries must cope. Intellectual property experts have not been extensively involved in the establishment of such rules, with the result that they are of limited practicality.[10] Developing countries, therefore, have a need for professional legal advice regarding the passage and implementation of effective laws, the formation and execution of appropriate biodiversity prospecting agreements, and also their enforcement in the event of a breach. Countries may also require assistance to enforce permitting laws in the event that a company engages in biopiracy – the taking of biological resources without the requisite permissions and agreements.

While some biodiversity prospecting agreements may be fairly straightforward contracts, many provide negotiated royalty payments in exchange for access and sample collection, and other agreements involve complex negotiations regarding the sharing and value of locally acquired and/or pre-existing indigenous knowledge regarding a developing country's biological resources.[11] Source countries may place a high value on these contracts in monetary, environmental and political terms. Thus, ensuring that such countries have legal representation that can adequately and appropriately handle the intellectual property issues that arise in the context of biodiversity prospecting agreements, such as licences for patent, trademark, and trade secret/know-how rights and material transfer agreements, is crucial.

Traditional knowledge

Over the past six years, WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the 'WIPO Committee') has been examining the existing intellectual property mechanisms that could be used to protect traditional knowledge and debating the development of a *sui generis* system for protection of traditional knowledge.[12] WIPO Members have indicated that depending on the country involved, a wide range of intellectual property laws may be available to protect traditional knowledge, ranging from patent to trademark to copyright to trade secret.[13] For instance, both Australia and Canada can cite examples where existing copyright laws were used to protect traditional knowledge and creations of Aboriginal peoples.[14] On the other hand, several members indicated that they either had adopted *sui generis* systems to protect traditional knowledge or intended to adopt a *sui generis* system of protection.[15] Significantly, in response to an inquiry about the existence of legislation providing for special measures 'to assist traditional knowledge holders to acquire, exercise, manage and enforce their rights', the vast majority of members 'stated that there are no special measures in place to assist traditional knowledge holders handling their intellectual property matters'.[16] Moreover, a number of Committee members have expressed concerns that traditional knowledge does not always easily fit into or fulfil the criteria to qualify for protection under existing intellectual property laws.[17] Thus, the EC and its member states, for example, have expressed their support for continued study of whether patent applications should disclose the origin of traditional knowledge where appropriate and for the development of an international *sui generis* model for the legal protection of traditional knowledge.[18] This issue is just now coming under discussion in the EC but not yet extensively in the US.

Given the WIPO Committee's findings regarding the current state of protection for traditional knowledge, it is clear that developing countries desiring to help protect traditional knowledge face a daunting challenge. In recognition of this fact, the Committee has designed a series of workshops and consultations with local and indigenous communities in developing countries.[19] In order either to determine whether and how traditional knowledge may be protected by existing intellectual property laws or to develop a *sui generis* system of protection, a substantial amount of work must be done. For either of these endeavours, there is a need for the expertise of intellectual property professionals with significant experience in finding, interpreting and applying, for example, copyright and trademark laws, to practical, real-life situations to achieve results desired by a specific person or group. Developing countries could gain valuable insights from the experiences of these professionals, who could also be of great assistance in shaping existing or developing new laws to protect traditional knowledge. This need may be particularly great, for example, in developing countries that export crafts and natural products, and those where tourism plays a significant role in the country's economy.

Moreover, concerns regarding the role of intellectual property also exist with regard to the protection of folklore. For example, China has expressed to WIPO its concerns relating to whether and how national folklore, such as traditional operas, music, performing skills, and literary and artistic works, can be protected.[20] To this end, the WIPO Committee is also studying various expressions of folklore and experiences with the legal protection of expressions of folklore.[21] As with traditional knowledge, developing countries have a great need for assistance in addressing the issue of whether intellectual property can protect some expressions of folklore with legal strategies and measures that can be implemented and deployed to fulfil the intended goals of preserving existing cultural diversity and stimulating a rich creative process as new folklore is produced.

Health care

The AIDS epidemic is one of the greatest challenges facing every nation in the world today. This is especially the case for the developing countries of sub-Saharan Africa,[22] where the challenges go well beyond the scientific problem of devising a treatment to the formidable task of obtaining affordable versions of any treatments.[23] Many have argued that the absence of affordable treatments can be traced to the deadly combination of sub-Saharan Africa's poverty, poor infrastructure, lack of ability to administer and monitor a pharmaceutical treatment regime and, more controversially, to strong patents under the intellectual property laws required by the TRIPS agreement. The counter-argument is that the innovations arising under a strong patent regime are the only hope, over the long run, for new cures for AIDS and other diseases. One way to resolve this debate between populist and economic views involves the practical use of intellectual property strategies on a case-by-case basis (Gollin, 2002).

TRIPS requires its members to award 'patents … for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application' [TRIPS 1994, Art. 27(1)]. Article 70(8) of TRIPS sets forth procedures for establishing 'patent protection for pharmaceutical and agricultural chemical products'. Developing countries have attempted to avoid the drug-restrictive effects of patents in developed countries and their own by relying on the TRIPS parallel importation and compulsory licensing measures, but these strategies have met with only limited success (Correa, 2000). In November 2001, WTO members concluded the Doha Development Agenda (the Doha Declaration), an agreement on patents and access to medicines. Unfortunately, the Doha Declaration did not fully resolve the problem of developing countries' access to medicines.[24]

In August 2003, the WTO waived member countries' obligations under Article 31(f) of the TRIPS Agreement, which states that production under compulsory licensing must be predominantly for the domestic market, and thus effectively limited the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented.[25] WTO members on 6 December 2005 voted to amend the TRIPS Agreement to make this waiver permanent.[26] This decision will now be formally built into the TRIPS Agreement when two thirds of the WTO's members have ratified the change. They have set themselves until 1 December 2007 to do this. The waiver remains in force until then.

Developing countries need professional assistance to develop strategies to cope with this amendment of the TRIPS Agreement and other matters raised by the Doha Declaration. Developing countries have many other needs relating to health care for which intellectual property is relevant. For example, another organization has identified 'the need for good management of IP in health R&D' as part of a broad-based plan to improve public health in developing countries.[27] In addition, complex intellectual property issues limit the ability of public–private partnerships to address the existing health research funding imbalance (the so-called '10/90 gap').[28] These sophisticated strategic alliances for research, production and the delivery of health products and services involve licensing and ownership of patents, trade secrets and trademarks. In sum, expanded intellectual property assistance should help to resolve the immediate need for access to affordable medicines, and the longer term need for sustainable management of innovation in public health, as global society seeks to find an equitable balance between the public health needs of today and of tomorrow (Gollin, 2002).

Technology transfer and the environment

Developing countries are essential players in environmental conservation. It has been recognized that transfer of technologies between countries should emphasize the transfer of environmentally sound technologies. For example, the Intergovernmental Panel on Climate Change (IPCC) has identified national governments and certain international agreements as key elements of an effective, environmentally sound technology transfer system.[29] Transfer of renewable energy sources, and low greenhouse gas emitting engines and generators are initiatives promoted by Global Environment Fund under the auspices of the IPCC.[30] Transfer of these and other technologies that reduce pollution to land and water or reduce consumption of natural resources may require skilled intellectual property negotiators to effectuate.

As efforts to ensure environmentally sound technology transfer continue to grow, developing countries will increasingly be called upon to navigate thickets of intellectual property rights in order to license and access the relevant technologies. Countries may need to ensure their policies and regulations conform accordingly. As such, developing countries could benefit greatly by having access to professional assistance from intellectual property professionals experienced in technology transfer.

Open-source, Internet access, and information technologies

As access to and reliance on Internet resources increases worldwide, including in developing countries, concerns about fair and equal access to these resources are also increasing. Organizations such as Open Source,[31] IP Justice,[32] the Electronic Frontier Foundation,[33] the Global Internet Liberation Campaign,[34] and The Digital Divide Network[35] have highlighted the public interest need for legal advice and representation in this evolving arena. Current concerns include the building of a global public domain of open source materials, copyright law and privacy, to name just a few.[36] The focus of these efforts has naturally followed the growth pattern of the Internet, with the primary historical focus being on the US, Europe and parts of Asia.

As access to the Internet becomes more globalized, so do concerns about access and fair use. Attempts to analogize Internet issues to locally relevant statutes or norms can lead to complicated and unpredictable legal scenarios for people in areas where the law of the Internet is still in a nascent stage, or when those same people are confronted with international treaties or laws of foreign nations regarding open source materials, access, privacy and censorship. Professionals experienced in these intellectual property issues can help address the public interest needs for information access.

THE FOUNDING AND ORGANIZATION OF PIIPA

In order to address the impacts of intellectual property on developing countries and others, PIIPA was founded in July 2002 by a global association of individuals with a variety of backgrounds, who perceived a growing need for an organization that facilitated the actual provision of public interest legal and professional assistance.[37] Individuals involved with the founding of PIIPA include lawyers and other professionals affiliated with a diverse group of organizations from throughout the world.[38] PIIPA began with a volunteer founding committee.[39] PIIPA then incorporated, as a tax-exempt non-profit corporation, with a small initial board of directors. An International Advisory Committee was established in 2003, and currently has 25 members.[40]

A principal goal of PIIPA is to improve the ability of developing countries to manage, protect or challenge intellectual property in the public interest. To this end, PIIPA was formed to help governments, government agencies and non-government public service organizations acquire intellectual property expertise on a *pro bono* basis, in order to meet the health, agricultural, environmental and cultural needs of poor and underprivileged people in developing countries and worldwide.

PIIPA seeks to promote volunteerism among private sector intellectual property professionals worldwide to serve developing country public interest needs. PIIPA serves as a mechanism for networking between intellectual property legal professionals in different countries, and as outreach to such professionals.

As outlined in more detail in the next section, PIIPA intends to achieve these goals, in part, by operating a web-based referral service. Through this service, PIIPA will help potential clients identify whether they have intellectual property-related needs and, if so, help them frame the issues they need to resolve. In addition, the service will help clients find suitable professional representation from an intellectual property professional or team who will be experienced and trained to deal with public interest issues. By dynamic management of the referral process, PIIPA will be able to assemble teams including expert specialists and professionals knowledgeable about local laws and situations in particular developing countries.

PIIPA envisions servicing clients from a broad range of areas, including: intergovernmental organizations (e.g. WHO, UNAIDS, FAO, South Centre); non-industrialized country governments and government agencies; certain research institutions (e.g. universities and government-funded public laboratories in developing countries); international research consortia (e.g. CGIAR centres, disease specific public–private partnerships); non-governmental organizations and non-profit entities (e.g. MIHR, Oxfam); and certain qualified small-to-medium enterprises and individual innovators.

For these clients, PIIPA would seek to arrange professional representation for a wide range of intellectual property services. These may include: patent prosecution, counselling, licensing and litigation; trademark prosecution, counselling, licensing and litigation; copyright counselling, licensing and litigation; trade secret protection, counselling, licensing and litigation; legislative counselling (e.g. drafting legislation and regulations in relation to intellectual property matters); and national, international and multinational dispute resolution.

The primary operations of PIIPA

PIIPA will pursue its principal goal of improving access to intellectual property services through two basic activities:

1 Matching prospective clients with professionals able to provide intellectual property services, including counselling, negotiation, protecting intellectual property, and challenging intellectual property rights

The purpose of PIIPA's service is to meet the needs of clients for advice and assistance from qualified intellectual property professionals including attorneys, patent agents and licensing specialists (IP professionals). PIIPA's role is (1) to identify clients and help them articulate their needs in particular cases; and (2) to introduce the clients to the Intellectual Property professionals and help them establish a case-specific engagement. The IP professionals will commit to provide services to clients on a *pro bono* basis. The *pro bono* commitment will be for a set number of hours or completion of a particular matter, whichever comes first.

PIIPA is developing a worldwide corps of IP professionals (IP Corps) able and willing to provide *pro bono* representation to developing country clients. Members of the IP corps will be solicited via professional associations, direct solicitations and professional firm networking. PIIPA plans to screen interested volunteers for the IP Corps as to their public interest experience and commitment, the level of expertise with the various types of IP (patent, trade secrets, trademark, copyright, plant protection), kinds of matters (licensing, counselling, prosecution, litigation), professional and ethical qualifications, and language skills. PIIPA will train candidates for the IP Corps in special issues arising in representing developing country clients, and will provide forms, guidelines, and materials useful to the IP Corps in carrying out their work in cases referred by PIIPA. The outreach will begin in the Washington, DC, and regional offices, and will involve attendance at various international IP organizations, Internet-based contacts (worldwide web and email), and personal networking. Public awareness of the need for intellectual property services in developing countries will also be created by PIIPA staff, directors and volunteers by participation in conferences and panel discussions attended by members of the IP Corps. PIIPA will promote the training of professionals in developing countries by arranging for them to work side by side with experienced members of the IP Corps from industrialized nations in particular matters, so they can learn skills and handle such matters in the future.

Services are being initiated on a small scale as PIIPA begins to receive case inquiries from potential clients and to compile a directory of intellectual property professionals. Clients in need of assistance will be directed to PIIPA by international agencies such as the World Intellectual Property Organization (WIPO), government agencies such as national patent offices and non-profit organizations. Inquiries will also come through PIIPA's website and from publicity regarding PIIPA's services.

PIIPA matches clients with members of the IP corps. This work is currently coordinated by a CEO and will expand as a worldwide network of PIIPA offices is established and case management coordinators are able to work under supervision of corporate officers and according to guidelines established by PIIPA's Board of Directors. PIIPA's headquarters are in Maryland and Washington, DC, with field offices strategically located worldwide, for example, in Geneva, Switzerland, China, India, various Central American countries, Thailand and various African countries. Each field office will serve as an increasingly autonomous focal point for providing assistance in the areas of translations, local laws and issues, identifying clients in need of intellectual property assistance, recruiting intellectual property professionals who are willing to assist as part of PIIPA's membership, and identifying local sponsors for funding PIIPA activities. PIIPA's activities will rely on an interactive website that will allow clients and professionals to submit and obtain information via the Internet.

By helping individual clients find qualified intellectual property professionals to represent them in specific matters, PIIPA will provide a unique and desperately needed service that is not met by existing commercial services or non-profit organizations.

2 Strengthening intellectual property counselling and management resources in developing countries through training, monitoring and collaborative arrangements.

In addition to assisting potential clients in finding intellectual property professionals for particular matters, PIIPA will provide educational and general training materials and programmes on how intellectual property rights may be applied (or challenged) to further the interests of poor and underprivileged people worldwide, particularly in developing countries.[41] This work will augment current initiatives by other organizations conducting research on the impacts of various intellectual property policies. The media will be produced by PIIPA and its volunteer IP Corps and can include web-based discussion groups, lectures, forums, panel discussions, conferences and the like. The audience will be officials of governmental and international agencies, non-governmental organizations and research institutes. This activity will be initiated as soon as funding is available. PIIPA will deliver such materials and assistance on its website, in one-on-one consultations with staff in PIIPA offices and, in collaboration with other organizations, in training sessions. PIIPA's website includes a growing set of links to current intellectual property cases, laws and other pertinent reference information.[42]

As funding becomes available, PIIPA will also assist clients with obtaining financial support from government agencies, non-government organizations and research institutes working in or with developing countries, to defray expenses associated with intellectual property management and implementation. These include, for example, paying government fees for registering patents, copyrights, or other intellectual property assets, travel costs for professionals, and other costs.

Legal, ethical and political issues

As a public interest organization seeking to provide generalized information and a matching service between developing country clients and intellectual property professionals, PIIPA must comply with a number of legal and ethical regulations and good practices relating to referral ethics, conflicts of interest, attorney–client privilege and so on. In addition, given the strong debates regarding the role of intellectual property in developing countries, PIIPA will undoubtedly face questions regarding its political agenda. These issues are addressed below.

Legal and ethical issues

Although each country has its own rules, many features of professional practice are shared. In the US, state legal ethics rules govern the manner and extent to which lawyers may accept referrals of clients. These rules vary widely. For example, in New

York '[a] lawyer may request referrals from a lawyer referral service operated, sponsored or approved by a bar association and may pay its fees incident thereto. Permitting lawyers to contribute to the administrative expenses of a non-profit lawyer referral service is consistent with the spirit of Canon 2'.[43] In contrast, the State Bar of South Dakota appears to take the view that all Internet-based referral services for which an attorney pays a fee to participate are prohibited cost-sharing arrangements.[44] However, other jurisdictions permit an attorney to sign up for a referral for *pro bono* or non-profit organizations meeting certain criteria.[45]

Other countries have different rules, and PIIPA recognizes that special referral rules may have to be devised to address requirements that are applicable to the professionals from particular countries. The rules in China apparently permit referrals of the type PIIPA contemplates.[46] In India, there is an absolute bar on attorney advertising that would preclude Indian attorneys from being listed on a referral website.[47] PIIPA can avoid such restrictions by not simply listing all IP Corps members, but instead screening and selecting suitable candidates for a potential client. Again, the rules for lawyers, patent agents and licensing specialists may vary.

Intellectual property practitioners obtaining cases with PIIPA's assistance would need to clear any representation according to the conflict of interest rules applicable to their profession and country. As those rules may vary from country to country, at a minimum, PIIPA would ask the practitioners to notify the prospective clients of any adverse or potentially adverse clients being represented by the practitioner. PIIPA itself does not currently plan to represent clients directly and, therefore, should not be subject to any conflict of interest rules. PIIPA refers to the organizations as assistance seekers or applicants, and notifies them that they are not clients of PIIPA.[48]

In regard to attorney–client privilege issues, PIIPA plans to avoid having prospective clients provide privileged information to PIIPA. The intake process may be 'filtered' by making it clear that prospective clients should not provide sensitive information, and by developing means to control the flow of such information, for example by limiting information provided by prospective clients, using prescribed database entry fields. PIIPA recognizes that privileges might apply to communications between clients and selected professionals according to the rules of various countries and professional groups, and intends to work with representatives of those countries and professional groups to try to ensure compliance with any applicable rules.

A final concern for PIIPA is to avoid making negligent referrals. Although it seems clear that some US courts would not hold a non-profit organization offering a legal referral service liable for a claim of negligent referral,[49] other courts have held that a referring *attorney* has 'a duty to exercise care in retaining the "successor lawyer" to ensure that he was competent and trustworthy'.[50] PIIPA intends to minimize the risk of negligent referral by several practices. First, PIIPA can require professionals to certify their level and area of expertise, as well as whether they have ever been subject to any professional disciplinary action. Second, PIIPA's referral forms and information disclosure include appropriate disclaimers regarding the referral process and PIIPA's obligations. Third, to the extent consistent with the rules in a given country, PIIPA intends to provide a list of professionals from which prospective clients are able to vet and choose their own intellectual property professional, as opposed to having a particular individual appointed by PIIPA itself. Fourth, PIIPA will ask clients for feedback regarding their level of satisfaction with the professionals with whom they have worked and will de-list any professionals whom PIIPA determines provide unsatisfactory service. These measures should help clients to find the right professional to help meet their particular needs.

Political issues

As discussed above, intellectual property has become a topic of great controversy in national and international public policy debates. 'Stronger patents are crucial to progress' says one side. 'Patents on drugs and living organisms are unfair and immoral' say others. Because PIIPA provides intellectual property legal services to developing countries, many people may assume that PIIPA, as an organization, takes a side in this polarized debate. However, PIIPA has no political agenda to promote in the sense of favouring any one regime of intellectual property rights over any other. Rather, PIIPA conceives its mission as growing out of the proposition that all people, regardless of their wealth or home or beliefs are entitled to legal and professional assistance, especially when dealing with the authority of the state (as with free criminal defence legal aid services).

Indeed, the American Bar Association's Model Rules of Professional Conduct Rule 6.1 exhorts lawyers to provide *pro bono publico* service. Although Rule 6.1 is not mandatory,[51] Maryland has instituted mandatory annual reporting of *pro bono* activities under its version of Rule 6.1. PIIPA believes that many lawyers feel obliged to extend assistance to persons in need. This is particularly true where parties may have unequal bargaining positions due to a lack of expertise, a common occurrence in cases involving the highly specialized area of intellectual property.

Intellectual property assets, laws and policies impact developing countries every day regardless of the role those countries or others believe intellectual property should play. To improve beneficial impacts and diminish harms, developing countries and public interest clients should have access to expertise about how particular aspects of intellectual property affect them – whether or not they endorse the adoption of strong western-style intellectual property legal regimes.

Intellectual property laws have existed for at least five centuries and will surely be impacting people and society for the foreseeable future. Even in the unlikely event that all future intellectual property rights were abolished, as the most extreme organizations may advocate, it would still be decades before the current assets expire, and there would be a long-lasting need to deal with these assets.

Giving access to intellectual property expertise will help developing countries deal fairly with technology-rich countries and will thereby improve their ability to obtain the best medicines, seeds and environmental technology while also negotiating favourable benefit sharing agreements that regulate access to, and protection of, these countries' genetic resources, traditional knowledge and cultural creations. In addition, access to intellectual property expertise may enable developing countries to use, challenge or reform existing intellectual property laws according to local requirements and conditions. These results should advance the goals of sustainable development, health, agriculture and cultural diversity. Helping developing countries access intellectual property expertise will improve their ability to acquire, research and independently develop medicines, agricultural products (including biotechnology and conventional crops and pesticides), conserve biodiversity and environmental technology, and protect their cultural heritage, traditional knowledge and folklore.

Combating ignorance and lack of know-how about intellectual property in developing countries will help to level the playing field in debates, disputes and opportunities for developing countries and public interest groups. Thus, PIIPA's political stance is that informed attention to and debate about individual matters can help solve problems on a case-by-case basis in pragmatic ways.

THE CURRENT DEVELOPMENT OF PIIPA AND FUTURE DIRECTIONS

The final part of this chapter will address the ongoing development of PIIPA, including representative cases, current limitations on its growth and future directions.

Representative requests for assistance and potential referral sources

PIIPA has received a number of specific requests for assistance,[52] and has been able to assist in providing representation for most of the assistance seekers. The following list is not exhaustive, but is sufficient to demonstrate the breadth and depth of the demand for public interest IP services in developing countries and confirms the importance of PIIPA's central mission of making such services available.

- The *Peruvian Working Group* (headed by INDECOPI, the Peruvian patent office), seeking to satisfy local concerns of biopiracy, asked PIIPA to find US patent counsel to challenge the validity of US patents on a Peruvian medicinal root, Maca (*Lepidium meyenii*). PIIPA arranged *pro bono* representation and the matter is proceeding.[53]
- The *Kenyan Wildlife Service* (KWS) asked PIIPA to recruit IP professionals to assert claims for misappropriation against a multinational company that is commercializing an enzyme product based on bacteria taken from a soda lake in Kenya without compliance, and to seek equitable benefit sharing. PIIPA helped identify and coordinate a team of professionals in Nairobi, the US and the UK, who are representing the KWS.[54]
- The *Fogarty Center of the U.S. National Institutes of Health* (NIH) requested that PIIPA assist its International Cooperative Biodiversity Groups (ICBGs) by arranging representation for negotiations on behalf of developing country

organizations. PIIPA has arranged for representation for the following developing country entities in their negotiations within the ICBG programme:
- Madagascar – University of Antananarivo, University of Fianarantsoa
- Vietnam – Vietnamese Academy of Science and Technology, Cuc Phong National Park
- Laos – Traditional Medicine Research Center
- Panama – Smithsonian Tropical Research Center.

- The *Peruvian Working Group* and other groups inquired about whether disclosure of biological origin laws are consistent with international treaties. PIIPA arranged for a report on Disclosure of Origin requirements from the IP clinic at American University's Washington College of Law. The report was delivered to the Peruvian Working Group and was made available to the public on PIIPA's website.[55]
- *Amazon Alliance* and *Amazonlink* asked for assistance in challenging US trademark applications filed by a Japanese company on Cupuacu (Theobroma grandiflorum). PIIPA identified US counsel to represent the organizations in this dispute.
- The *Public Intellectual Property Resource for Agriculture* (PIPRA), a non-profit organization based at the University of California, Davis, asked PIIPA to identify patent attorneys to assess freedom to operate issues raised by agrigultural patents. PIIPA has identified several *pro bono* attorneys who are assisting PIPRA.
- The *Sierra Leone Ministry of Trade and Industry* asked PIIPA for assistance in developing national legislation to satisfy TRIPS requirements. PIIPA arranged for the Glushko-Samuelson Intellectual Property Law Clinic of the Washington College of Law, American University to provide advice to the Government of Sierra Leone on this issue.
- The *Jamaican Patent Office* requested assistance with reviewing and drafting a new intellectual property law. PIIPA arranged for the Samuelson Law, Technology and Public Policy Clinic at the University of California, Berkeley to assist with this.
- The *Vietnamese Patent Office* also requested assistance with reviewing and drafting its laws. The Intellectual Property and Business Formation Legal Clinic at Washington University School of Law accepted this as a project and has completed several iterations of its legal analysis.
- The *International Alpaca Association* in Peru asked PIIPA to identify counsel to challenge a Certification Mark in the US. PIIPA arranged legal representation and an opposition was filed in the USPTO (United States Patent Office).

Potential referral sources

PIIPA, consistent with its network model of providing services, has made arrangements with several organizations that can serve as referral sources for new inquiries. The following list illustrates the types of collaborations that PIIPA is entering as it expands is matching services:

- The *World Intellectual Property Organization* (WIPO) is in discussions with PIIPA about handling developing country organizations who approach WIPO needing referrals to advisors to assist in handling individual intellectual property matters such as disputes, preserving rights in traditional knowledge, prosecuting patents and technology transfer strategies.

- The *Global Bioresources Development Institute* conducts generalized training, including intellectual property, for professionals in developing countries and has agreed to collaborate in referring specific requests for assistance that may arise.
- The *International Intellectual Property Institute* conducts intellectual property training worldwide and has also agreed to collaborate as to referrals on a case-by-case basis.
- The *Center for the Management of IP in Health R&D* (MIHR) is collaborating with PIIPA to refer professionals who can help draft training materials and assist MIHR's developing country constituents. MIHR promotes access to health technologies for the poor through improved management of intellectual property in research and development. PIIPA will provide assistance to MIHR in creating effective licensing practices for public sector management of IP, improving exchange of information, and providing training.
- *Millennium Ecosystem Assessment* (MEA), initiated by various UN agencies, the World Bank, the World Resources Institute, the Convention to Combat Desertification, the CBD, and international scientific organizations and individuals to 'improve the management of the world's natural and managed ecosystems' by providing 'the scientific underpinning to a wide range of national and international efforts' including 'climate, biodiversity, freshwater, marine and forest issues'.[56] MEA approached PIIPA about providing intellectual property counselling, licensing and negotiating relating to collection and worldwide publication and dissemination of environmental data.
- The *African Agricultural Technology Foundation*[57] has discussed with PIIPA how to address the needs of AATF's African collaborators for professional assistance with multiple projects involving licensing existing proprietary agriculture technologies, know-how and materials from corporations and public research institutes to African institutions, and counselling regarding management of innovations developed in these projects. Technologies include, for example, existing and new crop varieties, tissue culture marker-aided selection, databases and crop management methods.
- Finally, developing country grantees of the Global Fund for AIDS, Tuberculosis and Other Diseases can be expected to require professional assistance relating to counselling on the impact of patents and technology transfer strategies for medicines to combat these diseases in developing countries.

Remaining challenges for the launch of PIIPA

This subsection describes three of the primary challenges that PIIPA is currently confronting. In particular, this subsection discusses issues involving the screening of potential developing country clients, the screening of intellectual property professionals and securing adequate funding.

Criteria for screening potential clients

A question fundamental to PIIPA's charitable purpose is: what criteria should PIIPA employ to screen clients in order to ensure adherence to PIIPA's public interest mandate? The criteria must reflect PIIPA's basic operations as a referral service to match needy clients with professionals of the IP Corps who will provide *pro bono* services. At present, PIIPA is refining three different criteria for screening potential clients, and will likely consider each as a factor.

One, a purpose-based test would focus on determining whether the activity for which PIIPA assistance is sought is one that is in the 'public interest' and/or in furtherance of developing country interests. One of the problems with applying a purpose-based test involves how to define in operational terms what is meant by 'public interest'. This is a particularly difficult issue where intellectual property is involved as opinions vary widely over the extent to which intellectual property laws act in or against the public interest.

Two, a financial, needs-based test would focus on assessing whether the entity/individual is financially able to pay for professional assistance in the absence of *pro bono* assistance provide through PIIPA. The primary difficulty with this approach is determining the threshold amount to use. This is a particularly thorny problem where professional intellectual property services for developing countries are involved because (1) the initial presentation of the problem may not accurately reflect the full extent of the issues and concomitant need for professional assistance; and (2) the disparities in wealth and cost of legal services are so great, with attorneys in New York charging 20 times the hourly rate of an attorney in New Delhi.

Three, an organizational test would make certain types of clients automatically eligible, such as, for example, developing country governments and agencies. Other organizations, such as non-profit organizations and developing country individuals or business entities, would have to satisfy one or both of the purpose test and the financial test. This screen also raises issues regarding the appropriate distinguishing characteristics to use in the threshold determination.

Criteria for screening intellectual property professionals

PIIPA requires that IP Corps members provide an initial consultation or certain number of hours to referred clients without charge (e.g. 50 hours, which is about the bar-recommended 3 per cent of the busy professional's 1800 billable hours). However, PIIPA's purpose will be served only if the donated services are of a competent level. Thus, PIIPA screens the IP professionals forming PIIPA's IP Corps.

PIIPA is reviewing criteria to use in enlisting individual IP professionals to provide client assistance. This task is greatly complicated by the differences between countries and between professions, which in effect negate the possibility of using a 'one-size-fits-all' approach. Thus, PIIPA is presently evaluating a number of different criteria that will most likely have to be applied flexibly to accommodate these differences.

PIIPA currently selects IP professionals for the IP corps based on their self-designated level of expertise with different types of matters. In other words, professionals can be screened and categorized based on whether they have experience with patent, trade secret, trademark, copyright or plant protection issues. In addition, factors such as experience in particular geographic regions and language skills are important in matching IP professionals to an applicant's needs. Similarly, PIIPA is screening professionals based on their experience with particular kinds of matters, such as licensing, counselling, patent prosecution or litigation.[58]

Among other possible mechanisms PIIPA is evaluating is a system that ranks IP professionals based on their level of expertise. For example, a system could differentiate between: (1) experts who are qualified as trainers and could be selected for high-profile, precedent-setting cases; (2) certified professionals, who display basic competence to handle routine cases; and (3) trainees or beginners.

The extent of prior public interest involvement is also a relevant screen for IP professionals. Those with a record of providing *pro bono* assistance may be better attuned to the types of matters PIIPA's constituents will have. Those without prior *pro bono* experience may require more training. In applying this screen, PIIPA examines the past experience and personal goals of the professionals.

Lastly, the ability of the intellectual property professionals to conform to the ethical requirements of their profession will be of paramount importance. For the reasons set forth above, PIIPA requires IP Corps volunteers to certify that assistance can be provided consistent with an individual's professional standards, specifically in accordance with the rules of conduct of all professional organizations, associations and bars of which the volunteer is a member. This may involve issues that differ among jurisdictions and professional categories, such as conflicts of interest, confidentiality, competence and, where appropriate, insurance. In addition, PIIPA is developing plans for intellectual property professionals to adhere to requirements such as that they advise clients about the terms and limitations of their representation and obtain informed consent, for example, ensure no conflicts, describe any limitations on confidentiality, etc.

Funding strategy

PIIPA has been, to date, a voluntary venture, with contributed time and effort and in-kind contribution of infrastructure (office facilities, postage, telephones and so on). Initial efforts involved a *pro bono* incubation at Venable LLP, which contributed time and effort and in-kind contributions of infrastructure (office facilities, postage, telephones and so on) as well as some initial expenses. Private donors added to Venable's contributions. PIIPA then received funds from the Fogarty Center of the NIH, which supported the resources on biodiversity prospecting, and some additional funds from the Venable Foundation. The Rockefeller Foundation promised substantial funding for 2005 to fund ongoing activities, and PIIPA's grant applications are being favourably reviewed by other philanthropic and development organizations. This funding will allow PIIPA to conduct a methodical assessment of needs in different regions, and to expand its activities in all sectors (health, agriculture, traditional knowledge, environment, science and information technology).

As with most start-up ventures, PIIPA now faces significant challenges in obtaining sufficient funding for large-scale and sustained operations. Following advice from PIIPA's founding committee and advisory board and other counsellors, PIIPA is forging ahead to provide benefits as quickly as possible. PIIPA is seeking funding from the following: law firms, philanthropic foundations, corporate foundations, government grants and service fees. Financial support is leveraged by a much higher return on investment measured by the time value of the *pro bono* contributions of the IP Corps. PIIPA is able to account for the leveraged value of services by polling its members as to their billing rates and the number of hours contributed, thereby defining a value for in-kind contributions of time.

Future directions

One of the main areas of growth for PIIPA is the formation of affiliated regional offices around the world. These offices are intended to serve as focal points for particular countries, where developing country representatives can gain information about PIIPA and its activities. Currently, PIIPA volunteers are active in China, India, Central Africa, Southern Africa, South and Central America and Europe. These volunteer affiliations may ultimately result in establishing regional offices. In either case, a number of practical and legal issues may arise.

Among the issues that must be resolved is overcoming language barriers for volunteers and participating intellectual property professionals. Unless regional offices have very narrow spheres of activity, major differences in the languages encountered will exist. PIIPA anticipates operating to some extent in English, French, Spanish and Chinese, but even this multilingual approach will not be sufficient for communication with all representatives in all countries. Interpreters may be required for such clients. But the international network model will simplify the translation barrier because PIIPA will not need to be extensively involved with less common languages in order to complete a referral. Once a Spanish-speaking client finds a Spanish-speaking member of the IP Corps, for example, no further language barrier will exist.

Beyond the obvious language concerns, the regional affiliates will help identify local legal and policy issues. PIIPA's International Advisory Committee is directing regional outreach. Effective outreach informs both developing countries and intellectual property professionals about potential issues and opportunities relating to intellectual property law in a way that communicates the substance of the matters to them in terms they can understand. Eventually, regional offices can play a critical role in framing and translating on-the-ground problems into legal issues. In addition, outreach involves facilitating communication between the volunteers already in place in China, India, Central Africa, Southern Africa, South and Central America and Europe so that they may learn from each other's experience.

The regional offices will help PIIPA's core activities of handling requests for assistance for projects related to developing countries, and identifying qualified IP professionals to assist on a *pro bono* and/or reduced rate basis. In particular, PIIPA seeks professionals with experience in negotiating and drafting IP licensing agreements, including material transfer agreements, biodiversity prospecting agreements and agreements relating to the licensing of traditional knowledge. PIIPA also seeks individuals who have experience with obtaining IP protection for traditional knowledge. In addition, IP professionals with patent and other litigation experience are sought.

CONCLUSION

International, multinational and national intellectual property laws and practices increasingly affect life in developing countries and bring about a great need for experienced professional assistance in the public interest. Currently, organizations that provide such assistance tend to be limited to policy initiatives or generalized training, not specific projects. Public interest clients seeking professional assistance do not have access to information about intellectual property professionals, or the ability to retain a suitable representative. Conversely, intellectual property professionals who are interested in providing public interest assistance, on a *pro bono* or reduced fee basis, do not have access to a source of information on such opportunities. PIIPA plans to fill this void, by providing a referral and matching service for potential clients and intellectual property professionals, and by providing appropriate education and training for both the public interest clients and the intellectual property professionals.

Developments in the law regarding patents, copyrights and traditional knowledge will increasingly affect developing country and other public interest concerns, such as agricultural development, biodiversity protection and health care. We can anticipate further efforts to strengthen, weaken or revise these laws and how they are applied, so there is a great opportunity for individuals to adopt practices in specific cases that best reflect the values and fulfil the goals of their society. Promoting relationships between developing country organizations and volunteer intellectual property professionals will advance the public interest in this crucial period of globalization. Fair access to IP expertise will promote just results worldwide.

ACKNOWLEDGEMENTS

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NOTES

1 See, e.g., WIPO Secretariat, *Review of Existing Intellectual Property Protection of Traditional Knowledge*, WIPO Doc. WIPO/GRTKF/IC/3/7 (6 May 2002); WIPO Secretariat, *Certain Decisions of the Sixth Conference of the Parties to the Convention on Biological Diversity*, WIPO Doc. WIPO/GRTKF/IC/3/12 (24 May 2002); European Community and its Member States, *Traditional Knowledge and Intellectual Property Rights*, WIPO Doc. WIPO/GRTKF/IC/3/16 (14 June 2002) www.wipo.int/documents/en/meetings/2002/igc/index_3.htm, accessed 17 September 2004.

2 *Commissioner of Patents* v *President and Fellows of Harvard College* (Can.), No. 28155, 12/5/02.

3 See, e.g., www.percyschmeiser.com, accessed 14 March 2003.

4 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/12, at Annex p. 7.

5 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/12, at Annex p. 7.

6 See WTO TRIPS Council Document No. IP/C/W/273/Rev.1 (available at www.wto.org/english/tratop_e/trips_e/intel6_e.htm).

7 Rice was engineered to include genetic material from daffodils causing vitamin A production. The resulting varieties have been as heavily praised by the biotechnology industry, see www.isaaa.org/kc/, GM Crops–rice–golden rice, accessed 14 March 2003), as they have been criticized by the anti-genetic engineering movement, see www.grain.org/publications/delusion-en.cfm.

8 See www.mcknight.org/science/cropresearch.asp.

9 See http://www.biodiv.org/world/parties.asp.

10 Anecdotal evidence suggests that the extremely restrictive model of regulation enacted in the Philippines in Executive Order 247 (available at www.elaw.org/resources/text.asp?ID=257) has resulted in widespread bypassing of the procedures by plant researchers.

11 Perhaps the most famous example of a developing country providing more than just access to biological resources is Costa Rica's National Institute of Biodiversity (InBio), which conducts its own commercial collections in protected areas and possesses a reliable information system on those collections. See, e.g., Barber et al (2002). See also Chapter 12.

12 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7 & 3/8.

13 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7, at 3–6; see also IPGRTKF/IC/4/7 (reporting further responses to a questionnaire on existing protection for traditional knowledge from the Fourth Session of the Committee).

14 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7, at 4–5.

15 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7, at 6 (noting that Brazil, Costa Rica, Guatemala, Panama, the Philippines, Samoa, Sweden and Venezuela all indicated that they had some type of special protection for traditional knowledge, and that Ecuador, New Zealand, Papua New Guinea, Peru, Solomon Islands, Tanzania, Tonga, Trinidad and Tobago and Vietnam all indicated they intended to adopt such a system in the future).

16 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7, at 9.

17 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/7, at 10–11.

18 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/16, at 4–5.

19 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/4/12, at 3–4.

20 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/14, at 1–2.
21 See WIPO IG-IPGRTKF, *supra* note 5, at WIPO/GRTKF/IC/3/10 & 3/11.
22 In 2000, it was estimated that since the AIDS epidemic began, over 15 million Africans have died from AIDS and almost 25 million sub-Saharan Africans are infected with HIV/AIDS. World Bank Press Release, 'World Bank Steps Up Fight Against AIDS in Africa', dated 14 September 2000.
23 See World Health Organization Essential Drugs and Medicines Policy (noting that 50 per cent of the population in developing countries lack access to essential drugs and that 50–90 per cent of drugs in developing countries are paid for out-of-pocket, which places the heaviest burden on the poor) (available at www.who.int/medicines).
24 For an overview and access to the relevant legal documents involved in the debate over TRIPS and the provision of pharmaceuticals to developing countries, including the latest materials relating to the Doha Declaration, see the website for the World Trade Organization (WTO) (available at www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm, accessed 6 March 2003.
25 See www.wto.org/english/news_e/pres03_e/pr350_e.htm.
26 See www.wto.org/english/news_e/pres05_e/pr426_e.htm.
27 See Mission Statement of Centre for the Management of IP in Health R&D (MIHR) (available at www.mihr.org/mission.htm, accessed 5 March 2003). MIHR defines its goals as: 'To define effective licensing practices for public sector management of IP so that new and improved products can become more readily available to the poor in developing countries. To promote the development of new norms for licensing and other management of IP. To become an international mechanism for effective exchange of information in the rapidly evolving field of IP management in health research. To deliver training to increase capacity in IP management for health technology R&D in developed and developing countries. To promote coordination and synergy in public sector product R&D'. See ibid.
28 See The Global Forum for Health Research, *Press Release 10/90 Report on Health Research 2000: Narrowing the 10/90 Gap in Health Research*, dated 2 May, 2000 ('Less than 10 per cent of the estimated US$56 billion spent annually on health research by the public and private sectors is devoted to diseases or conditions that account for 90 per cent of the global burden of disease'.) Available at www.globalforumhealth.org/non_compliant_pages/report00/presserelease.htm, accessed 5 March 2003; see also Initiative on Public–Private Partnerships for Health Mission Statement, available at www.ippph.org/presentation/affich_mission.cfm?chap=4&sous_chap=0, accessed 5 March 2003.
29 See IPCC Special Report on Methodological and Technological Issues in Technology Transfer, available at www.ipcc.ch/activity/srtt-out.htm, accessed 6 March 2003.
30 Global Environmental Facility (2004), at http://gefweb.org.
31 See www.opensource.org.
32 See www.ipjustice.org/.
33 See www.eff.org/.
34 See www.gilc.org/.
35 See www.digitalopportunity.org/features/success_stories/.
36 The range of concerns even extends into international criminal law. See International Treaty on Cyber Crime, www.tilj.com/content/litigationarticle10110001.htm.
37 PIIPA was accepted as a Type 2 partnership during the Johannesburg Worldwide Summit on Sustainable Development in August 2002.

38 These organizations included, among others: AstraZeneca Research Foundation (India); University of Capetown (South Africa); Foundation for International Environmental Law and Development (UK); Global Bioscience Development Institute (US); Initiative on Public–Private Partnerships for Health (Switzerland); the Central Advisory Service of the Consultative Group on International Agricultural Research (The Netherlands); Liu, Shen & Associates (China); National Institutes of Health (US); National Law School (India); Natural Science Collections Alliance (US); Sidley & Austin (US); Smithsonian Tropical Research Institution (Panama); Southern Africa Research & Innovation Management Association (South Africa); The Concept Foundation (Thailand); Venable LLP (US); Washington University School of Law (US); and World Bank Global Environment Facility. This list of organizations is provided for identification purposes only in order to illustrate the diverse array of groups that deal with developing country issues relating to intellectual property. The inclusion of an organization on this list does not necessarily imply that the organization endorses PIIPA's goals or adheres to a particular viewpoint regarding the role of intellectual property in developing countries.

39 In addition to the author, the founding committee included Shyamkrishna Balganesh, Todd Capson, Beatrice Chaytor, Elliot Eder, Mark Epstein, Roberta Faul-Zeitler, Robert Frank, James Gollin, A. D. Heher, Victoria Henson-Apollonio, Gerald Keusch, John Kilama, S. Anand Kumar, Charles McManis, Alan Miller, Tina Kuklenski Miller, Kent Nnadozie, Joachim Oehler, Gerard Treanor, Roy Widdus, Richard Wilder, Rosemary Wolson and Jianyang Yu. The founding board included the author, John Kilama and Richard Wilder. The founding president is Tina Kuklenski-Miller.

40 The members are listed at http://piipa.org/advisory_committee_04.asp.

41 See, e.g., Bioprospecting Resource Manual and Designation of Origin memo, available at http://piipa.org/library.asp.

42 http://piipa.org/resource_sites.asp.

43 See New York State Bar Assoc. Committee Professional Ethics Opinion 651 (available at www.nysba.org/Content/NavigationMenu/Attorney_Resources/Ethics_Opinions/Committee_on_Professional_Ethics_Opinion_651.htm, accessed March 6 2003.

44 See State Bar of South Dakota Ethics Opinion 98-10 (noting that Ethics Opinion 90-3 advised that a lawyer could not make payments to a referral service that would run television commercials listing a toll-free number and that while 'the medium may have changed, the Internet has not changed a lawyer's professional obligations') (available at www.sdbar.org/members/ethics/Opinions/1998/eo98-10.htm, accessed 6 March 2003). For further information on the views of other state bars, see the listing and links to other state bar ethics opinions at the end of the State Bar of South Dakota Ethics Opinion pp98–10 *Id.*

45 See, e.g., Iowa Sup. Ct. Bd. of Professional Ethics Opinion 97–11 (noting that Iowa lawyers can participate in *pro bono* referral service as long as the referral service qualifies under applicable provision of the code of professional responsibility, available at www.iowabar.org/ethics.nsf/e61beed77a215f6686256497004ce492/e9253868bf0280ed8625651c0051daed!OpenDocument, accessed 6 March 2003; Nebraska State Bar Assoc. Ethics Opinion 95–3 (noting that it is 'clear that a lawyer may pay the "usual charges" of a not-for-profit lawyer referral service or other legal service organization'), available at www.nebar.com/ethics/Opinions/93-3.htm, accessed 6 November 2006.

46 Email from Jianyang Yu to author (13 February 2003).

47 Email from Shyamkrishna Balganesh to author (February 2003).

48 See Applicant Consent Form, available at http://piipa.org/consent_application.asp.

49 See generally *Bourke* v *Kazaras*, 746 A.2d 642, 643–45 (Pa. Sup. Ct. 2000) (holding that no cause of action exists under Pennsylvania law against bar association's lawyer referral service for allegedly negligent referral to lawyer who committed malpractice); *Weisblatt* v *Chicago Bar Assoc.*, 684 N.E.2d 984, 990 (Ill App. Ct. 1997) (holding that no cause of action for 'negligent referral' exists under Illinois law against not-for-profit organization that provides a lawyer referral service even though organization collects referral fee because organization is not a 'lawyer' and therefore has no duty of care to monitor or maintain responsibility for legal services ultimately rendered).

50 *Tormo* v *Yormack*, 398 F. Supp. 1159, 1159 (D.N.J. 1975). For a discussion of the various factual and theoretical bases upon which negligent referral claims have been predicated, and suggestions for minimizing potential liability for such claims see Lassiter (2000).

51 For a discussion of the current status of efforts to mandate *pro bono publico* service, including the experiences of jurisdictions with mandatory requirements and the arguments and reactions against mandatory requirements see Kellie and Sawle (2002); Baillie (2002); Rhode (2002).

52 These summaries are provided for information purposes only. PIIPA has not represented that any of the descriptions precisely characterizes the actual assistance that may be required. Moreover, the organizations listed here may not be eligible for *pro bono* services, although their constituents may be.

53 Upano (2004)

54 Sheridan (2004), p1337, available at www.nature.com/cgi-taf/dynapage.taf?file=/nbt/journal/v22/n11/full/nbt1104-1337.html.

55. Ibid.

56 See generally www.millenniumassessment.org/en/about.overview.aspx.

57 Gillis (2003, pA1)

58 See Volunteer Form, http://piipa.org/memberregister.asp.

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Chapter 29

Answering the Call: The Intellectual Property and Business Formation Legal Clinic at Washington University

Charles R. McManis

Parts I–III of this volume have presented the latest global thinking on three broad issues: (1) the problem of biodiversity loss and what is to be done about it; (2) the national and international debates over the appropriate legal protection and regulation of biotechnology, particularly agricultural biotechnology, in view of its potential impact on the problem of biodiversity loss; and (3) the question whether and to what extent to develop legal protection for traditional knowledge, as a means of conserving and promoting the sustainable use of biological diversity. Earlier chapters in Part IV have described a number of the most important local instantiations of the global thinking presented in Parts I–III. As Michael Gollin points out in the preceding chapter, one of the principal obstacles in responding effectively to any of these international issues is the lack of access to affordable intellectual property legal counsel in many parts of the developing world, where the majority of the Earth's biodiversity is located.

Just as the *pro bono* organization, Public Intellectual Property Advisors (PIIPA), which Michael Gollin was instrumental in organizing, is responding to this need by matching prospective clients with volunteer *pro bono* IP professionals, thereby strengthening IP counselling and management resources in developing countries, so too is the Intellectual Property and Technology Law Program[1] at Washington University School of Law seeking to respond to this need with the establishment of the Intellectual Property and Business Formation Legal Clinic. A primary objective of the Legal Clinic is to develop expertise in the overlapping fields of biodiversity, biotechnology and traditional knowledge protection and to make that expertise available, both to prospective developing-country clients and to local IP professionals who wish to participate in the *pro bono* activities of PIIPA. Funded in part by a generous grant to Washington University by the Ewing Marion Kauffman Foundation,[2] as a part of its Campus Entrepreneurship Initiative, the Intellectual Property and Business Formation Legal Clinic began operations in January 2005.

The Clinic's activities are initially to be devoted to four programme areas, which will involve two-member teams of law students, who will:

- Participate in interdisciplinary innovation and entrepreneurship courses at the University, such as the Senior Design Course in the Department of Biomedical Engineering,[3] and the Hatchery course in the Olin School of Business;[4]
- Work with St Louis-area business incubators, particularly those, such as the Nidus Center for Scientific Enterprise, that are involved with biotechnology startups;[5]
- Work with non-profit organizations, such as the St Louis Volunteer Lawyers and Accountants for the Arts[6] and Public Interest Intellectual Property Advisors;[7]
- Work with two St Louis area research organizations, the Missouri Botanical Garden[8] and the Donald Danforth Plant Science Center,[9] on international projects involving genetic resources, biotechnology, and the protection of traditional medicinal and agricultural knowledge.

Each of these four programme areas will enable Washington University law students, working under the supervision of an experienced intellectual property attorney who serves as the Administrative Director of the Clinic and Lecturer in Law,[10] to develop expertise in providing early-stage legal assistance to innovators in a variety of contexts. The four teams of students and their specific activities are as follows:

1 The *Interdisciplinary Innovation Team* provides legal expertise in two interdisciplinary innovation courses currently offered at Washington University. The Biomedical Engineering Design course is a capstone design experience to prepare undergraduate engineering students for engineering practice.[11] These engineering students, together with graduate business, law and graphic design students, work in small groups to develop an original design or redesign of a component or system of biotechnological significance. The design experience incorporates engineering standards and realistic constraints, including consideration of economics, the environment, sustainability, manufacturability, as well as ethical, health and safety, social and political requirements. The student teams prepare written reports and present their designs orally to a panel of faculty members and industrial representatives. Law students are responsible for conducting patent searches and identifying other legal issues that are relevant to the design and commercialization process. The Hatchery course, which is a part of the Skandalaris Entrepreneurship Program at the Olin School of Business,[12] enables teams of students to support entrepreneurs from the St Louis community, and includes interdisciplinary teams that work with the University's Office of Technology Management[13] to assess the feasibility of commercializing various of the university's scientific discoveries, including those made by the Medical and Engineering Schools. Here, too, law students are responsible for conducting patent searches and identifying other legal issues that are relevant to the commercialization process.

2 The *Business Incubator Team* works primarily at the Nidus Center for Scientific Enterprise, which was established in 2000 to assure the success of start-ups and early-stage plant and life science companies.[14] The team also develops and presents training modules for and at the Center for Emerging Technologies,[15] a public–private–academic partnership founded in 1995 to develop specialized services and facilities to accelerate the growth of advanced technology companies in the St Louis region. At the Nidus Center, law students also work for BioGenerator,[16] an incubator-within-an-incubator, which is designed to fill a gap – sometimes called the valley of death or a no man's land – in the progression, from academic research to revenue, in the creation of a company. BioGenerator works closely with the technology transfer offices of Washington University and St Louis University to identify company concepts with the most potential, and then provide funding for such things as proof-of-concept tests, market research and management consultants, preparatory to applying for space at one of the St Louis area business incubators.

3 The *Pro Bono Team* works with the St Louis Volunteer Lawyers and Accountants for the Arts (VLAA)[17] and the Public Interest Intellectual Property Advisors (PIIPA)[18] to provide assistance to St Louis area attorneys who are providing to qualifying clients *pro bono* legal assistance in the fields of copyright, trademark and patent law, as well as associated matters relating to business formation, contracts and acquisition of non-profit tax exempt status. The St Louis VLAA provides free legal and accounting assistance and sponsors a wide range of educational programmes for artists and art administrators. PIIPA is an international non-profit organization that makes intellectual property counsel available for developing countries and public interest organizations seeking to promote health, agriculture, biodiversity, science, culture and the environment. PIIPA engages in three main activities: (1) expanding a worldwide network of IP professional volunteers (the IP Corps); (2) operating a processing centre where assistance seekers can apply to find individual volunteers or teams who can provide advice and representation as a public service; and (3) building a resource centre with information for professionals and those seeking assistance. Working under the supervision of the Administrative Director of the Intellectual Property and Business Formation Legal Clinic, the *Pro Bono Team* will develop and provide training modules for, and work with, a St Louis node of IP lawyers participating as PIIPA volunteers.

4 The *International Research Team* works with the Missouri Botanical Garden[19] and the Donald Danforth Plant Science Center[20] on national and international research projects. For example, the Missouri Botanical Garden partners with a number of other research organizations, including the Donald Danforth Plant Science Center, and is currently partnering with the University of Missouri-Columbia (UMC) and the University of Western Cape (UWC) in South Africa, in The International Center for Indigenous Phytotherapy Studies (TICIPS), directed by Bill Folk (UMC) and Quinton Johnson (UWC), a new and unique project designed to test traditional South African herbal remedies in contexts

ranging from in vitro assays to a clinical trial.[21] During the summer of 2004, a rising third-year Washington University Law School J.D. student, Edward Kim, served as a summer intern at the University of Western Cape, working on the Center's proposed intellectual property policy,[22] and became a member of the Clinic's inaugural *International Research Team*. Likewise, the Donald Danforth Plant Science Center partners not only with the Missouri Botanical Garden[23] but also with a variety of other organizations, including an organization called Public Sector Intellectual Property Resource (PIPRA),[24] an initiative by a variety of universities, foundations and non-profit research institutions to make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world.[25] The *International Research Team* works on this and other intellectual property-related projects at the Danforth Center.

The activities of the Intellectual Property and Business Formation Legal Clinic are supported by an associated Center for Research on Innovation and Entrepreneurship, a university-wide research centre, housed at the law school, and likewise initially funded by the Kauffman Campus Entrepreneurship Initiative.[26] The Center is committed to becoming a premiere research centre for Washington University, the larger St Louis research community, and other academic, government and private sector entities interested in bridging the gap between research and development (R&D) in academia. The Center focuses its conceptual and empirical research activities on the research and development process itself to explore how optimally to 'move R to D', particularly with respect to university and other early-stage public or non-profit research.

The research activities of the Center include both directed research, in the form of periodic academic conference and workshops, and administration of a university-wide competitive grant programme to support individual and collaborative group research on innovation and entrepreneurship. For its inaugural directed research project, the Center organized an academic conference, held in November, 2005, on the topic, 'Commercializing Innovation', which brought together leading thinkers in diverse fields to develop modern tools and strategies for improving the complex process of innovation commercialization, with a focus on both domestic and international implications.[27] As a part of its competitive grant programme, the Center announced the award of eight entrepreneurial research grants, the first year of funding for which totals over $140,000, to Washington University faculty members who applied for funding for a variety of individual research projects focusing on some aspect of innovation and entrepreneurship. Included among the research grants funded is a $21,250 research grant to the author for a project entitled 'A Pilot Project to Collect Data and Design an Empirical Study on the Impact of Early-stage Access to Affordable Intellectual Property and Business Formation Legal Services on the Innovative Process', which is utilizing the experience of the Intellectual Property and Business Formation Legal Clinic to examine how early-stage access to affordable legal services (and the lack thereof) affects the innovative process. Thus, the Clinic not only provides a valuable professional service, it also serves as a valuable research tool to determine the effect of early-stage access to affordable legal services on the innovative process.

The Clinic will also seek outside grant funding to support exchange programmes that will provide lawyers and law students from the developing world with full-tuition scholarships to enrol in the law school's Intellectual Property LLM Program,[28] and will provide Washington University law students with summer internships, similar to the experience of Washington University law student, Edward Kim, in South Africa, in the summer of 2004,[29] and Washington University alumna, Susanna E. Clark, who in the summer of 2003 arranged an internship with the Peruvian Environmental Law Society, in Lima, Peru, as a result of having participated in an international academic conference held at Washington University in April 2003,[30] which included a number of participants in the International Cooperative Biodiversity Group (ICBG)–Peru Project,[31] (one of a number of ICBG projects funded by the National Institutes of Health,[32]) including representatives of the Peruvian Environmental Law Society.[33]

The goal of the Intellectual Property and Business Formation Legal Clinic in all of its activities is to highlight, for law students, clients and the legal profession as a whole, that the purpose of national and international intellectual property law is a public one – to 'Promote the Progress of Science and the useful Arts'[34] – and that the protection and enforcement of intellectual property rights 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.'[35]

NOTES

1 For a description of the Intellectual Property & Technology Law Program, see http://law.wustl.edu/LLMIP/Fall2004/WashU_IPbroch.pdf (hereinafter IPTL Brochure).

2 See www.kauffman.org/. For a description of the Kauffman Campus Entrepreneurship Initiative, see www.kauffman.org/news.cfm/396. For a description of the Washington University grant, see http://news-info.wustl.edu/news/page/normal/599.html.

3 For a description of this course, see http://biomed.wustl.edu/courses/bme_401/bme_401.asp.

4 For a description of this course and the Skandalaris Entrepreneurship Program at the Olin School of Business, see www.olin.wustl.edu/entrepreneurship/PDF/SEP.pdf.

5 For a description of the Nidus Center, see www.niduscenter.com/.

6 For a description of this organization and its activities, see www.vlaa.org/.

7 For a description of this organization and its activities, see www.piipa.org/index.asp.

8 For an introduction to the research activities of the Missouri Botanical Garden, see www.mobot.org/plantscience/default.asp.

9 For an introduction to the Donald Danforth Plant Science Center, see www.danforthcenter.org/.

10 The Administrative Director for the Intellectual Property & Business Formation Legal Clinic is Mr David Deal, formerly a patent attorney with the St Louis law firm of Thompson Coburn, and a patent examiner with the US Patent and Trademark Office. Deal is a graduate of the University of Missouri-Columbia School of Law, and a *Magna Cum Laud* graduate of the University of Missouri-Columbia School of Engineering.
11 See note 3.
12 See note 4.
13 For a description of the operations of the Office of Technology Management, see http://roles.wustl.edu/OfficeTechnologyManagement.htm.
14 See note 5.
15 For a description of this organization and its activities, see http://www.emergingtech.org/.
16 For a description of this organization and its activities, see www.biobelt.org/news/pd_110103.html.
17 See note 6.
18 See note 7.
19 See note 8.
20 See note 9.
21 See www.mobot.org/MOBOT/research/diversity/medicinalPlants.htm.
22 See IPTL Brochure, note 1, at 3.
23 See note 21.
24 For a description of the Danforth Center's involvement with PIPRA, see www.mobot.org/MOBOT/research/diversity/medicinalPlants.htm. For a more detailed description of the activities of PIPRA, see www.pipra.org/.
25 See www.pipra.org/.
26 See note 2.
27 See http://law.wustl.edu/CRIE/index.asp?ID=818.
28 For a description of the law school's IP LLM program, see http://law.wustl.edu/LLMIP/index.html.
29 See note 22 and accompanying text.
30 For a summary of the conference agenda, video clips, and conference papers, see http://law.wustl.edu/centeris/pastevents/biodivsp02.html.
31 For a detailed description of the ICBG–Peru Project, and Washington University's leading role in it, see McManis (2003)
32 For a description of the NIH-funded ICBG projects, see McManis (2003, pp565–569).
33 For two published products of Ms. Clark's summer internship, see Ruiz et al (2004), and Caillaux and Clark (2004).
34 US Constitution, Article I, section 1, clause 8.
35 Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, 15 December 1993, 33 I.L.M. 81 (1994), available online at www.wto.int.

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