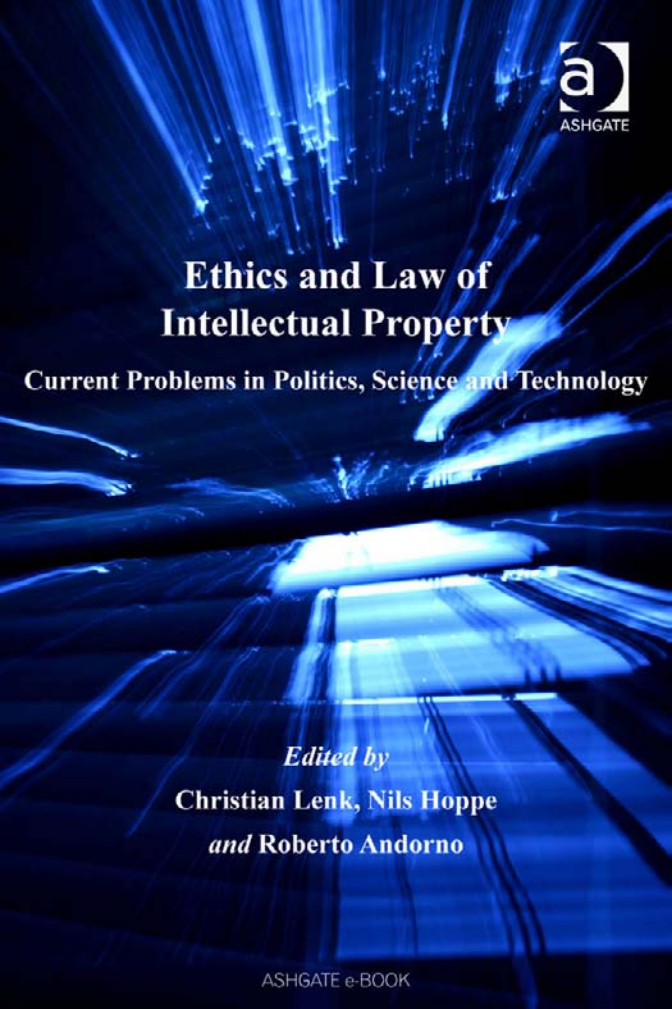
ASHGATE
Ethics and Law of Intellectual Property
Current Problems in Politics, Science and Technology
Edited by
Christian Lenk, Nils Hoppe
and Roberto Andorno
ASHGATE e-BOOK

ETHICS AND LAW OF INTELLECTUAL PROPERTY

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Ethics and Law of Intellectual Property

Current Problems in Politics, Science and Technology

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Series Editor's Preface

The objective of the Applied Legal Philosophy series is to publish work which adopts a theoretical approach to the study of particular areas or aspects of law or deals with general theories of law in a way which focused on issues of practical moral and political concern in specific legal contexts.

In recent years there has been an encouraging tendency for legal philosophers to utilize detailed knowledge of the substance and practicalities of law and a noteworthy development in the theoretical sophistication of much legal research. The series seeks to encourage these trends and to make available studies in law which are both genuinely philosophical in approach and at the same time based on appropriate legal knowledge and directed towards issues in the criticism and reform of actual laws and legal systems.

The series will include studies of all the main areas of law, presented in a manner which relates to the concerns of specialist legal academics and practitioners. Each book makes an original contribution to an area of legal study while being comprehensible to those engaged in a wide variety of disciplines. Their legal content is principally Anglo-American, but a wide-ranging comparative approach is encouraged and authors are drawn from a variety of jurisdictions.

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Table and Figure

Notes on Contributors

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Roger Brownsword is Professor of Law at King's College London where he is Director of TELOS (the KCL centre for the study of technology, ethics and law in society) and Honorary Professor in Law at the University of Sheffield. His recent books include *Human Rights* (2004) and (with Deryck Beyleveld) *Consent in the Law* (2007); his recent papers include "Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'" (2003) 17 *NDJLEP* 15, "The Cult of Consent: Fixation and Fallacy" (2004) 15 *KCLJ* 223, "Stem Cells and Cloning: Where the Regulatory Consensus Fails" (2005) 39 *New England Law Review* 535, and "Code, Control and Choice: Why East is East and West is West" (2005) 25 *Legal Studies* 1.

Dr John Cahir is a senior lawyer in the Intellectual Property Group of Matheson Ormsby Prentice – one of Ireland's leading law firms. Previously, John worked as a lecturer and research associate with the Queen Mary Intellectual Property Research Institute, University of London, where he also undertook his doctoral studies. John has published extensively in both academic and professional journals on intellectual property law, in particular on the topic of digital copyright. John is a member of the Licensing Executives Society (LES) and is a national representative of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI).

Dr Lucie Guibault is senior researcher at the Institute for Information Law of the University of Amsterdam (IViR). Born and raised in Canada, she studied law at the Université de Montréal and received her doctorate in 2002 from the University of Amsterdam, where she defended her thesis on copyright limitations and contracts,

which addressed the question of the contractual overridability of limitations on copyright. She has written studies and articles on topics of international and comparative copyright, contract and intellectual property law.

Nils Hoppe read Law at Nottingham Trent, Erlangen-Nürnberg and Göttingen. He was legal assistant in the North Wales Children's Homes Litigation until 2001, and legal counsel for Göttingen University Hospital until 2003. He worked as a research associate in the Department for Ethics and History of Medicine at the University of Göttingen until 2004 and has been a Lecturer in English for law and head of the Medical Law and Bioethics Group at the University of Hannover since 2004. He is Visiting Fellow to the Department of Forensic Medicine, University College Dublin and doctoral candidate of the faculty of law, University of Hannover.

Rainer Kuhlen is a professor in the Information Sciences at the University of Konstanz. His scientific and teaching profile includes information retrieval, hypertext, information markets and information politics, and ethics. Recent projects treated collaborative knowledge management, electronic dictionaries (ENFORUM) and collaborative e-learning (K3). He has been a professor for Information Science at the University of Konstanz since 1980 and since 2000 guest professor at Humboldt University, Berlin. He also is a member of the Committee for Communication and Information of the German Commission for UNESCO and the UNESCO Chair for Communications (ORBICOM). He is the chairperson of NETHICS e.V. (Ethics in the Net) and a member of the Board of the German Society for Information Science (HI). Recent book publications include *Konsequenzen der Informationsassistenten* ("Consequences of Information Assistants", Frankfurt, 1999) and *Informationsethik* ("Information Ethics", Konstanz, 2004).

Dr Christian Lenk studied philosophy, political science and social anthropology at the University of Hamburg. From 2000 to 2002 he worked in two projects in the field of medical ethics and bioethics at the Universities of Marburg and Münster, financed by the German Research Community (DFG). He received his doctoral degree for a study on the ethical issues of enhancement technologies in biomedicine at the University of Münster in 2002. Since 2002, he has been a researcher, and since 2004, assistant professor, at the Department for Ethics and History of Medicine at the University of Göttingen. He also is a member of the research ethics committee of the University of Göttingen and was in charge of the Göttingen project PROPEUR.

Dr Vural Ozdemir studied medicine in Ankara, Turkey, followed by interdisciplinary graduate research training in the fields of pharmacogenetics, clinical pharmacology, personalized medicine and pharmaceutical regulatory policy at the University of Toronto with Professors Werner Kalow and Laszlo Endrenyi. His professional hands-on experience in both private and academic spheres of biomedical research, together with work as a developing country physician, have led to a motivation to research the socio-ethical context associated with the daily practice of science/medicine as a profession and ways to address equity issues in postgraduate education. He is a senior scientist and adjunct professor at the University of Montreal in affiliation

with the Bioethics Programs, Department of Social and Preventive Medicine. At present, he is engaged in independent academic research in pharmaceutical policy, health technology assessment and personalized medicine with a focus on socio-ethical analysis of '-omics' biomarker technologies across their maturation cycle. This work ranges from early exploratory technologies such as 'nutrigenomics' to more mature -omics technologies including pharmacogenomics. The overarching objective is to develop a deeper understanding of the ways in which science, new health technologies and medicine interact within their socio-ethical contexts.

Alyna C. Smith, B.Sc., M.A., J.D. candidate (University of Toronto). In 2001, Alyna joined the Joint Centre for Bioethics as a research assistant, where she contributed to several publications and to capacity building initiatives on genomics and public health. In 2003, she accepted a position as Ethics Officer for the World Health Organization's Human Genetics Program (Geneva), responsible for the unit's ethics-related activities, including a publication on patents, genomics and health in developing countries. She later worked for the Secretariat for the Commission on Intellectual Property Rights, Innovation and Public Health on the creation of its report, until 2005 when she returned to Canada to pursue further studies.

Dr Sigrid Sterckx obtained an M.A. in Moral Science in 1994 and a Ph.D. in Moral Science in 2000, both from Gent University (Belgium). In her doctorate dissertation she studied the moral legitimacy of patents. Sigrid is currently a professor of ethics at the Department of Philosophy and Moral Science at the Vrije Universiteit Brussel, a senior research fellow of the Fund for Scientific Research Flanders and a professor of Ethics at the Department of Philosophy and Moral Science at Gent University. She teaches courses in ethics, medical ethics, bioethics and environmental ethics. She is also a member of the Belgian Advisory Committee on Bioethics.

Dr Antony S. Taubman is currently acting director and head of the global intellectual property issues division of WIPO, a position he assumed in May 2002, with responsibility for programs on intellectual property and genetic resources, traditional knowledge and folklore, and the life sciences. After a diplomatic career, he left the Australian Department of Foreign Affairs and Trade (DFAT) in 2001 to join the newly formed Australian Centre for Intellectual Property in Agriculture, at the College of Law, Australian National University, teaching and researching on international IP law. He has also held a teaching appointment at the School of Law at the University of Melbourne, delivering a specialist postgraduate course on TRIPS Law and Practice. From 1998 to 2001, he was Director of the International Intellectual Property Section of DFAT, and in that capacity was engaged in multilateral and bilateral negotiations on intellectual property issues, domestic policy development, regional cooperation and TRIPS dispute settlement.

Dr Sivaramjani Thambisetty B.A, LL.B (Hons), BCL, DPhil. is a lecturer in intellectual property law at the London School of Economics and Political Science. Her teaching interests are in patent law and innovation policy. She has written papers on the patent protection of biotechnological inventions, innovation in developing

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Dr Heather Widdows is a senior lecturer and the acting director of the Centre for the Study of Global Ethics. Her research interests include moral realism and virtue ethics; communication across belief-systems and value frameworks; and bioethical issues, particularly, reproductive, research and genetic ethics. From January to June 2005 she was a visiting fellow at Harvard University, where she worked on moral neocolonialism. Dr. Widdows' publications include a monograph on *The Moral Vision of Iris Murdoch* and an edited collection on *Women's Reproductive Rights*, in addition to articles and book chapters on all her areas of interest.

Dr Bryn Williams-Jones is an assistant professor in the Département de Médecine Sociale et Préventive and a member of the Groupe de Recherche en Bioéthique at the Université de Montréal, Canada. An interdisciplinary scholar, Bryn employs analytic tools from applied ethics, health policy and the social sciences – and collaborates with humanists, social scientists and applied scientists – to explore the socio-ethical implications of new technologies. Bryn is also involved in Canadian and international initiatives to facilitate cross-disciplinary dialogue on genomics and society. Current research focuses on commercial genetic testing, biotechnology and intellectual property rights, and university–industry relationships in genomics research.

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The editors of this book have been project partners at the University of Göttingen[1] and, as such, have organised the international workshop which was to be the starting point to this volume. They are very grateful to all colleagues from the PropEur research network who made this publication possible as well as to Ashgate Publishing, in particular Tom Campbell, Alison Kirk, Carolyn Court and Pam Bertram for having kindly accepted to publish this volume and for their patience in advising us on the preparation of the manuscript. We are also very grateful to Nina McGuinness for her endurance in proofreading and editing the manuscripts for this book.

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Introduction

The notion of private property and, in particular, intellectual property in science and technology has in the recent past not been very controversial in the Western world. Since then, these concepts have been softened considerably due to a profound concern for global justice, societal changes and political considerations in relation to the proper relationship between the state and its citizens. The reason for this is that property in general, and intellectual property in particular, is not natural fact but "rights" that is regulated and guaranteed by the state. One of the central tasks traditionally assigned to the modern liberal state has been that of securing private property as an important right of citizens. Although this approach has proved very successful in terms of economic and industrial development and is a source of welfare for a majority of citizens in the developed countries, it led to an increasing number of ethical and legal questions in cases of conflict with other essential interests of society. This is particularly evident in the field of intellectual property and seems to be connected with an innovation landslide in the field of knowledge and information, which is characterized by the transformation towards the so-called "information society", meaning a society which depends by and large on its ability and capacity to produce, distribute and exploit knowledge and information. The situation briefly described above, with the notion of property becoming ever more fluid, provides an heuristic and analytical framework for the scientific contributions included in this volume.

The first conclusion which can be drawn from the phenomenon of the redefinition of intellectual property is that it entails a change in the relationship between the public and the private spheres. This is one of the recurring themes in most of the contributions to this book and addresses the question of which goods can be legitimately treated as commodities. Because everybody would agree that some resources – the air we breathe being the classic example – are of such fundamental importance that they cannot be appropriated by anybody. Other basic goods, like food or energy, can be traded, as long as private enterprises can guarantee comprehensive supply at reasonable prices. Where private markets do not function as desired the state would in most cases intervene to guarantee the supply of its citizens with the essential resource.

In the field of intellectual property, patents are exclusive rights or temporary monopolies on a specific invention. This may be unproblematic in many cases, but it is problematic where it harms a legitimate public interest in broad access to such an invention. This is especially clear in the case of patent protection of drugs which grants a monopoly for the production of a drug to a private entity. It is therefore clear that there may be certain arenas in which the state should abstain from granting patents. In some areas, such as scientific research, scientists are required to obtain patent protection for their inventions which are – in some cases – the result of publicly funded activity. This may also pose some problems where the patent holder

is not a public institution, but a private person or enterprise. Governments should actively commit themselves to public access to intellectual property and innovations on as broad a scale as possible. The product of publicly financed research should not be privatized, but freely accessible by all.

Clearly, some areas of intellectual property are far more essential to the operation of a fair, open and democratic society than others. Although it is, of course, highly legitimate to secure entitlements to innovations and specific knowledge, one cannot deny that such an exclusive entitlement to this knowledge and intellectual property also implies some responsibility in relation to the application of this knowledge. Unfortunately, the most important international agreement on intellectual property, Trade-Related Aspects of Intellectual Property Rights (TRIPS), argues against the special relevance of some fields of intellectual property and aims at a homogenous level of property protection, independent of the area of application. This means that we are expected to treat the design of cars and the quest for innovative medical treatment to crippling diseases on the same level of property protection. Although TRIPS does contain a section which allows compulsory licensing, a mechanism to force enterprises to issue a license to protect intellectual property in case of essential public interest, this construction appears to be wide of the mark right from the start. Beyond the ambit of medicine, areas such as culture, education and research seem to be of special importance for a free and open society, as almost tangible prerequisites for the successful development of such a society. We simply do not know how a society which privatizes and commercializes all spheres of its cultural productivity develops. Nevertheless, as Andrea Glorioso pointed out at the Second International PropEur Workshop held in Sofia, Bulgaria in March 2006, we are already experiencing a transformation in the perception of intellectual property because a younger generation is growing up in the knowledge that one has to pay every time one wants to hear a pop song. Equally, some contributions to this book point out that property protection and the economic exploitation of property rights may create an obstacle to the advancement of science, which crucially needs the free circulation of knowledge and information.

There are two opposing views on the relation between knowledge and intellectual property rights: one side argues that a strong intellectual property protection serves as an incentive to create new knowledge and to foster industrial and economic development; the other view argues that too strong a protection makes it impossible to transfer knowledge and can seriously harm the public interest. Obviously, it would transcend the scope of this book to try to solve this question, but there are at least some clues in this volume's contributions, which show that the degree of intellectual property protection should be in relation to a country's level of economic and industrial development. This hypothesis is also supported by historical experiences, which show that most of the classic industrial countries fostered their own industrial development partly due to a rather weak initial range of mechanisms for the protection of intellectual property. It appears to be inappropriate that the very same countries nowadays demand strong protection of their intellectual property in developing countries which are themselves as yet in a weak economic position and are to some degree dependent on knowledge transfer. This is of special relevance in the case of multilateral treaties that are signed equally by industrialized and developing

countries. While the public good was the intellectual starting point for the granting of intellectual property and of patents in the past, it has now to be redefined in the international context, respecting the rights of both citizens in industrialized as in developing countries. From a transnational point of view, the essential interests of the citizens of all concerned countries should be equal, because formal equality is one presupposition of justice.

Structure of this book

This book is organized into three parts, covering key international political and institutional issues relating to public health and human rights, the ethical and policy dilemmas posed by intellectual property rights when faced with public health needs, and the search for a proper balance between the protection of copyright and the public interest in broad access to information.

In Part 1, Roger Brownsword's chapter presents different possible models of biobank governance and predicts that the model combining strong provisions for privacy and consent with weak provisions for property is likely to prevail for two reasons: firstly, because it balances the interests of participants with those of the research community and secondly, because international legal instruments relating to bioethics tend to reject property and commerce with regard to human body parts. However, the author expresses his discontentment with the triumph of the model he calls "the compromise approach", as it does not fit well with the ethics of human rights. This conclusion is reached through an examination of four issues which provide the structure of the chapter. The first section identifies the salient features of the compromise approach, using the U.K. Biobank as an example. The second section discusses the general orientation of human rights towards consent, property and privacy. The third section considers the extent to which the compromise approach conforms to human rights standards. The fourth section identifies utilitarianism as the ideological basis of the compromise approach.

Roberto Andorno examines the ethical and policy dilemmas raised by the establishment of population genetic databases. He focuses on the recent experience of Iceland and Estonia in this field and analyzes the special legislation concerning this issue that has been put into place by the respective countries. The comparative study of both experiences, which are quite opposite in many respects, provides the author with a basis to suggest some possible solutions to the new dilemmas that conform to human rights principles. The chapter concludes by summarizing the policy measures proposed by the author: to ensure an open, public, and transparent debate about the implications of genetic databases; to require an explicit and specific informed consent of participants, at least for the initial collection of data; to explicitly recognize the right of participants to decide not to receive potentially harmful information about themselves; to apply high-quality confidentiality safeguards; to prevent genetic discrimination; to involve independent ethics committees to guarantee compliance with ethical and legal standards; to avoid the creation of databases based on purely commercial criteria and, finally, to establish a mechanism of benefit-sharing with society.

Alyna C. Smith addresses one of the most controversial public health issues of our time: how to harmonize the human right to health care and the intellectual property rights of pharmaceutical companies. The chapter opens with the consideration that the problem is to a large extent caused by the dual character of drugs, which are simultaneously a commodity and an essential component of human rights. To tackle this complex issue, the chapter analyzes the current international health law instruments and, in the light of them, examines two main questions: firstly, what does the "right to health" mean and, secondly, to which medicines can we claim a right of access to? In consideration of the four essential dimensions of the right to health (availability, accessibility, acceptability and quality), Smith asks whether new drugs address the needs of poorer populations coming to the clear and unequivocal conclusion that *they do not.* For this reason she argues in favor of unambiguously situating "access to medicines" within a human rights framework. This would have several advantages, in particular, that of putting in evidence the duty of all involved actors to work together to advance the right to health.

Tobias Schulte in den Bäumen compares different models of governance in human genetics and expresses his preference for the "fundamental rights model" proposed by Lori B. Andrews. This latter approach has the ethical advantage of attaching paramount importance to self-determination of patients and research subjects. The chapter focuses on a detailed analysis of the UNESCO International Declaration on Human Genetic Data of 2003, highlighting some possible shortcomings of this document on issues such as confidentiality, informed consent, ownership of data, the conflict between the right to know and the right not to know one's genetic data, the involvement of ethics committees, and genetic discrimination and stigmatization. The author's conclusion is that the development of a global and coherent approach to the dilemmas posed by the large-scale collection of human genetic data is still pending. There is a need for further reflection to find an adequate balance between the requirements of genetic research and the rights of participants on a global level.

Antony Taubman analyses the current international debate on ethics, patenting and intellectual property rights. He focuses on the tendency of the involved parties to ignore compromise solutions and their apparent preference to construct polarities. He gives a striking number of such polarities which structure the debate, but which also seem to obscure the possibility of political compromises. The examples given include public–private, consumer–producer, developing–industrialized countries, human rights–trade law and collective good–private property. Indeed, these poles establish a normative matrix of the intellectual field, but are sometimes inadequate when confronted with the practical problems in the field of intellectual property. Due to the author's professional background, the debate on the TRIPS agreement forms an important part of this chapter. Although some critics go as far as seeing TRIPS as "a form of imperialism in itself", this seems to be one step too far in a critical discussion of the topic. Without idealizing the function of TRIPS, Taubman's balanced assessment shows that – despite justifiable objections – there are some well-founded reasons for a multilateral agreement on intellectual property in a globalized world.

In Part 2, Christian Lenk examines the ethical implication of patents in the biosciences as exclusive rights in the field of intellectual property. In the history of

patenting, there were some classical reasons to deny patent protection. One of these reasons was the essential character of specific inventions or resources. Especially in the biosciences, many products carry this essential character because of their importance for medical supply. Unfortunately, Article 27 of the TRIPS Agreement defines as a legal standard that "patents shall be available for any inventions, whether products or processes, in all fields of technology" Exclusions from this principle have to be justified. This seems to be inappropriate as patents can create barriers for an adequate drug supply to patients. Another reason for the cautious use of patents at the beginning of the age of industrialization were considerations concerning the citizens' common welfare and the public good. This means that patents and exclusive rights do not represent an aim in themselves, but should promote the public interest of the majority of a country's citizens. In view of the conditions imposed by globalization, such demands obviously require reformulation. As the author concludes, the public good for the purpose of common welfare for international treaties must be both the interests of citizens of developed, developing and threshold countries.

Bryn Williams-Jones and Vural Ozdemir analyze the consequences of the extensive use of patents in research on the practice of science and the "knowledge commons". With this term the authors describe the ideal of "sharing knowledge without restrictions" – which seems to be endangered by different problematic developments in the academic system. Today it is expected, at least in the natural sciences, that scientists should not only engage in research and teaching, but also in the search for funding for their projects. This requires the active cooperation of universities with industrial and commercial actors and leads partly to the commercialization of public research at universities. Against the so-called "tragedy of the commons", Williams-Jones and Ozdemir cite the "tragedy of the anticommons", which produces a tendency towards the "under-usage" of knowledge (see also the contribution of Kuhlen in this volume). It is essential for the success of academic research that there are as few barriers as possible to the access to knowledge and new scientific procedures. Privatized knowledge with commercial access and patented genes or procedures represent barriers in this sense. The authors conclude that the process of privatization of knowledge – although sometimes practiced by academic actors themselves – poses severe risks to scientific research.

Heather Widdows's chapter examines ethical problems in the production and use of person-related genetic data. Traditionally, ethical and legal regulations in Western societies focused on the individual as the most important authority to meet decisions in private matters. However, this individualistic view can be problematic in the field of genetics because genetic information is not only an individual, but also a family affair. Moreover, such data may have great relevance to other members of society belonging to the same genetic group. It follows that person-related genetic data does not count as an element of somebody's private sphere, and this constellation poses some problems for traditional approaches in medical law and ethics, such as confidentiality and informed consent. Additionally, there are a number of problematic phenomena in the practical field, for example patenting of indigenous populations' cell lines by third parties. Regardless of the question whether or not the patenting of human cell lines should be allowed, it is debatable that a valid informed consent in the case of indigenous populations can take place. Similarly, it remains unclear

whether the public should have access to such material. The author concludes that further work for a "reconceptualization" of medical ethics is necessary to fulfill the demands posed by the collective nature of genetic information.

Sigrid Sterckx's contribution deals with the relationship between drug patenting and the medical situation in developing countries in the ethical and economical context. There are a number of diseases in developing countries – tuberculosis, HIV, sleeping sickness, leishmaniasis – which could be treated more effectively through lower drug prices and higher investments in research and development. Both these factors seem to be connected with the arrangement of patent laws, as patents reduce economical concurrence and lead on average to higher product prices. Theoretically, international patent protection could also serve as an incentive for pharmaceutical companies to produce drugs for developing countries but, as the author argues, this is rather unlikely as the affected patients are too poor to pay for innovative drugs. International patent protection rather poses a danger for local drug manufacturers in threshold countries which, through agreements like TRIPS, are threatened with legal consequences in the case of product copying. The conflict between Brazil and the Pharmaceutical Manufacturers of America, supported by the U.S. government, in 1990, which resulted in the acceptance of product patents for pharmaceuticals by the Brazilian government, provides an example for this point of view. She concludes that alternative incentives for research and development of drugs for tropical diseases have to be found, for example, a joint international approach for publicly funded research.

Nils Hoppe goes back to the roots in terms of legal reasoning and finds parallels between the law of equity, having been created originally to address situations where the strict application of common law would lead to manifestly unfair results, and the modern day situation in relation to commodification – in particular the Moorean disenfranchisement of the, arguably defrauded, original source of the material for the sake of research advancement. Separating different interests in human tissue and the information contained within it into legal and moral categories results, in his view, in a just system. He calls the concept of applying equitable doctrine to questions of conflicting interests in human biological material "bioequity" and suggests it is a viable alternative to other models of governance.

In Part 3, Rainer Kuhlen's chapter deals with the question of the public or private nature of knowledge and information. The author sees the special meaning of knowledge in its resource character for the so-called "information society", that is, a society which depends just as much on knowledge and information as on tangible goods. This development also seems to foster a new understanding of the commons in critical disassociation from theoretical considerations like the "tragedy of the commons". The classical argument on the limits of the joint use of resources, that is, that it leads to overuse and the destruction of resources, seems to be incorrect in the case of knowledge and information. The process of knowledge dissemination does not lead to the exhaustion of these resources, but on the contrary, the resources in question gain more importance the more often they are used. There is also a special responsibility of the state in the case of knowledge and information in the spheres of culture, education and science, as one of the democratic state's core functions is to uphold and enable free communication. The privatization of resources

like knowledge by the "information industry" could lead to a "scientific two-tier system", where large parts of information are excluded from free circulation and dissemination by public libraries or other public institutions (indeed as is already the case in some parts of the academic system, for example, some commercial highly expensive scientific journals). However, the author remains optimistic about the future of the information society due to the growing number of collaborative and non-commercial endeavors which could serve as a counterweight for the activities of commercial enterprises in this area.

Lucie Guibault discusses the shortcomings of the use of levies to compensate copyright holders for the private use of their works. In particular, she maintains that the emergence of digital technologies, which allow easy and nearly perfect copying of such works, raises doubts about whether the levy system is the most suitable instrument to balance the interests of rights owners and users of copyrighted material. In addition, the author argues that the assumption on which the levy system is based, that is, that private copying of protected works, cannot be controlled and exploited individually, needs to be re-examined. Guibault develops her arguments in two sections: the first, which focuses on the notion of "private use", presents a historical overview of this limitation to copyright and analyzes the provisions of the EC Directive 2001/29/EC dealing with this issue; the second section identifies some possible deficiencies of the levy system from both the rights owners' and the users' perspectives. In conclusion, the chapter gives an overview of the different elements that should be taken into consideration when deciding whether to extend the levy regime to the new digital environment. It emphasizes in particular the need to provide a "fair compensation" to the rights owners for the legitimate use of their works, while avoiding the imposition of double payment obligations on the users, for instance, where digital rights management (DRM) makes it possible to compensate right holders directly for the private use of a work.

Sivaramjani Thambisetty explores some of the reasons for the shortcomings in the current patent system, which tends to increase patentatibility instead of giving a response to bioethical concerns. To this end, she discusses the role of patent offices and courts in the United States and Europe in the first two sections and considers their impact on the general process of change and transition in the law. In the third section, she explores in particular the ability of strong research funding bodies such as the National Institutes of Health (NIH) in the U.S. (which does not have any comparable equivalent in Europe) to modify patenting behavior among scientists. She concludes by pointing out the need to better understand the institutional nature of the patent system and study the inertias, the competencies and the dynamics within the system that lead to expansive patent rights and which thwart debate on the social optimality of patenting certain kind of subject matter.

John Cahir deals with one of the most fascinating features of cyberspace: the emergence of a new "information commons". Cahir's chapter aims to show that explanations of this phenomenon from particular disciplines such as economics, sociology and computer sciences fail to capture the whole picture. He therefore suggests that a broader approach is needed and proposes a comprehensive explanatory framework. The basic concept behind his proposal is that one of the key causal factors of the information commons is the Internet's communicative architecture because

its decentralized structure facilitates the unleashing of material and social forces, which had no equivalent facility in pre-Internet mass media. Cahir's explanation distinguishes three different factors that have given rise to various information commons manifestations: the individual level, the social level and the structural level. The first factor refers to the personal reasons that motivate some individuals to donate their time and skills to participate in an information common project; the second one involves the social practices behind this phenomenon; the third factor is concerned with the macrofoundational structures that facilitate the above-mentioned individual motivations and social practices. Having described the "external" causal factors of the emergence of information commons, Cahir's chapter focuses on the Internet architecture itself as a source of this phenomenon, in particular, its original organization of production and its logic of open access.

PART 1
Political Regulations and Institutions

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Chapter 1

Biobank Governance: Property, Privacy and Consent

Roger Brownsword*

Introduction

If "biobank"[1] governance is to be ethically clean, then – guided by the UNESCO International Declaration on Human Genetic Data[2] – its principal aim should be "to ensure [respect for] human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data…and of the biological samples from which they are derived…".[3]

Crucially, biobank governance must adopt the right approach with regard to property in the collection and associated privacy (including confidentiality) issues[4] as well as attend in the right way to the consent of participants. In principle, there are three options:

- An across-the-board regime of *strong* provisions on property, privacy and consent.
- A mixed regime of provisions relating to property, privacy and consent, some *weak*, some *strong*.
- An across-the-board regime of *weak* provisions on property, privacy and consent.

In a culture committed to human rights, the third type of regime will not be an option; rather, the first type of regime will be the obvious choice. Yet, if the U.K. Biobank[5] is a representative test-case, some form of mixed regime is likely to prevail.

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1 In the sense of collections of biological materials, combined with medical or genetic information, or both.

2 Adopted unanimously on October 16, 2003, by the 32nd session of the General Conference of UNESCO.

3 Ibid., Article 1.

4 For simplicity, I will use the term "privacy" in a broad sense so that it encompasses access to information as well as its subsequent processing and distribution to third parties.

5 See http://www.ukbiobank.ac.uk and J.V. McHale, "Regulating Genetic Databases: Some Legal and Ethical Issues", *Medical Law Review* 12 (2004): 70.

Within the category of mixed regimes, a number of governance permutations are possible. However, a regime (the "compromise approach" as we may term it) that combines *strong* provisions for privacy and consent with *weak* provisions for property has particular appeal. First, it balances the interests of participants against those of the research community – biobank operators being shielded against the objection that consent is not taken sufficiently seriously (this being the standard bioethical criticism of the Icelandic scheme)[6] while, at the same time, it cannot be complained that participants' upstream proprietary rights are interfering with downstream research and intellectual property rights. Secondly, it connects with both the Convention on Human Rights and Biomedicine (which rejects property and commerce in human body parts)[7] and the International Declaration on Human Genetic Data[8] (which expresses strong consent requirements where human genetic data is banked).

Notwithstanding the superficial attractiveness of the compromise approach, it does not fit well with an ethic of human rights. While its requirements for consent are too strong relative to participants' rights, its position on property is too weak. If, by contrast, we test out the compromise approach against a utilitarian ethical standard, we find that it fits rather well. Alas, this is no happy ending; the reason biobank governance regimes are now a matter for intense bioethical scrutiny is precisely because of a concern about the abuse of individual rights that utilitarian thinking is capable of licensing.

The chapter is in four sections. First, using the U.K. Biobank as an illustrative example, the salient features of the compromise approach are identified. Second, the general orientation of human rights to consent, property, and privacy is discussed. Third, the degree of fit between the compromise approach and a human rights ethic is considered. Fourth, the credentials of utilitarianism as the implicit ethic of the compromise approach are reviewed. The upshot of the discussion, as I have said, is the worrying thought that, instead of being responsive to concerns about human rights, biobank governance might already bear the imprint of utilitarian ethics.

The U.K. Biobank and the compromise approach

The aim of the U.K. Biobank is to develop a major health care resource that will throw light on the interaction between genetic make-up, environment and lifestyle, so that more effective measures for the prevention and treatment of disease might be developed.[9] To this end, lifestyle and environmental information from some 500,000

6 See, for example, L. Schulz, "Genetic Data Banks" *Jahrbuch für Recht und Ethik* 9 (2001): 43; but compare V. Árnason, "Coding and Consent: Moral Challenges of the Database Project in Iceland", *Bioethics* 18 (2004): 27.

7 See, in particular, Articles 21 and 22, and, for comment, see D. Beyleveld, R. Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: Oxford University Press, 2001), Chapter 8.

8 See especially Articles 6(d) and 8; and, for withdrawal, Article 9.

9 For the background, see McHale, "Regulating Genetic Databases", especially pp. 72–73.

volunteers (aged 45–69) will be collected, such information being linked to medical records and biological samples. The reason for selecting this particular age group is that these are the persons most likely to succumb to common serious illnesses such as heart disease and stroke. Typically, participants will stay active with the project until their death (in some cases, many years after they have been first enrolled); and, indeed, even after the death (or mental incapacitation) of participants they maintain a passive involvement because the Biobank will retain and continue to make use of their samples and data.[10] Broadly speaking, so far as the Biobank's relationship with participants is concerned, the compromise model has been adopted – in other words, the governance framework designs in strong consent, weak property and strong privacy.

Strong consent

The governance regime seeks to ensure that participants fully understand the purpose of the Biobank (that is, that no one will subsequently complain about having signed up on a false prospectus), that consent is free, and that the process of maintaining consent is ongoing. Crucially, participants should understand that the Biobank is not a health care program but a research resource, that there will be a link to the medical record, that commercial entities might apply to make use of the Biobank, and that the full assemblage of data will be maintained in a reversibly anonymized form.

With regard to the ongoing nature of the relationship, participants should be told that they have an unconditional right to withdraw at any time (without having to give a reason and without penalty) and that they might be re-contacted if fresh consent is required to cover new research purposes.

The right to withdraw is seen as "essential to preserve and demonstrate the voluntary nature of participation".[11] While the recruitment and induction of participants will emphasize the desirability of long-term participation (until death do us part, and even beyond), there is neither an obligation to participate (the initial decision to participate is voluntary) nor an obligation to stay in the project for a minimum term. Participants, so to speak, opt-in and then opt to stay in. Where a participant elects to discontinue, this might signify:[12] (i) complete withdrawal (meaning that the participant's samples and linkages are destroyed); (ii) discontinued participation (meaning that, although the link with the participant's medical record is broken, materials in anonymized form remain available to researchers) and (iii) no further contact (meaning that the participant's materials and data are maintained exactly as if the participant was continuing, but there would be no further contact with the participant). If the right to withdraw is to add anything over and above the voluntary nature of participation, it must be by virtue of either the first option (for destruction) or the second (for discontinuance). This is a matter to which we return later in the chapter.

10 *UK Biobank Ethics and Governance Framework* (Version 1.0, September 24, 2003), pp. 13–14. If potential participants express the view that they would want to be withdrawn on death or mental incapacity, they will not be recruited.

11 Ibid., p. 13.

12 See ibid.

As for the need to refresh a volunteer's original consent "to participate in U.K. Biobank", the governance framework gives no clear indication of how or when this might arise. Where the scope of each participant's consent is drafted in a bespoke narrow fashion, it is easy to understand how the need for fresh authorization would arise.[13] However, where broad consents are taken (as seems to be the intention) then the idea is to cover all anticipated purposes and minimize the occasions when fresh consent for secondary purposes is required. Nevertheless, the compromise approach, even if it employs broad consents (and, to this extent, is not as strong on consent as it might be), recognizes the need to return for further authorization if the terms of the original consent no longer apply.

Weak property

Participants enrolled to the U.K. Biobank are informed that:

> the UK Biobank will be the legal owner of the database and the sample collection, and that participants have no property rights in the samples.[14]

This weak approach to property is underlined by emphasizing that participants will not be offered any significant financial or material inducement to participate;[15] and, in the section dealing with the relationship with research users, it is reiterated that participants "will not have property rights in the samples".[16]

Of course, if U.K. law provided that each person (pre-enrolment) has proprietary rights in his or her tissues or samples (including where such tissues or samples are removed), a bald declaration that participants have no such rights would be of no legal effect. However, the legal position is far from clear and settled: while proprietary rights over removed body parts, tissues and samples certainly may be recognized, seemingly this is limited to claims made by persons other than the source.[17] On this basis, it is arguable that the governance framework merely rehearses the background legal position (not, it should be said, that this would preclude the Biobank operating in a way that, de facto, treated participants as having proprietary rights).

Strong privacy

Given the background provisions of human rights and data protection legislation,[18] and given that the Biobank will collect *inter alia* medical and lifestyle information

13 Compare the U.S. National Bioethics Advisory Commission's report on *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (1999), Recommendation 9.

14 *UK Biobank Ethics and Governance Framework*, p. 9.

15 Ibid., p. 14.

16 Ibid., p. 18.

17 See, in particular, *R. v. Kelly* [1998] 3 All ER 741. For a helpful summary, see McHale, "Regulating Genetic Databases", p. 79.

18 Human Rights Act, 1998; Data Protection Act, 1998.

about the participants, it is no surprise to find its governance principles reflecting the importance of privacy and confidentiality:

> UK Biobank will maintain strict measures to protect confidentiality of data and samples, and will ensure that samples are (reversibly) anonymized, linked and stored to very high standards. The same protection will be extended under contract for any handling or analysis of data or samples by third parties engaged to provide services necessary for developing the resource.[19]

The framework principles go on to provide further and better particulars about anonymization (including that "sensitive" data will be kept separate from identifying information and only linked using a code that has no external meaning), re-identification and security. Quite clearly, the intention is to instate a strong regime of privacy protection with regard to the information collected for and held by the Biobank.

Human rights, consent, property and privacy

Elsewhere, I have suggested that bioethics, particularly when applied to issues concerning reproductive and medical biotechnology, involves a trilateral debate between utilitarians, proponents of human rights, and a constituency that I have termed the "dignitarian alliance".[20] However, in the case of biobank governance, the debate is more traditional, with utilitarians and human rights theorists lined up against one another, the former emphasizing the public health goods to be derived from biobank research and the latter insisting that public goods, however good, must be pursued in a way that fully respects individual rights. For present purposes, we can put the dignitarian view to one side and focus on the bilateral debate between utilitarians and proponents of human rights.

The general approach of utilitarian ethics is very easy to state: no matter what the particular issue, utilitarians consistently hold that governance regimes should seek to maximize utility and minimize disutility. Regulators should aim to optimize welfare (human health and happiness), making whatever provision for property, privacy and consent seems appropriate relative to overriding utilitarian objectives. The specific application of a utilitarian ethic is, however, a rather different matter. Utilitarians might disagree about which of various regulatory options will generate the best utilitarian consequences, judgments about particular regimes of biobank governance depending on the particular context. For example, if utilitarians were confident that biobank research would generate sufficiently large benefits, they might contemplate conscription of participants, processing of information that would violate every canon of data protection, and confiscation of property rights. On the other hand, in another context, they might advocate a strong across-the-board regime of protection

19 *UK Biobank Ethics and Governance Framework*, p. 16.

20 See, for example, Roger Brownsword, "Bioethics Today, Bioethics Tomorrow: Stem Cell Research and the 'Dignitarian Alliance'", *Notre Dame Journal of Law, Ethics and Public Policy* 17 (2003): 15.

for participants. It always depends on context, circumstance, contingency and the perceived consequences of a particular governance approach.

Against the utilitarians, the proponents of human rights insist that it is vital that the entitlements of individuals should not be neglected for the sake of the larger good – individuals ought to be taken seriously, their rights are "trumps", and the person, property and privacy of each human is to be respected. However, if biobank governance is to be guided by respect for human rights, we need to be clear about the orientation of this ethic to questions of consent, property and privacy.

Consent

Viewed from a human rights perspective, consent by *A* (a rights-holder) might signal either a change of position or the creation of a new relationship. There is a tendency to focus more on the former than the latter, that is, on consent signaling *A*'s willingness to modify his or her position in relation to the background scheme of rights and duties that regulates his or her relationship with *B* (the recipient of the consent). As George Fletcher puts it:

> When individuals consent to undergo medical operations, to engage in sexual intercourse, to open their homes to police searches, or to testify against themselves in court, they convert what otherwise would be an invasion of their person or their rights into a harmless or justified activity.[21]

In other words, where *A* consents, then (other things being equal) *A* is precluded (or stopped) from asserting that *B* may not justifiably rely on, or hold *A* to, the agreed change of position or the terms of the new relationship. There are many points of elaboration to make about the operation of consent within a framework of human rights and responsibilities; but, for present purposes, the essential point is that consent does not function at large but by reference to a particular right held by a particular right-holder.[22]

Property (in biological samples)

Modern technologies have given rise to a clutch of issues concerning property. In the field of information technology, for example, there has been a heated debate about the "propertization" of the information highway;[23] and, in a parallel debate in biotechnology, the "propertization" of the human genome was a famously divisive issue as research teams raced to sequence the genome, some racing to get the results of their research into the public domain, others to get their inventive work protected

21 G.P. Fletcher, *Basic Concepts of Legal Thought* (Oxford: Oxford University Press, 1996), p. 109.

22 For full analysis, see D. Beyleveld, R. Brownsword, *Consent in the Law* (Englewood Cliffs, NJ: Prentice Hall, 2006).

23 For discussion, see L. Lessig, *The Future of Ideas* (New York: Random House, 2001).

by patent. Here, the key issue is whether, relative to a human rights perspective, property should be recognized in biological samples.

The question of whether, in principle, *A* can have property rights in his or her own body parts or samples is deeply contested in both legal and philosophical circles.[24] Some arguments badly miss the mark. For example, it is clearly a non-sequitur to hold that, because *A* has a claim-right to his bodily integrity, it follows that *A* has a *property* right in relation to his removed body parts.[25] Even if *B* does wrong by lopping off *A*'s arm (against *A*'s will), this does not entail that *A* has proprietary rights over the removed arm. Equally, it is a poor argument (against property) to hold that, where *A* donates body parts to *B*, *A* has no *ex ante* property rights. Clearly, *A* has no property rights *ex post* (otherwise this would not be a case of donation); but this says nothing about whether *A* has property rights in removed body parts *prior* to donation.

Approaching the question philosophically, and conceiving of property rights as preclusionary entitlements (in the sense of a right to control access to or use of some resource simply by asserting one's proprietorial stake and without further reason), the application of property rights to agents' body parts seems eminently appropriate.[26] Granted, the recognition of such rights would be controversial and it would be moot how many of the characteristic entitlements that make up the property bundle should be enjoyed in relation to body parts. Nevertheless, there is, at worst, an arguable human rights basis for such a claim.

In the legal community, too, the question of property in removed body parts is unsettled. Most famously, the question was squarely addressed in the Californian case of John Moore. However, different courts took different views of the matter; and, although the case itself was settled, the general issue was not.[27] More recently, in *Greenberg v. Miami Children's Hospital Research Institute, Inc*,[28] the view that there is no property in one's own body parts has been followed. However, in addition to showing deference to the rejection of property in *Moore*, the reasoning in *Greenberg* is unpersuasive insofar as it fails to draw a clear distinction between the donor's *ex ante* and *ex post* property rights.

To some extent, these differences turn on conventional ideas concerning what property is and where its boundaries lie; but, in the background, the main fault line is between utilitarians (who resist the idea because of its transaction costs

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24 See, for example, S.R. Munzer, *A Theory of Property* (Cambridge: Cambridge University Press, 1990), especially pp. 37–58.

25 As pointed out in J.W. Harris, "Who Owns My Body?", *Oxford Journal of Legal Studies* 16 (1996), p. 55.

26 See Beyleveld, Brownsword, *Human Dignity*, Chapter 8.

27 See *Moore v. Regents of the University of California* (1988) 249 Cal. Rptr. 494; (1990) 271 Cal. Rptr. 146, (1990) 793 P2d 479; cert. denied (1991) 111 S.Ct. 1388.

28 See 2002 WL 1483266 (N.D. Ill.); 264 F. Supp 2nd 1064 (S.D. Fla. 2003) (02-22244-CIV-MORENO (Miami)). For comment, see G. Laurie, *Genetic Privacy* (Cambridge: Cambridge University Press, 2002), pp. 322–323; and F. Bellivier, C. Noiville, "The Commercialisation of Human Biomaterials: What are the Rights of Donors of Biological Material?", paper presented at workshop on "Property in Human Tissue", University of Tübingen, January 21–22, 2005.

for researchers) and human rights theorists. From the latter perspective, there are reasons for thinking that the logic of property rights tends towards recognizing a donor as having *ex ante* entitlements in relation to removed body parts (or biological materials to be banked).

Privacy (in information held at the biobank)

Privacy is a protean idea.[29] While spatial conceptions of privacy emphasize the right to be alone,[30] informational conceptions emphasize the right to control the outward (and perhaps inward) flow of information about oneself.[31] In both conceptions, we might detect more than a sprinkling of proprietary notions. Thus, spatial conceptions sometimes draw rather explicitly on a recognized interest in property – for example, when an occupier (with property rights) asserts a privacy interest against surveillance from beyond the boundaries of the property in question. Similarly, the informational conception of privacy might present itself as an extension of a property interest – for example, when (without authorization) information is abstracted from private papers.

We can detect these complexities in the much-debated *Source Informatics*[32] case, where the question was whether the rights of patients would be violated if their prescription information was processed (and commercially exploited) without their consent. If we take a narrow privacy approach, there is no problem provided that the information is anonymized. But, if we take a broader privacy approach or a proprietary approach, anonymization is not sufficient; the information should not be used without the consent of the patient. The Court of Appeal, reversing Latham J (who took the broader approach), acted on the narrow approach:

> The concern of the law here is to protect the confider's [patient's] personal privacy. That and that alone is the right at issue in this case. The patient has no proprietorial claim to the prescription form or to the information it contains….[The patient has] no property in the information and no right to control its use provided only and always that his privacy is not put at risk.[33]

Which of these interpretations fits better with human rights thinking is too large an issue to pursue here. However, as we will see shortly, the compromise approach to biobank governance joins Latham J in thinking that anonymization does not suffice. In other words, the compromise approach presupposes a privacy right that

29 See, for example, A.L. Allen, "Genetic Privacy: Emerging Concepts and Values", in M.A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven: Yale University Press, 1997), p. 31.

30 Compare S.D. Warren, L.D. Brandeis, "The Right to Privacy", *Harvard Law Review* 4 (1890–91): 193.

31 Compare C. Fried, "Privacy", *Yale Law Journal* 77 (1968): 475.

32 *R v. Source Informatics Limited*, [2000] 1 All ER 786. For criticism, see D. Beyleveld, E. Histed, "Betrayal of Confidence in the Court of Appeal", *Medical Law International* 4 (2000): 277 and Laurie, *Genetic Privacy*, pp. 225–226.

33 [2000] 1 All ER 786, p. 797 (per Simon Brown LJ).

puts participants in a position to control who shall have access to, and who may obtain and use, information about their health and lifestyle. Whether or not this also presupposes a proprietorial right (and, if so, in relation to both information and biological samples) is a matter to be taken up.

Biobank governance I: Based on rights

How well does the compromise model of biobank governance fit with an ethic of human rights? We can test this out by reference to three configurations of property and privacy rights as follows:

- Model A: participants have privacy rights in their information (without these privacy rights being understood as having a proprietary dimension of control) but no property rights in their biological samples.
- Model B: as per Model A save that participants' privacy rights are understood as having a proprietary dimension of control.
- Model C: participants are recognized as having privacy rights of the kind accepted by Model B but also property rights in their biological samples.

In each of these models, it is settled that agents have rights in their bodily integrity. *De minimis* touching is not an issue; but, otherwise, consent is required and we can assume that biobanks need the consent of participants to authorize the taking of biological materials. This common ground apart, the question is: how well does each of these configurations fit with the compromise approach to biobank governance?

Model A

Under Model A, participants have a right to their bodily integrity which bears on the taking of biological samples; but, this right apart, the only relevant recognized right is one of informational privacy.

To clarify the scope of any right of informational privacy, we need to distinguish three sub-rights as follows:

- a right against unauthorized access to, or abstraction of, personal information;
- a right against unauthorized use of personal information;
- a right against unauthorized circulation or distribution of personal information.

Model A recognizes the first of these sub-rights; but this is as far as it goes – or, at any rate, this is as far as it goes provided that the information is anonymized. Once information is anonymized, it may be put to any use and circulated to any person without violating informational privacy. Quite simply, as the Court of Appeal ruled in *Source Informatics*, the target for the privacy right is not personal information as such but information about an *identifiable* person.

Given a right to bodily integrity, the taking of biological materials requires an adequate consent. So, for example, if a biobank procured samples by deceiving participants, the "consents" would be ineffective, the transactions invalid, and the rights of the sources violated. However, such restrictions apart, once a biobank has the biological material, the source participant has no right to prevent the utilization of the material for whatever research purposes the biobank sees fit; and, because there is no such covering right, there is no requirement on the biobank to seek the participant's fresh authorization for secondary research purposes. Moreover, even if participants are aggrieved by downstream commercial exploitation or privatization, or the assertion of intellectual property rights and the like, in the absence of their own proprietary stake in the source materials they are in no position to object.

Once the biological materials are in the bank, the logic of Model A is that participants are denied a right to withdraw and recover the materials that they have donated. But what if the participant no longer wishes to participate and wishes to have all *information* contributed returned or destroyed (so far as this is practically possible)? While participants have no duty (or, so we assume) to continue and, thus, can disengage from the project, they have no right to withdraw their information from the bank. These are not like documents deposited in a bank for safe-keeping and return on demand. To be sure, participants may exercise their privacy right to insist that their personal information be anonymized. If they consent to some personal information being handled or used without anonymization, this is a consent that they may withdraw. However, this is not at all the same as withdrawing the information itself.

Model B

Under Model B, participants have not only a right to their bodily integrity (which bears on the taking of biological samples) but also a privacy right interpreted in a way that is thicker than in Model A.

According to the informational conception of privacy in Model B, an agent unequivocally has all three sub-rights (against unauthorized access, use and circulation). Crucially, *even if the information is anonymized*, it may only be used for purposes authorized by the agent, and it may only be circulated or distributed to the extent authorized by the agent. The rights-holding agent, thus, is to be viewed as the gatekeeper with regard to personal information.[34]

The right to control access to personal information is a right to control who has such information (who knows), at what time, and for what purpose.[35] It follows that,

34 Compare Fried, "Privacy".

35 Compare D. Beyleveld, D.M.R. Townend, "When Is Personal Data Rendered Anonymous? Interpreting Recital 26 of Directive 95/46/EC", *Medical Law International* 6 (2004): 73–86, p. 79: "Now, rendering personal information non-personal [anonymous] is surely not by itself sufficient to preclude a violation of one's moral integrity [*qua* a privacy interest]. That this is so should be clear from contemplation of the idea that information on the menstrual cycles of Roman Catholic women, who have provided the information for their treatment, might be used for purposes of research into chemical contraceptives without

in a case such as *Greenberg*, if the sources have a privacy right so conceived, they should be able to resist commercial exploitation of the information where this is against their will.

When we turn to the taking of biological samples, consent of course is required. However, as in Model A, this is where control ends. Yet, while the lack of a property right in the biological materials entails that there is no right to withdraw (or demand the destruction of) the materials, the more robust privacy right implies continuing control over personal information held by the biobank. The point is that Model B recognizes a proprietary element underlying the privacy interest. The participant is not just a gatekeeper; what lies behind the gate is the participant's own information. On this analysis, it is plausible to say that the participant has the option of (in effect) making a gift of the information or of granting the biobank a license to make use of it. Allowing that these basic options might be fine-tuned, the rights of the participant will hinge on which option applies; and this might vary from one scheme to another and, indeed, from case to case.

In the light of these remarks, we might recall the options for destruction or discontinuance sketched in the governance framework of the U.K. Biobank. The option for discontinuance is compatible with either Model A or Model B (where the participant elects to abandon the information). However, the option for destruction is compatible only with Model B. Unless the privacy right has some proprietorial dimension, the participant cannot retain this level of control. If the compromise regime adopts the latter option, it advertises again the tension between the strength of its commitment to consent and the weakness of its approach to property.

Arguably, a parallel analysis applies to the question of whether the operators need to return to participants for fresh consent where a secondary use of the banked materials is proposed. Because participants are treated as having no property rights in the biological samples, there is no rights-based requirement to return for fresh consent – at any rate, this is so unless the biobank has given some special undertaking in this matter, in which case the obligation flows from promise rather than property. However, with a stronger conception of privacy, it is arguable that participants retain some proprietary control over the information held by the bank, including genetic information derived from the biological samples. Where, on this analysis, a participant has elected merely to license the use of the information, and where the license is subject to a condition limiting the range of permissible research purposes for which the information may be used, it would indeed be incumbent on the biobank to obtain further permission for fresh applications (going beyond the bounds of the original license). This results in the curious position that, while the participant has no right to control the use of the biological samples for secondary purposes, the proprietor does have this right in relation to information, including information derived from the samples.

To underscore the oddness of all this, imagine that biobank participants were required to keep a diary in which, on a daily basis, details of one's lifestyle were to be recorded. Diaries would be handed over to the biobank at the end of each year.

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offending their moral integrity merely because the information processed was first rendered non-personal."

Now, compare the lifestyle diary with the biological sample that contains information about the source's genetic make-up. According to the stronger model of privacy, the personal information in the diary, just like the personal information in the biological samples, would be subject to full threefold protection. However, whereas the diary would be treated very straightforwardly as subject to standard property rights (no one would suggest that notions like ownership and rightful possession of the diary are inapplicable), Model B denies that the source has (and has ever had) proprietary rights in the biological samples.

Because of these tensions, it is not clear that Model B can find a place in any coherent theory of rights. However, there is no gainsaying that this model has some degree of fit with the compromise regime.

Model C

Model C recognizes the same set of rights that we have in Model B but, *in addition*, it recognizes that participants have property rights in their biological samples. This betokens a strong property approach, the effect of which is to give participants a large measure of control over the application not only of their information but also of their biological samples. To be more specific, there are two ways, in particular, in which Model C improves the position of participants over and above that in Model B.

First, as in both Models A and B, consent is required to take biological samples; however, control does not end at this point – at any rate, control does not end unless the participant so elects. Where control has not been ceded to the biobank, the source participant retains the right to confine the use of the materials to whichever purposes have been authorized. With a property right in the background, when the biobank goes back to the participant to seek authorization for secondary research purposes, this is no mere courtesy; consent is strictly required, it cannot be assumed to be a forgone conclusion, a refusal is a possibility. Similarly, if commercial exploitation of the research falls outside the authorized application of the materials, it is for the property-holding participant to consent or refuse; and a biobank enrolling a property-holding participant would need to clarify the position with regard to intellectual property rights that might become an issue downstream.

Second, when a property-holding participant decides to withdraw from the project, any license to use the participant's materials terminates and, subject to practicability and safety, there would be a right not merely to demand the destruction of the materials but to demand their return – after all, these are the participant's materials.

In addition to improving the position of participants, Model C removes the tensions that beset the compromise approach and Model B. For example, it now becomes quite clear why there has to be fresh authorization for secondary purposes and why this is so regardless of whether the further research purposes involve use of biological samples (in which the participant retains property rights) or information (over which, via an appropriate conception of privacy, the participant retains proprietary control).

Taking stock

Is there a rights model that is a reasonable fit for the compromise regime and that is internally coherent? Apparently, there is not. On the ground of fit, neither Model A nor Model C looks eligible because each maps rather poorly onto the compromise regime. In the case of Model A, the regime's consent requirement is far too strong – even if the consents given are broad, the basis of the need for fresh consents is unclear; and, in the case of Model C, the regime's approach to property is too weak. This leaves Model B as the best fit. The problem with this model, however, is that it is riddled with internal contradictions and tensions. Indeed, if it fits the compromise regime it expresses the tensions of the regime itself all too clearly. Hence, this too seems to be a selection to avoid.

Biobank governance II: Based on utilitarian thinking

Does a utilitarian ethic fit better with the compromise approach? The question is whether in a particular place at a particular time, the utilities line up in favor of this particular regime. Where the media have feasted on researchers proceeding without consent (including retaining organs and tissue without consent);[36] where trust in scientific and medical researchers is shaken;[37] where data protection, confidentiality and privacy are valued; and where a great deal of money rests on downstream research and development (which can do without the inhibiting effect of upstream property rights or the transaction costs of putting in place benefit-sharing agreements) the compromise regime surely will make a lot of utilitarian sense.

Strong consent

Utilitarians have no commitment to consent. This is not saying merely that they will advocate stronger or weaker requirements of consent depending on the context; it means that, in some contexts, utilitarians will see no merit in requiring consent of any kind. Consent is a dispensable commodity. Moreover, where utilitarians do see some merit in consent, the way in which they specify the conditions of adequacy will vary from one context to another. There is no utilitarian standard specification of an adequate consent, with all that that entails in relation to unforced and informed choice, express and unequivocal signaling, and so on.[38]

From a utilitarian perspective, the right of participants to withdraw will probably be seen as unhelpful and wasteful of resources. However, it might be much worse.

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36 See the concerns about non-consensual organ retention at Bristol Royal Infirmary (Bristol Inquiry Interim Report, *Removal and Retention of Human Material* (2000), http://www.bristol-inquiry.org.uk) and Royal Liverpool Children's Hospital (Alder Hey) (*Report of the Inquiry into the Royal Liverpool Children's Hospital (Alder Hey)* (2001), http://www.rclinquiry.org.uk.

37 See O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002).

38 See further, Beyleveld, Brownsword, *Consent in the Law*.

If the withdrawal relates to tissue or samples that are difficult to substitute and that are of significant medical benefit or commercial value, this could really weigh the utilitarian scales against making it easy to withdraw. Indeed, from a utilitarian perspective, the most efficient consent is likely to be one that is (a) broadly drafted (so that researchers do not have to keep returning to the consenting parties to seek their authorization for variation of the terms of the consent) and (b) non-retractable. Nevertheless, where public preference and prejudice runs strongly in favor of consent, utilitarians can, for the time being, line up with those rights theorists who argue that, as a matter of principle, consent is required.

Strong privacy

If the utilitarian default position treats consent as a disutility, much the same applies to privacy, confidentiality and the bureaucratic nightmare that is data protection. What sense is there, the utilitarian will ask, in committing such a disproportionate resource to securing these interests? Moreover, the regulatory framework is so complex and of uncertain application that, lawyers apart, it is unclear who benefits. Is it not better, the utilitarian will wonder, to permit the free circulation of information (by and large, the more that we know, the better things are) hedged with some remedial protection in cases of serious abuse?[39]

Despite these misgivings, a utilitarian will concede that in some places at some times, the utilities might favor recognizing rights of this kind, even strong privacy rights. One such time is when personal information (such as medical or health-related information), having been previously held in hard copy files, is moved across into (much more accessible) electronic files;[40] and it is eminently arguable that, at this time, the United Kingdom is precisely the kind of place where assurances about privacy are essential lest potential participants decline to step forward to co-operate with utility-generating projects. In such a place at such a time, even a utilitarian will know that recognizing privacy rights makes sense.

Weak property

Going against the grain of *Moore*, the Federal Genetic Privacy Act 1995 recognized a proprietary right in one's own genetic samples. Six years later, however, the Act was repealed under the weight of the lobbying power brought to bear by the pharmaceutical industry.[41] This is an all too common story of business as usual – that is, the financial interests of downstream business interests prevailing over the

39 Compare D.F. Partlett, "Misuse of Genetic Information: The Common Law and Professionals' Liability" *Washburn Law Journal* 42 (2003): 489.

40 In the context of the U.S. health care system, this point is strikingly made in J.M. Zekan Makdisi, "Commercial Use of Protected Information Under HIPAA's Privacy Rule: Reasonable Disclosure of Disguised Marketing?" *Nebraska Law Review* 82 (2004): 741–782, see especially pp. 757–758.

41 See McHale, "Regulating Genetic Databases", p. 81.

financial interests of upstream sources.[42] But, in addition, there is a concern that too many property stakes can be as counter-productive as too few – a case, as it were, of too many cooks spoiling the commons. On this point, therefore, the utilitarian will see the sense at once of the compromise approach.

Conclusion

Bioethics has become a natural home for human rights thinking because rights are designed to reduce the risk that individuals will be mistreated by researchers who, however well intentioned, have their gaze fixed on larger goods.

Relative to this human rights standard, the compromise model of biobank governance does well in insisting that individual participation should be voluntary and that no one should be coerced or tricked into participating. This is exactly as it should be. The regime also adopts a strong approach in relation to privacy and confidentiality. Again, from a human rights perspective, this is as it should be. However, it is far from clear that all is well when the governance regime, responding to the concern that upstream property rights might clog up downstream research as well as making IP negotiation more complex, denies that participants have any proprietary rights in their biological samples. The compromise that results is unconvincing.

There is a good deal of unfinished business here. In particular, the question of whether participants should be recognized as having *ex ante* property rights in their biological samples remains to be resolved. Does an ethic of human rights require (or, possibly, merely permit) such recognition? If such *ex ante* rights were recognized, would this have an adverse impact on the supply of willing participants or would it encourage more business-like negotiation of the terms of participation (including perhaps preservation of proprietary interests *ex post*)? If so, would this simply adjust the balance of power between the private interests of participants and downstream corporate interests, or would it raise more complex conflicts between the human rights of participants and the human rights of potential beneficiaries, or between private right and public good? There is also the question of whether the recognition of *ex ante* property rights has implications for stake-holding in the biobank – the issue then seeming to be whether a human rights ethic pushes for compliant but passive governance or active participatory democracy backed by property interests. These are complex questions. However, if our investment in biobanks is to promote both our physical and our moral well-being, these are questions that merit further consideration.

42 For a famously biting critique, see J. Boyle, *Shamans, Software, and Spleens* (Cambridge, MA: Harvard University Press, 1996).

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Chapter 2

Population Genetic Databases: A New Challenge to Human Rights

Roberto Andorno

Introduction

Large-scale collections of human genetic data have the potential to contribute to identify, in a specific population, genetic predispositions to complex diseases that are not caused by single genetic mutations, but rather result from an interaction of environmental, lifestyle and genetic factors. They are expected to achieve this by bringing together several streams of information about individuals: genetic data; data on health, lifestyle and environment from interviews and medical records; and in some cases, genealogical data. In this way, population genetic databases will presumably provide in the years to come an unprecedented insight into the role of gene–environment interaction in the disease process. Furthermore, they are viewed as an important research tool in the emerging field of pharmacogenetics, which is intended to tailor drugs to particular constitutions and to screen for genetic suitability before prescribing, since this kind of research needs the access to large pools of genetic information. Therefore, we can reasonably expect that the current trend towards the establishment of genebanks will contribute in the next decades to fight diseases at a population level and to help to develop more personalized medicines.

On the other hand, genetic databases create a number of challenging ethical and policy dilemmas, in particular regarding informed consent, confidentiality, feedback to participants, benefit-sharing and possible emergence of new forms of discrimination and eugenic practices. These issues, which are posed by any collection of human genetic information, become especially complex in the case of long-term mega-biobanks.

How to conciliate the undoubted benefits of the "genetic revolution" with the respect for human rights? Or, to summarize the dilemma in a few words: "who should have access to genetic information?".[1] From this fundamental question springs forth myriad ethical and legal issues such as: Is the opt-out model (which presumes individuals' consent to enter their data into a database unless they explicitly refuse) an acceptable solution? Can individuals give a "blanket consent" concerning the future use of their samples for other research purposes? Is the coding of personal genetic information by the database operator (which presupposes that this latter has always

1 B.M. Knoppers, "Who Should Have Access to Genetic Information?", in J. Burley (ed.), *The Genetic Revolution and Human Rights* (New York: Penguin, 1999), pp. 38–53.

the possibility to identify individuals) sufficient for ensuring the confidentiality of that data? How could we prevent the use of genetic information for discriminatory purposes in the areas of employment and insurance? Do people have a "right not to know" their genetic make-up? Should private companies be allowed to manage genetic databases of the entire population of a country?

The aim of this chapter is to provide an overview of some ethical and policy challenges posed by the establishment of population genetic databases for research purposes. To illustrate the topic, the chapter focuses on the recent experiences of Iceland and Estonia, the first countries that have decided to establish biobanks of the entire population, or of a high proportion of the population, having simultaneously passed specific laws to address the new challenges. Since the approaches followed by these two countries are quite different in many respects, the comparative analysis of both experiences is extremely helpful to better understand what the issues at stake are. In the light of the Icelandic and the Estonian experiences, the chapter summarizes some ethical and policy issues posed by large-scale collections of human genetic data.

Two large-scale genetic databases: An overview

The Icelandic Population Genetic Database

In December 1998, without any previous public debate, the Icelandic Parliament (*Althingi*) passed a law innocuously called the "Healthcare Sector Database Act" that stirred considerable controversy in Iceland and around the world. The law creates a nationwide centralized database of medical records of the whole Icelandic population to be used for genetic research. According to Article 1, the database's purpose is "to increase knowledge in order to improve health and health services". In more precise terms, Article 10 stipulates that the database will be used "to develop new or improved methods of achieving better health, prediction, diagnosis and treatment of disease, to seek the most economic ways of operating health services, and for making reports in the health sector." In January 2000, on the basis of this law, the Minister of Health granted an exclusive 12-year license to operate the database to the Icelandic subsidiary of the American bio-tech company deCode Genetics.

Why was Iceland chosen for this project? One of the reasons that have been advanced for this is that the Icelandic population is more genetically homogenous than any other developed society thanks to thousands of years of relative isolation. Icelanders descend from 9th and 10th century Nordic settlers and were almost isolated from the rest of the world until the beginning of the 20th century. The assumption is that detecting disease-causing mutations would be easier in a homogenous gene pool and in a population exposed to similar environmental factors.[2] Another reason

2 Einar Arnason, a geneticist at the University of Iceland in Reykjavik, maintains that the supposed "genetic homogeneity" of the Icelandic population is not supported by evidence. See E. Arnason, "Genetic Heterogeneity of Icelanders", *Annals of Human Genetics* 67(1) (2003): 5–16. See also A. Abbott, "DNA Study Deepens Rifts Over Iceland's Genetic Heritage", *Nature* 421 (2003): 678.

is that genealogy has been very popular among Icelanders for centuries. Iceland possesses an extensive record of genealogical information that enables scientists to link together genealogy and medical records in a way that is not available in other countries. In addition to this, the Icelandic population of about 280,000 inhabitants is large enough to make research valuable but still small enough to be manageable. Finally, the national health coverage that has existed since 1915 provides extensive and detailed medical records of the Icelandic population.

For several reasons, the Icelandic database has been very controversial and is still hotly debated both in Iceland and amongst medical and privacy experts around the world. The main reason for the controversy was that deCode was authorized not only to obtain new health data from volunteers but also to collect the already existing patient records from Iceland's national healthcare system without the explicit consent of data subjects. Thus, personal health information of all Icelanders can be entered in the database under an assumption of consent (presumed consent), unless they voluntarily opt out by filling out a form and sending it to the Director General of Public Health.[3] In addition to this, the Health Sector Database Act does not contain any provisions regarding the deletion of the respective information from the database once an individual has notified his or her wish to opt out. The government has informed that opt-outs are only relevant for future recording into the database, but previously entered data will not be removed.[4] The absence of a real informed consent process stirred controversy in the country. On this and other grounds, the Association of Icelanders for Ethics in Science and Medicine (*Mannvernd*) has led the opposition to the project.[5] The Icelandic Medical Association has also opposed the presumed consent model and many doctors have refused to hand over their patients' records without consent.[6] In 1999 the World Medical Association supported the Icelandic Medical Association's opposition to the database and declared that the Icelandic legislation "violates the WMA's commitment to confidentiality, the principles of real and valid consent, and the freedom of scientific research".[7] In 2002 the WMA adopted a Declaration on Health Databases that implicitly condemns the Icelandic experience.[8]

A second reason for the opposition to the project is the confidentiality issue. Although the Health Sector Database Act stipulates that the database would only

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3 DeCode intends to conclude financial agreements with hospitals and health care providers to obtain the transfer of their patients' data.

4 See H. Jónatansson, "Iceland's Health Sector Database: A Significant Head Start for the Biological Grail or an Irreversible Error?", *American Journal of Law and Medicine* 26 (2000): 48.

5 *Mannvernd* reports that as of June 30, 2003, 20,426 people had opted out of the database. See http://www.mannvernd.is/.

6 A. Berger, "Private Company Wins Rights to Icelandic Gene Database", *British Medical Journal* 318 (1999): 11.

7 World Medical Association (WMA) (ed.), *Workgroup Report on Patient Confidentiality and Personal Health Information* (1999), cited by V. English et al., "Ethics Briefings: Confidentiality", *Journal of Medical Ethics*, 26 (2000): 215–216.

8 World Medical Association (WMA) (ed.), *Declaration on Ethical Considerations Regarding Health Databases* (Washington: WMA, 2002).

contain "non personally identifiable health data" (Articles 1, 7 and 10), critics of the project maintain that confidentiality safeguards are not secure enough, because the one-way coding of personal identifiers does not really render the data non-personally identifiable.[9] It should be noted that the law does not provide any clear guidance as to what information from medical records must be encrypted prior to transfer to the Database. According to the Annex to the license, the only data that are encrypted are the name of the patient and his or her address. But the medical records include other personal information, such as age, city of residence, profession, marital status and the indication of a particular disease. In a small country like Iceland, all this information, if combined, could allow to establish which data belongs to which individual, particularly in cases of rarer conditions. Therefore, since an *indirect identification* of individuals would be possible, it can be argued that the Icelandic database violates the European Directive 95/46 on data protection that requires (explicit) informed consent for the storage and use of personally identifiable information.[10]

Taking into account the possibility of indirect identification of individuals, Iceland's Supreme Court ruled on November 27, 2003 against the State of Iceland and in favor of an 18-year-old girl, who did not want her dead father's health records to be transferred to the database. The Director General of Public Health had rejected her request, arguing that information entered into the database is personally non-identifiable and therefore, she had no interest in opposing to the storage of her father's data. The court said that the one-way encryption system was, in general, a sufficiently safe mechanism for data protection, but in this case, the possibility of an indirect identification is increased by the fact that the Health Sector Database would allow information to be linked with data from genetic and genealogical databases. Consequently, including the records in the database might allow the plaintiff to be identified as an individual at risk of any heritable disease her father might be found to have had. According to the decision, although the Act repeatedly stipulates that health information should be non-personally identifiable, "it is far from being adequately ensured that this objective will be achieved." The ruling has been interpreted to

9 E. Arnason, "Personal Identifiability in the Icelandic Health Sector Database", *Journal of Information, Law and Technology (JILT)* 2 (2002), at http://www2.warwick.ac.uk/fac/soc/law/elj/jilt/.

10 According to Article 2(a) of the Directive, "an identifiable person is one who can be identified, *directly or indirectly*, in particular by reference to an identification number or to one or more factor specific to his physical, physiological, mental, economic, cultural or social identity" (emphasis is ours) (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and to the Free Movement of Such Data). It is important to point out that the Directive 95/46 was incorporated into Icelandic law in 2000 by Act N° 77 on the Protection and Processing of Personal Data, amended by Acts N° 90 of 2001, N° 30 of 2002 and N° 81 of 2002. See H. Jónatansson, "Iceland's Health Sector Database: A Significant Head Start for the Biological Grail or an Irreversible Error?", *American Journal of Law and Medicine* 26 (2000): 31–67; R. Adalsteinsson, "The Constitutionality of the Icelandic Act on a Health Sector Database", in J. Sandor (ed.), *Society and Genetic Information. Codes and Laws in the Genetic Era* (Budapest: Central European University Press, 2003), pp. 203–211.

mean that the 1998 law is unconstitutional because it fails to protect confidentiality adequately.[11]

A third reason that has played an important role in the controversy around the project is the idea that a for-profit company cannot have a monopoly on the use and exploitation of Icelanders' health data that belong to the national health system. The rationale behind this criticism is that health issues of an entire nation cannot be managed with purely commercial criteria, but should be guided by the idea of public interest. It is important to note that the licensee is explicitly authorized by the Health Sector Database Act to use the database for purposes of financial profit (see Article 10). This is why, when it was known that deCode, after having paid an initial fee of about U.S.$700,000 to the State in exchange for the license, had concluded an agreement with the Swiss-based pharmaceutical company Roche to sell for U.S.$200,000,000 the rights to develop and market drugs resulting from the findings of the database, the controversy became even more passionate. The circumstance that the licensee is a foreign company increased the criticism of the project, because the exploitation of the database was regarded as a "theft" of national common-pool resources, comparable to the depletion by foreign companies of key fishing stocks of the continental shelf surrounding Iceland that was denounced in the 1970s.[12]

In May 2000 the Healthcare Sector Database Act was completed by a second law, the Biobanks Act, which sets rules for the storage of biological samples (blood samples) to obtain genetic sequences. On the basis of this law, deCode was granted a license to also operate the biobank and to link the information it will contain with the data entered into the healthcare database, as well as with Iceland's extensive public genealogical records. Although the Act mandates the "informed consent of the persons giving the biological sample", this requirement does not apply to samples that have been collected in the past for clinical purposes, in which case patients' consent is presumed (Article 7). The only condition for use of the samples for "other purposes than those for which [they] were originally collected" is the approval by the Data Protection Authority and the National Bioethics Committee (Article 9). Concerning the withdrawal of consent, although the law provides that "a donor of a biological sample may at any time withdraw his/her consent…and then the biological sample will be destroyed", it adds that "material that has been produced from a biological sample by performance of a study or the results of studies already carried out shall however not be destroyed" (Article 7). The importance of confidentiality safeguards is vaguely mentioned by Article 11 and there is no provision specifying levels of coding and anonymization of data.

11 "A Landmark Decision by the Icelandic Supreme Court: The Icelandic Health Sector Database Act Stricken Down as Unconstitutional", press release of *Mannvernd*, March 30, 2004. Available online at http://www.mannvernd.is/english/index.html.

12 J.H. Barker, "Common-Pool Resources and Population Genomics in Iceland, Estonia, and Tonga", *Medicine, Health Care and Philosophy* 6 (2003): 133–144.

The current situation of the Icelandic project is that financial struggles at deCode, delays in obtaining necessary government approval, and continuing opposition from doctors are raising serious doubts about the construction of the database.[13]

The Estonian Population Genetic Database

Trying to learn from the mistakes of the Icelandic experience, Estonia launched in September 2002 the Estonian Genome Project (EGP). The legal framework for the project was provided by the Human Genes Research Act, which entered into force in January 2001. Simultaneously, the government incorporated the Estonian Genome Project Foundation (EGPF), a non-profit organization which has the responsibility of carrying out the project in order to create a database of health, genetic and genealogical data of a high proportion of the Estonian population (about 1,000,000 people, which represents 70% of Estonians). By the end of 2002, the first samples and health data of volunteers began to be collected into the database. In 2004, it already contained the data of approximately 10,000 donors. The short-term plan is to collect health data and samples of 100,000 donors by the end of 2007. If the project advances as planned, the database will be the largest of its kind in Europe.

It is true that several reasons call for careful and limited comparison between the Icelandic and the Estonian projects: not only is the scale of the databases (1,000,000 Estonians versus 280,000 Icelanders) very different, but also the financial and technical obstacles facing the Estonians, and the specific political and historical trajectories of both countries, cannot be more dissimilar.[14] In addition to this, unlike the Icelandic database, the Estonian Genome Project is original in the sense that it plans to incorporate genetic information into medical care by releasing data to individuals and their physicians.[15] Despite all these differences, a comparison between both projects seems not only valid, but extremely helpful to illuminate the ethical issues at stake.[16]

The Estonian approach to population genetic databases is, for several reasons, ethically preferable to the Icelandic one. First, the Estonian Human Genes Research Act places a strong emphasis on individuals' *rights.* Participation in the project is strictly voluntary and informed consent is required for the collection of biological samples, health information and genealogical data (Article 9.1). The information in this informed consent is specified to include not only the means and risks of obtaining the sample but also all the rights to which participants are entitled.[17] The law guarantees the confidentiality of data through high-level technical encoding of

13 A. Abbott, "Icelandic Database Shelved as Court Judges Privacy in Peril", *Nature* 429 (2004): 118.

14 Estonia is a former member of the Soviet Union, while Iceland has a long democratic tradition.

15 It is important to note that the feedback to participants can only be made at the request of the doctor and with the previous patient's consent (Articles 24.7 and 16.2 of the Estonian Genes Research Act). See also Estonian Genome Foundation, "Estonian Genome Project", p. 3, at http://www.geenivaramu.ee/mp3/trykisENG.pdf.

16 Barker, "Common-Pool Resources", p. 139.

17 See the donor consent form at: http://www.geenivaramu.ee.

personal identifiers (Articles 22 to 24). All research studies have to be previously approved by an Ethics Committee (Article 29).[18] Several specific rights are explicitly recognized to participants: the right to have access to their information stored in the database (Article 11.2)[19]; the right not to know their genetic data (Article 11.1); the right to have access, free of charge, to their data stored in the database (Article 11.3); the right to genetic counseling (Article 11.4); the right to submit additional information on themselves to the database (Article 11.5); the right to withdraw their consent until their tissue samples or health data are coded (Article 12.4.7). Once the coding is done, participants can demand the destruction of the information that enables decoding of personal identifiers (Article 10), but the biological sample could only be destroyed in the exceptional case that the donor's identity was unlawfully disclosed (Article 12.6).[20] The law includes also specific norms to prevent genetic discrimination in insurance and employment contracts (Articles 25 to 27). If one considers that the Icelandic Health Sector Database Act contains only one article (Article 8) that vaguely refers to the "rights of patients" (and in fact, is only aimed at presuming their consent!), the contrast with the Estonian law could not be more striking. The founders of the Estonian database acknowledge that the legal framework of the project was developed with the help of international experts, such as Bartha Knoppers, and has taken into account international legal instruments like the European Convention on Human Rights and Biomedicine ("Oviedo Convention") and the UNESCO Declaration on the Human Genome and Human Rights.[21]

Concerning the confidentiality issue, as mentioned above, the Estonian Human Genes Research Act provides that all data in the genebank "shall be processed

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18 The lack of independence of the Ethics Committee has been criticized. Since its members are appointed by the supervisory board of the Project, which has also the right to remove them, it is obvious that they might be biased towards uncritical support of research studies (B. Elger, "Ethical Issues of Human Genetic Databases. A Challenge to Classical Health Research Ethics?", thesis for habilitation as professor, University of Geneva, Faculty of Medicine (2004), p. 39).

19 The participants' access to their genealogies is, however, excluded by Article 11.2.

20 This limit to the right to withdraw consent could *a priori* be seen as contrary to the European Convention on Human Rights and Biomedicine of 1997, which provides that "the person concerned may freely withdraw consent at any time" (Article 5). However, the project's supporters argue that the right to withdraw consent at any time has been recognized having in mind biomedical research that operates on the human body and therefore entails some risk to the physical integrity of participants, but this is not the case of research that only deals with biological samples and genetic data, especially since they have been anonymized (A. Nómper, K. Kruuv, "The Estonian Genome Project", in J. Sandor (ed.), *Society and Genetic Information. Codes and Laws in the Genetic Era* (Budapest: Central European University Press, 2003), p. 222). Note, in support of this interpretation, that according to the UNESCO International Declaration on Human Genetic Data of 2003, withdrawal of consent is possible unless data "are irretrievably unlinked to an identifiable person" (Article 9).

21 A. Rannamäe, "Estonian Genome Project. Large Scale Health Status Description and DNA Collection", in B. Knoppers (ed.), *Populations and Genetics: Legal and Socio-Ethical Perspectives* (Leiden: Martinus Nijhoff Publishers, 2003), p. 23. See also Estonian Genome Foundation, *Estonian Genome Project*, p. 5, at http://www.geenivaramu.ee/mp3/trykisENG.pdf.

in compliance with the highest standards of data protection" (Article 22). In this respect, several safeguards are put in place to prevent indirect identification. Each tissue sample, description of DNA, health information and genealogy is given a unique 16-digit code (Article 23.1). This code replaces any information that could enable identification, such as name, address, personal identification number and date of birth (Article 23.2). The same code will be noted on the consent form and therefore the consent will be the only possible key for decoding (Article 23.3). In order to prevent indirect identification of a donor, the database operator may release information from the database as a set of data and on the condition that samples or data concerning at least five donors are issued at a time (Article 22.4). In the interests of greater security, the database operator "may give an additional code" to coded tissue samples, coded genetic data and coded genealogical data (Article 23.4).

The different approach of the Estonian project is also visible in the way the database is managed. The owner of the database, the Estonian Genome Foundation (*Eesti Geenivaramu*), is not a private for-profit company but a non-profit organization, whose directors are appointed by the government and by the Estonian Academy of Sciences. Certainly, the mercantile dimension of the planned research is not *a priori* excluded from the project.[22] However, the non-profit nature of the database's owner indicates that it will not be managed with purely commercial criteria, but taking mainly into consideration the public interest. A good illustration of this is the fact that the law allows the use of the database for academic research free of charge (Article 19).[23] In order to finance the project and to target potential investors, the Estonian Genome Foundation initially reached an agreement with a biotechnology company, EGeen. The Foundation granted EGeen the exclusive rights to commercialize the results of the research. However, in December 2004 the agreement was terminated and the Foundation is currently seeking another way of financing the project.[24]

Ethical and policy dilemmas posed by population genetic databases

The Icelandic and Estonian experiences clearly illustrate the serious ethical and policy challenges posed by large collections of human genetic data, in particular regarding informed consent, confidentiality, the risk of genetic discrimination and stigmatization, feedback to participants, and issues of property and benefit-sharing. This chapter aims to summarize these new challenges.

22 According to the physician and molecular biologist Andres Metspalu, one of the key figures in the Estonian Genome Project, the database "is a resource for basic science. But with good basic research, it can also lead to good economic benefits." (A. Tzortzis, "Good Science, Good PR", *The Boston Globe*, August 19, 2003, p. E4).

23 In contrast with this, in Iceland, other researchers are not allowed to use the database, if such use could be contrary to the interests of the database operator.

24 See http://www.geenivaramu.ee.

Informed consent

Since the Nuremberg Code established the ground rules for ethical research in 1947, researchers have been required to get informed consent from people participating in studies. This requirement is based on the principle that competent individuals are entitled to decide freely whether to participate or not in any research study. This means basically that participants should understand the nature, risks, benefits and alternatives of the research, and should be able to knowledgeably and voluntarily decide whether or not to participate in the proposed research.

After the Nuremberg Code, the famous Declaration of Helsinki of 1964/2000, adopted by the World Medical Association, further developed the necessity of *informed consent* of research subjects.[25] At the legal level, this principle was recognized for the first time in a treaty in 1966, with the adoption of the International Covenant on Civil and Political Rights.[26] There is *a priori* no obvious reason to depart from this principle when creating genetic databases for research. This requirement means in this case that every individual from whom a biological sample and derived genetic information are collected, stored and used has to be clearly informed and, on that basis, should be free to decide whether to participate or not in the research. At present, this principle is included in virtually all guidelines and research codes dealing with genetic research.[27]

Although the general principle of informed consent of research subjects is widely accepted, there are serious differences among experts regarding the modalities and content of consent in genetic research. As Bernice Elger points out, not without humor, "the controversy [on the modalities of consent] is so difficult to resolve that even authors of the same article do not find a consensus".[28] In this respect, some of the controversial issues are the following ones: Is it ethically acceptable to enter individuals' health information into a database unless they explicitly object (opt-out model)? Can individuals give "blanket consent" to future use of their samples and data for any secondary purposes or do they need to be consulted again? Clearly, the big challenge here is how to conciliate the necessary respect for individuals' autonomy and the need to promote genetic research, which is intended to contribute to the common good. The spectrum of solutions to this dilemma includes two extremes

25 See Articles 20 to 26 of the Declaration of Helsinki.

26 According to Article 7 of the International Covenant on Civil and Political Rights of 1966, "no one shall be subjected without his free consent to medical or scientific experimentation".

27 See for instance, UNESCO Universal Declaration on the Human Genome and Human Rights 1997, Article 5; UNESCO International Declaration on Human Genetic Data 2003, Article 8; European Commission Experts Group, The 25 Recommendations on the Ethical, Legal and Social Implications of Genetic Testing, Brussels, 2004, Recommendation 23; World Medical Association (WMA), Declaration on Ethical Considerations Regarding Health Databases, 2002, paragraphs 16–21; Human Genome Organization (HUGO), Statement on Human Genomic Databases, 2002, Recommendation 4; World Health Organization (WHO) (Regional Office for Europe), Genetic Databases. Assessing the Benefit and the Impact on Human and Patient Rights, Report for Consultation, 2001, section 4.

28 B. Elger, "Ethical Issues of Human Genetic Databases", p. 146.

positions and several intermediate solutions. The two extreme positions are: (i) the one that requires specific informed consent for the initial collection of samples and data and for each future new use of those data and (ii) the other one, which allows participants to consent to "research in general" (blanket consent) or simply to conduct research without the consent of data subjects (waiver of consent).

"Blanket consent" to the use of samples and data has been proposed in 1998 by the WHO Guidelines on Ethical Issues in Medical Genetics and Genetic Services: "A blanket informed consent that would allow use of a sample for genetic research in general, including future as yet unspecified projects, appears to be the most efficient and economical approach, avoiding costly re-contact before each new research project".[29] The International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) accept waivers of informed consent if the procedure is approved by an ethical review committee and other conditions are fulfilled.[30]

Nevertheless, most experts and guidelines seem to reject the use of blanket consent (which in reality is not "informed" consent at all) and of waivers of consent for the initial collection of data, and adopt an intermediate solution. In fact, with the exception of the Icelandic database, all other large-scale genebanks that are being established around the world use a process of voluntary participation with specific informed consent for the initial collection of data.[31] A good example of an intermediate solution is the position of the German National Ethics Council, which acknowledges that a requirement to obtain fresh consent for any new proposed research "may give rise to problems in the case of biobanks", especially in those that intend to collect samples and data of several hundred thousands of donors.[32] This is why it suggests that "it must be made possible for donors to consent to the use of their samples and data for undefined research projects to be specified only at some future data".[33] Similarly, the U.K. Human Genetics Commission recognizes "the importance of consent at the outset", but considers that "repeated processes of re-consent for subsequent use are impractical and, moreover, may be considered as unnecessarily invasive". Therefore, the HGC considers that "it is acceptable to seek general consent in cases where

29 World Health Organization (WHO), Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services, 1998, section 11.

30 Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002: "Use of medical records and biological specimens. Medical records and biological specimens taken in the course of clinical care may be used for research without the consent of the patients/subjects only if an ethical review committee has determined that the research poses minimal risk, that the rights or interests of the patients will not be violated, that their privacy and confidentiality or anonymity are assured, and that the research is designed to answer an important question and would be impracticable if the requirement for informed consent were to be imposed" (Guideline 4).

31 M. Austin, S. Harding, C. McElroy, "Genebanks: A Comparison of Eight Proposed International Genetic Databases", *Community Genetics* 6 (2003): 43.

32 German National Ethics Council (ed.), *Biobanks for Research. Opinion* (Berlin: German National Ethics Council, 2004), p. 51.

33 Ibid., p. 52.

there is to be irreversible or reversible anonymization of data and samples".[34] A similar approach is followed by other international guidelines such as the Statement on DNA Sampling of the Human Genome Organization (HUGO),[35] the UNESCO International Declaration on Human Genetic Data of 2003,[36] and the 2001 report on genetic databases prepared for the World Health Organization Regional Office for Europe.[37]

In our view, since it would be impossible to seek consent at the time that the original samples were taken to cover all future eventualities, and considering the high potential of genetic research to improve health care, the adoption of an intermediate position seems preferable. Thus, in our opinion, informed consent must be required for the initial collection of data into the database and, at this occasion, donors should have the choice to limit their participation to already known research projects about which they receive detailed information, or to provide, in addition, a general consent to future research projects the precise scope of which is still unknown. It is important to point out that we are not dealing here with the consent to research activities that

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34 U.K. Human Genetics Commission (HGC) (ed.), *Inside Information. Balancing Interests in the Use of Personal Genetic Data* (London: Human Genetics Commission Publications, 2002), pp. 94–95.

35 "Research samples obtained with consent and stored may be used for other research if; there is general notification of such a policy, the participant has not yet objected, and the sample to be used by the researcher has been coded or anonymised. For the use of research samples obtained before notification of a policy, these samples may be used for other research if the sample has been coded or anonymized prior to use" (Human Genome Organisation Ethics Committee, *Statement on DNA Sampling. Control and Access*, 1998).

36 According to the 2003 UNESCO Declaration, genetic data and samples "should not be used for a different purpose that is incompatible with the original consent, unless the prior, free, informed and express consent of the person concerned is obtained…or unless the proposed use, decided by domestic law, corresponds to an important public interest reason and is consistent with the international law of human rights" (Article 16a). Although this provision is ambiguous, it seems that a general consent for future uses of data and samples may be permissible under certain conditions.

37 WHO Regional Office for Europe, *Genetic Databases: Assessing the Benefits and the Impact on Human and Patients' Rights, A Report for the World Health Organisation's European Partnership on Patients' Rights and Citizens' Empowerment* (Geneva: WHO, 2001). The report suggests that "participants should be informed of the possibility of future uses of data, beyond the limits of the present consent" (p. 12), but recognizes that "in some cases it might be desirable to seek broad, open-ended consent to future research, the purposes, limits or consequences of which are currently unknown. In such cases, blanket future consent is only permissible where anonymity can be guaranteed, and there is no risk that unexpected results will filter back to the subjects concerned" (p. 14). Strangely, the report considers also that departure from the practice of requiring active informed consent prior to the participation in the creation of a genetic database could be legitimate when some conditions are fulfilled: "(a) a clear, realisable and significant public health benefit must be identified, (b) the widest possible educational programme must be instituted among the population that will participate, including an opportunity for public debate, (c) strong privacy protection measures must be implemented, (d) individuals must at all times be given the opportunity to refuse to participate, and (e) every stage of the process must be subject to the most stringent ethical scrutiny" (p. 16).

may involve a risk to the physical integrity of participants. Rather, in this case, the general consent only covers the use of biological material and data about an individual where there is no potential for physical harm. In such cases, provided that confidentiality is properly safeguarded and there is no possibility of other personal detriment, it is difficult to see why general consent would be intrinsically unethical. This solution seems especially reasonable if there is an independent review body that oversees research on stored data and samples. Several experts have proposed in recent times intermediate solutions of this kind.[38]

Confidentiality of data

Because of the significant harm that misuse of health information can cause to individuals, it is a widely accepted ethical and legal standard that health care professionals have a duty of confidentiality towards their patients. This is a fundamental principle of the fiduciary nature of the doctor–patient relationship and, of course, also applies to biomedical research. In the context of genetic databases for research purposes, the duty of confidentiality presupposes that researchers are not allowed to disclose participants' genetic information to third parties without donors' consent,[39] provided that such consent is in accordance with law.[40]

While all forms of personal health information have a sensitive nature, this is, for various reasons, especially true of personal genetic information.[41] The UNESCO

38 See T. Caulfield, R. Upshur, A. Daar, "DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model", *BMC Medical Ethics* 4 (2003): 1; A. Cambon-Thomsen, "The Social and Ethical Issues of Post-Genomic Human Biobanks", *Nature Genetics* 5 (2004): 866–873; Elger, "Ethical Issues of Human Genetic Databases".

39 See UNESCO, Universal Declaration on the Human Genome and Human Rights (1997): "Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions set by law" (Article 7); Council of Europe's Convention on Human Rights and Biomedicine (1997): "Everyone has the right to respect for private life in relation to information about his or her health" (Article 10.1); WMA, Declaration of Helsinki (1964–2000): "Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity…" (paragraph 21); WMA, Declaration of the Rights of the Patient (1981–1995): "(a) All identifiable information about a patient's health status, medical condition, diagnosis, prognosis and treatment and all other information of a personal kind, must be kept confidential, even after death. Exceptionally, descendants may have a right of access to information that would inform them of their health risks. (b) Confidential information can only be disclosed if the patient gives explicit consent or if expressly provided for in the law. Information can be disclosed to other health care providers only on a strictly 'need to know' basis unless the patient has given explicit consent." (Article 8).

40 This means that, in order to protect vulnerable individuals against undue pressures, domestic law can prohibit disclosure to third parties, even with the consent of data subjects. See Article 14 of the UNESCO International Declaration on Human Genetic Data (2003).

41 This does not necessarily mean falling into a "genetic exceptionalism", that is, the idea that genetic information is a completely separate category of personal data. The fact is that genetic information is not but a kind of personal health information. However, we cannot

International Declaration on Human Genetic Data of 2003 has summarized such reasons: "Human genetic data have a special status because: i) they can be predictive of genetic predispositions concerning individuals; ii) they may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs; iii) they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples; iv) they may have cultural significance for persons or groups" (Article 4). Two additional reasons for a special consideration of genetic information are provided by a report of the U.K. Human Genetics Commission: first, unlike other health data, genetic data provide uniquely identifying information because, with the exception of identical twins, each individual has a unique genetic make-up. Second, genetic information can be obtained from a very small amount of biological material (from a hair, a blood sample, and so on), without a lengthy observation or study and even without the knowledge of the person.[42]

Most guidelines on biomedical research consider coding of genetic data as a sufficient measure to protect confidentiality.[43] In this regard, an important terminological clarification is needed: Although coding is often referred to by guidelines as "anonymization" of data, one has to be aware of the fact that this term is somehow misleading since codes allow to identify individuals, provided there is access to the original encoding. This is why some guidelines prefer to use the expressions "reversible anonymization", or "pseudo-anonymization". Certainly, as experts recognize, irreversible anonymization is to a large extent impossible in the case of genetic data. Since an individual's unique identity is embedded within DNA, this identity could theoretically be revealed if an anonymized sample were matched up with another sample that has not been anonymized.[44] Despite this eventuality, which is likely to be rare, the concept of "anonymization" (with the meaning of "coding") is regarded as valid by most guidelines.[45] The fact is that in all of the large-

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deny that it has some peculiarities and raises particular issues that deserve specific solutions. See European Commission Experts Group, The 25 Recommendations on the Ethical, Legal and Social Implications of Genetic Testing (Brussels: European Commission Experts Group, 2004), Recommendation N° 3, p. 9 and the more detailed Report on Ethical, Legal and Social Aspects of Genetic Testing: Research, Development and Clinical Applications, elaborated by the same body (Brussels: European Commission Experts Group, 2004), pp. 41–45.

42 U.K. Human Genetics Commission (HGC), *Inside Information. Balancing Interests in the Use of Personal Genetic Data*, pp. 28–32; J.K. Mason, A. McCall Smith, G. Laurie, *Law and Medical Ethics* 6th ed. (London: Butterworths, 2002), p. 207.

43 See for instance, the CIOMS guidelines, according to which "secure coding" seems to be the generally accepted and sufficient protection, if combined with "restricted access to the database" (Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), Guideline 18).

44 U.K. Human Genetics Commission (HGC), *Inside Information. Balancing Interests in the Use of Personal Genetic Data*, p. 91; see also R. Wellbrock, "Datenschutzrechtliche Aspekte des Aufbaus von Biobanken für Forschungszwecke" *Medizinrecht* 2 (2003): 78.

45 U.K. Human Genetics Commission (HGC), *Inside Information. Balancing Interests in the Use of Personal Genetic Data*, p. 17.

scale databases that are being established at present, genetic data are at some point coded, so that it may be linked to databases of medical, genealogical and lifestyle information.[46] This can be explained by the circumstance that this form of research requires access to further health information about individuals.

Obviously, since the anonymization of samples and data is aimed to protect confidentiality, it is essential for the relevant codes to satisfy certain quality criteria and for them not to be easily breakable. Nevertheless, guidelines do not provide any concrete *a priori* guidance as to what degree of anonymization or coding is considered adequate. They tend to provide that the issue cannot be decided in general, but depends on the particular circumstances of the planned research.[47]

One of the main purposes of confidentiality safeguards is to prevent a misuse of genetic information to discriminate against people. The principle of non-discrimination on genetic grounds means that, for instance, employers and insurance companies are not allowed to use genetic information to affect the hiring of an individual, or the conditions of employment or of insurance. This principle is already included in several international instruments.[48] Unlike genetic discrimination, which can be prevented by law, the risk that people may be stigmatized by the results of genetic research is much more difficult to avert. Stigmatization of a certain category of people (for instance, an ethnic group) is a phenomenon that may result from the knowledge that it has a higher probability of developing a certain disease (for example, Tay-Sachs disease in Ashkenazi Jews or sickle cell anemia in Africans). Since the risk of stigmatization is especially serious in the case of population-based genetic studies, it is strongly recommended to pay "appropriate attention" to the interpretation of such studies' findings.[49]

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46 M. Austin, S. Harding, C. McElroy, "Genebanks: A Comparison of Eight Proposed International Genetic Databases", *Community Genetics* 6 (2003): 43.

47 Elger, "Ethical Issues of Human Genetic Databases", p. 187. Even the use of non-coded data is allowed if required by the nature of the research, provided that such procedure is approved by an ethical review committee and other confidentiality safeguards are established. See Article 14d of the UNESCO International Declaration on Human Genetic Data of 2003, which stipulates that genetic data and samples "can remain linked to an identifiable person, only if necessary to carry out the research and provided that the privacy of the individual and the confidentiality of the data or biological samples concerned are protected in accordance with domestic law."

48 See UNESCO, Universal Declaration on the Human Genome and Human Rights (1997): "No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity" (Article 6); UNESCO, International Declaration on Human Genetic Data (2003): "Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe, or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities" (Article 7a); Council of Europe's Convention on Human Rights and Biomedicine (1997): "Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited" (Article 11).

49 See Article 7b of the UNESCO International Declaration on Human Genetic Data (2003).

Feedback to participants

Large-scale genetic databases are normally not intended to feed back health information to donors of samples and data because they are conceived for research, not for direct clinical purposes. As mentioned above, the Estonian Genome Project is an exception in this regard, since it plans to release relevant information to participants and their physicians. But most similar projects exclude such feedback, not only because this is not their aim, but also for practical reasons, because of the difficulties of making individual contacts and of the problem of ensuring genetic counseling to all those who would like to receive information. This does not exclude, of course, that when research findings show that a number of participants are at particular risk of a condition, then this should be reported in a general feedback to all participants, for instance, through the use of newsletters.[50] In any case, it is important to ensure from the outset of the enrolment process that participants are well aware of the possibility and modalities of any feedback of information.

The perspective of a feedback raises an interesting ethical and legal issue: Do participants have a "right not to know" their own genetic information? This is not a purely academic question. Since most genetic conditions cannot be treated, the knowledge that one has a high risk of developing a serious disease may become unbearable for many people, leading them to a severe psychological depression and having a negative impact on their family life and on their social relationships in general. In such situations, "it may not be justifiable to take away hope from a person by exposing them to knowledge they do not want".[51] Therefore, it seems reasonable to allow these people to choose not to receive that potentially harmful information and to continue their lives in peace. Far from being contrary to autonomy as it might appear at a first glance, the right not to know one's genetic information can be regarded as a legitimate expression of autonomy because the decision to know or not to know is not taken out of the hands of the patient by health care professionals.[52] Precisely with this broad understanding of autonomy, the right not to know is widely recognized, for example, by the German legal literature as a part of the "right to informational self-determination" (*Recht auf informationelle Selbstbestimmung*).[53] Certainly, the right not to know, as in fact most rights, is not an absolute but a relative right, in the sense that it may be restricted when disclosure to the individual is necessary in order to avoid a risk of serious harm to family members, for instance, if that some form of prevention or treatment is available. Several recent international

50 See U.K. Human Genetics Commission (HGC), *Inside Information. Balancing Interests in the Use of Personal Genetic Data*, p. 106.

51 R. Chadwick, "The Philosophy of the Right to Know and the Right Not to Know", in R. Chadwick, M. Levitt, D. Shickle (eds), *The Right to Know and the Right Not to Know* (Aldershot: Avebury, 1997), p. 18.

52 See R. Andorno, "The Right Not to Know: An Autonomy Based Approach", *Journal of Medical Ethics* 30 (2004): 435–440.

53 J. Taupitz, "Das Recht auf Nichtwissen", in Peter Hanau, Egon Lorenz, Hans-Christoph Matthes (eds), *Festschrift für Günther Wiese* (Neuwied: Luchterhand Verlag, 1998), pp. 583–602.

instruments and guidelines recognize the right not to know one's health status or, more specifically, one's genetic information.[54]

Issues of property and benefit-sharing

The establishment of population genetic databases has raised concerns about the "privatization" of human genetic resources and their exploitation for commercial purposes. In the Icelandic case, as mentioned above, there was particular criticism of the monopoly that was granted to a single private company to make a profit with health data and genetic information of an entire nation. The unease with a purely for-profit approach to human genetic resources is even greater if one maintains that the human genome should be regarded as a "common heritage of humanity"[55] and that genetic databases are "global public goods".[56] Therefore, it is clear that one of the key issues that emerges in this field is the proper balance between the private and public domain in managing such infrastructure for research. In the last few years various alternatives to the proprietary model have been proposed for managing genetic databases. One of the most promising ones is that of a *trust.* In the fiduciary relationship of a trust, one person, the trustee, holds title to the property vested by the settler but has as an obligation to use it for the benefit of another, the beneficiary. In our case, the settler would be the source of the samples and the beneficiary would be the patients. Advantages of the trust model include the fact that it respects altruism of donors while ensuring that their good will is not misused, that the repository would have a duty to make the property in human material productive, and that

54 Council of Europe's Convention on Human Rights and Biomedicine (1997): "Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed" (Article 10.2); UNESCO, Universal Declaration on the Human Genome and Human Rights (1997): "The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected" (Article 5c); UNESCO, International Declaration on Human Genetic Data (2003): "When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results." (Article 10); WHO Guidelines on Ethical Issues in Medical Genetics and the Provision of Genetic Services (1997): "The wish of individuals and families not to know genetic information, including test results, should be respected, except in testing of newborn babies or children for treatable conditions" (Table 7); WMA Declaration of the Rights of the Patient (1981–1995): "The patient has the right not to be informed on his/her explicit request, unless required for the protection of another person's life" (Article 7d).

55 See Article 1 of the UNESCO Universal Declaration on the Human Genome and Human Rights (1997); Human Genome Organization (HUGO) Ethics Committee, Statement on Benefit-Sharing, April 9, 2000.

56 B.M. Knoppers, C. Fecteau, "Human Genomic Databases: A Global Public Good?", *European Journal of Health Law* 10 (2003): 27–41.

fiduciary law recognizes the power imbalance between the settler/beneficiaries and the trustee.[57]

Other concerns focus on whether benefits resulting from database findings should be shared with participants and, if so, what could be a fair way of sharing. The issue is complex because it appears to contradict a long ethical tradition according to which research subjects are not allowed to receive payments for their participation in a study if such rewards are "so large as to persuade them to take undue risks" or if "they undermine a person's capacity to exercise free choice".[58] This principle is clearly aimed to avoid coercion and to prevent the exploitation of poor people. However, one has to bear in mind that genetic research puts the issue in a different light than traditional biomedical research because participants in genetic studies are not assuming any particular bodily risk and, after all, they are making their biological samples and data available to the database. Therefore, why could they not somehow benefit from the profit resulting from research based on the use of their material and data? Alas, the issue is not so simple because, in addition to the norm that proscribes payment to research subjects, there is the more general principle of non-commercialization of body parts, which is included in several international instruments.[59] This principle is a corollary of the idea of human dignity and means that body parts and tissues (like blood) should not be bought or sold, or give rise to financial gain for the person from whom they have been removed or for a third party.[60] In connection with this, it is interesting to note that neither the Icelandic nor the Estonian laws recognize any share of benefits to the donors of samples and data.[61]

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57 D. Dickenson, "Property in Tissue: New Models", paper submitted to the Launch Workshop of the Property Regulation in European Science, Ethics and Law (PropEur) Project, April 1, 2004, University of Birmingham. Available online at http://www.propeur.bham.ac.uk/ See also D.E. Winickoff, R.N. Winickoff, "The Charitable Trust as a Model for Genomic Biobanks", *The New England Journal of Medicine* 349 (2003): 1180–1184; German National Ethics Council (Nationaler Ethikrat) and French National Advisory Committee on Ethics (Comité consultatif national d'éthique), "Joint Declaration by the NER and the CCNE Supplementing Their Opinions on Biobanks", (2003), in German National Ethics Council (ed.), *Biobanks for Research* (Berlin: German National Ethics Council, 2004), pp. 101–102.

58 See Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects 2002, Guideline 7.

59 See Council of Europe's *Convention on Human Rights and Biomedicine*: "Prohibition of financial gain: The human body and its parts shall not, as such, give rise to financial gain." (Article 21); UNESCO, *Universal Declaration on the Human Genome and Human Rights* (1997): "The human genome in its natural state shall not give rise to financial gains" (Article 4).

60 This principle does not exclude however that technical acts (sampling, testing, pasteurisation, purification, storage, culture, transport,and so on), which are carried out on the basis of human materials, may legitimately give rise to reasonable remuneration for those who performed such acts. See *Explanatory Report to the European Convention on Human Rights and Biomedicine*, paragraph 132.

61 The Estonian Human Genes Research Act explicitly proscribes the payment of fees to donors of samples and data (Article 15.3).

An analogous dilemma is posed by benefit-sharing at a population level, because there has been criticism that data collected in developing countries will promote profit for the sponsors and bring no benefit to the community from which the samples and data are obtained. Moreover, fear has been expressed that in this case even an apparently generous benefit-sharing would be "merely bribing people to become commodities".[62] In spite of this latter criticism, it seems to us preferable in the current circumstances to promote some form of benefit-sharing at a population level (even at the risk that this could be seen as a "bribe") rather than allowing a whole community to be exploited without obtaining any benefit. In this respect, it has been said that "in population studies, benefit to the population has become one of the critical issues in determining the ethical justification for the study itself, and sharing benefits with the population is critical in preventing exploitation".[63] Several proposals have been made suggesting various ways in which benefits can be shared at a population level. For instance, the Human Genome Organization Ethics Committee proposed that 1 to 3% of the net profit from genetic research should be returned to healthcare infrastructure and/or to humanitarian efforts.[64] Also UNESCO has suggested various forms of benefit-sharing with the society from which the data are obtained.[65]

Conclusion

The setting up of large-scale population databases poses new challenges to human rights, especially regarding informed consent, confidentiality of data, discrimination

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62 D. Dickenson, "Consent, Commodification and Benefit-Sharing in Genetic Research", *Developing World Bioethics* 4/2 (2004), p. 119.

63 G.J. Annas, "Reforming Informed Consent to Genetic Research", *Journal of the American Medical Association* (JAMA) 286/18 (2001), p. 2327. See also U.S. National Research Council. Committee on Genome Diversity, *Evaluating Human Genetic Diversity* (Washington, D.C.: National Academy Press, 1997), p. 57: "[A] common theme in the international reaction to calls for human genome diversity research is concern over potential commercial exploitation of the participating individuals and social groups. The concern is extrapolated from the experiences of indigenous peoples with expatriate pharmaceutical and agricultural research efforts that led to commercially profitable discoveries for the sponsors but not for the peoples whose natural resources were used."

64 Human Genome Organization (HUGO) Ethics Committee, *Statement on Benefit-Sharing*, April 9, 2000.

65 See Article 19(a) of the UNESCO *International Declaration on Human Genetic Data* (2003): "Sharing of benefits: In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms: (i) special assistance to the persons and groups that have taken part in the research; (ii) access to medical care; (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research; (iv) support for health services; (v) capacity-building facilities for research purposes; (vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems."

on genetic grounds, feedback to participants, and issues of property and benefit-sharing. In this regard, the comparison of the Icelandic and the Estonian experiences is very fruitful, because it shows that the new ethical and legal issues should be adequately addressed at the very beginning of the process. In sum, in the search for solutions to the emerging dilemmas it appears especially important to ensure an open, public and transparent debate about the implications of genetic databases; to require an explicit and specific informed consent of participants, at least for the initial collection of data; to recognize the right of participants to decide not to receive potentially harmful information about themselves; to apply high-quality confidentiality safeguards; to prevent genetic discrimination; to involve independent ethics committees to guarantee compliance with ethical and legal standards; to avoid the creation of databases based on purely commercial criteria and to establish some mechanism of benefit-sharing with society.

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Chapter 3

Intellectual Property Rights and the Right to Health: Considering the Case of Access to Medicines

Alyna C. Smith

Introduction

Access to medicines is without a doubt an important issue for public health, and the 192 countries with World Health Organization (WHO) membership have acknowledged this repeatedly in their endorsement of resolutions and programs in this regard. Notably, on May 18, 2002, the World Health Assembly adopted a resolution entitled "ensuring accessibility of essential medicines", which called upon the WHO, among other things:

> to pursue all diplomatic and political opportunities aimed at overcoming barriers to access to essential medicines, collaborating with Member States in order to make these medicines accessible and affordable to the people who need them.[1]

The same resolution makes specific reference in its opening paragraph to the World Trade Organization (WTO)'s Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), and more particularly the TRIPS Declaration on public health which emerged from the Doha round of negotiations, explicitly linking access to medicines with intellectual property rights. This is not surprising, in view of the historical background to the Doha Declaration, which was importantly influenced by acrimonious battles over access to antiretroviral (ARV) treatment to treat HIV/AIDS patients, particularly in lower income countries.

Indeed, it is unfortunate that the access to medicines debate has frequently been very polarized, and often framed as a contest between economic interests, on the one hand and human well-being, on the other – or, more acutely, in terms of rent-earning and monopoly-permitting intellectual property rights versus the plight of the poor and sick, who have a basic right to medicines and care. Indeed, human rights language has in recent years become an important part of the arsenal of public health and civil society groups in raising the profile of the issues and the need for action.

In this chapter, I consider the basic tension at bottom of this debate, which I argue in part is a consequence of the kind of things that medicines are, and then consider

1 Ensuring Accessibility of Essential Medicines, WHA55.14, May 18, 2002, available at http://www.who.int/gb/ebwha/pdf_files/WHA55/ewha5514.pdf, accessed June 8, 2005.

what a human rights framework brings to the debate in terms of suggesting a way forward.

Basic human right or ordinary commodity: the dual character of pharmaceutical products

Drugs are funny things. Like fast food chains, the trademarks of multinational drug companies are often well known, and their products recognizable as commodities that can enhance people's lives in innumerable ways. But drugs are also increasingly considered vital to the most basic aspects of our quality of life, and in some cases, our survival. For people suffering from debilitating illness, drugs are akin to basic necessities, like food and water that can preserve, improve or prolong life.

It is this dual character of pharmaceutical products that underpins much of the tension that exists in the access to medicines debate. More and more commonly, advocates of increased affordability and accessibility of life-saving drugs invoke human rights language, linking the imperative to make available drugs to the intrinsic rights of persons. Human rights are based on an acknowledgement of the basic "dignity and worth of the human person"; if access to medicines is a human right, then it becomes a moral and legal imperative. International human rights law, which found its first incarnation in the Universal Declaration of 1948,[2] in essence defines the relationship between states and their citizens. Granting that the right to have access to medicines flows from the right to health imposes specific obligations on the part of governments.

But it is not principally governments that create or manufacture drugs. Indeed, the discovery, development, manufacture and sale of pharmaceuticals has, for the past three decades, been dominated by the pharmaceutical industry, which has emerged as a powerful sector of the economy in more industrialized countries. The private sector, albeit with critical contributions from public or publicly funded research institutions, has developed a high degree of specialization in the often complex work of conducting research and development to generate therapeutic products. In one regard, it is precisely because of the relative success of the private sector in generating drugs with perceived social value that there is a debate in the first place about the right to access these products. The right to access medicines therefore depends in the first place on the existence (or the likelihood of the existence) of medicines. But according to international human rights law, governments are nevertheless accountable for the provision of basic essential goods and services. Though the private sector is the institutional engine behind the production of pharmaceutical products, governments can and have had a great deal of influence over their behavior, through regulation and well as through the funding of scientific research programs, the fruits of which often feed efforts in the private sector. One tension, then, that arises in considering the dual character of drugs is with regard to the respective roles of the state and private sector entities in the discovery, development and delivery of drugs.

2 United Nations (UN) General Assembly, Universal Declaration of Human Rights, 1948, available at http://www.un.org/Overview/rights.html, accessed June 8, 2005.

A related tension is ideological, and relates to the differing ways in which social good is believed to be best achieved – that is, through free markets and global capitalism or through government intervention. Human rights can be seen by some to suggest more of the latter, insofar as it puts the onus on governments to take responsibility for rights embedded in international law. But those in favor of freer and less-regulated markets as the best way to achieve long-term social gain are generally opposed to an increased role for governments, which they perceive as inefficient and lacking the requisite expertise. For people faced with the acute realities of disease and suffering, it may appear perverse to question the special status of medicines or the need for governments to intervene to ensure access. But the position that markets deserve protecting, and that they indeed serve the long-term best interests of consumers, is a powerful; for its proponents, denying private rights is perverse because it undercuts the model which under girds the present economic system that is the principal generator of pharmaceutical innovation.

It has been argued that medicines should be treated as commodities for the simple reason that private markets have proven themselves to be far more efficient at the creation and distributing goods than public mechanisms. In this view, not only are medicines as a class not special, as only one among innumerable goods that can improve or extend our lives; furthermore, while it may well be that we should prefer outcomes that are biased towards the poor, it does not necessarily follow that we should favor government-driven process over market process. That conclusion depends on some further argument to show that the outcome of political processes is likely to modify the market outcome towards equality and not away from it – that the poor can be expected to do better on the political market than on the economic market. In other words, "there is no adequate theory of government behavior that implies that government would choose to do the right things – that its intervention would make things better rather than worse".[3]

Others are equally skeptical that governments can be relied upon to meet the task of improving access to medicines, albeit for very different reasons.[4] One author makes the case for health as meriting special status, and of the pragmatic work that can be done by health and allied professionals, including those in the social sciences, to advance economic and social rights. He therefore puts his faith not in markets but in civil society, communities and health professionals to advance a cause that governments are too often, in his view, incapable or unwilling to take forward.

The rest of this chapter considers in more detail what a human rights framework has to say about the right to health, and more specifically what a right to health framework, from the point of view of existing medicines and from the standpoint of those that do not yet exist, suggests could (or should) be the role of both states and non-state actors in better respecting, protecting and fulfilling this right.

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3 D. Friedman, "Should Medicine Be a Commodity: An Economist's Perspective", in T. Bole, W.B. Bondeson (eds), *Rights to Health Care* (Dordrecht: Kluwer Academic Publishers, 1991), pp. 259–307.

4 P. Farmer, "Pathologies of Power: Rethinking Health and Human Rights", *American Journal of Public Health* 89(10) (1999): 1486–1496.

What is the right to health?

The right to health is a core element of the work of the World Health Organization. It its preamble, WHO's 1948 Constitution states that the "enjoyment of the highest attainable standard is one of the fundamental rights of every human being, without distinction of race, religion, political belief, economic or social condition".[5] The Constitution itself is clear that WHO's objective is no less than the attainment by all peoples of this standard.

Table 3.1 The right to health in international instruments

UNICESCR	Universal Declaration of Human Rights	WHO Constitution
Article 12 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) the provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child (b) the improvement of all aspects of environmental and industrial hygiene (c) the prevention, treatment, and control of epidemic, endemic, occupational, and other diseases (d) the creation of condition which would assure to all medical service and medical attention in the event of sickness.	***Article 25*** (1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.	***Preamble*** The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. ***The Organization's objective*** The attainment by all peoples of the highest possible level of health.

5 See WHO Constitution (1948), available at http://www.who.int/about/en/.

WHO defines health as a "state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity". With this definition, WHO establishes a universal goal to strive towards perpetually. This is in contrast to the Universal Declaration of Human Rights, adopted by the United Nations (UN) General Assembly in 1948, where the word "health" appears only once (see Table 3.1) and in a much more limited way. The International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966), which came into being nearly twenty years later, requires parties to the Covenant to "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and lays out in a more concrete fashion the specific steps that should be taken by states to achieve the fulfillment of this right.

Article 12 of the ICESCR, along with Article 25 of the Universal Declaration of Human Rights, explicate the content of the right to health, and in the former case enumerate a list that is not intended to be exhaustive of States parties' obligations with respect to the this right. These include:

a) the provision for the reduction of the stillbirth rate and of infant mortality and for the healthy development of the child;
b) the improvement of all aspects of environmental and industrial hygiene;
c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases;
d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

In its General Comment No. 14 on Article 12, the Committee on Economic, Social and Cultural Rights (CESCR) elaborates on the obligations of states to respect, protect and fulfill the right to health. Notably, in addition to the obligations laid out in Article 12, the General Comment enumerates core obligations, which include the provision of essential drugs (as defined by WHO).[6] Moreover, it emphasizes that it is incumbent on states and "other actors in a position to assist" to provide international assistance and cooperation, especially economic and technical, to enable developing countries to fulfill obligations under the Covenant. Although the General Comments of the CESCR (Committee on Economic, Social and Cultural Rights) do not have legally binding effect, they are considered authoritative guidance on clarifying the contents of rights and obligations enshrined in the Covenant. They therefore constitute an important foundation for arguments that treat access to essential drugs as a right, and entails particular obligations on states.

Human rights have a moral and legal authority, which add an important dimension to the access to medicines movement. Moreover, this authority is not trivial; most countries have already acknowledged the primacy of human rights by signing and ratifying the international agreements in which they are enshrined, and many have further made provision in national constitutions and legislation. But governments' obligations are not intended to be understood as utopian. In this regard, the notion of progressive realization is an essential part of human rights law,

6 For more information, see http://www.who.int/medicines/.

because it acknowledges the inevitable resource limitations that impose constraints on the ability of governments and other actors to fully advance the right to health. It nevertheless imposes an actual responsibility to move forward in as effective and expedient a manner as possible, and through concrete and targeted measures, towards the realization of this right.[7] For instance, the right to the "highest attainable standard" of health implicitly acknowledges practical limitations, both in terms of the biology of the organism in question as well as economic and social constraints.

At a minimum, human rights, and the right to health in particular, prescribe that States have an obligation to give consideration to the health implications of their policies. Health policies, as well as *inter alia* those addressing trade, the environment and commerce, should be equally subject to assessments as to their impact on the right to health. Once a policy has been shown, based on reliable evidence, to undermine the right to health, countries need not cast it aside out of turn; they are, however, obliged to take concrete steps to ameliorate the policy or rule so that it advances rather than hampers achievement of the right to health. The emphasis on evaluation based on reliable evidence, and by means of transparent mechanisms, are important and often under recognized components of a human rights approach.

According to Gruskin and Tarantola, "[h]uman rights are progressively being understood to offer an approach for considering the broader societal dimensions and contexts of the wellbeing of individuals and populations, and therefore to be of utility to all concerned with health".[8] Such an emphasis on bettering the lot of the poor, marginalized and displaced has also been said to be important on equity grounds – that is, on the basis of a particular view of what is required by distributive justice, and which is independent of the specific consequences of the action in question. In other words, focusing on so-called vulnerable groups is just the right thing to do.[9] In another view, it is good policy to focus on these groups, because by giving them systematic consideration, one is most likely to get at the root cause of many health-related challenges. This view, then, claims that focusing on vulnerable groups is not only good in itself – it's also, at least in the long run, good policy.

The right to health and the right to access medicines

What is access and to which medicines?

It is useful to consider first what it means to have "access" to medicines, and human rights provide helpful guidance in this regard. The right to health has four interrelated and essential dimensions, whose application depends on the conditions prevailing

7 Preliminary Report of the Special Rapporteur to the UN General Assembly, A/58/427, October 10, 2003.

8 S. Gruskin, D. Tarantola, "Health and Human Rights", in R. Detels et al. (eds), *The Oxford Textbook of Public Health*, 4th ed. (Oxford: Oxford University Press, 2003), pp. 311–335.

9 P. Braveman, S. Gruskin, "Poverty, Equity, Human Rights and Health", Bulletin of the World Health Organization, 81(7) (2003): 539–545.

in a particular country: availability, accessibility, acceptability and quality.[10] These frame distinct indicators of governments' success in advancing the right to health. "Availability" requires that medicines be on hand in sufficient quantities within the country, while "accessibility" requires that all sections of the population, without discrimination, be within physical reach of and able to afford them. "Acceptability" relates to the degree to which medicines are ethically and culturally appropriate, and "quality" refers to their scientific and medical appropriateness. This means that a failure to have access to quality medicines that are within reasonable reach and at an affordable price is a human rights issue and individuals have recourse to the law to hold states accountable.

In the next section, we consider what kinds of medicines one can legitimately claim a right to have access to. It is useful to think of medicines in terms of three categories: essential medicines, new medicines, and medicines that do not yet exist.[11] Though they overlap, these categories provide a means of identifying issues that may be particular to medicines of a certain kind. We deal with the third category of drug in the next section, when we discuss the question of innovation and the right to access medicines.

Essential medicines

Not all medicines are equal, at least in terms of their social value. WHO acknowledged this when it defined the category of essential medicines, namely:

> [T]hose that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.[12]

The great majority of essential medicines are off-patent. This is not surprising in view of the criterion of cost-effectiveness, because off-patent generic copies of drugs tend to be less expensive than patented drugs. Often off-patent drugs also have the advantage of having been on the market for a long time, and therefore having proven themselves through years of use.

Because essential medicines are often older drugs, it may be easy to assume that they are necessarily of low cost and adequate efficacy, and that the principal obstacle is *accessibility*, or more particularly, inadequate health infrastructure to appropriately deliver medicines. But this assumption is undermined by the existence of drugs, often for the most neglected diseases, that are old and off-patent, but also expensive and of inadequate effectiveness. For instance, antifungal treatment for leishmaniasis is U.S.$200, beyond the reach of many who suffer from the disease

10 CESCR, General Comment No. 14 (2000). E/C.12/2000/4.

11 M.R. Reich, "The Global Drug Gap", *Science* 287 (2000): 1979–1981.

12 http://www.who.int/medicines/.

in the absence of subsidized care. According to one report,[13] treatments for other neglected conditions like Buruli ulcer and sleeping sickness are by and large "old, toxic and difficult to use, requiring hospitalization, well-equipped clinics and trained staff", or "are parenteral in use, need multiple administrations, have serious side effects and are increasingly becoming ineffective due to resistance". The report concludes: "Simpler, more effective drugs and diagnostics are needed, designed for use in resource-poor settings". We can seen, then, that affordability remains a problem for some essential medicines and the appropriateness of treatments for use in resource-settings can leave much to be desired.

On the one hand, there is WHO Model List of Essential Medicines, which is updated each year subject to decisions by an expert committee. On the other hand, there is the intuition that many ordinary people have about the "essential" quality of medicines, as more akin to life's basic necessities than to commodities. In one regard, this intuition about medicines is not unlike intuitions we may have about some other categories of goods, such as food. Indeed, comparing branded medicines and well-known trademarks like McDonald's is a useful comparison for a number of reasons. First, McDonald's is an international mega-franchise "with more than 30,000 local restaurants serving nearly 50 million people in more than 119 countries each day".[14] It is therefore unambiguously a success story for global capitalism. Second, McDonald's is in the food sector, and food, like medicines, is considered an essential good for human well-being. Indeed, Article 11 of the ICESRC states:

1. The States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps to ensure the realization of this right, recognizing to this effect the essential importance of international co-operation based on free consent.
2. The States Parties to the present Covenant, recognizing the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programmes… (emphasis added).

International law has, therefore, protected the right of everyone to adequate food, and related right to be free from hunger. But "food" is a broad category. When development agencies bring food supplies, they bring staples, like rice and flour and sugar. For the purposes of our present discussion, we can consider that Big Macs are not unlike a significant proportion of medicines that would not be naturally classed by most people as "essential", though they may provide some very real benefit. The standard examples are treatments for male pattern baldness and acne, conditions that can be the cause of considerable mental suffering for those who have them, but which are unlikely to find their way onto the essential drug list of any country. This is not to deny their value; it is only to point out that it is different, and that the

13 Caines 2004.

14 See http://www.mcdonalds.com/corp/about.html, accessed March 29, 2006.

right to access this species of goods is weak, though the right to the good, itself, is irrefutable.

We see, then, that the concept of "essential medicines" has both a descriptive element and a normative one. For a product to find its way on the Model List of Essential Medicines is to identify certain of its features according to pre-established criteria. The drugs on this list are *de facto* "essential medicines". But "essential medicines", whether understood intuitively or as defined by WHO, address "priority public health needs" – that is, their public health (and by association, their social) value is higher than other sorts of drugs. In other words, essential medicines are not just any medicines: they describe a sub-category that is not only different but somehow special, to the extent that there is an expectation that governments will take measures to make them widely available.

One point that we come to later is the responsibility that large multinational companies might share with states in the advancement of human rights. We note that there is a growing recognition that the impact of private companies on the health of populations is often considerable. One suggestion of this is WHO's increasing engagement with companies outside the health sector, in particular tobacco and food producers, to diminish the negative impact of their products on human health. To date, the response on the part of particular companies has been voluntary, though WHO recently launched the first ever health treaty, the Framework Convention on Tobacco Control, which requires signatory states to impose wide-ranging regulation on the activities of the tobacco manufacturers and, indirectly, on the behavior of smokers, with the explicit aim of reducing health risk in the population.

New drugs

The second category we consider here is new medicines, whose main producers are multinational pharmaceutical companies. This category is not watertight, and does have important points of convergence with the other categories of medicines. For instance, new drugs can be essential medicines. For instance, WHO recently added several patented drugs, all antiretrovirals, to its Model List, a move precipitated by the extent of the devastation of the HIV/AIDS, and the lack of effective alternatives. Indeed, one common criticism levied against pharmaceutical companies is with regard to the proportion of new drugs that address "priority health needs", and in particular neglected diseases. Critics often cite a recent study which found that, between 1978 and 1999, 2.4% of new chemical entities (NCE) approved were for HIV/AIDS, tuberculosis and malaria, and 0.9% for tropical diseases.[15]

A more broad-ranging concern relates to the pharmaceutical industry's ability to produce genuinely innovative products, irrespective of the therapeutic category. A report by the United States Food and Drug Administration (FDA) in 2004 notes a marked downward trend in the number of NCEs submitted since the early 1990s.[16]

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15 P. Trouiller et al., "Drug Development for Neglected Diseases: A Deficient Market and Public-Health Policy Failure", *Lancet* 359 (2002): 2188–2194.

16 United States Food and Drug Administration (FDA), Innovation and Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products (2004), available at

The implication is that fewer truly novel drugs are coming out of the research pipeline. An initiative has been set up by the U.S. government to identify "critical paths" that can facilitate the translation of biomedical research into new products of therapeutic value. This tack sees the faltering number of NCE applications as an important technical challenge, relating to the state of science. Another view sees the decline as importantly related to companies' investment into research and development as compared, for instance, to the amount invested in the marketing of their products. In part, this behavior is taken to be the natural response by companies to incentives that spur them to concentrate on making relatively minor changes to existing products, which may be rewarded by patent protection or other market exclusivities, rather than investing in the creation and development of breakthrough treatments.

Intellectual property is unquestionably one of the major drivers of pharmaceutical research and development; pharmaceutical companies often cite the reputedly high costs and high uncertainty associated with drug development, and the consequent need to be assured a protected market for products that make it all the way through the pipeline.[17] The question, from the point of view of those concerned with advancing public health goals, is whether patents provide incentives to produce the right *kinds* of therapeutic products – in other words, products that introduce substantive therapeutic improvements over existing treatments, which address existing treatment gaps such as for neglected diseases, or which introduce adaptations to existing drugs that make them suitable for use in low-income settings.

If we think in terms of the four dimensions described earlier – availability, accessibility, acceptability and quality – we can ask whether new drugs address the needs of poorer populations. The answer in most instances is that they do not, either because they do not exist (as in the case of dengue fever) and are therefore by definition unavailable; because they address important health burdens (for example, cancer, cardiovascular disease) but are inaccessible because they are too expensive or poorly adapted for use in low-income settings; or because they are unacceptable, in terms of their safety and efficacy (as in the case of sleeping sickness). This is largely because existing incentive structures encourage pharmaceutical companies to invest in the creation of products targeting those with purchasing power. So even though useful products exist that address real health needs affecting populations worldwide, the more economically disadvantaged do not share equally in their benefits.

For pharmaceutical products that do find their way onto the market, less industrialized countries often wait much longer to gain access to new treatments than wealthier markets. A recent study shows that approximately 98% of new drugs marketed over the past twenty years were first launched in high and upper income countries, with only a 9% chance of being launched in a low or middle income country within two years.[18]

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http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html.

17 International Federation of Pharmaceutical Manufacturers Associations (IFPMA), *Pharmaceutical Innovation Platform: Sustaining Better Health for Patients Worldwide.* (Geneva: IFPMA, 2004), available at http://www.who.int/intellectualproperty/Pharmaceutical_innovation.pdf.

18 J.O. Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry", background paper, WHO Commission on Intellectual Property Rights,

Access to medicines and the right to health: country examples[19]

New drugs are generally patented, and the majority of product patents are owned by multinational corporations. Some high profile cases in national courts have pitted companies against governments on the basis of perceived conflicts between the economic rights protected by companies in international agreements like TRIPS, and the rights of governments to intervene in the interest of public health. One prominent example occurred in 1998, when a group of thirty-nine pharmaceutical companies filed a lawsuit against the government of South Africa over its Medicines and Related Substances Act. The dispute centered on Amendment 15(c) of the Act, which would allow compulsory licensing and parallel imports of medicines in South Africa. The case was not explicitly framed as a right-to-health issue, but rather as non-compliance with international intellectual property right norms. However, the case engendered tremendous debate about the right of companies to protect their interests and the right of governments to take action that might facilitate access to medicines for their citizens. In April 2001, the pharmaceuticals companies, under high international pressure, dropped their case. The disputed amendments to the Act were ostensibly intended to address potential barriers to access posed by the price of patented treatments, and the consequent need to put in place measures to make possible the importation or local manufacture of lower cost products. This case is widely cited, and has been influential in shaping subsequent debate on access to medicines, including within international fora such as the World Trade Organization (WTO).

Other cases have challenged countries' policies regarding the adequate provision of medical products and services. For instance another South African case, brought before the Constitutional Court of South Africa, concerned a challenge to the government's policy on prevention of mother-to-child transmission of HIV, on the grounds that it violated two constitutional provisions, namely "the right to have access to health care services, including reproductive health care" (section 27) and the right of every child "to basic nutrition, shelter, basic health care services and social services" (section 28). The Court's finding was that the South African government had acted unreasonably in refusing to make a new antiretroviral drug, nevirapine, available in the public sector where the attending doctor considered it medically necessary, and not setting out a timeframe for a national program to prevent mother-to-child transmission of HIV. Nevirapine was approved by the FDA in 1996 for use in combination with nucleoside analogues in adults with HIV-1 infection. As part of a programme to deal with mother-to-child transmission of HIV, the government had imposed restrictions on the availability of nevirapine in the public sector.

Innovation and Public Health (2005), available at http://www.who.int/intellectualproperty/studies/Lanjouw_Price&LaunchFinal.pdf.

19 A. Clapham, M. Garcia Rubio, "The Obligations of States with Regard to Non-State Actors in the Context of the Right to Health", Health and Human Rights Working Paper Series No. 3, available at http://www.who.int/hhr/information/en/Series_3%20Non-State_Actors_Clapham_Rubio.pdf.

In India, the right to medical treatment in cases of emergency is not recognized, as such, in the country's constitution as a fundamental right, but only referred to in the Directive Principles of the State Policy, which are not in principle judiciable. The Constitution does, however, guarantee a right to life, and in public interest litigation cases it has been interpreted to mean not just basic existence but life befitting human dignity, so that it effectively encapsulates a right to health. In one case where a person dying due to the non-availability of medical treatment came before the Supreme Court, it was confirmed that the right to medical treatment is a Fundamental Right of the people until Article 21 of the Constitution:

> There can be no second opinion that preservation of human life is of paramount importance.… The patient whether he be an innocent person or be a criminal liable to punishment under the laws of the society, it is the obligation of those who are in charge of the health of the community to preserve life so that the innocent may be protected and the guilty punished….

Innovation and the right to health

The third category of drugs – those that do not yet exist – is most closely related to research, because it concerns not products as such, but *potential* products that are the fruit of the research process. It is here where we consider in more depth the specific question of intellectual property rights (especially patents) in relation to human rights, because patents are widely seen to be key elements of the research process, not only in the private sector but also increasingly in public research institutions.

In this section, we consider three issues that pertain to innovation and the right to health: the distinction between intellectual property rights and human rights, the need to balance respect for the rights of inventors and the rights of society more generally, and what human rights says about the role of actors – both state and non-state – in assuring the creation of useful products.

Intellectual property and human rights

Patents create incentives for companies to make products for a market that will reward their time and investment. In other words, patents protect innovative activity, but they do not themselves distinguish between products of high social value and those of low social value.[20]

In 2000, the Committee on Economic, Social and Cultural Rights published a Statement on human rights and intellectual property rights, and the preparation of a General Comment on the topic is presently under discussion.[21] The document is useful for at least two reasons: first, it marks the distinction between human rights and intellectual property rights, and second, makes it clear that there is an

20 Unless one is prepared to accept that social value correlates strongly, for drugs as well as other products, with the size of the market and how much it is willing to pay.

21 CESCR, Statement by the Committee on Economic, Social and Cultural Rights. Human Rights and Intellectual Property. E/C.12/2001/15, December 2001.

expectation that human rights regimes and treaties (including TRIPS) be consistent with international human rights law.

The Committee notes that "human rights are fundamental, inalienable and universal entitlements belonging to individuals", whereas "intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits".[22] Moreover, intellectual property rights can be revoked, limited in time and scope, licensed, traded, amended, assigned or forfeited. This makes it clear that human rights and intellectual property rights have fundamentally different origins: the former arise from the basic dignity of persons in which they inhere, and the latter from State-imposed economic systems. The Committee makes a further distinction, which spells out an important difference in terms of who they protect:

> Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments.

In other words, while it may be the case the intellectual property systems have economic and social value, it cannot be taken as given that they protect or advance human welfare and well-being.

The right to health and the right to enjoy the benefits of scientific progress

Though it does not go into great detail, the CESCR in Comment No. 14 points to the importance of finding an appropriate balance between two components of Article 15.1 of the ICESCR, which appear to address different parts of the innovation equation. Namely, there is a need to balance the rights:

(b) To enjoy the benefits of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.[23]

In particular, there is an important debate ongoing about whether Article 15.1(c) encompasses intellectual property rights. On the one hand, section (c) makes reference to the authors of scientific products, which suggests that inventions may qualify and consequently that patents protecting the "moral and material interests" of the author can be said to constitute a means of fulfilling this right. On the other hand, the historical reasons for the inclusion of section (c) within Article 15 suggest a stricter scope limited to the protection of copyright. This view draws a line between inventions and works of art on the basic assumption that the latter represent genuinely original works of imagination that would not otherwise have existed had it not been for the artist in question. This is in contrast to inventions which, being more closely

22 Ibid.
23 CESCR, General Comment No. 14 (2000). E/C.12/2000/4.

link to the state of the art, are on this view more likely to come into being through the ingenuity of any number of individuals.

In any case, the latter argument still accepts that section (c) encompasses intellectual property; it merely restricts the form of intellectual property covered to copyright. One point that seems clear, particularly in view of the Committee's Statement on Intellectual Property Rights and Human Rights, is that section (c) should not be taken to give intellectual property rights the status of human rights. Even if it is granted that intellectual property rights is one acceptable means of protecting the rights of authors, as the Committee has articulated, it does not follow that intellectual property in whatever form should be taken *prima facie* to advance human well-being – whether it be the well-being of the inventor (who often does not hold the rights to his or her invention) or the well-being of the wider society (which depends on many other conditionalities).

Some take the position, usually on strategic rather than on strictly legal grounds, that intellectual property right is not in *any* way captured in section (c), either as a human right or more weakly a means of advancing this particular right. Behind this stance is a concern that attaching intellectual property rights in any way to section (c) is politically dangerous and leaves the door open for interpretations that lean towards augmenting the status of intellectual property rights or blurring their role, as purely economic policy tools into something more foundational and less contestable.

Section (b) makes it clear that all people have a right to benefit from scientific progress, which implicitly includes existing tools, interventions and knowledge as well as those that do not yet exist. This part of Article 15 therefore importantly connects with a host of important issues from the point of view of scientific research, from benefit sharing, access to the upstream research tools and scientific know-how, to technology transfer and international cooperation. Consistent with provisions in most high-level instruments, it does not prescribe how countries should proceed with regard to these issues; it only sets the standard, or benchmark against which to assess policy in these areas – namely, that they maximize the benefits of all people to the fruits of scientific advances.

Intellectual property across the innovation chain

If we consider the so-called innovation chain, which spans the research process from the discovery of a promising lead compound to the delivery of a final product, the issues relating to intellectual property differ, as do the actors principally engaged in patenting. For instance, at the upstream end of the chain, biotech companies and universities are often most active in basic research, both in the identification of molecular targets and the creation of platform technologies. Over the past decade, with the explosion of data coming out the various genome projects and the increasing sophistication of scientists' ability to do molecular research, it has become common in many countries to patent so-called biotechnological inventions, which include sequences of DNA and other tools that are themselves not final products in the standard sense but instead feed back into the research process. Most notably, those doing the patenting tend not to be pharmaceutical companies, but small biotech companies and public sector institutions. The United States government, for

instance, through its National Institutes for Health (NIH) owns the most patents on gene sequences of any institution in the country, public or private.[24] The patenting of research tools and platform technologies has, as a result, become an important issue in the overall debate about access to medicines, in part because of concerns that proprietary claims on upstream tools pose potential barriers, by introducing new layers of costs and administrative complexity to research in the health sector. The evidence is inconclusive as to the true extent of the problem. In many instances, researchers have found ways to work around patents on research tools, either by entering into licensing agreements or by infringing the patents outright.

In the product development stage of research, patents become a vital tool to companies more often engaged in this phase of the process – namely, multinational pharmaceutical firms – and this less because patents are valuable assets for trading and attracting capital (as is the case for biotech firms), but because they promise market exclusivity at the end of the long and costly road of product development and clinical testing. What is at issue for the public-health minded is whether this road leads to final products of clinical value, and whether the market exclusivity conferred by patents on new products encourages companies to recoup heavy R&D costs by charging high prices that make them unaffordable for some segments of the population. These are issues that are highly relevant within the context of the right to health, and the related right to access medicines. If the structure of the present R&D system, including the incentives to which public and private sector actors naturally respond, fails systematically to generate products suitable for some groups – particularly if they are the poor and marginalized – then there is an expectation either to modify the system or to redress the imbalance through other measures. Because the existence of medicines is so dependent today on the activity and productivity of companies that operate chiefly on financial incentives, the question of how to balance measures to encourage innovation and measures to ensure widespread benefit of its fruits is central to the challenge facing governments in advancing the right to health.

Human rights articulates the expectation, and demands that frameworks be put in place to transparently assess the extent to which it is met in practice; it does not, however, stipulate how the balance can or should be struck. Countries are left to decide on their own on the most suitably policies, which is probably well advised, given the particularities of their situations.

One way of considering the implications of human rights standards in practice is to consider their relevance or application in defining the obligations of particular actors. This is our task in the next section.

States, non-state actors and human rights obligations

It was after World War II when the importance of human rights in bringing accountability to government action was widely recognized. Human rights are therefore principally concerned with the relationship between the individual and the

24 WHO, Genetics, Genomics and the Patenting of DNA 2005, available at http://www.who.int/genomics/FullReport.pdf, accessed June 8, 2006.

state and international human rights law, in essence, defines what governments can do, what they cannot do, and what they should do.[25]

More particularly governments have an obligation to *respect*, *protect* and *fulfill* human rights. This means that they must refrain from interfering in the enjoyment in the right to health, including through denying equal access to all persons to care; they must take measures to prevent third parties from interfering in enjoyment of the right to health; and, finally, they have positive obligations to actively facilitate, provide and promote enjoyment of the right to health through appropriate policies and other measures.[26] Moreover, states have an obligation to respect the enjoyment of the right to health in other countries, providing necessary aid when required. This means refraining at all times from imposing embargos or other measures, or entering into agreements, that restrict another countries' ability to advance the right to health for their citizens. It is states, then, that bear principal responsibility for making quality drugs and other health products (and services) available, acceptable and accessible to their people, without discrimination. But where a government is incapable of achieving this due to severely limited resources, other governments are bound to provide assistance, and may not impede its ability to meet its obligations.

In addition to their obligation to their own citizens, states have an obligation to take steps, individually and through international assistance and cooperation, towards the full realization of the right to health more generally. This entails, as pointed out by Paul Hunt, the UN Special Rapporteur on the Right to Health,

> respect for enjoyment of the right to health in other jurisdictions, to ensure that no international agreement or policy adversely impacts upon the right to health, and that their representatives in international organizations take due account of the right to health, as well as the obligation of international assistance and cooperation, in all policy-making matters.[27]

Moreover, while states have primary responsibility for the realization of international human rights, all actors in society, including individuals, local communities, intergovernmental and non-governmental organizations, health professionals and private companies, have responsibilities regarding the realization of the right to health.

Of note, the Universal Declaration of Human Rights – the first human rights instrument to make reference to the right to health – is not addressed only to governments. This is evident from its introductory paragraph, which states:

> This Universal Declaration of Human Rights as a common standard of achievement for all peoples and all nations, to the end that *every individual and every organ of society*, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and

25 Gruskin, Tarantola, "Health and Human Rights".

26 Ibid.

27 P. Hunt, "Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations", *WHO Health and Human Rights Working Paper Series* No. 4 (Geneva: WHO, 2003), available at http://www.who.int/hhr/news/en/Series_4_neglected%20diseases_social_justice_human_rights%20Paul_Hunt.pdf.

> international, to secure their universal and effective recognition and observation, both among the peoples of the Member States themselves and among the peoples of territories under their jurisdiction (emphasis added).

A resolution recently adopted by the UN Sub-Commission on the Promotion and Protection of Human Rights underlines the fact that, even though states have the primary responsibility towards human rights, "transnational corporations and other business enterprises, *as organs of society*, are also responsible for promoting and securing the human rights set forth in the Universal Declaration of Human Rights".[28] Furthermore, the resolution emphasizes that companies, too, have a duty to respect and contribute towards the realization of the right to health and refrain from actions that obstruct or impede the realization of this right.

Pharmaceutical companies

The role of states is changing, and non-state actors have an increasing power to affect people's lives. One author laments:

> We lag behind trade and finance, since we are still at the first steps in the press for universal rights while the "masters of the universe" are already "harmonizing" their own standards and practices.[29]

This is a decidedly pessimistic comment, but it nevertheless reflects a growing view that larger forces are operating on a global level, but their impact is felt at local levels. The existence of multinational companies whose staff number in the tens of thousands and whose assets are more than some small countries, has important implications for their influence on government agendas and their market dominance on the lives of consumers.

Klaus Leisinger, President and Director of the Novartis Foundation for Sustainable Development, notes:

> As transnational corporations are seen to be the principal drivers of globalization and also its primary beneficiaries, they are increasingly expected to fulfill obligations that go beyond what national laws require and certainly beyond the satisfaction of short-term stakeholder interests.[30]

It is clear that governments still have considerable power both to advance and to hinder the ability of their citizens to enjoy the fullness of the right to health. But it is also increasingly clear that their ability to do so is constrained by binding international agreements, the policies of international financing institutions, and

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28 Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, E/CN.4/2002/13.

29 Farmer, "Pathologies of Power".

30 K.M. Leisinger, "The Corporate Social Responsibility of the Pharmaceutical Industry: Idealism Without Illusion and Realism without Resignation" (Washington, D.C., 2003), available at http://www.iipi.org/Conferences/IP&Health/leisinger_paper.pdf, accessed May 30, 2005.

the claims of private companies with growing economic and political clout. Some have argued that, in view of their mounting influence on the health and lives of individuals, there is a consequent need to revisit the responsibility of non-state actors in the advancement of human rights.[31]

The argument in favor of increased responsibility for pharmaceutical companies in the advancement of humanitarian-oriented health goals can be made on several levels. First, it can be argued that companies should, on a voluntary basis, do what they can to facilitate access to critical medicines, and indeed many companies have established donation programs, drug discovery facilities focused on neglected or tropical diseases, and have entered into partnerships with the public sector to conduct research in areas that advance an area of strictly public interest. Companies, particularly large pharmaceutical firms, have a real interest in undertaking such voluntary programs. Given their vast revenues, the financial loss is relatively small, but the reputational gain is enormous. Moreover, for many companies, there has been a strong incentive to engage in such initiatives, and broader activities that tend to fall under the rubric of "corporate social responsibility". The pharmaceutical industry, until recent years among the most trusted institutions in industrialized countries, is widely perceived to be facing difficulties in terms of public trust and reputation today.[32] A recent survey conducted of eight major pharmaceutical companies revealed an extensive range of activities undertaken under the heading of corporate social responsibility.[33] For smaller companies, such voluntary programs are less likely to be feasible or sustainable, unless financial incentives are part of the package. Though attractive, hanging the responsibility of firms purely on good will poses the problem that there is no guarantee that the present largesse of companies will continue. There are diverse social and economic factors that make it in the overall interests of companies to invest in projects of high social value and their engagement depends on whether the compelling factors continue to find traction; if the social and economic climate changes, and it is no longer in the interest of companies to contribute to socially valuable programs, then there is no recourse to insist that they continue.

Second, it has been argued that companies have an indirect obligation to respect, protect and fulfill human rights, including the right to health. As we saw, the introduction to the Universal Declaration makes it clear that its statutes are addressed to "organs of society", which would include private entities such as drug companies. It its General Comment on the right to health, the Committee has also stated that:

> Payment for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, *whether*

31 Leisinger, "The Corporate Social Responsibility"; M.T. Kamminga, "Corporate Obligations under International Law", paper presented at 71st Conference of the International Law Association, August 17, 2004.

32 Environics: The Millennium Poll (New York, 1999); and Edelman Public Relations World Wide (Poll, November 2001).

33 Claudia Trezza, WHO (unpublished data).

> *privately or publicly provided*, are affordable for all, including socially disadvantaged groups.[34]

The basic responsibility, on this view, still lies with the state; however, companies can indirectly be held accountable, insofar as they administer products or services to which the public has a right. In this instance, the principal responsibility borne directly by all companies across sectors is the assurance of working conditions that meet appropriate health and safety standards, and the treatment of research subjects in a manner consistent with legal and ethical norms.

A third position is that companies have a direct obligation to contribute to the advancement of the right to health. This is argued in part on the grounds that their responsibility should be commensurate with their "sphere of influence" – that is, with the extent of their impact on the lives of individuals. Given the growing political and economic power of the pharmaceutical industry, there is a concomitant requirement to respect, protect and fulfill the rights of citizens whose lives they affect. There are several challenges to this position. The first is whether expanding human rights, which were first conceived to define the relationship between the state and the individual, is a legitimate move in legal terms. The second is whether, even were it legally justifiable, it is politically or tactically desirable. For instance, some fear that "treating corporations in the same way we treat states may implicitly suggest that corporations have the right and obligation to take on state like functions".[35]

A recent paper on health and human rights has argued that:

> From a health and human rights perspective, the desirable forms and extent of responsibility for multinational actors within the international legal system have yet to be defined in ways that help to shape international trade agreements effectively and to ensure their accountability. This is the next and most important challenge in the world of human rights, and it will have far-reaching health consequences.[36]

There is a great deal of controversy about whether human rights do, or should, impose direct and binding obligations on non-state actors, and in the case of the right to access medicines, on the producers of medicines (namely, pharmaceutical companies). There is the further question of whether imposing binding obligations on corporations is in fact necessary, given the widespread involvement of companies in philanthropic health-related activities, from donation programs to drug discovery firms dedicated to identifying drug targets for neglected diseases. Historically, codes of conduct have been designed to create voluntary standards incorporating obligations on the treatment of employees, environmental issues and regulations on employment policy and social policy. Many codes of conduct have been

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34 CESCR, General Comment No.14, E/C.12/2000/4, at para. 12(b)(iii), emphasis added.

35 D.S. Weissbrodt, "Non-State Entities and Human Rights within the Context of the Nation-State in the 21st Century", in M. Castermans-Holleman, F. van Hoof, J. Smith (eds), *The Role of the Nation-State in the 21st Century: Human Rights, International Organisations and Foreign Policy* (The Hague, Boston, London: Kluwer Law International 1998), pp. 175–195.

36 Gruskin, Tarantola, "Health and Human Rights".

developed by companies themselves, but several international codes also exist. For instance, the International Standards Organization has established standards of good practice relating to companies in global markets, and addressing three dimensions of company performance: economic, environmental and social. The International Labor Organization has published the Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy, and the United Nations has published the Draft Norms for the Responsibilities of Transnational Corporations, which are widely seen as the most comprehensive code of conduct to date.

However, the most widely recognized code of conduct is the Global Compact, created at the Davos World Economic Forum on January 31, 1999 "to support the participation of both the private sector and other social actors to advance responsible corporate citizenship and universal social and environmental principles to meet the challenges of globalization". According to the Global Compact Office:

> Human rights are a key priority for the Global Compact Office as there exists a fundamental lack of understanding on the part of many actors concerning the operational meaning of the human rights principles. In part, this is because human rights have traditionally been the concern of states, and international human rights law has generally been addressed to them only.[37]

The Global Compact Office sees its role as providing clarity and guidance for companies on their own role in the implementation of human rights. But though it incorporates human rights principles, participation in the compact is entirely voluntary. As of May 2005, over 2,000 companies participate in the Global Compact.

An important underlying question is what constitutes a fair societal division of labor. According to one author, one industry representative has proposed a schema to describe the three categories of activities that companies can engage in, comprising what they must do to simply exist (namely, abide by existing laws and regulation), what they ought to do as good corporate citizens and what they can do, within their means, that would be worthy of public praise.[38] The argument is that it is in companies' interest to move beyond the category of "must" and towards "can" – but that this requires "enlightened leadership" and vision, rather than the imposition of binding guidelines. In part, this is because companies generally favor flexibility in pursuing activities that suit their mission and resources.

In any case, the critical point to make is that if it is granted that corporations, like states and other actors, have responsibilities, these responsibilities should be definite and limited. Corporations, no more than countries, can provide the whole solution to problems of the scale of those that exist in relation to access to medicines. Sustainable solutions require the involvement of actors in civil society, including companies, together with governments and donors shouldering responsibility, given their competencies.

Paul Hunt, the UN Special Rapporteur on the Right to Health, has called for the establishment of a group of experts to define the rights and responsibilities of the pharmaceutical industry and public a report, including concrete proposals for action.

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37 http://www.unglobalcompact.org/Portal/Default.asp?.

38 Leisinger, "The Corporate Social Responsibility".

This would be followed by a three-year pilot during which time ad-hoc experts would periodically review the policies and practices of pharmaceutical companies in relation to the right to health, and then produce reports and non-binding recommendations for companies.

International organizations

In its General Comment on the right to health, the ICESCR Committee refers to "obligations of actors other than states parties", referring specifically to United Nations agencies and programs at the international, regional and country levels. The Committee encourages cooperation among the agencies in the realization of the right to health, and that states avail themselves of the technical expertise residing in these bodies.

The World Trade Organization, the World Bank and the International Monetary Fund are included among those who have a responsibility to "cooperate effectively with States parties, building on their respective expertise, in relation to the implementation of the right to health at the national level".[39] The World Intellectual Property Organization (WIPO), though not mentioned specifically, is presumably also included among the agencies addressed. These institutions do not, of course, exist outside of the globalizing forces that are presently shaping the world; rather, they are key players in promoting economic growth, trade, health and development, goals that some might argue are not easily reconciled. The difficulty in aligning the mandates of these agencies with an overall aim of promoting the right to health, and relating economic and social rights, is made manifest in the current experience of WIPO, which is being pushed to adopt a more "development-centered" approach to its work. WIPO's objective, according to the Convention that established it, is twofold:

i) to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization,
ii) to ensure administrative cooperation among the Unions.

Given the disagreements that we have touched upon briefly above about the merits of markets in advancing the public good and the related value of intellectual property in addressing inequities, WIPO is facing an important political challenge from those countries and civil society groups pressing for its reform. The WTO, for its part, has faced regular attacks from anti-globalization movements, and more specifically from advocates who claim that, through the harmonization of intellectual property systems globally, it serves the interests of private companies to the detriment of the poor. With regard to the right to health, however, WTO's members made an

39 CESCR, General Comment No. 14 (2000), The right to the highest attainable standard of health, E/C.12/2999/4.

important political statement in their adoption of the Doha Declaration on the TRIPS Agreement and Public Health (2001), which asserts:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

This statement explicitly accepts the primacy of health-related considerations over strict economic rules or interest, and in this way implicitly accepts the right to health as preeminent over the right of companies to the legal protection of their commodities. It is important to note that the Doha Declaration refers to "access to medicines", and not to any subclass of medicines, essential or otherwise.

In terms of the specific nature of the obligation of international organizations under human rights law, many of the arguments that we have sketched before for corporations apply equally here. Two important differences are the centrality of human rights within the UN Charter[40] and the fact that UN agencies are accountable to governments, in whom human rights obligations reside directly. In this sense, then, it could be said that UN bodies are bound directly, through their own statutes, and indirectly, through the obligations of their members, to comply with and to advance human rights norms.

Civil society

As we have seen, non-state actors are held to some degree of responsibility under human rights law. Furthermore, it has been explicitly argued that human rights are best served by an increased role of non-governmental organizations as well as other civil society groups, in part because of the perceived impotence or apathy of governments. Bringing in a health-centered approach also suggests bringing in expertise of a more clinical or health-focused nature, arguably turning the tide in more pragmatic directions by mobilizing those who can directly address some of the basic causes of inequalities. In a certain sense, this argument claims that an approach that takes seriously the social and economic determinants of health goes further than poverty, and finds that health is often at the bottom of inequality.

In concrete terms, human rights law and the bodies that monitor it cannot police nations. Consequently, the extent to which governments adhere to international law is largely a component of pressure from the international community – other governments, civil society groups, and so on – that invoke their responsibilities, in cases where governments themselves do not take the initiative. There is pessimism on some fronts about the extent to which human rights have the teeth to bring about real change:

40 UN Charter, available at http://www.un.org/aboutun/charter/.

> No one doubts that there exists a norm prohibiting torture. No state denies the existence of such a norm; and, indeed, it is widely recognized as a customary rule of international law by national courts. But it is equally clear from, for example, the reports of Amnesty International, that *the great majority* of states systematically engage in torture. If one takes the view that noncompliance is relevant to the retention of normative quality, are we to conclude that there is not really any prohibition of torture under customary international law?[41]

Nevertheless, the growing use of human rights language in public health spheres, and vice versa, suggests an increase in the degree of international consensus, which one can hope will translate into increased pressure on governments to live up to their obligations. As recently noted by Hans Hagerzeil (2003) of WHO's Department of Essential Drugs and Medicines:

> By the end of 2002, 142 States parties had signed and ratified the International Covenant [on Economic, Social and Cultural Rights]; 109 countries have the right to health incorporated in the constitution; and 83 countries have ratified one more regional treaties which include aspects of the fundamental right to health. All the world's countries are bound by one or more of these instruments. These commitments can be used as a tool for public pressure on national governments by nationals or national NGOs.

Pressure is therefore a critical mechanism for bringing about change, by leveraging the moral and legal authority of human rights law. According to one investigation, 67% of the constitutions of all nations have provisions regarding health and health care important for efforts to promote recognition and implementation of the international human right to health.[42] In particular, it identified five types of constitutional provisions that address health and health care in national constitutions:

1. A statement of *aspiration* stating a goal in relation to the health of its citizens.
2. A statement of *entitlement* stating a right to health or health care or public health services.
3. A statement of *duty* imposing a duty to provide health care or public health services.
4. A *programmatic* statement specifying approaches for the financing, delivery or regulation of health care.
5. A *referential* statement incorporating by specific reference any international or regional human rights treaties recognizing a human right to health or health care.[43]

Nevertheless, the authors note that: "It is clear that not all of the countries which have provisions regarding health and health care in their constitutions have in practice lived up to these mandates". They nevertheless conclude that:

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41 R. Higgins, cited in Farmer, "Pathologies of Power".

42 E.D. Kinney, B.A. Clark, "Provisions for Health and Health Care in the Constitutions of the Countries of the World", *Cornell International Law Journal* 37 (2004): 285–355.

43 Ibid., p. 290.

> Policy imperatives created by constitutional provisions and international human rights treaties can be used as standards for the evaluation of government performance with respect to the realization of economic and social rights. They can also be used as a basis of political advocacy.[44]

Civil society therefore can play a critical role in invoking human rights not only to raise the flag in relation to potential human rights concerns, but also to propose appropriate remedies on the part of states and other actors. Civil society groups, in particular non-governmental organizations, have a long history of effective work at the grass-roots level; they are therefore well placed both to sound the alarm when important issues emerge, and to work with other groups to mobilize initiatives effective in addressing the problem.

Conclusions

Within the context of access to medicines discussions, human rights (in particular the right to health) and intellectual property rights are often pitted against each other. This, I argue, is at least partly due to the peculiar thing that medicines are: both commodities that are the product of an IP-centric market system, and "essential" goods that can contribute significantly to quality of life and even to basic human survival. This dual character makes it easy to set up the debate as a contest between dueling – and incompatible – interests.

In the foregoing, we have seen that access to medicines is indeed a legitimate and core component of the right to health, as is the right to benefit from the fruits of scientific progress. Situating "access to medicines" within a human rights framework has a number of specific advantages:

- *It orients the debate towards the poor and marginalized*. A human rights approach is intrinsically preoccupied with the impact of various policies and rules on the welfare of the poorest and more marginalized.
- *It provides a model to facilitate a more systematic tracking of the obstacles impeding the enjoyment of the right to access medicines.* An important schema employed in human rights in the analysis of policies is based on assessing the degree to which *access*, *availability* and *quality* are promoted.
- *It provides a lever for advocacy.* All countries in the world are bound by one or more human rights treaties, which embody basic human values explicitly endorsed by nations, and bolstered by law. This provides a powerful base for advocacy, and for putting pressure on states to meet their obligations.
- *It links access-related issues to explicit freedoms and entitlements, duties and obligations.* Rights, while grounded in fundamental values, are themselves tied to concrete entitlements, on the one hand, and obligations, on the other. This means that the values in question provide a foundation of shared ideals, from which flow explicit expectations, attached to particular actors.

44 Ibid., p. 301.

- *It sets high, but not utopian, standards.* Through the notion of progressive realizability, human rights acknowledges that inevitable limitations in resources that impose constraints on the ability of governments and other actors to fully realize the right to health. However, it nevertheless imposes an actual responsibility to move forward in as effective and expedient a manner as possible, and through concrete and targeted measures, towards the realization of this right. The UN-Sub-Commission on the Promotion and Protection of Human Rights likewise acknowledges that a major challenge to access to medicines is the allocation of scarce resources, which will require a stepwise and gradual approach, but one which nevertheless is committed to continuous improvement.

But even in acknowledging these advantages, a critical question remains: given the nature and scale of the challenge in assuring access to medicines, what is an equitable and sustainable division of labor for the actors involved? In other words, *who* is responsible, and precisely *what for*?

We have seen that human rights have traditionally defined the relationship between states and their citizens, and international human rights instruments spell out the duties and obligations of governments. But the subject that is now on the horizon is the extent to which human rights imposes real obligations – either direct or indirect – on *non*-state actors, including multinational organizations, civil society groups and NGOs, and international organizations. The legal and pragmatic basis for extending human rights to these groups is still a matter of deep and widespread scholarly and political debate, but the shifting balance of international power suggests that these debates are timely. One industry representative has noted:[45]

> The immense poverty related health problems of the worlds [*sic*] destitute have become a challenging frame of reference for a new corporate social responsibility debate for the research-based pharmaceutical industry.

What is clear is that the complexity and magnitude of the problem requires a multi-stakeholder approach. This implies that obligations would best be linked the specific competencies and "spheres of influence" of various actors, and suggests that a vital first step is to identify who are the players whose engagement is critical to advancing access to medicines within the context of the right to health. It further implies that a process should be set in motion whereby these actors can come together in order to arrive at some basic agreement about the nature and scale of the problem, and the particular nature and scale of their respective contribution to a solution.

The highly publicized contest between human rights and intellectual property rights can be explained in terms of the differing ideological views about how to reach publicly and economically ends, and the consequent trickiness of the sorting out the status of medicines. But this contest is unproductive: it fails to see that the ultimate end – the good of patients – is served by fostering both the continued productivity of the industry, which is responsible for the bulk of innovation in the pharmaceutical

45 Leisinger, "The Corporate Social Responsibility".

sector, and a very active role for *other* actors, most notably governments and civil society.

In a certain respect, there can be no contest between human rights and intellectual property rights, because they are different things serving different purposes: the right to health is a fundamental right linked to the dignity of persons, whereas intellectual property rights are economic tools to advance particular policy objectives. In essence, a human rights approach would appear to suggest that *everyone* has *some* duty, and an implicit obligation on the part of all actors is a willingness to work together to advance the right to health. So while a human rights framework leaves some space to discuss and deliberate about the nature and extent of these duties, it leaves it beyond any doubt that they exist and that we are all accountable for our efforts to take the issue forward.

Chapter 4

International Protection of Human Genetic Data – The UNESCO Declaration on Human Genetic Data and the Possible Impact on Genetic Governance Models

Tobias Schulte in den Bäumen

Introduction

After the completion of the first chapters of the Human Genome Project, the use and abuse of human genetic data has become a focus of international awareness concerning human genetics. This awareness has led to some – not binding – international agreements on the protection of human genetic information, and the idea of special protection for genetic data is being transferred to the national legislation to a greater degree. Legislators are merely using two different approaches to protect individuals: either the direct prohibition of discrimination or the protection of genetic privacy.[1] Yet, on a global level, no widely acknowledged legislative approach or conceptual framework has been developed to shape the technical transformation of the aims of fair protection and the sharing of genetic data into model of governance for genetics.[2] UNESCO has tried to provide an answer with its Declaration on Human Genetic Data, offering new guidelines for national legislators, as well as a platform for international discourse regarding the potential threats and benefits of human genetics.

1 S.M. Suter, "The Allure and Peril of Genetic Exceptionalism: Do We Need Special Genetics Legislation?", Working Paper No. 19, George Washington University (2001), p. 26.

2 RAND has urged that "efforts to control biotechnology will run into the same practical hurdles as the attempts to control IT". Any national control of genetic privacy might be undermined by the effectiveness of the global information and logistics structure. As information is becoming global, human genetic information is becoming global as well. See F. Fukuyama, C.S. Wagner, *Information and Biological Revolutions: Global Governance Challenges – Summary of a Study Group* (Santa Monica: RAND Publications, 2000).

The medical, public health and fundamental rights model according to Lori B. Andrews[3]

As the uncertainty regarding the future impact of human genetics remains noticeable, legislators need to outline potential implications for the social, legal and political framework of society. As few authors have developed a shared conceptual mode, an article by Lori B. Andrews shall therefore serve as a benchmark for further analysis. Andrews names potential frameworks for genetic technologies and it should be noted in advance that all of them are ethically acceptable despite the fact that all of them have implications which may potentially be ethically unacceptable.[4] None of the concepts mentioned are necessarily suitable as a global framework for a model of governance as they reflect merely a "western" approach to ethics and genetics. They should therefore serve more as guidelines for further discussion on a global level.

The medical model

The medical model has been the standard for centuries in North America and Europe where the physician has been noted as an expert who serves as a "gatekeeper" to medical knowledge.[5] The relationship between patient and physician consisted of an isolated upstream and downstream, or in short, the patient described the problem and the physician acted solely based on his or her expert knowledge without seeking the consent of the patient. The medical model has come under pressure in most western countries due to the rise of the idea of autonomy and self-determination, but most scientists argue that the concept of informed consent is rarely witnessed in practice.[6] Information and counseling are at the center of the debate of modern medicine, but, in genetic practice, the degree of disclosure is predominantly influenced by the professional standard.[7]

The public health model

The public health model has been transferred to the healthcare system due to rising concerns regarding diseases which are likely to spread amongst the population

3 L.B. Andrews, "A Conceptual Framework For Genetic Policy: Comparing The Medical, Public and Fundamental Rights Models", *Washington University Quarterly* 79 (2001): 221 ff.

4 For example, the possible rise in abortions due to modern views on public health and the deriving informal pressure on couples to abort a fetus with a less than perfect genetic equipment. See A. Asch, "Prenatal Diagnosis and Selective Abortion", in J.S. Alper et al. (eds), *The Double-Edged Helix: Social Implications of Genetics in a Diverse Society* (Baltimore, London: Johns Hopkins University Press, 2002), pp. 123 ff., also D.W. Brock, N. Daniels, "Why Not the Best?", in A. Buchanan et al., *From Chance to Choice* (Cambridge: Cambridge University Press, 2001), pp. 156–203.

5 Andrews, "A Conceptual Framework", p. 231.

6 J. Katz, *The Silent World of Doctor and Patient* (New York: Free Press, 1984).

7 For more information on standards of disclosure in common law, Andrew Grubb, *Principles of Medical Law*, 2nd ed., (Oxford: Oxford University Press, 2004), pp. 3116–3135.

if no intervention occurs on the level of the entire population. The (involuntary) participation of the population in traditional screening and information programs may be ethically justified in cases where a substantial risk exists that each member of the designated target group might transmit the disease through voluntary contact with infected and healthy persons, or in cases when large population groups set necessary conditions for the "infection" of other healthy groups (for example, smoking). The dimension of public health aspects for the further development of genetic services is an underdeveloped issue in many European countries, for example, in Germany, but U.S. scientists such as Khoury[8] view genetics as the ultimate tool for the preservation of public health. To date, the idea of public health is most predominant in prenatal and newborn testing, but further extension to other (multi-factorial) diseases, such as adiposities, seems to be inevitable. This might be supported by the fact that only few therapeutic options exist to cure or ameliorate genetic conditions and therefore the public health related idea of prevention might become the main focus of genetic health policies.[9]

The fundamental rights model

The third model has a reverse notion of health care services when compared with the public health model, as autonomy, self-determination and voluntariness are central to this approach. Health is not seen as a public but as an individual good, with the individual having the control to define his or her own desired health standard, as well as selecting ethically valid measures to reach this individual standard.[10] Therefore "any use of a particular health care service…must be voluntary and uncoerced".[11] As any participation in genetic research or any use of a genetic service must be voluntary according to this concept, no discriminating pressure should be put on patients and groups of patients. Voluntariness also requires the existence of different options, in the sense that more than just a yes/no decision exists. These options need financial support and, therefore, the fundamental rights model also advocates the public funding of genetic services in cases where the creation of options is not in agreement with the economic limits of health care plans and personal insurance.

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8 M.J. Khoury, "From Genes to Public Health: The Application of Genetic Technology in Disease Prevention", *American Journal of Public Health* 86(12) (1996): 1717–22.

9 A.E. Guttmacher, F.S. Collins, "Ethical, Legal, and Social Implications of Genomic Medicine", *New England Journal of Medicine*, 2003: 562 ff. [567 f.]; for Germany, see A. Brand et al., *Gesundheitssicherung im Zeitalter der Genomforschung* (Bielefeld: Friedrich Ebert Stiftung, 2004).

10 Therefore the Fundamental Rights Model does not imply a specific notion of medical knowledge. The execution of fundamental or inalienable rights, as they are also called, may have a negative impact on the health state of the individual. Accepting fundamental rights requires accepting illogical and harmful decisions; also see T. McConnell, *Inalienable Rights – The Limits of Consent in Medicine and the Law* (New York: Oxford University Press, 2000).

11 Andrews, "A Conceptual Framework", p. 238.

The possible impact on genetic governance

If we evaluate the potential impact of these models of governance and the UNESCO Declaration on Human Genetic Data on legislation, it seems to be necessary to reconsider the meaning of governance in this context. Governance is described as the attempt to control, direct, shape or regulate human activities. It has been a function of the state in the past but revolutionary developments in sectors, such as biotechnology, have shown that new models of governance need to be introduced. Different solutions have been described within in the three different models Andrews uses in her argumentation. The medical model seems to be an expert system, with medical experts setting the standards of access to genetics and with regard to the feasibility of genetic services,[12] whereas the public health model combines medical (scientific) knowledge with ideas of political utilitarianism, setting genetic standards in a top-down process in accordance with public needs and financial limits. The fundamental rights model seems to follow a different approach, as it is highly individualistic and is not based on an inherent notion of medical knowledge. Whereas the first two models require material rules designed to balance all possible conflicts, the last model calls for a genetic dispute resolution mechanism rather than a set of strict rules.

The governance-related contents of UNESCO International Declaration on Human Genetic Data

Aim and scope

According to Article 1(a), the declaration has the broadest possible aim of preserving human rights and human dignity. Even if this is not immediately obvious, the main addressees are states and other legislative bodies,for example, professional groups and their internal guidelines on best practice. Following the Anglo-American tradition, the declaration defines the use of terms in Article 2. Human genetic data is defined as information on the heritable characteristics of an individual, a definition that opens up potential for dispute. With regards to complex genetic diseases and the idea of prevention, one may doubt the logic of differentiation between purely genetic information and information about the environment/external risks of the person concerned in the fields of multifactorial diseases.

Individuality and the right to dispose of genetic data

To date, the individuality of each human being is an undisputed presumption of the declaration that is shared with other declarations, agreements and legislative acts around the globe. Individuality leads to the question of to which extent the individual is authorized to endue her or his genetic data. So far, two different ideas

12 Regarding the impact of intra-professional codes on privacy, see Leino-Kilpi et al., *Patients Autonomy, Privacy and Informed Consent* (Amsterdam: IOS Press, 2000), pp. 40 ff.

have been raised in order to integrate the right to endue genetic data into the legal system: in the Anglo-American sphere, predominantly the idea of property rights,[13] and in central Europe, the approach of privacy as a personal right derived from human nature and dignity.[14] Taking a look at other fields of law where governance is a subject of debate, there is a model which has not yet been considered with regard to human genetics: the idea of the human genome as an open source of mankind. The Icelandic model may come close to it, but with the transfer of genetic knowledge to the private sphere, the genome is used as a resource and not as a source for further "open" research in the best interests of society. Thus, this article will focus on property and privacy as the fundamental distinction in legal reasoning in the field of human genetics.

Rule and Hunter have advocated property rights in personal data as they "generate a new balance of power".[15] Laurie has supported this view, stressing that the concept of "ownership…is a strong and significant means by which to control and to protect our interests".[16] According to these authors, the market for data offers the individual the opportunity to weigh up the pros and cons of disclosure, offering the right to individually judge the desired level of protection for genetic data. The concept of ownership in genetic data refers to a market model, giving the individual the opportunity to ask for a monetary or non-monetary compensation for the "sale" of genetic data.[17] This concept of ownership rights is criticized by researchers who give higher priority to research, arguing that these rights would lead to an obstruction of scientific work.[18] In consequence, this criticism is shared by researchers from non–common-law countries, as ownership might cause the concern that an absolutistic view on data and ownership in data might prevail over the necessary process of balancing the different interests and rights involved.

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13 Regarding property and personality, see J.A. Bovenberg, *Property Rights in Blood, Genes and Data: Naturally Yours?* (Leiden: Martinus Nijhoff Publishers, 2005); H. Beverley-Smith, W.R. Cornish, F. Dessemontet (eds), *The Commercial Appropriation of Personality* (Cambridge: Cambridge University Press, 2002), pp. 273 ff.; for the genetic field, R.A. Spinello, "Property Rights in Genetic Information", *Ethics and Information Technology* 6(1) (2004), pp. 29–42; critical from a German point of view, I. Schneider, "Körper und Eigentum – Grenzverhandlungen zwischen Personen, Sachen und Subjekten", in E. Kuhlmann, R. Kollek (eds), *Konfiguration des Menschen. Biowissenschaften als Arena der Geschlechterpolitik* (Opladen: Leske + Budrich, 2002), pp. 41–59. As a legislative example, the Georgia Code 33-54-1 includes the article: "(1) Genetic information is the unique property of the individual tested…".

14 H. Hubmann, *Das Persönlichkeitsrecht*, 2nd ed. (Köln: Boehlau, 1967), pp. 85–99.

15 J. Rule, L. Hunter, "Towards Property Rights in Personal Data", in C. Bennet, R. Grant (eds), *Visions of Privacy: Policy Choices for the Digital Age* (Toronto: University of Toronto Press, 1999), pp. 168–181.

16 G. Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002), p. 317.

17 L.B. Andrews, "My Body, My Property", *Hastings Center Report* 28 (1986): 28–38.

18 R.A. Spinello, "Property Rights in Genetic Information", *Ethics and Information Technology* (2004): 29–42.

The ownership of data is a problem in itself as data may not be of value per se, but receives weight and the need for protection from the context in which it is collected or processed.[19] This might lead to the point of view that genetic data, such as any other medical data, is a product of a communication process, receiving its particular weight through an analysis and review by the people concerned and members of relevant professions.[20] In this sense, it constitutes a part of human nature as its value depends on the situation of the participants in a legally recognized situation.[21] The UNESCO declaration favors the position of referring to genetic data as being comparable to property but rejects the common market model. In its definition section in Article 2(iii), the text defines "consent" as the agreement of a person to the collection and/or processing of "his or her genetic data". The market model is seen as ethically inappropriate and the inducement of potential "donors" by financial or other personal gains to give consent is criticized. In Article 4, the declaration refers to the special status of genetic data, pointing out that genetic data may have, besides the potential predictive quality, a significant impact on the family, including offspring. In its reflection of genetic determinism in Article 3, it also acknowledges that the individual has "emotional, social, spiritual and cultural bonds with others".

The position of the declaration seems to be inconsistent because it admits that genetic data is not purely individual because it has an impact on people who share the same "gene pool" within a family.[22] UNESCO itself has mentioned the family dimension of genetic data – or in a broader sense, the data relevant to the assessment of a genetic condition within a family – in the preliminary study of the International Bioethics Committee (IBC).[23] Taking into account the relevance of the genetic data of one person ("the person concerned") for a family member, the boundaries of individuality may have two dimensions: in the case of an monogenetic or an otherwise autosomal-dominant disease, the collection of data of one person of a family discloses information about other members of the family, whereas the examination

19 Furthermore in the field of genetics, the same information may have a different impact on different mono-, polygenetic or multifactorial diseases. For a more general approach, see J.N. Druey, "Information Cannot Be Owned" (Berkman Center for Internet and Society, Harvard Law School, 2004), at http://cyber.law.harvard.edu/home/uploads/339/Druey.pdf, pp. 6 ff.

20 A position that is traditionally shared by German data protection experts; according to the "old" (pre-E.U.) German data protection law, any data receives its weight because it is assigned to a particular use or purpose. See S. Simitis (ed.), *Kommentar zum Bundesdatenschutzgesetz*, 5th ed. (Baden-Baden: Nomos Verlagsgesellschaft, 2003), §1, No. 58 ff.

21 Druey, "Information Cannot be Owned", pp. 9 ff.

22 Even more precise in the report of the UNESCO International Bioethics Committee (IBC), *Human Genetic Data: Preliminary Study by the IBC on Its Collection, Processing, Storage and Use* (Paris, 2002), p. 6 (IV 26, 27, s. 2). For complex diseases, the term "share the same risk(s)" should be added.

23 Ibid., p. 4 (III 23a).

of a polygenetic or multifactorial disease usually requires the collaboration of other members of the family or relevant sub-groups of society.[24]

Regardless whether a jurisdiction follows a property or a privacy model, consent may only be valid under the condition that the person in question has the right to dispose of the genetic data. Should the person disclose information which includes relevant genetic information of other members of the family, for example, the offspring, this person might infringe protected legal interests of these other family members.[25] With regard to the structure of the legal positions, both rights – the right to know and the right not to know – are derived from the same source and have *a priori* an identical moral value, offering the individual a right of self-determination in a field where the core of personality is at stake.[26] If the potential donor of genetic material *A* has to step back because of a contradictory "right not to know" of *B*, then *A* has never had the right to receive information about the "shared genes". The conflicts between both rights and the impact of the different models may become more apparent if we take a look at the possible interactions.

So far the elaboration of the divergence between both rights has raised the impression that we are discussing a unilateral conflict, but more dimensions have been depicted, for example, by Häyry and Takala, indicating an unsolved complication in governance.[27]

If we assume that *A* has a right to know "his" genetic constitution, then we can adhere to the statement, that:

(a) *A* has no duty to remain ignorant;
(b) others have a duty not to interfere with *A*'s quest for information;
(c) *B* has a positive duty to assist *A* in his quest for information.

If we presume that *B* has a right not to know about his genetic composition, then we can say that:

(d) *B* has no duty to know;
(e) others have a duty not to inform *B* against his will;
(f) *A* has a positive duty to assist *B* in remaining unaware.

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24 L.B. Andrews, "Gen-Etiquette: Genetic Information, Family Relationships, and Adoption", in M.A. Rothstein (ed.), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era* (New Haven, CT: Yale University Press, 1997), pp. 255–280.

25 C. Lerman et al., "Family Disclosure in Genetic Testing for Cancer Susceptibility: Determinants and Consequences", *Journal of Health Care Law & Policy* 1 (1998): 353–373.

26 Again this statement is not depending on the legal source. In a personal rights model the idea of conflicting interests is very common; in a property-based jurisdiction we face a dilemma as only the idea of a common-hold seems to be applicable in such a situation. For a bioethical explanation of the two rights and possible ethical dilemmas, see R. Andorno, "The Right Not to Know: An Autonomy Based Approach", *Journal of Medical Ethics* 30 (2004): 435–439, with a commentary by G. Laurie.

27 The following description is taken from M. Häyry, T. Takala, "Genetic Information, Rights, and Autonomy", *Theoretical Medicine* 22 (2001): 403–414.

If we analyze our findings, a concept of ownership rights which neglects the contractionary rights of other genetically related persons might be insufficient in the adjustment of the "right to know" and the "right not to know".[28] In the case of (a) we control our property according to our will and the same applies to (d).[29] In the cases of (b) and (e) the situation becomes more complex as we have to handle a so-called "negative claim right", which is still typical of a property right. The owner of the respective right has a "right to be left alone" in his decisional process or, in other words, no interference from outside can be lawful under these conditions. The cases (a), (b), (d) and (e) could be solved in the same manner under the personal rights doctrine; in (a) and (d) the respective person executes his right to autonomous self-determination, and in the cases (b) and (e) a second person is obliged to accept the autonomous decision of the counterpart. In the cases of (c) and (f), the concept of property rights inevitably comes under pressure as either *A* or *B* need to transfer their right to the counterpart without receiving a remuneration. Presuming that both rights have the same ethical value, we face a legal dilemma as neither *A* nor *B* is forced to hand over his property against his will. *A priori*, neither of them has a duty to assist in this case, ergo, a person who executes his right infringes upon the right of a counterpart under the property rights model. The personal rights model might be able to avoid this conflict, as the question has to be posed in a different manner: whose right is more valuable?

A solution is more complex than the declaration tries to convey to its addressees. On the level of interpersonal conflicts, the declaration does not offer a solution, prescribing the need of a valid consent without setting limits to the free disposition of genetic data of the person who is donating the biological material. The IBC report mentions the dilemma of genetic relations within a family in section IV, "General Issues Concerning Human Genetic Data": "Because families share genes, it can sometimes be very difficult to protect the right of one person to know about his or her genetic future while simultaneously protecting the right of a related person not to know".[30] Nevertheless, the report refers to the free and informed consent as recognized in Articles 5 and 9 of the UNESCO Universal Declaration on the Human Genome and Human Rights in Part VIII(b), "Autonomy and Freedom". In a research context, the IBC limits, without quoting specific reasons, the consent to the "person", stating in its Guideline 11 that the informed consent of the person from whom the biological sample is collected is sufficient for a valid justification. The problem of contradictory interests within families may have been recognized but it is far from being solved.

28 Laurie, *Genetic Privacy*, p. 317, seems to disagree, when he argues: "Property protection is, however, by no means an absolute, and as with all our other legal rights, property rights can be tempered in our own interests or in those of others". A further analysis of national property rights regimes might be necessary to give a definite answer. An allusion to neighbor rights or other potentially conflicting property rights may be a little on the short side if the necessary transferal of genetic property is included into the debate.

29 Häyry, Takala, "Genetic Information", p. 404, call this a "licence".

30 UNESCO IBC, *Human Genetic Data*, p. 6 (IV 27, s. 2).

A third concept revives the concept of property rights, replacing sole ownership with a partly collective ownership of those people sharing particular genetic information as a common heritage. Consequently, this would lead to the necessity for a statutory acknowledgement of a family or group consent (when common information is involved) and its procedural consideration.[31] If we think of a shareholder right, we ought to also consider whether one person should have the right to execute his or her will despite the denial of access of other co-owners. An ethical mandatory instruction that is derived from the idea of humanity as the right to privacy and the right to self-determination is the ethical value of healing. Thus, in the property rights model, the competence to consent without a compulsory consultation of family members could be restricted to data where disclosure and processing enables the person concerned to choose a therapeutic option which is capable of preventing a serious disorder, ameliorate the conditions of a disease or have an impact on a reproductive decision if the potential disorder is of significant importance. A property right in this sense would be subject to a social restriction preserving the property rights of other family members in cases where a preponderance of the "right to know" may not be detected. As a consequence the growing knowledge regarding medical applications of genetic data requires dynamic, procedural governance, which enables community and family members to limit or to prohibit the use of co-shared information unless a course of action is available to cure or to alleviate a disease.

Purposes of data collection

Along with other international regulations, the UNESCO Declaration on Human Genetic Data seeks an answer to the challenge deriving from the unparalleled opportunities of the collection of genetic data. The text includes a non-exhaustive enumeration, starting with diagnosis and health care, medical and other scientific research, forensic medicine and legal proceedings, as well as any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and international law of human rights. Regarding the three aspects mentioned by the declaration itself – medical care, research and legal proceedings – the declaration is rather reluctant to offer a definition or a more in-depth view of the problems related to these fields of data collection and processing. Medical purposes have always been an ethically valid purpose to collect data, either against the background of personal medical care or under the aspect of public health and epidemiology.[32] The historical importance of personal rights and the recognition of informed consent[33] as a legally and ethically necessary condition for an invasion into personal rights have implied

31 For communities see C. Weijer, E. Emanuel, "Protecting Communities in Biomedical Research", *Science* 289 (2000): 1142–1144; from a point of view of genetic scientists, see B. Godard et al., "Data Storage and DNA Banking for Biomedical Research: Informed Consent, Confidentiality, Quality Issues, Ownership, Return of Benefits", *European Journal of Human Genetics* 11 (2003), Supp. 2: S88–S122.

32 R. Faden, T.L. Beauchamp, N.P. King, *A History and Theory of Informed Consent* (Oxford: Oxford University Press, 1986) pp. 60 ff., showing that the traditional medical model implies the use of data without any consent.

33 Instead of informed consent the concept of informed contracts might be used as well.

a growing significance of the self-determination of sound people.[34] The more the individual is granted the definitive power to consider genetic conditions as being healthy or not, the more the reference to medical and genetic knowledge is blurred. Further individualization of the idea of health could obstruct the validity of health as a criterion to justify data collection and/or processing. Health could be replaced by risks, uncertainty and fear as relevant indications in the genetic era. As both aspects complicate the validity of the informed consent principle, the following question needs to be considered: does the purpose of health care require that the declaration needs to be tied up to an "old-fashioned" medical indication leading to a course of action[35], as argued above?

Medical care is only one purpose mentioned in the text of the declaration. In Article 5(ii), the text refers to research for medical and non-medical purposes as a valid and justifying reason to collect and process genetic data.[36] Amongst the specific research areas mentioned, epidemiology, anthropology and archaeology are allocated particular importance. The current demand for genetic data is significantly affected by the scientific uncertainty in the field of genetics and therefore the research aspect remains at the center of the data protection discussion. The development of biobanks in Iceland and Estonia has aroused attention regarding threats deriving from genetic research as a result of data collected in biobanks.[37] In these biobank projects, a huge bulk of genetic and non-genetic data is collected and stored for an indefinite period of time without a particular research objective. The current knowledge regarding the function of genes and the structure of the different types of genetic diseases requires a preliminary collection of data without a particular application being at stake.[38] RAND has underlined that the current development in global genetic research amplifies the need for global governance as the economic importance of genetic research is rising.[39] So far, existing surveys regarding the attitude towards genetic research show that even small communities are far from having a consistent position on genetic research.[40] Thus, no governance model has been fully implemented, as the public discourse has not yet reached a decision-making stage.

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34 Regarding situations when competence is questioned, see B. Cox White, *Competence to Consent* (Washington, D.C.: Georgetown University Press, 1994), pp. 7–9.

35 The German position described by R. Damm, "Gesetzgebungsprojekt Gentestgesetz", *Medizinrecht – MedR* (2004): 1–19; see pp. 9 ff.

36 An overview of development in Europe was presented by Godard et al., "Data Storage".

37 References at Spinello, "Property Rights", pp. 31–33.

38 J. Kaye, "Abandoning Informed Consent – The Case of Genetic Research in Population Collections", in R. Tutton, O. Corrigan (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (London: Routledge, 2004), pp. 117–138; see pp. 120 ff.

39 Fukuyama, Wagner, *Information and Biological Revolutions*, p. 21, arguing: "If one country or region of the world appears to be producing genetically superior individuals through its relaxed rules on biotechnology, there will be pressure for other countries to catch up."

40 Ibid., as well as the NHANES survey, as described in G.M. McQuillan et al., "Consent for Genetic Research in a General Population: The NHANES Experience", *Genetics in Medicine* 5/1 (2003): 35–42.

Protection of privacy rights by procedural regulations

As a consequence of the uncertainty in the public discourse on genetics, Article 6(a), section 1 of the declaration outlines the need for ethically acceptable and transparent procedures. This line of approach corresponds with our findings above. We have seen that a model of governance in genetics has to structure a reasonable adjustment of conflicting rights of the persons involved. The analysis has shown that a line does not need to be drawn between property and privacy rights, as both legal systems offer the possibility to balance rights according to a mandatory ethical instruction. Thus, the answer must be found in a dynamic, procedural governance model, which offers shareholders a fair opportunity to execute their interests. UNESCO encourages states to use means of direct democratic decision making to create procedural rights that reflect ethical views shared by a democratic majority or relevant (sub) groups within the community. This necessity of consent from sub-groups could potentially include the approval of relevant procedural rights by the sub-group. A democratic legitimization by the majority of society may not be able to fully compensate for the lack of self-determination inside a group. In this case, a double majority should be required to justify procedural laws, a democratic decision by society, as well as a democratic decision within a sub-group with both groups having the right to object to genetic research projects.

As already introduced in Article 16 of the Universal Declaration on the Human Genome and Human Rights, ethics committees are seen as one option to ensure ethically acceptable standards for the collection and processing of human genetic data. The declaration encourages states to promote ethics committees at all levels of decision making, assigning them to consultation in the drafting of guidelines and other standards on a state level to national committees, if appropriate under domestic law. In the case that no domestic law applicable to the collection and processing of human genetic data exists, ethics committees are intended to replace domestic legislation by drafting guidelines and other regulations.

The ethical value of decisions and guidelines drafted by ethics committees depends on the legitimization of the committee itself. As the declaration requires an independent and pluralist composition of the committees, only those member states that have equivalent structures have the opportunity to match the requirements of the declaration when appointing members of the committee.

The aspect of non-discrimination and non-stigmatization

Discrimination and stigmatization of human beings due to genetic disorders or an otherwise abnormal genetic condition are fears that have influenced the discussion regarding the use of genetic data for a long time.[41] Discrimination is of particular importance if full anonymization is not possible due to the unique structure of genetic data or due to the design of research activities, which often require follow-

41 Mostly connected to employment and insurance, for example, T. Lemmens, "Selective Justice, Genetic Discrimination and Insurance: Should We Single Out Genes in Our Laws?", *McGill Law Journal* 45/2 (2000): 347–412; see pp. 367–369.

up examinations or cross-comparisons of genetic and lifestyle data over a certain period of time. The potential threat of discrimination is merely discussed against the background of fair access to insurance and the labor market, as these two markets have an inherent tendency for customer/employee selection. Tendencies in doping[42] and research aiming at human enhancement foster the anxiety that powerful market participants might require a test in future that proves the "good" genes of applicants and insurance customers. The declaration recognizes the increasing economic importance of genetic data but the terms of discrimination and stigmatization are not defined within the text of Article 7. It chooses a clearly political approach, asking member states to ensure that genetic data is not used to discriminate against individuals, families, groups or communities. As such, an abuse of genetic data might emerge specifically from population-based research studies or behavioral genetic studies and their evaluation; both types of studies are explicitly mentioned in Article 7(b). The concept of a social contract that prohibits inequality on genetic grounds may reach its limits as behavior and lifestyle-affected genetic disorders are increasingly analyzed. If genetic factors combined with smoking cause cancer, then a non-discrimination approach might be ethically invalid if the inequality is based on smoking as a necessary condition for cancer. Many multifactorial diseases require lifestyle decisions such as smoking, drinking or unhealthy food consumption and no society has yet agreed on a social contract under which a distinction shall be made on the basis of a deliberate decision for a particularly "bad" lifestyle.

Informed consent

The principle of informed consent or closely related concepts, such as shared decision making or the idea of an informed contract, have become an integral part of international legislation regarding medical intervention and participation in research projects in the second half of the 20th century.[43] Within the declaration the informed consent principle plays a major role, not only in Article 8 where it is mentioned expressly but also in Articles 16 and 6(d). As already shown above, the idea of genetic individuality, as mentioned in Article 3, and the approach of genetic data as the property of the person concerned or as an integral part of the personality and therefore as a personal right, have a decisive impact on the principle of informed consent because they structure the range of personal disposition rights regarding human genetic data. The principle of informed consent was developed in the medical setting and therefore it is necessary to examine the roots of this concept in order to assess whether the subsequently developed application of informed consent in the data protection environment is in alignment with these roots.[44]

42 See A. Miah, *Genetically Modified Athletes – Biomedical Ethics, Gene Doping and Sports* (London: Routledge, 2004).

43 For an introduction to the principle of informed consent, see C.W. Lidz et al., *Informed Consent – A Study of Decisionmaking in Psychiatry* (New York: Guilford Press, 1984), pp. 10–23.

44 O. Corrigan, "Informed Consent – The Contradictory Ethical Safeguards in Pharmacogenetics", in R. Tutton, O. Corrigan (eds), *Genetic Databases: Socio-Ethical Issues*

Within the field of genetics, consent to the collection of data has different conditions as it is not the body (that is, an invasive procedure) but rather privacy that is at stake. The conventional concept of informed consent was based on the idea that the person concerned has the competence to decide on her or his own fate after being properly informed about risks, potential benefits and therapy options.[45] In the *Schloendorff* case, Judge Cardozo argued that "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[46] The right to self-determination as expressed by Judge Cardozo implies that every bodily invasive procedure is *a priori* forbidden from a legal point of view as long as it is not justified (in advance) by the informed consent of the person concerned. This concept is widely accepted in medical law, whereas the justification of the intrusion on privacy follows a different model.[47] Informed consent is only one possible way of justifying the collection or processing of data. Data collection is justified if it is allowed by law; if it is not allowed by law, it can also be justified if there is a preponderant interest in the data. Only in the rare cases, when both methods of justification do not apply, must the collector seek the informed consent of the person concerned. Thus, the basis of the protection of privacy is inverse to the protection of autonomy in health care decisions.

The declaration must be examined against the background of this differentiation between medical and data protection law, as the underlying concept could otherwise be misconstrued when applying the declaration. In Article 8(a), the text refers directly to the informed consent principle, asking member states to make sure that informed consent is obtained for data and biological sample collections, as well as for the further processing of data included, regardless the institution which performs the collection or processing. Limitations to this principle shall only be permitted under domestic legislation consistent with international human rights law in cases with compelling reasons. If the person concerned is incapable of giving free consent, his or her legal representative shall have the right to consent and the person concerned shall be able to participate in the consent process according to his or her individual capabilities.[48] The same applies to minors whose opinion should be increasingly considered as they reach maturity, even if they not yet have the legal right to consent.

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in the Collection and Use of DNA (London: Routledge, 2004), pp. 78–96, p. 86, has argued that informed consent has undergone different stages; from the pure medical model times to the protectionist era and finally the stage of "empowered citizens". Therefore he claims that medicine is nowadays "Governed through freedom", ibid., p. 85.

45 Different standards of disclosure have been developed which have an outstanding impact on the ethical validity of the principle of informed consent, as the different disclosure standards presuppose different models of genetics. See Faden, Beauchamp, *A History and Theory of Informed Consent*, pp. 305–316.

46 211 N.Y. 125, 105 N.E. 92 (1914).

47 This chapter does not engross the thoughts of a right to know versus a right not to know. Regarding these, potentially conflicting rights a legal concept of priority setting has been outlined above. Regarding the bioethical recognition of the two rights and possible influences on governance models, see Andorno, "The Right Not to Know", with a commentary by G. Laurie.

48 The UNESCO IBC report *Human Genetic Data*, No. 49 (b).

These policies of the declaration are more than just subtle hints that it follows the concept of informed consent in medicine.

If we adhere to our findings, the need for a dynamic governance model which enables shareholders to reflect their views in a structured, institutionally fused procedure, we have to face the need for the integration of this multi-personal informed consent model in the outlined idea of a new form of genetic governance. The basic message of the declaration is that the informed consent of the person concerned remains the key to the justification of any intrusion into genetic privacy. Any procedural concept has to refer to this primacy of informed consent, limiting justification by law or by decisions based on a preponderant interest to a very minimum. In a common-hold system the legal concept could differentiate between a personal and a shared property in genetic data, with priority for group consent in the case of shared data if the data is not absolutely necessary for medical intervention. Only in these rare cases must the law intervene in the interests of the patient. On a conceptual level the same could apply to the personal rights model.

Competence to consent

As Faden and Beauchamp[49] have shown, the competence of the consenting person is a key feature necessary to determine whether informed consent is ethically valid. If the person participating in the genetic dispute settlement procedures is not legally competent, the justification of this governance model collapses. The competence can be per definition divided into general competence and a specific, task-oriented competence, as examined by Faden and Beauchamp.[50] The general competence of person is always necessary for a legally valid consent. If a person is not able to fulfill the requirements of law, a representative is necessary to consent for the legally incompetent person.[51] The declaration refers to legally incompetent people in Article 8(b) and (c) when it suggests offering the person concerned a right to participate in the consent process. In cases where minors cannot legally consent, their opinion shall be recognized congruent to their increasing maturity.

Conclusion

The preoccupation with the UNESCO Declaration on Human Genetic Data has revealed an urgent need for a united approach regarding the collection and disclosure of genetic data and data related to this. Governance in the fields of genetics suffers from an uncertain scientific (and therefore ethical) basis as the dynamic evolution of genetic knowledge challenges large-scale integration of regulation. Therefore, conflicts have been avoided and modes of regulation like the idea of

49 Faden, Beauchamp, *A History and Theory of Informed Consent*, pp. 287–294.

50 Ibid.

51 This concept is widely known, for example in the U.S. Genetic Privacy Act 1995, Part E, s. 143 and 144 or in one of the oldest existing laws on genetics, the Austrian Gentechnikgesetz 1991, §65, Abs. 4.

a "co-ownership" of genetic data have been shunned so far. A genetic governance model has to integrate individual rights and social concerns regarding genetics, the fostering of communication and the adjustment of conflicting positions. In contrast to the weight it seems to carry in the current discourse, the dispute between property and personal rights is of less importance if the mechanisms that structure both concepts are unfolded. The general conception behind genetic governance on the level of individuals ought to be the idea of a regulated self-regulation with easy-to-access dispute resolution institutions. The institutionalization of dispute resolution procedures might turn out to be the key to a successful dynamic genetic governance model. Institutions in this sense have to provide parties with genetic and bioethical knowledge, in this way stimulating reflection and consensus building amongst those concerned. Any international regulation should allow local institutions and people to apply local values in a systematic procedure. In this sense any model of governance in genetics has to be sensitive to values. The recurring question as to whether the translation into local jurisdictions should be carried out by acknowledging a genetic property or a personal privacy right is of less importance because both models face the same dogmatic challenge. Seldom does a person have the right to execute his or her personal will as he or she has to be considerate of other family members or people who have an identical risk structure. Thus, the core of any model of governance must serve the quest for genetic justice for individuals and relevant groups. The aim of a genetic concordance of conflicting rights and social/political restrictions needs more interdisciplinary consideration, both on the conceptual and on the legal/technical level.

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Chapter 5

TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic*

Antony S. Taubman

The crafting of intellectual property (IP) law and policy may be structured as a zero-sum trade-off between opposing policy interests, or as a coherent harnessing of diffuse interests to deliver a net contribution to public welfare that is fairly distributed. Actual experience of drafting national laws and international treaties would naturally predispose one towards the former view, as it is a closer mapping of actual, contentious drafting processes which are dominated by zero-sum logic; but an IP law or treaty may be greater than the sum of its parts, or at least a more coherent policy instrument than a simple register of the sectoral interests that it accommodates to greater or lesser extent.

This chapter argues that IP law and policy, and the international law of IP in particular, should not be read as a bare, zero-sum trade-off between competing interests. The negotiating origins of the international law of IP, rooted in the realist assertion of national economic interests and in the zero-sum dynamic of trade negotiations, can and should be dissociated from the actual nature and effect of the text as a legal regime. The IP system is ostensibly a means of ordering and producing certain public goods, and of promoting overall public welfare, through precisely crafted exclusions from the public domain. IP law and policy offers more than a forum for bartering between certain rights (IP rights, user rights, rights of access, rights of remuneration and so on), rights that are naturally seen as having intrinsic worth by those who hold them. A more coherent and productive reading would see it as a means of encouraging the dynamic interplay of rights and interests for overall welfare. IP law may be seen as a utilitarian means of promoting public welfare, its legitimacy assessed in teleological terms or in terms of actual welfare delivered; or it may be seen as a means of dovetailing diverse rights and interests to produce a positive-sum accommodation. Enticingly, taking it at its word, the WTO

* Based on research undertaken at the Australian Centre for Intellectual Property in Agriculture, College of Law, Australian National University. This chapter presents the author's personal views only, has no linkage whatever with the author's subsequent appointment with WIPO, and does not represent views that can be attributed to WIPO, its member states or its secretariat. The author is currently Acting Director, Traditional Knowledge (Global IP Issues) Division, WIPO.

TRIPS Agreement offers both: IP protection should yield a "balance" of rights and obligations, the *mutual* advantage of different interest groups, and overall social and economic welfare. Implementing that "should" open the way for a systematic jurisprudence of international IP law that achieves the seemingly impossible goal of robustness in settling international disputes, legitimacy in terms of breadth of interests accommodated and efficacy as a guide to welfare enhancing domestic law making.

Introduction: The polar geography of IP

Following is a naïve and simplistic caricature of a complex and subtle debate, but it is a caricature drawn from contemporary life and discourse, and it may have some analytical utility. In the current debate over the ethics, policy and law of IP, the very complexity and range of issues covered can promote a tendency to vacate the middle ground, and to categorize views and to construct analysis in terms of opposing polarities. Depending on the issues and interests engaged, these polarities arise in diverse forms: public as against private interest;[1] consumer as against producer interest; the interests of the developed as against the developing "worlds";[2] profits in the North or sustainable development in the South; rent-seeker or sectional interests as against the defense of the public domain or of free trade; a public international law (human rights and environment) approach as against a trade-law or narrow IP-law approach; public domain publication of academic research as against the assertion of private rights over public-origin or publicly-funded research; technological innovation as a collective good or social good, as against innovation as a private good bounded by exclusive property rights; access

1 The Report of the High Commissioner on "The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights" comments that "[t]he balance between public and private interests found under article 15 [of the International Covenant on Economic, Social and Cultural Rights (ICESCR)] – and article 27 of the Universal Declaration – is one familiar to intellectual property law". The report comments that Article 15 "identifies a need to balance the protection of both public and private interests in intellectual property. On the one hand, article 15 recognizes the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. On the other hand, the same article recognizes the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. Taking these two aspects of article 15 together, ICESCR could be said to bind States to design IP systems that strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge."

2 The delegation of Pakistan at the 1999 Seattle WTO Conference: "The costs of TRIPS are becoming especially evident. The balance between producers of IP, mainly the industrialized countries, and the developing country users has been heavily tilted in favour of the former…. Industrialized countries have also brought in new subjects, such as software and biotechnology, under the ambit of IP protection. In contrast, developing countries face a situation where their traditional knowledge in medicine, music, art and design are often appropriated by the developed countries without any compensation."

to technology as against innovation; generic medicines as against "branded" or "research" products; exclusivity of property rights as against a bare entitlement to equitable or adequate remuneration; those privileged by the digital divide, as against the digitally disenfranchised; individualistic atomistic innovation and creativity as against the cumulative and collective innovation of indigenous communities; "strong" protection of copyright works against unauthorized reproduction as against the promotion of the dissemination of knowledge and creative works; patients and pills, or patents and profits; user rights as against producer rights; and so on. Tellingly, to take sides in one specific debate can lead to assumptions about one's interests and values in other, related debates, beyond the scope of IP altogether, such as the aesthetic, economic and moral divide between artisanal or organic agricultural production, as against integrated agribusiness, GMOs and industrial winemaking. But several common themes can be detected: public or collective interests as against private interests; and exclusive rights as a means of promoting or rewarding the production of knowledge goods as against limitations and exclusions to such rights as a means of diffusing and accessing such goods.

The essence of IP policy making is often characterized as an appropriate balancing of these opposites – the "balance of rights and obligations" of Article 7 of TRIPS; bad policy would excessively favor one interest over the other, and good policy would restore the Yin–Yang balance. But for all the talk of "balance," we typically invest higher ethical or utilitarian value on one side of the scales – we take sides, or are assumed to take the other side if reluctant to utter the shibboleths that betoken solidarity – and the debate sounds less Taoist, more Manichaean.

Pairwise constructions of opposing positions, values or interests contribute much to the structure and lexicon of debate on current legal and policy issues concerning IP, and the current discussion does not seek to devalue them, nor to take issue with the search for balance. Opposing interests and values naturally arise in important current policy debates, and it would be mischievous to discredit the balances struck between them. In a recent instance, the policy debate over interoperability of digital music pivots on contrasting goals: (i) promoting innovative Schumpeterian competition between closed platforms[3] and (ii) interoperability as a "matter of public policy in core networks".[4] The policy maker's role is characterized as finding "the right mix of public obligations and private incentives to achieve open, competitive platforms that provide a dynamic, consumer-friendly economy".[5] A distinction between "pre-competitive" information and competitive derivative research has been used to argue for open access to basic genomic information, as the basis for productive research and innovation building upon this substrate of data.[6] The U.S.

3 See "Digital Music Interoperability and Availability: Hearings Before the Subcomm. on Courts, the Internet, and Intellectual Property of the House Committee on the Judiciary", statement of Raymond Gifford, President, The Progress & Freedom Foundation, April 6, 2005.

4 Ibid., statement of Mark Cooper, Director of Research, Consumer Federation of America.

5 Ibid.

6 Thus the Statement on Patenting of DNA Sequences in Particular Response to the European Biotechnology Directive of the Intellectual Property (IP) Committee of the Human

Supreme Court's *Grokster* decision[7] refers to the "balance between the respective values of supporting creative pursuits through copyright protection and promoting innovation in new communication technologies by limiting the incidence of liability for copyright infringement."[8] The administration of copyright law is "an exercise in managing the trade-off" between artistic protection and technological innovation.[9] Notably, this "balance" counterpoises two sets of sectoral innovator interests, exactly corresponding to precise industry interests (whose identity is readily identifiable in the amicus briefs lodged), and corresponding to two conceptions of the public interest – promoting and rewarding new music, and disseminating new technologies for playing it.

These polarities are not, therefore, simplistic rhetorical flourishes in a set of set-piece debates. They can represent fundamental policy choices and contradictory value systems, they can serve as valuable forensic tools, and they do often embody substantive divergences in significant debates, the practical recognition of which is essential for politically robust and equitable policy outcomes. These polarities also have deep empirical and doctrinal roots in the law of IP, its evolution and its current practice. The notion of a balance between the poles of private and public interest is well established in the doctrine of IP law, routinely drawn on in conventional justifications for bounded IP rights. But as an established form of analysis and conventional rationalization of IP mechanisms, the notion of "balance" can bring with it an assumption that the pairs of interest that are weighed in the balance are discrete and even mutually exclusive; the decision maker is thus called on to manage the kind of "trade-off" referred to in *Grokster*: a zero-sum game. The *Grokster* court describes the subject of that case as "[t]he tension between the two values" of supporting creative pursuits through copyright protection and promoting innovation in new communication technologies by limiting the incidence of liability for copyright infringement.[10] In patent administration, any decision on the patentability of a borderline invention can be represented as a choice between two mutually exclusive interests – a judgment whether to sustain a private right over an invention in recognition of some innovative character, harnessing private interest to spur development and dissemination of the technology; or to consign it to the public domain, avoiding an undue encumbrance on others' freedom to operate. This is a

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Genome Organization (HUGO), April 2000, emphasized the Committee's "basic understanding that DNA molecules and their sequences, be they full-length, genomic or cDNA, ESTs, SNPs or even whole genomes of pathogenic organisms, if of unknown function or utility, as a matter of policy, in principle, should be viewed as part of pre-competitive information. Therefore efforts such as the new Consortium of industry and academia to map all SNPs and put them into public domain, are welcomed. Such Consortia will greatly contribute to innovation and stimulate international standardized use of data, which will beneficially influence, inter alia, cooperation between industry and academia", available at: http://www.hugo-international.org.

7 *Metro-Goldwyn-Mayer Studios, Inc., et al. v. Grokster, Ltd., et al.*, (04-0480), 545 U.S. (2005).

8 Ibid, at 10.

9 Ibid.

10 Ibid.

blunt dilemma: what choice better promotes overall welfare; what choice is more just or more fair, or a better policy outcome? How can this be determined *a priori*, before the claimed invention is actually brought through the development pipeline to the market and its actual benefits are felt? Weighing the binary option of granting or refusing a borderline patent, can the public interest wholly be served by one choice, and denied by the other? Not only is it possible that both choices might be "right"; both sets of interests might be better served by an approach that subordinated the grant of a patent to a broader and richer conception of IP law as a platform for promoting mutual advantage, so that the grant of an IP right is not assumed to be a loss to the public unless proven otherwise.

Repopulating the excluded middle

The tendency for the debate to polarize interests can give unwarranted momentum to policy divergences. It gives emblematic status to an assumption that interests and values are mutually exclusive. An antithetical characterization of interests and values can obscure the prospects for mutual advantage or collective gain: the "mutual advantage of producers and users of technological knowledge" of TRIPS Article 7. Specific pairs of interests, and the focused policy differences they represent, can be pressed into service on one side or the other in what can become a fundamental conflict over the essential legitimacy or otherwise of the IP system as it is currently construed; and in the perceived tension between "rights maximalist" proponents of "strong" IP protection as an end itself and cultural critics of IP rights as illegitimate privileges. This binary opposing of positions is not exhaustive and can indeed lead to paradox or oversimplification. The actual interests and policy questions involved are complex, and it is difficult to construe the dynamic, evolving composite of IP treaties, laws, policies, administrative practices, and patterns of rights exploitation as one monolithic "system." For instance, the same steps taken to defend public domain knowledge against illegitimate patenting may be viewed either as (i) bolstering the proper application of existing patent principles – taking steps to prevent patenting of traditional knowledge (TK), insisting on more rigorous application of the test of non-obviousness, which implicitly validates those underlying principles, if not their imperfect execution in practice, because the call is for those principles to be better respected; or (ii) resisting the patenting process on principle, because such exclusions from the public domain are improper privileges or are detrimental to beneficial innovation. And trade-offs arise between different forms of IP protection, and between distinct sets of right holders (or right-claimants), rather than over a simple choice as to whether a right to exclude from the public domain should be granted or not. The establishment of performers' rights, for instance, raised as much concern that other exclusive rights may be diminished or more difficult to exercise, as concern about incursions on the public domain.[11] The debate over biopiracy concerns both curbing the patenting of public domain materials and affirming rights

11 A.S. Taubman, "Nobility of Interpretation: Equity, Retrospectivity, and Collectivity in Implementing New Norms For Performers' Rights", *Journal of Intellectual Property Law* 12 (2005): 351–426.

to exclude unauthorized third party use of TK and genetic resources, even when users assume these materials to be in a "public domain".[12]

Policy making should therefore be viewed a process of re-evaluating and recalibrating the dynamic alignment between a complex array of interests and values, on the one hand, and the formal laws, norms and standards, and their manner of implementation, on the other – its legitimacy cannot be limited to a simple summation of profit and loss incurred by one set of static interests or another. The continuing reassessment of the role of TRIPS and its role in constraining and defending domestic policy space is an exemplary example of this kind of more flexible conception of the component parts of the composite IP "system": the one, more or less static, legal text has been construed both as an outright realist imposition of the interests of a coalition sited one side in each of these antinomies (TRIPS as a blunt instrument[13]); and as a shield for the defense of domestic policy space (this is the symbolic and deeply practical implication of projects to construe a development-friendly jurisprudence of TRIPS[14]).

In general discourse, accentuating the division and clustering of interests and values into pairwise contradictions can predispose debate towards a zero-sum analysis, and an overly limiting assumption that values and interests are mutually exclusive. Despite having characterized the case in terms of "tension" between two values, the *Grokster* court itself points out that "[t]he mutual exclusivity of these values should not be overstated…. On the one hand technological innovators, including those writing filesharing computer programs, may wish for effective copyright protections for their work…. On the other hand the widespread distribution of creative works through improved technologies may enable the synthesis of new works or generate audiences for emerging artists."[15] Some debates on IP issues manifest an *a priori* assumption that the gain of a private right is a loss to the public interest; or that the legitimacy of a policy choice is measured by the degree to which exclusion from the public domain is minimized. Polemical analysis can conflate three distinct notions: advancing the public interest, preserving the public domain and promoting the provision of public goods. In the law and practice of IP, at least in principle, the promotion of private interests is not intended to thwart the public interest, but rather

12 A.S. Taubman, "Saving the Village: Conserving Jurisprudential Diversity in the International Protection of Traditional Knowledge", in K.E. Maskus, J.H. Reichman (eds), *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime* (Cambridge: Cambridge University Press, 2005), pp. 521–564.

13 The cover of the Indonesian journal *Warta Ekonomi* in January 2000 memorably depicted TRIPS as a destructive hammer, just as the major provisions of TRIPS came into effect in that country.

14 For instance, UNCTAD–ICTSD Resource Book on TRIPS and Development (Cambridge, 2005) is a practical illustration of the link between the depth and confidence of knowledge of the legal provisions, and the capacity to define and defend desired policy options; it was conceived as a survey of TRIPS law "to facilitate an informed participation by developing countries in the ongoing negotiations on IPRs issues including the WTO and to assist national authorities, in general, in the implementation and adoption of IPRs policies in the broad context of growth and development."

15 *Grokster*, p. 11.

directly to enhance it. When society chooses to produce and finance public goods through deliberate construction of exclusions from the public domain, this requires a counter-intuitive divergence between "public interest" and "public domain".

The public interest in exclusions from the public domain

As a minimalist conception, the core responsibility of a utilitarian and objective IP policy maker is to determine what privately held exclusions from the public domain of otherwise non-excludable knowledge resources are required to harness sufficient private interest to provide for the production of certain public goods that would not otherwise come into existence;[16] these may be higher order public goods such as fairness in the rewards and recognition offered to creators or the suppression of deceptive behavior in the marketplace, or material public goods such as new technological products and creative works. But how does the objective policy maker, ideally placed in the "original position" behind a Rawlsian veil of ignorance,[17] determine what exclusions would be just, or legitimate, or effective? From this perspective, a possible utilitarian line of analysis would, in effect, adapt the classical liberal economic analysis (the "invisible hand")[18] and apply it to the intangible goods generated by the IP system: public goods result from the pursuit of private interest, as the spontaneous ordering of the market and communication through market exchange promotes beneficial investment and innovation.[19] Classically applied to goods and services,[20] this analysis extends to intangible knowledge products, in

16 This is not, of course, by any means the mechanism for harnessing private interest to provide for public goods. There is, for example, a considerable economic literature on the private provision of public goods, considering such phenomena as corporate philanthropy, political campaign donations. See E. Ley, "On the Private Provision of Public Goods: A Diagrammatic Exposition", *Investigaciones Economicas* 20/1 (1996): 105–123, at IMF, Washington, D.C., available at http://econwpa.wustl.edu/eprints/pe/papers/9503/9503001.abs. See the economic model for non-cooperative provision of public goods in T. Bergstrom, L. Blume, H. Varian, "Private Provision of Public Goods", *Journal of Public Economics* 29 (1986): 25–49, available at http://econwpa.wustl.edu/eprints/pe/papers/9503/9503001.abs.

17 J. Rawls, *A Theory of Justice*, rev. ed. (Cambridge, MA: Belknap Press of Harvard University Press, 1999).

18 For a brief historical review of these aspects of liberalism, see S. Horwitz, "From Smith to Menger to Hayek: Liberalism in the Spontaneous Order Tradition", *The Indep. Rev.* 6 (2001): 81–97, p. 81.

19 Compare Adam Smith's classic formulation: "by directing that industry in such a manner as its produce may be of the greatest value, he intends only his own gain, and he is in this, as in many other cases, led by an invisible hand to promote an end which was no part of his intention. Nor is it always the worse for the society that it was no part of it. By pursuing his own interest, he frequently promotes that of the society more effectually than when he really intends to promote it." A. Smith, "An Inquiry into the Nature and Causes of the Wealth of Nations" (1776), Henry Frowde (ed.) (Oxford: Oxford University Press, 1909).

20 With the assumption that intangible knowledge products are not economically significant: note Smith's reference to the intangible or ephemeral product of "players, opera-singers, opera-dancers, etc." as producing "nothing which could afterwards purchase or

the event that certain exclusions from the public domain are essential to capture and direct private interest towards the production of public goods: paradoxically, a conscious system of exclusion from the public domain is required to provide for the spontaneous order that works for society's gain.[21] Privatizing of knowledge through statutory exclusions creates public goods.

Yet, because of an innate disposition towards zero-sum analysis, as soon as this argument is advanced, it is suspected as a defense of private IP rights as ends in themselves. It is seen as problematic to invest simple faith in the beneficial operation of private rights as spontaneously advancing the collective public interest, when exclusion is the chosen policy tool. It goes against the intuitive grain to provide public goods (which are by definition not excludable) by means of exclusive rights. This tension can be resolved in principle, for instance with respect to patents, by pointing out that if the public good in question is: (i) publicly available knowledge *as such* (material in the public domain of knowable information), then the function of the patent system is to deliver technological teaching into *that* public domain almost as soon as it exists[22] and (ii) tangible public goods, then the protected innovation is in itself only an intermediate towards that end – its "protection" through exclusive rights is one element of the pipeline that delivers the material public good – not the invention as an abstract notion – but a new useful product actually delivered to the public.

Yet there are long-standing concerns that any policy tools that rely on exclusive rights may be subject to excessive influence by sectoral interests and regulatory capture. The beneficiaries of economic privileges typically justify them through special pleading that conflates sectoral interests with the general public interest. This was apparent in the early industrial age; patent law was being gradually distilled out of the general law of monopolies as a legitimate exception. Commenting on the mercantilist tendency to grant monopolies, Marshall observes that "restrictive regulations, which have an indirect constructive result in promoting national power and dignity, are rightly judged with exceptional favor. But this fine feeling is not without its perils; for it is apt to be turned to account by persons who stand to gain by the restrictions. Such persons are most dangerous when they are honestly convinced, as they often are, that they are striving for the public good as well as their own." He refers to the "sectional jealousies" provoked by monopolies that enabled the

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procure an equal quantity of labor. Like the declamation of the actor, the harangue of the orator, or the tune of the musician, the work of all of them perishes in the very instant of its production." Ibid., p. 119.

21 The imposition of an exclusion means that they cease to be true public goods, as these are by definition not excludable, but the disclosure requirements of technology-related IP protection are intended to ensure that protected subject matter passes into the public domain firstly as a public knowledge good (patent information is not, in principle, excludable from the time of its publication), and through limited term.

22 See an extended discussion of the different modes of public domain in A. Taubman, "The Public Domain and International Intellectual Property Law Treaties", in Waelde and MacQueen (eds), *Intellectual Property. The Many Faces of the Public Domain* (Cheltenham, U.K.: Edward Elgar Publishing, 2007).

suppression of "inconvenient rivals"[23] Such special pleading, still present today, underscores the need for objective principles to determine the utilitarian benefit of such restrictions, so that they become a genuine mechanism for social benefit and not a bare favor or sectional privilege.

Moreover, privately vested exclusivities should be distinguished from private interests as such. The grant and exercise of exclusive rights over IP subject matter need not be solely or even marginally directed towards private interest: it is inaccurate to conflate the private or exclusive nature of IP rights with the narrow pursuit of private interest. IP management that is solely and explicitly directed towards promoting public interest outcomes may include pre-emptive public domain status (for example, defensive publication, statutory measures[24] or simply waiving IP rights[25]). But it can also entail the judicious deployment of legal exclusions. For instance, the IP-based right to exclude certain uses of protected materials can be used to encourage direct allocation of private resources towards public interest outcomes, in the absence of market incentives.[26] Exclusive rights can be licensed to preclude commercial use of protected materials, to promote non-commercial creative exchange and adaptation.[27] A right to exclude can be applied judiciously to safeguard the open quality of a shared innovative domain for agricultural biotechnology (exercising exclusive IP rights to preclude third parties from excluding access to derivative innovation).[28] Standards bodies use IP licensing structures to ensure open access to standards while encouraging technology developers to pool their technologies for mutual benefit, such as by defining fair, reasonable and non-discriminatory (FRAND) terms and conditions for licenses.[29] The claim for protection of traditional knowledge (TK)

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23 Marshall, *Trade and Industry*, 2nd ed. (London: Macmillan and Co., 1920), p. 457. Amplifying, in a footnote, he comments "as e.g., to Bridport for rope making, to Worcestershire towns for woollen cloths, to York for coverlets, etc. In some cases plausible reasons were suggested: and indeed the Tudors were masters of the fine art of writing preambles."

24 For example, the statutory waiver of copyright in U.S. government works.

25 See, for example, the public domain dedication of the Eldritch Press: "Eric Eldred hereby releases any creative addition to the literary materials at the Eldritch Press – including but not limited to any copyrightable compilation of materials or HTML formatting – to the public domain with a Creative Commons Public Domain Dedication." Available at http://creativecommons.org/licenses/publicdomain/eldred/.

26 See discussion of public interest IP management in A.S. Taubman, "Public–Private Management of Intellectual Property for Public Health Outcomes in the Developing World" (Global Forum for Health Research, 2004), available at www.ippph.org.

27 See, for example, the "Attribution-NonCommercial-ShareAlike 1.0" draft license at (U.K.): "You may not exercise any of the rights granted to You in Section 3 above in any manner that is primarily intended for or directed towards commercial advantage or monetary compensation." (Available at creativecommons.org.tw/files/lc_by-nc-nd_2.0.pdf, last visited August 29, 2006.)

28 See, for example, Biological Open Source License for Genetic Resources Indexing Technologies at http://www.bios.net/daisy/GRITLicense/750/1170.html.

29 Concerning the resolution of conflict between the exclusivity of IP rights and open access to standards in the United Kingdom, "most standards bodies include procedures that take IPRs into account where a standard is in the process of being drawn up. Each participant is expected to declare at an early stage the IPRs it holds which are (or might be) essential

against misappropriation and misuse is expressed by some proponents, at least, as a collective right or custodial responsibility to prevent illegitimate use of this knowledge, entailing the exercise of rights to exclude third parties in the name of "a" public – the traditional community which maintains the knowledge according to customary law and practice – if not "the" public at large (claims of misappropriation of TK arise when TK is used on the assumption that it has fallen into the public domain, and when it has that actual legal status in the jurisdiction where it is used).[30] Programs of public sector knowledge management that entail obtaining and asserting IP rights can be construed both as a form of privatization of public knowledge, and as maintaining collective public-interest control over how public knowledge is developed and applied.

But despite this diversity of experience, much current discourse on IP policy ranges along a single dimension, between the two extreme nodes – the grant of private rights to exclude and the defense of the public domain. The merit of a policy outcome or a form of knowledge management, the degree of regulatory capture by specific interests and the expression of social values can then be measured according to gradations along this spectrum.[31] A yardstick calibrates the space between two opposing polarities: producer against consumer interests; private-right and public-domain (or other forms of collective domain) forms of knowledge management; atomistic and collaborative forms of innovation; "strong" and "weak" IP laws; strict property rights and residual rights to remuneration or liability regimes, implicitly reducing the space to one dimension. This linear yardstick is then used to analyze IP mechanisms in terms of how they define and regulate private right in the public interest. Policy "balance" is reduced to giving enough to either side of the divide, to ensure neither is unduly penalized at the expense of the other.

When considered as a trade-off between two sets of antithetical interests, the heavily worked metaphor of "balance" in IP policy making can be misconceived as validating a zero-sum analysis of these interests: the merit or legitimacy of a policy position is assessed with reference to which side of the ledger is seen to have been favored, and by assessing how far along this linear scale of interests the balance is set; so striking the elusive balance entails robbing public-interest Peter to pay into

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to the draft standard if it were to be adopted. The owner is requested to give an undertaking in writing that it is prepared to grant irrevocable licenses on royalty-free or fair, reasonable and non-discriminatory (FRAND) terms and conditions under such IPRs, with a waiver of copyright in documentary material. The standards body also makes sure that the patent in question is endorsed as a 'License of Right' at the Patent Office. This ensures that licenses under the patent are available to all applicants as of right and that any disagreement of licensing terms is subject to settlement by the Patent Office", M. Clarke, "Standards and Intellectual Property Rights" (London: BSI Business Information, 2004), p. 64.

30 Taubman, "Saving the Village".

31 The metaphor of the spectrum finds an echo in an initiative such as "Creative Commons" which is characterized as defining "the spectrum of possibilities between full copyright – *all rights reserved* – and the public domain – *no rights reserved*. Our licenses help you keep your copyright while inviting certain uses of your work – a 'some rights reserved' copyright." Learn more about Creative Commons at http://creativecommons.org/learnmore (visited August 29, 2006).

Paul's private account. For all the non-rivalrous quality of knowledge resources, it is an approach that seems influenced by the psychology, the ethics and the economics of scarcity. In the current debate over genetic resources, the view is widely advanced that it is a loss or damage, even a misappropriation, if another party simply secures a patent in a foreign jurisdiction on an invention derived from a genetic resource. In a zero-sum framework, the idea of balance may be construed in terms of distributive justice, fulfilling the notion of "equity" implicit in "equitable benefit sharing", or in terms of a compromise between fundamental rights asserted by opposing interests, such as entitlements to access to knowledge or access to the fruits of knowledge such as medical technology; rights of authors, creators, inventors or source communities; and rights to equitable benefits. Yet a knowledge-based economy is inherently not zero-sum, focused as it is on the production of non-rivalrous knowledge goods that did not exist before. A simple balancing of competing interests will tend to favor a static or shorter-term perspective, overlooking dynamic welfare gains from innovation and knowledge diffusion (although the "balance" between static and dynamic efficiency is a conventional way of framing analysis of the welfare costs and gains of IP mechanisms) and may lack a longer-term or dichronous dimension (although the intergenerational dimension of the ethics of IP has been acknowledged from diverse perspectives – intergenerational environmental equity and indigenous rights,[32] or as one way of characterizing the social contract implicit in the patent system[33]).

But if "balance" comes to serve as a simple euphemism for zero-sum trade-offs, can it really do justice to the policy making process? Is it an analytical and polemical mode that obscures the common ground and thus impedes attempts at objective, positive policy making? The inherent tendency towards polarization in IP debate, and the structuring of interests in binary opposition, is perhaps succinctly illustrated in the debate on geographical indications (GIs). The current, complex international debate has a lengthy provenance, with its roots in the opposing sets of interests apparent in the negotiation of Article 10 of the original (1883) text of the Paris Convention, the failed attempt at the preliminary Paris Conference in 1880 to introduce an absolute prohibition on false indications of origin in the original draft Convention, the attempt at Rome in 1886 to strengthen Article 10 (which was not ratified), and the decision at the 1890 Madrid Conference to develop a separate arrangement to protect indications of origin. This debate has largely been constructed in terms of two polarized sets of producer interests (to be sure, backed by differing conceptions of the public interest of the countries or societies concerned); this

32 "Concern was expressed that the current IPR regimes…do not address a range of equity issues including intergenerational equity", Statement and Recommendations, Workshop on Biodiversity Conservation and Intellectual Property Rights, New Delhi, January 29–31, 1999, at http://www.jiwlp.com/contents/21biodiversity.html.

33 "[T]he patent system is designed to require that each generation pay for research and development costs associated with the development of new drugs with the understanding that the next generation will get them free of those costs. Thus we are all the beneficiaries of all the drug development that occurred prior to around 1980 and our children will get all of what we have developed to date free", M. Adelman, "Compulsory Licensing of Drugs: TRIPS Context", ATRIP 2003 Annual Meeting, Tokyo, August 4–6, 2003.

obscures deeper questions about the public domain status of the common language, and the appropriate rules for governing exclusions to that domain.[34] Most recently, the GI debate has been framed by TRIPS, leading to polarized views concerning the range of goods for which a test of consumer deception or unfair competition need not apply in assessing the legitimacy of the use of a geographical indication (the "extension" question concerning TRIPS Article 23.1). In negotiations across this division of interests, a debate over the precise list of goods[35] or individual terms[36] to be protected naturally takes on the form of a trade-off between the commercial and broader policy interests represented by those specific items, rather than an attempt at objective assessment of the actual import of a term within current linguistic usage,[37] just as trade-mark courts use empirical evidence to assess distinctiveness and genericization.

Coloring the ethical palette

A monochrome view of the IP policy process would assess the morality and public policy merit of a particular legislative or administrative outcome according to the degree to which a text is seen to favor or prejudice specific interests, especially sectoral economic interests. Ethical and policy concerns over the impact of IP laws tend to be measured against a linear scale. For instance, the extent to which an IP law responds to ethical concerns is likely to measured by the *exceptions* that are allowed on grounds of morality, rather than against the full moral landscape that includes the ethical and socially beneficial grant and exercise of positive IP rights. Legal texts – the laws and treaties that enact and embody the policy "balance" – take on a moral weight according to the textual imprint of inclusions and exclusions from protection, reflecting specific policy preferences, values or interests. Analytical and advocacy firepower concentrates on this polemical front line: weighing the breadth of protection (the range of subject matter, the scope of legal rights, the term of protection) against the scope of limitations and exceptions. This focus has a strong basis in experience, and may be the most practical way of structuring what might otherwise become an irretrievably complex and multidimensional debate. It is often

34 See, more extensively, A.S. Taubman, "Geographical Indications, International Trade, and Linguistic Communities: Thinking Locally, Acting Globally" (forthcoming, draft available from the author).

35 See the proposal to broaden the scope of products covered by Article 23.1 of TRIPS in Geographical Indications, Communication from the European Communities, WT/GC/W/547 (June 14, 2005).

36 See Press Release IP/03/1178, Brussels, August 28, 2003, "WTO talks: E.U. steps up bid for better protection of regional quality products" referring to a "short list of 41 E.U. regional quality products whose names the E.U. wants to recuperate".

37 The Canada–E.U. Agreement on Trade in Wine stipulates that, from a specified date, "Canada shall no longer deem" that certain wine names are "customary in the common language of Canada as a common name" for the wines in question: these include contested terms such as "port" and "sherry", which had been viewed by different communities as either distinctive geographical references or generic descriptions.

derived from the actual process of drafting legal texts, which can be marked by explicit trade-offs between the preferred textual outcomes of identifiable interest groups; TRIPS itself as a package has all these hallmarks.[38] But it may be insufficient, if the goal is to achieve robust, effective and coherent policy outcomes that are secured against challenge from sectoral interests, and which are buttressed by a clearly articulated, systematic legal framework. It may conceal pathways towards defining and promoting collective interests that transcend the immediate polarities. Crucially, this entails detaching the text from the partisan dynamics of the drafting process, so as to conceive and implement it as a coherent policy instrument.

This tendency towards polarization and a linear view of "balance" creates a disabling irony. The very process of stepping back from the polarities, analyzing the way they structure the debate, and exploring broader ways of casting the issues, can be seen from an *engagé* perspective as a more or less direct assault on the values or interests that epitomize one or other cluster of views; sometimes both sides at once. Yet, to fashion a broader legal and ethical canvas, and to add nuance to the ethical palette, need not advance or repudiate any position in current debates. But it does suggest that a kind of ethical zero-sum fallacy can inhibit objective analysis of the full range and potential impact of legal instruments. A conscious reclamation of the excluded, or vacated, middle ground would build upon a basic sense of fairness in the development, maintenance and dissemination of knowledge resources, a conception of overarching rightness and a conscious, utilitarian construction of public welfare outcomes through the conscious engagement of and due respect for private interests within a public policy context. This approach goes beyond a fairness that merely – even grudgingly – acknowledges the legitimacy of both "sides" of a policy issue and simply strikes a static balance between them – or worse, depending on the degree of perceived mutual exclusion, a judgment of Solomon. It may assist the policy maker in working towards a utilitarian optimization of how exclusive rights are deployed to promote public welfare outcomes. Moral legitimacy may be derived from the positive harnessing of disparate interests – wholly public, collective and strictly private – for overall collective gain.

Monarchs and monopolies

A skeptical, realist account of the development of IP norms would concentrate on the extent to which treaty negotiators or legislators have enclosed public domains to accommodate private, sectoral or rent-seeking interests. Interested parties will focus on the extent to which their interests and concerns (or even preferred text) were accommodated in the final legislative or treaty outcome. It is more difficult to develop a synthetic and utilitarian approach to assessing objectively how to generate and fairly manage knowledge resources in a market economy, based on the abstracted conception that private interest must be harnessed to advance the longer term public good. But it can be done. One of the neatest examples is one of the earliest: the

38 See, for example, the narrative of TRIPS negotiation in P. Drahos, J. Braithwaite, *Information Feudalism. Who Owns the Knowledge Economy?* (New York: Earthscan Publications, 2002).

Statute of Monopolies,[39] frequently cited as an early patent statute, was developed in 1623 principally to abolish monopolies and privileges which "upon misinformations and untrue pretences of public good…have been unduly obtained and unlawfully put in execution, to the great grievance and inconvenience of [the public]". Crucially, then, it declared such monopolies as being "utterly void and of none effect", invoking the "ancient and fundamental laws" of England but also codifying[40] a utilitarian approach to safeguarding the public welfare in a non-discriminatory manner and promoting freedom to carry out trade,[41] thus ensuring that the greater good would be advanced instead of that of a few favorites, an exemplary instance of utilitarian policy setting as also an expression of fairness or justice,[42] indeed as safeguarding individuals' economic rights. Certain exclusive rights were recognized as a strictly bounded *exception* to a firmly stated general norm against monopolies. Thus, one of the fundamental elements of Anglo-American patent law resulted from a principled exception to the abolition of abusive or illegitimate monopolies, the legitimacy of this limited exception grounded in the expectation of public welfare gains resulting from such exclusive rights. For instance, the Statute codified the duration of protection on a utilitarian basis, the term of fourteen years representing the two periods of apprenticeship which would be required to establish the new trade based on a new manner of manufacture thus protected. The question whether this exclusion is "fair" or "legitimate" may be cast in teleological terms: are the scope and duration of exclusion necessary but only sufficient to achieve the intended practical effect? The Statute is of historical interest as both a political and conceptual advance: on the one hand, it marked the evolution in political sentiment that had moved the

39 An Act concerning Monopolies and Dispensations with Penal Laws, and the Forfeitures thereof (21 Jac. 1, c. 3, 1623).

40 "Though the monopolies granted to the great trading companies were originally part of a constructive, rather than a restrictive policy; yet no similar defense can be maintained on behalf of the great majority of industrial monopolies. A very few of them were granted on the plan of modern patents, to encourage and reward those who had devoted trouble and expense to victory over some difficulty in manufacture; and they were constructive in tendency. But such invention was of the rarest occurrence in England during the time when monopolies were granted most freely: in fact most of them were given to favorites, or sold for sums not comparable in value to the injury inflicted on the people." Marshall, "Trade and Industry", p. 526.

41 Hume remarks how "the ideas of men were much changed, during about twenty years of a gentle and peaceful administration. The commons, though James, of himself, had recalled all patents of monopolies, were not contented without a law against them, and a declaratory law too; which was gaining a great point, and establishing principles very favorable to liberty: But they were extremely grateful, when Elizabeth, upon petition (after having once refused their requests) recalled a few of the most oppressive patents; and employed some soothing expressions towards them." D. Hume, *The History of England* (1754–1762), Chapter XLV, note N.

42 Concerning "an exclusive patent granted [by Queen Elizabeth] to a company of merchants in Bristol", Hume comments that "it is remarkable, that the patent, which the queen defended with such imperious violence, was contrived for the profit of four courtiers, and was attended with the utter ruin of seven or eight thousand of her industrious subjects." Ibid., Chapter XLIV.

Commons from being "extremely grateful, when Elizabeth, upon petition (after having once refused their requests) recalled a few of the most oppressive patents" to a position where "though James, of himself, had recalled all patents of monopolies, [the Commons] were not contented without a law against them, and a declaratory law too; which was gaining a great point, and establishing principles very favorable to liberty"; on the other hand, the conceptual progress it represents (especially its counter-intuitive quality, as a utilitarian tool for promoting dynamic gains in public welfare through creating exclusions from the public domain) is illustrated by the grounds of Elizabeth's earlier rejection of a monopoly over a genuine innovation. She was "one of the most wantonly mischievous traders" in Monopolies: "when Lee brought to her notice an epoch-making invention for knitting stockings by a machine – almost the only invention of any considerable genius and practical force which is known to have been made by an Englishman before the eighteenth century – she said, 'I have too much regard for my poor people who obtain their bread by knitting.' So he took his invention to France. The practical problem to be solved was not easy: but Elizabeth's solution was clearly a wrong one."[43] A similar failure today to wager the future on such dynamic welfare gains may reveal a similar assumption that the poor or developing economies should continue to "obtain their bread by knitting."

Self-evidently, a principled, systematic and utilitarian approach to analyzing and synthesizing interests is more likely to achieve optimal results either in utilitarian terms or in a broader sense of economic and social welfare, rather than a process of balancing sectoral interests or offsetting competing claims of gain or loss. The invocation of basic economic liberties in the progress towards the Statute of Monopolies recalls, also, that this kind of policy-setting process need not be construed from the perspective of sectoral interests. Rather, IP policy making can be confidently and legitimately situated within seemingly antithetical forms of discourse; indeed, it may be necessary for both legitimacy and utility. Considering the international plane, commentators have argued that an inclusive and syncretic approach is more likely to be politically robust and promote welfare. For example, Helfer argues the virtues of integrating an explicit human rights dimension in international IP law: "Although the debates within the WTO and WIPO will surely be contentious, trade and intellectual property negotiators should embrace rather than resist opening up these organizations to human rights influence. Allowing greater opportunities for airing a human rights perspective on intellectual property issues will strengthen the legitimacy of these organizations and promote the integration of an increasingly dense thicket of legal rules governing the same broad subject matter. Such integration will also allow national and international law makers and NGOs to turn to the more pressing task of defining the human rights–intellectual property interface with coherent, consistent, and balanced legal norms that enhance both individual rights and global economic welfare."[44] The opposing view is that too inclusive an approach would render the system unworkable or unpredictable;

43 Marshall, "Trade and Industry", pp. 655–656.

44 L.R. Helfer, "Human Rights and Intellectual Property: Conflict or Coexistence?", *Minn. Itell. Prop. Rev.* 47 (2003), available at http://mipr.umn.edu/archive/v5n1/Helfer.pdf, at 61.

international discourse would be rich and diverse, but the international public good of a multilateral trade regime that settles disputes in a predictable and stable manner would be diffused in a welter of unbounded debate. Behind this perspective is the realist observation that the ultimate function of the international regime is to provide a workable alternative to more damaging or less symmetrical ways of managing actual bilateral trade disputes on IP matters and practically setting the terms of mutual expectations between trading partners. It is striking that these analyses of IP law and human rights law tend to start from the assumption that they are polar opposites, that their reconciliation will inevitably be "controversial"; this may be because the broader human rights perspective may be reduced to specific policy interests, rather than deeper points of principle. In any event, a robust reconciliation of these competing demands on IP law would entail constructing an inclusive international jurisprudence of IP that is at once seen as legitimate by all interested parties and yet is also sufficiently systematic and predictable to serve as a practical means of pre-empting disputes or at least resolving them in the non-contentious manner foreseen by the WTO Dispute Settlement Understanding.[45]

TRIPS, from contention to coherence

The TRIPS Agreement has come to the center of policy debate on IP and, more broadly, on how policy makers and legislators should shape the framework for knowledge management to promote the public interest. In this sprawling debate, TRIPS has often served as a metonym or an emblem for one view of the world, and is presented as a neat encapsulation of the values or interests situated on one side of the polarities identified in the opening paragraph of the first section. It has been characterized as favoring privatization of knowledge (and knowledge resources such as genetic resources), and entrenching economic privileges centered in the developed world and neglecting the "social function" of IP laws.[46] At another level, TRIPS has been criticized as having served as a direct instrument for promoting or imposing this view of the world upon policy makers and legislators in developing countries who otherwise would have explored and implemented more diverse possibilities, more favorable to economic and social development. At times, as the debate evolves, these two levels have overlapped, so that the connotative reach of TRIPS as a metonym and as the expression of a set of values seems to be blended with its actual scope and effect as a legal text. This tendency for the legal text of TRIPS to shade into its broader political penumbra may be influenced by critical accounts of the genesis and negotiating dynamics of TRIPS, its initiation and formulation having been documented as a form of regulatory capture of trade negotiations by several specific

45 Article 3.10 provides that: it "is understood that requests for conciliation and the use of the dispute settlement procedures should not be intended or considered as contentious acts and that, if a dispute arises, all Members will engage in these procedures in good faith in an effort to resolve the dispute."

46 See Sub-Commission on Human Rights Resolution 2000/7, "Intellectual Property Rights and Human Rights" (August 17, 2000).

producer interests.[47] Yet, if TRIPS is to serve its formal function effectively – to resolve disputes between states[48] over intellectual property issues related to trade, by reference to an objective legal benchmark – and if it is to attain the social and economic welfare promise implicit in its objectives and principles – then it needs to be repositioned in the discourse. The remainder of this chapter explores how this re-centering – this orienting[49] – of TRIPS is happening.

In a binary structuring of interests, then, TRIPS has served as a metaphor for a broader set of processes: privatization of knowledge; a calculated assault on the public domain; an imposition of one form of knowledge management on the south and, in its "implementation" at least, an inadequate reflection of human rights and the social dimension of IP.[50] This is due in part – only in part, it is emphasized – to the assertion of its effect beyond its actual formal scope as a legal instrument, in the political and analytical discourse that inevitably surrounds TRIPS. A number of its many critics have therefore viewed TRIPS as a symbol of imbalance, or as one extremity of a polarized construct of knowledge management and policy flexibility, to the extent that it becomes a form of imperialism in itself.[51] Yet, just as these broader issues have opened up a debate about the true impact and legal effect of TRIPS, and critiques of TRIPS were expressed from alternative perspectives, this closer and critical scrutiny had the gradual effect of distinguishing the political and axiological penumbra of TRIPS from its core legal effect, and its positive role in setting bounds to and alleviating trade disputes on IP issues between WTO members. In turn, this opens up possibilities for a perception of TRIPS that – assisted, as necessary, by a syncretic but robust juristic interpretation – would affirm it as a means of defense

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47 P. Drahos, J. Braithwaite, *Information Feudalism. Who Owns the Knowledge Economy?*

48 And separate customs territories.

49 A.S. Taubman: "TRIPs Goes East: China's Interests and International Trade in Intellectual Property", in D.Z. Cass, B.G. Williams, G.Barker (eds), *China and the World Trading System: Entering the New Millennium* (Cambridge: Cambridge University Press, 2003), pp. 345–362.

50 See Sub-Commission on Human Rights Resolution 2000/7 ("Intellectual Property Rights and Human Rights"), which affirms that "the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which one is the author is, in accordance with article 27, paragraph 2, of the Universal Declaration of Human Rights and article 15, paragraph 1(c), of the International Covenant on Economic, Social and Cultural Rights, a human right, subject to limitations in the public interest" and declares that "since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other"

51 If TRIPs is successful across the breathtaking sweep of signatory countries, it will be one of the most effective vehicles of Western imperialism in history...[TRIPs] imposes presuppositions about human value, effort and reward. M.A. Hamilton, "The TRIPs Agreement: Imperialistic, Outdated and Overprotective", Vanderbilt J. *Transnational Law* 613 (1996): 614–16.

of legal pluralism and policy flexibility, while still positively guiding policy makers towards a convergence on the policy settings most effective in promoting desired welfare outcomes. The sustained critique of TRIPS had the positive effect of unearthing flexibility that was innate and implicit, but not explicitly stated: this was the consequence of the negotiations leading to the Doha Declaration on TRIPS and Public Health;[52] but deeper doctrinal flexibilities that are embedded in TRIPS are less frequently acknowledged. These flexibilities go beyond mere permission to make certain legislative choices. For example, the standard commentary of the Berne Convention – which largely defines copyright standards under TRIPS – underscores that the very core conception of copyright is unresolved under the treaty: "the very concept of copyright from a philosophical, theoretical and pragmatic point of view differs country by country, since each has its own legal framework influenced by social and economic factors. To define it in a manner binding on all member countries would be difficult, if not impossible". [53] Apart from its formal legal effect, therefore, TRIPS begins to serve as a broadly accepted benchmark for an overall balance of interests (notwithstanding certain strongly contested elements), that leaves open such diversity in legal doctrine and its social context; the acceptance of TRIPS as a *de facto* benchmark is the logic behind the critical analysis of other norm-setting processes on the basis that they are "TRIPS-plus" (and thus seen as inherently undesirable). Thus, an agreement that sets minimum standards is argued by some as setting an appropriate ceiling as well, indeed – from this perspective – a ceiling that some maintain might be beneficially established as a binding norm.[54]

This greater suppleness in the perception of TRIPS as a legal instrument has opened up greater practical possibilities than its relegation to one or other side in set-piece debates. Identifying the tactical and technical possibilities that the law of TRIPS offered ceased to be seen as a proxy defense of the interests of its original proponents, and was seen more as a basis for practical action to promote public policy outcomes. This transformation in its perception – from being seen as a bare expression of specific sectoral interests, to its broader acceptance as a mechanism for mediating diverse interests for the broader public interest – is an absorbing and important study in itself. For the practical interpreter of TRIPS, this serves as a reminder that public interest safeguards were incorporated by its negotiators to provide guarantees that, if systematically interpreted and implemented, it would

52 WT/MIN(01)/DEC/2, November 20, 2001.

53 "Guide to the Berne Convention" (Geneva: WIPO, 1978).

54 The writer does not necessarily share this view, influenced by the developmental and public welfare gains that would arise from continuing formulation of shared policy platforms as a strengthened basis for a cooperative approach to shared policy and administrative challenges: in this context, TRIPS provisions for cooperation on enforcement, technical cooperation and "positive comity" on the repression of anti-competitive practices are relevant, as are continuing efforts to find cooperative pathways for the improvement of patent quality (for a regional perspective on TRIPS as a framework for positive policy coordination in a non-binding legal context, see A.S. Taubman, "Collective Management of TRIPS: APEC, New Regionalism and Intellectual Property", in C. Heath, C. Antons, M. Blakeney (eds), *Intellectual Property Harmonization within ASEAN and APEC* (Dordrecht: Kluwer Law International, 2003), pp. 161–202.

indeed reconcile diverse interests and promote broader social and economic welfare. It illustrates how IP policy making can broaden from a limited focus on crafting trade-offs between rivalrous interests, so that the policy process of framing, administering and bounding exclusive rights is conceived as a positive-sum synthesis of interests. So this crucial shift serves as an illustration of the richer analytical options that open up when an emphasis on polarities is supplemented by a fuller conception of the policy process. Ultimately, it should move beyond the essentially defensive tactic of preserving policy flexibility, towards taking guidance from the general normative framework on how to exercise policy options for optimal welfare outcomes; the more capacious the policy space that is defended and sustained, the greater the opportunity (or onus) to make full, knowing and cooperative use of it: the collective management of TRIPS.

This evolution may be illustrated by the following instances:

- the growing confidence in TRIPS as a positive source of law that serves the interests of developing countries, illustrated by the increasing attention paid to the jurisprudential and policy implications of some of the safeguarding principles and measures introduced by developing country negotiators into the text of TRIPS: most obviously the role of Articles 7 and 8 in interpreting and implementing TRIPS, both as a guide to specific TRIPS provisions and as a justification or defense for policy choices not explicitly addressed within TRIPS), but also increasing attention given to other measures such as Article 40 (on anti-competitive practices, including licensing practices that constrain transfer of technology) and Article 66.2 (on incentives for transfer of technology to least developed countries), and potentially in comparatively neglected areas such as the provisions requiring enforcement of IP rights to be fair and balanced, and not to conflict with legitimate trade, and for enforcement to be at least as much a cooperative exercise between members as a focus of dispute between them;
- following the more intensive phase of TRIPS implementation on the domestic plane, a renewed concentration on the systemic benefits of multilateral regime for dispute settlement and norm-setting, reflected in debate over the implications of new IP standards and dispute settlement procedures in bilateral and regional mechanisms; and
- the consolidation of TRIPS as a benchmark of international standards, with the assertion by some commentators that it should serve as a *de facto* ceiling on any international norm-setting and indeed that its standards should be transformed into a *legal* ceiling on IP laws.

Behind these developments is the continuing dynamism and changing *de facto* effect of TRIPS as a legal text and as a guide or constraint on actual state behavior, and the natural evolution in the perceived ethical status of the standards which it prescribes, as the framework for their interpretation and implementation moves into clearer focus and the complementary notion of a permissive policy space is also more clearly established. A fundamental ambivalence lingers: are these treaty provisions essentially a benchmark for objective dispute settlement between WTO members,

or are they a positive guide for domestic policy makers seeking to promote social and economic welfare? Of all the polarities cited in this discussion, perhaps the one in most need of resolution and the restoration of common ground is this one – the polarity between TRIPS as a source of law for international dispute settlement, to be complied with either due to the principle of *pacta sunt servanda* or for fear of the adverse economic impact of so-called sanctions (the withdrawal of concessions by another WTO member[55]); and TRIPS as, in effect, the essential elements of a model law with the purported goal of promoting the social and economic welfare benefits of IP protection. To put it another way, is TRIPS compliance another zero-sum game – specific acts of compliance by one member entail "concessions" to its detriment which translate into expected benefits for other members – or is it integral to the promotion of domestic interests in its own terms? The role of the responsible interpreter of TRIPS – principally and practically, the domestic policy maker or legislator – is perhaps actively to conceive and carry out a commonality of purpose, transcending the polarization of interests, and thus shifting from compliance with international rules as a concession in a zero-sum environment to compliance as one component of domestically sensitive policy making. Or, again to recast the question, is TRIPS at core an artifact of old-style GATT negotiation rounds (the multilateralization of bilateral concessions, a congeries of trade-offs conceived in zero-sum terms, despite the acknowledged common benefits of unilateral trade liberalization), or is it – at least in inchoate form – an expression of a collective policy making endeavor, a multilateral fashioning of a positive tool for public welfare in the knowledge-based economy?

TRIPS jurisprudence as a realist instrument

The development of a systematic and equitable TRIPS jurisprudence is therefore more than an arid survey of analytical options and abstract methodological approaches to treaty interpretation. The need for an objective and robust jurisprudence of TRIPS has emerged as a realist interest in itself, both as a means of defending the bounds of necessary policy space, and perhaps more importantly as a prompt to making optimal use of that policy space (the domestic "policy space" that it is currently vigorously defending should not, of course, be a policy void or policy vacuum; nor, arguably, is it sufficient for it to be defined and exercised in terms of limitations and exceptions, since an exclusive focus on these measures as the chief tools of promoting positive social and economic welfare outcomes is to endorse an absolute polarization of interests). The momentum towards such a jurisprudence of TRIPS can be illustrated by a brief, selective review of the continuing debate and negotiations over access to pharmaceuticals under TRIPS, together with a review of the shifts in perception

55 It should be noted more than ten years after entry into force of TRIPS, no concessions have been withdrawn (so-called "sanctions") between WTO members as a consequence of TRIPS dispute settlement. The United States has agreed to compensate the E.U. in DS 160: *s. 110 U.S. Copyright Act*, and Ecuador gained permission to suspend the effect of some TRIPS obligations vis-à-vis the E.U. in the Bananas litigation (DS 27: E.U. – Bananas III – Article 22.6 arbitration).

resulting from practical experience of TRIPS dispute settlement. The present review does not attempt a comprehensive account of an important array of debates and negotiation processes, but briefly considers the implications of the Doha Declaration on TRIPS and Public Health ("Doha"). Doha was a political landmark and initiated the "paragraph 6" process to amend TRIPS enable countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing. It is no diminution of this momentous, but highly specific, aspect of Doha to point out that the declaration was mostly, in strictly legal terms, a tautology, asserting the existing law of TRIPS so as to validate options within that law. With the crucial exception of the paragraph 6 issue, Doha thus served more as a realist tool to assert political interests, rather than as a formal legal mechanism (curiously, not unlike the Statute of Monopolies, which was in formal terms an expression of the existing law, serving the political role of reinforcing respect in practice for existing principles). Doha hints at how a systematic and inclusive TRIPS jurisprudence may be formulated, drawing out principles and entitlements deeply embedded in the text.

The TRIPS Agreement entered the second decade from its entry into force with its legitimacy still contested, partly because it has served as a symbol for one side in the pairwise sets of antinomies considered above. The intensity of debate over TRIPS, and the tendency for interests to cleave into polarized camps, may obscure its inherent fluidity as a legal text, and the key role of the domestic legislator as a practical interpreter of such international legal texts: the construction of municipal IP law is at once a judgment as to what measures will resist challenge as to their treaty consistency, and the only effective means of delivering the positive benefits expected from treaty standards.[56] Political characterizations of TRIPS, teleological readings of the text of TRIPS influenced by the dynamics of and political background to its negotiation, a tendency to focus on TRIPS compliance as an end in itself and specific, high-profile set-piece debates, can all divert attention from the vital task of developing a positive public-interest conception of TRIPS implementation, and thus taking TRIPS in hand as an effective means of promoting the purported public welfare benefits that a consistent literal reading of the text would entail. This approach would require treating TRIPS (and the cluster of international IP law that it incorporates and which builds upon it) as a stable legal platform for the domestic policy maker to explore policy choices on a host of topical issues, ranging over public health policy, management of biodiversity, education, and regional development, choices that are contested by a widening range of domestic and foreign constituents.

It is well documented that the background political dynamics that led to TRIPS included bilateral trade negotiations and bilateral trade pressure, and that TRIPS formed part of a trade-off between sectoral interests in constructing a final deal in the Uruguay Round. Even though IP protection under TRIPS is purportedly welfare promoting, it is not a deal that most developing country negotiators would have accepted in isolation.[57] In part due to this political background, TRIPS, as a

56 See the extended discussion in Taubman, "Nobility of Interpretation".

57 The Tudors were not the sole "masters of the fine art of writing preambles": see note 23.

legal regime, is viewed as requiring rule-compliance for its own sake, rather than essentially functioning as an avenue for settling bilateral disputes. Yet the impulse behind negotiation and conclusion of TRIPS was not so much the desire to create a compliance-based multilateral law, as to create a remedy for or refuge from unilateral or asymmetric bilateral dispute settlement. Uncertainty about the nature of TRIPS as a regime has led to the overlapping or conflation of ethical, axiological and strictly legal analyses of TRIPS: to what extent is TRIPS assumed positively to embody, express and impart a specific set of values, imposing those values on societies through its legal effect; and to what extent does it more clinically and simply delimit the agreed bounds of state behavior, without predetermining the ethics and values that drive policy choices? Ironically, the more wide-ranging the critique of TRIPS as a legal regime, the more this critique can reinforce assumptions that its provisions do forcibly impose certain values and interests on the regulatory framework that deals with the dispensation of knowledge resources. Yet TRIPS has a more fruitful potential function as a means of ordering trade relations for a more robust defense of domestic policy choices, as the public health debate may now illustrate.

Making use of TRIPS in the defense of domestic policy choices needs to be distinguished from retrospective validation of the politics and dynamics of the negotiations; in effect, during its evolution as a legal regime, it will progressively be detached from the political circumstances of its negotiation. One underlying rationale for TRIPS was to provide a multilateral refuge for domestic policy choices taken within agreed bounds. How TRIPS is perceived and understood as a legal regime will in turn influence its enabling or chilling effect on policy makers and legislators seeking appropriate domestic policy outcomes within the international framework. This entails, in turn, acknowledging the unsettled quality of TRIPS jurisprudence, and working towards resolution of the interpretive and doctrinal legal uncertainties of TRIPS. This would allow TRIPS to be fully assimilated in the domain of international trade law but also accommodate the challenges to TRIPS law from the broader perspectives of public international law, notably human rights law. This process of embedding TRIPS within its broader legal and policy context should, ideally, not be done in an *ad hoc* or reactive fashion, responding to the immediate political clamor, but should be carried out through the conscious construction of a systematic and inclusive TRIPS jurisprudence. A robust and stable jurisprudence, well communicated and understood by policy makers, is integral to the more effective use of TRIPS in constructing domestic policy space and using it to safeguard and effectively deploy policy options, as technological, social and cultural change throws up continuing challenges for policy makers. Coherent core principles, transparently stated and effectively defended, provide a firm anchor against the ebb and flow of more ephemeral or sectoral influences on policy makers.

A systematic jurisprudence of TRIPS would need to be formulated within the actual context in which treaties are interpreted, applied and thus influence actual policy choices. Much domestic legislation on a wide range of IP policy questions in developing countries was termed "TRIPS implementation" for over a decade. The legislature was conceived at times as a passive recipient of externally imposed TRIPS standards. Yet full-blooded "TRIPS implementation" entails a more active role for the legislature in fashioning IP measures that comply with TRIPS within

acceptable bounds, but also actively promote the utilitarian welfare and mutual advantage that TRIPS ostensibly promises. The practical interpreter of treaty text – the legislator or domestic policy maker – is caught between competing goals of a legal clarity established through precise formalist interpretation, and a robust realist stability grounded in the actual political context in which diverse, even opportunistic, interpretations of treaty text guide actual behavior and determine choices. In practice, there are two competing jurisprudences of TRIPS that ultimately count: an oral tradition or customary law of TRIPS; and the actual jurisprudence that dispute settlement panels and the Appellate Body would apply in practice in cases that can realistically be expected to be brought before them. The former, oral jurisprudence has been dominant, not merely in policy discourse about TRIPS but also in determining actual legislative choices, when the most influential voice, and the political imprint of past treaty negotiations and ongoing trade negotiations, can sway the policy maker to take a limited view of TRIPS requirements. The alternative is to deploy black-letter law as a guarantee of flexibility and as a true safeguard for diversity of choice in a broader policy space. This is not to suggest a formalistic or overly text-bound approach to interpreting treaty law, as such an approach is demonstrably inadequate, lacking explanatory power, diverging from actual experience and, most importantly, failing to settle actual bilateral trade disputes on IP between sovereign states and customs territories (to recall: this is the fundamental function of TRIPS). Indeed, it is necessary to go well beyond the text, at least in framing its operational context, to grasp its legal character as a squarely positivist construction, to acknowledge its nature as an international regime, and to accept its norms as an expression of state interests in a most directly realist conception of international relations. TRIPS is a realist multilateral response to the realist unilateral assertion of state interests. Many countries have a pragmatic interest in developing predictable and transparent binding international rules that govern bilateral trade disputes. Therefore, their pragmatic interest is served by a systematic jurisprudence of TRIPS that synthesizes and assimilates the diverse streams of conventional international trade law, municipal intellectual property law, the diplomatic history of legally independent IP treaties, and the broader stream of international law and the diverse constituencies it engages. This process of constructing a systematic jurisprudence is, in itself, the formulation of an inclusive conception of equity in the regulation of knowledge resources through IP law, and the objectives for IP protection in TRIPS operates as vector for the introduction of a broad conception of equity into the operation of IP law. This way forward has tentatively been sketched by the limited actual practice of panels in dispute settlement.

Six impossible things

This process of detaching TRIPS jurisprudence from the background perception can be assisted by exploring six “impossible things” about TRIPS; these are not asserted here as factual truths, but as antinomian or seemingly paradoxical observations, to probe assumptions about the role of IP standards within international trade law. They may assist in loosening the links between TRIPS and the political background that

colors its interpretation, and thus may help distinguish TRIPS as a legal text from political and institutional assumptions that are not germane to its essential character as a legal regime.

- In form, if not in substance, TRIPS is a "fair trade" agreement. Merely to state this may be seen as a provocative political position. Fair trade activists call for the reform or withdrawal of TRIPS from the WTO. But this is only intended as a far more modest comment on its formal structure. TRIPS is posited on a form of "legitimate trade" as a minimum standard, in tension with the "maximum standard" logic of mainstream WTO trade law: IP protection is an *exception* to GATT rules, subject to the Article XX necessity test. IP law was originally considered within trade law as an allowable constraint on trade, rather than a necessary element of positive trade rules. Yet, the logic of TRIPS is that trade in IP-related goods is only permissible if it meets the TRIPS standard of legitimacy – other trade is presumably illegitimate, or unfair. Thus a regulatory floor sets the minimum standard of legitimacy rather than a regulatory ceiling imposing a maximum level for legitimate government intervention into trading activities.
- TRIPS is conservative, not revolutionary, on substantive standards, at least from the point of view of most developed countries; its flexibilities had to be unearthed, but the text retains a deep background of policy flexibility in IP law, carried over from the foundational international treaties. TRIPS (as essentially captured in the Dunkel text of 1991) was – largely – a relatively conservative codification of a typical common law jurisdiction in the developed world. There are some exceptions to this observation (and some genuine policy and fundamental doctrinal difficulties with TRIPS implementation and compliance experienced by developed countries[58]), but overall the substance of TRIPS is essentially a retrospective consolidation of developed countries' IP standards in the late 1980s. Its revolutionary qualities lie not in the formal substance of its normative standards, but how those standards are applied. TRIPS standards on copyright, for example, can be contrasted with the distinctly new normative directions of the WIPO Copyright Treaty, concluded a year after TRIPS enters into force. This invites consideration of what the essentially revolutionary quality of TRIPS is, if not its standards *per se*.
- TRIPS emerged as a negotiating concession in the logic of the Uruguay Round rather than a collective policy making endeavor. Yet it is the first international IP treaty explicitly to articulate a utilitarian, public welfare ethic as the policy basis of IP protection, even though its conclusion and implementation are

58 In terms of the broader judicial system and constitutional guarantees of natural justice, for example, several Nordic countries had initial difficulties in implementing the TRIPS provisions requiring the possibility of *ex parte* injunctions, and were challenged by the U.S. (Sweden – Measures Affecting the Enforcement of Intellectual Property Rights DS86 and Denmark – Measures Affecting the Enforcement of Intellectual Property Rights DS83); on substantive legal standards and policy choices on IP issues, the E.U. successfully challenged exceptions in U.S. copyright law (U.S. – s. 110(5) Copyright Act DS160) and in Canadian patent law (Canada – Pharmaceutical Patents, DS114).

seen as submission to a realist exertion of sectoral interests by rich countries. On paper, at least, it contributes to international IP law a novel and potentially valuable act-utilitarian ethic of IP protection, while its implementation and evaluation are mired in, at best, a rule-utilitarian ethic and, at worst, a passive compliance model. Formally, this creates the paradox that self-interested TRIPS compliance is construed as a cost to welfare, while TRIPS itself interprets compliance with its standards as a welfare gain. Implementation of TRIPS is conventionally viewed as a concession by developing countries, imposing costs that can only be justified by offsetting gains from the access to agricultural and textile markets that the Uruguay Round package ostensibly offered. Yet IP protection under TRIPS is nominally intended to promote social and economic welfare, and a utilitarian optimal balance of rights and obligations (the "should" of Article 7). Thus, compliance with TRIPS is at once a costly negotiating trade-off and a beneficial act of public policy making. This is the paradox of WTO dispute settlement more generally – even if trade liberalization is a negotiating "concession," it is still, according to classical trade theory, in the mutual interest of all parties, so the suspension of concessions as the remedy in trade disputes incurs costs on the victorious complainant. This paradox may be resolved in the context of TRIPS by dismantling the conception of the Agreement as a monolithic set of provisions, as a form of multilateral legislation for domestic laws (a conception that would view TRIPS as, in effect, a binding model law, rather than – "merely" – an international treaty defining relations between states and customs territories, and one ingredient only in the domestic legislative process).

- There has been a general tendency in debate to see TRIPS compliance as a legislative end in itself, with non-compliance subject to "sanctions" with "teeth", although many countries have maintained some form of non-compliance for extended periods. TRIPS was itself the consequence of what Hudec has termed "justified disobedience"[59] under GATT. And one of the chief proponents of TRIPS has illustrated how pragmatically to manage a choice to remain non-compliant in the light of delayed implementation of a recommendation to amend laws to bring them into compliance, through negotiation and arbitration of compensation. Indeed, given that the cause of action in TRIPS dispute settlement essentially concerns nullification and impairment of benefits, and given the nature of the methodology used so far, it is has emerged that it can, at least provisionally, be less burdensome to settle for compensation than to comply.
- Developing countries' choices have been constrained by perceptions that anything but direct textual compliance with TRIPS runs the risk of triggering trade sanctions, yet more than ten years into its life as a regime, the only sanctions imposed under TRIPS have been the compensation agreed between the two dominant developed economies within the WTO, and a developing country has used the threat of TRIPS-related sanctions in the course of WTO dispute settlement to leverage access for agricultural exports.

59 R.E. Hudec, *Essays on the Nature of International Trade Law* (London: Cameron May, 1999), p. 174.

- While it was conceived by some as a cure for bilateralism in dispute settlement, and important policy processes were established to deal with core outstanding issues in a multilateral forum, the entry into force of substantive TRIPS provisions for most countries has been followed by a strong upswing in bilateral determination of IP regulatory issues. Early developed country interest in multilaterally advancing norms under TRIPS in areas of interest to developed countries largely gave way halfway through the first decade of the operation of TRIPS to see greater prominence of norm-setting goals of developing countries, particularly in the field of genetic resources and traditional knowledge.

The debate over access to pharmaceuticals exemplifies the question of whether TRIPS can potentially return to its roots as a means of stabilizing and objectifying bilateral trade negotiations on IP matters, rather than as a strict compliance mechanism. To attempt an objective but realist appraisal of the scope for national policy making concerning pharmaceuticals raises delicate political assessments. To assess the impact of TRIPS in this domain, one must contrast the costs of (passive) compliance with or (active) implementation of the multilateral regime as a defendable regulatory minimum; and the costs and limitations of policy making in an anarchic international environment, in which formal freedom to set policy directions is constrained by the assertion of political, commercial and other sectoral interests, potentially creating a greater *de facto* constraint than any international legal standards. This assessment varies, too, according to the degree and distribution of ownership of interpretative authority over those multilateral standards, and the related capacity to make robust and defensible interpretations. From a realist point of view, TRIPS should be understood as a legal bargain to restrict any material trade retaliation in two key ways – on the grounds of trade retaliation, which TRIPS within the WTO regime restricts to violation of the agreed standards (and potentially other non-violating nullification and impairment of benefits); and perhaps just as importantly on the *quantum* of retaliation, which is capped by the ceiling imposed by a strict restitution rule (as opposed to a punitive standard of retaliation),[60] a limit which is proportionate to the size of the economy of a losing respondent.

In the late 1980s and early 1990s, in the absence of established international rules governing the appropriate scope and limits to patents on pharmaceuticals, several developing countries had to balance IP and public health issues (including patentability of patents) against continued access to export markets in areas of comparative advantage as one basis for economic development (another factor in public health). Experience showed how unilateral measures, rooted in the domestic law of the *demandeur* state, could be invoked in developed country markets, with the effect that punitive tariffs would curb sensitive and valuable imports from developing countries if their domestic IP regimes were considered to be inadequate – according to an essentially unilateral, external standard of what is adequate or appropriate. Actual cases of sanctions were very rare (although there was one instance in the

60 DSU, Article 22.4: "The level of the suspension of concessions or other obligations authorized by the DSB shall be equivalent to the level of the nullification or impairment."

late 1980s of failure to protect pharmaceutical patents leading to the imposition of punitive tariffs, in turn provoking domestic legislative changes). Yet the degree of bilateral monitoring and the potential for targeted trade sanctions and more general damage to a cooperative trading and political relationship meant that unilateral standards of adequacy or acceptability of protection could be highly persuasive. Given the substantial nature of the trade interests involved, and the inevitability that they will be asserted and defended, a realist analysis at least suggests that bilateral diplomatic channels to settle disputes will lead to asymmetric and unilateral outcomes (this is to distinguish bilateral dispute settlement from broader bilateral norm-setting initiatives, particularly in the context of free-trade agreements, which are not considered here).

Policy space as a legal construction and a realist interest

By contrast, the conclusion of TRIPS as a multilateral means of resolving bilateral disputes concerning IP trade has at least opened up possibilities for a more explicit exploration of domestic policy options, within the framework of agreed international trade obligations. Here, the distinction between an oral tradition of TRIPS jurisprudence and its formal reach became explicit. The present discussion considers strictly legal questions only, setting aside the crucially important policy debates of when such measures are desirable and in what circumstances they are beneficial or harmful. Legally, TRIPS did not preclude measures such as government-use authorizations in the context of public sector programs, or compulsory licenses as a remedy in regulating competitive relations between enterprises or otherwise ensuring that business activities are competitive. TRIPS, and the provisions of the Paris Convention embedded within it, did provide for compulsory licenses and government-use authorizations, setting certain procedural constraints and safeguards for the patentee's interests. Yet for a government actively to consider such measures or to implement them was described in some cases as non-compliant with TRIPS obligations, or as "breaking" a patent or "violating" international trade law. This arose in 2001 in the context of proposals for government-use authorizations (one form of "compulsory license") programs for gaining access to patented antiretroviral drugs, whether through government-authorized manufacture for public health programs (potentially a form of public non-commercial use), or authorization of the production of competing generic products (through compulsory licensing). In practice, at least until recently, these mechanisms were kept in reserve as public sector procurement agencies negotiated with the patentee on price for supply of the products in question. To assert these measures, in the face of concerns on the part of trading partners and a policy debate about their desirability, required a degree of confidence in the legal position, sufficient to dispel concerns about the international legal consequences so that clearer decisions could be made in the agreed policy space created by international standards, without the distraction of competing oral traditions of TRIPS law.

Upon the adoption of TRIPS as part of the WTO package, at Marrakech in 1994, Indonesia expressed a wider apprehension about the invocation of legal measures:

> Among the new obligations which we consider as a major concession is the agreement on intellectual property. In order for us to implement the agreement fully, we require technical assistance from our developed trading partners. As we make our adjustment, what we need most is technical cooperation and not legal harassment.

The background of concern led to the potentially paradoxical outcome that TRIPS was both constructed as a multilateral refuge from bilateral "legal harassment" and yet served as a means of legitimizing and giving multilateral force to such coercion. This tension was resolved in the debate over legitimate responses to concerns over access to pharmaceuticals, and patented antiretroviral drugs, in particular, through the elaboration of Doha. It recognized "flexibilities" under TRIPS as including:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
(b) Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
(c) Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Notably, the conventional means of treaty interpretation are themselves characterized as a "flexibility" under the treaty: recall that the implementation of treaty-consistent domestic legislation is the most thoroughgoing form of treaty interpretation. The objectives and principles of TRIPS[61] are also explicitly invoked as relevant guides to interpretation, setting these precise legal provisions within a broader policy context. This underscores the point[62] that the domestic legislator or policy maker, in seeking to implement domestic law and legal measures in a good-faith endeavor to promote beneficial public policy outcomes, is not acting in tension with treaty obligations and treaty implementation – is not caught in a cleft stick or a true dilemma, faced with a choice between polarized interests – but is in fact carrying out a deeper form of treaty interpretation, one that ultimately serves as a contribution to a shared conception of how implementation of treaty obligations can function to deliver on the public welfare promise implicit in the treaty's objectives and principles. Precisely because

61 This appears to refer (at least) to Articles 7 and 8 of the Agreement, although Article 7 does not literally define the objectives of the agreement as such (as an agreement between sovereign international entities, rather than a legal instrument directly protecting intellectual property), but nominally at least refers to the objectives of IP protection in general.

62 Taubman, "Nobility of Interpretation".

TRIPS does reach to an unprecedented degree into domestic policy making, the very policy choices, equitable considerations and how they are resolved, that arise at the domestic level reach back into the interpretative context of TRIPS. Beyond the domestic environment, and the good-faith and legitimate endeavors undertaken there to harness and to bound exclusive rights in the expectation of broader welfare outcomes, there is no alternative forum for determining and implementing some of the important policy balances and policy provisions that define the essential architecture of TRIPS. Rather than insisting on an exclusive cleavage between domestic policy space and the formal imposition of international legal obligations, there is the possibility of construing the active exploration of beneficial and equitable welfare outcomes within the domestic policy environment both as a higher form of treaty implementation and as in itself a more compelling and legitimate means of treaty interpretation, one that lends justice and validity to the standards embodied in the treaty. Gerhart comments that compliance and substantive validity are intertwined, defining "substantive validity" as "the issue of whether the obligation in question meets an articulated standard of welfare".[63] From this perspective, "a statement that a standard is substantively valid is the statement that the standard is just". Compliance with international standards and their substantive validity are set in terms of "the issue of whether international law is moving the world towards a better position by improving the world's welfare under defined and defensible criteria".[64] But the very process of domestic implementation of standards such as TRIPS is not (or should not be) a simple act of compliance with externally based standards: it is an active reading of the text, a practical interpretation of its effect, which can itself both inform and lend substantive validity. This is because the extent to which the "world's welfare" is influenced by international IP standards ultimately can only depend on choices and actions taken at the municipal level, under domestic laws and legal measures that apply and operationalize more abstract and remote international standards, and in so doing mediate and interpret them, in such a way that either delivers or denies the "articulated standard of welfare." This brings treaty compliance as a process closer to the validation of standards as welfare-promoting, rather than construing standards in an external and static sense; from this practical perspective, international standards have an ethical neutrality that is portrayed as flexibility, and the ethical onus falls to some degree on the domestic policy maker to integrate the process of compliance with international standards with a deeply rooted sense of how the deployment of IP laws harnesses private interest to promote actual welfare delivered at the national level.

This in part helps to explain the role of Doha. As noted, it is on its face mostly a legal tautology – simply restating in more explicit form what was implicit in the agreement as a legal text. But it also returned the domestic policy maker to the center of treaty interpretation and implementation. In focusing on the flexibilities that are available, in articulating explicitly what was only implicit and in highlighting the "freedom" to determine the grounds for compulsory licenses, the "right" to determine

63 P. Gerhart, "Beyond Compliance Theory – TRIPS as a Substantive Issue", *Case Western Research Journal of International Law* 32 (2000): 357–385, p. 361.

64 Ibid., p. 362.

what constitutes a national emergency or other circumstances of extreme urgency, and the freedom to establish a regime for exhaustion of rights *without challenge*, Doha empowers the domestic policy maker, and shifts from a perception of TRIPS as essentially foreclosing or precluding options, towards a TRIPS as a safe harbor for legitimate domestic policy making. In this sense, Doha arguably operated more at a political level than a legal level, as a realist recalibration of interests within an unexpectedly permissive legal environment. It may be seen as a political validation of policy tools that were perhaps considered strictly legal but in other, undefined senses illegitimate or inappropriate, because of confusion between the legally defined bounds of legitimate domestic policy choices and the still harder, more crucial debate about how to take optimal policy choices within those bounds. In this sense, then, the declaration may be argued to have some normative force – even in its recognition, in paragraph 6 and the negotiations and decision that it initiated, that countries needed the capacity to make "effective use of compulsory licensing" as a policy tool.

In working towards a systematic and equitable TRIPS jurisprudence, it is necessarily to revisit the question of what was the "revolutionary" quality of TRIPS. It was not, for the most part, the substantive content of its provisions, which were essentially conservative (at least from the perspective of developed country economies), reflecting accumulated domestic experience rather than charting new legal ideas. Its radical effect lay, perhaps, more in the manner in which TRIPS was intended to influence state behavior – how it was intended to influence or to determine the choices available to the domestic policy maker and legislator. This is partly a legal question – the bounds that TRIPS formally sets are, or should be, legal ones – but is also partly a question of the political role of TRIPS, and the way TRIPS as a regime is perceived by those subject to it – TRIPS lore as against TRIPS law. Several ways of seeing TRIPS can be discerned – as requiring reactive compliance as an end in itself; as a means of setting a multilateral legal boundary, an agreed and objective ceiling, on the grounds for and the degree to which damage to IP-related trade interests can be the subject of legitimate retaliation; as an agreed policy space within which the domestic policy maker is entitled – or even obliged – to work towards forms of exclusion from the public domain, and limitations and exceptions to these exclusive rights (and other forms of exclusion such as the legal measures required under TRIPS Article 22 and Paris Convention Treaty Article 10bis), which promote public welfare in an equitable manner, whether this is construed in utilitarian terms or rights-based terms.

A systematic TRIPS jurisprudence can operate as a safeguard, underpinning the rule of law internationally as it sets limits on the grounds for and extent of retaliation for claimed damage to IP-related trade interests. In turn, this should reduce the chilling effect on policy formation that is created by uncertain, or ill understood, or diffidently defended, or inaccurately asserted legal standards. The consolidation of a central body of multilateral jurisprudence may also help to constrain the diffusion effect of bilateralism or regionalism in norm-setting, the current centrifugal tendency in establishing, elaborating or glossing the fundamental framework of multilateral standards.

TRIPS is a pioneer agreement in the evolution of international trade law, a forthright "trade and" agreement within the WTO system, and the most far-reaching in "behind the border" regulation. In formal or structural terms (if not in its policy

thrust) it is the first "fair trade" agreement, in that it seeks to determine a minimum standard of legitimate trade, which governments must take positive action to ensure is maintained. Jurisprudentially, it has a strikingly hybrid quality: IP protection is an unwelcome intruder in world of classical trade law, given its earlier status as a potentially justifiable exception to trade law obligations. But TRIPS has also brought to a head the long-standing question of how to integrate, systematically, the technical provisions of domestic IP law with general public policy questions. This is at one level a question of formal treaty interpretation and, more broadly, a question for public international law. But the very domestic reach of TRIPS means also that many of the complex issues of balance it raises are only resolved in municipal law; the challenge then becomes less how to ensure domestic law complies in a strict formal sense within international standards, and more how to bring, systematically, to the international level all the lessons of domestic law making and judicial consideration of these issues? The domestic environment remains the only available forum for creating a positive, mutually beneficial resolution of the opposed sets of interests and values that define set-piece policy debates, and provide the elements for the "balance" at the heart of IP policy making. The true resolution of these polarities is ultimately not found in "balanced" international forms of words, brokered between negotiators, but in actual implementation, exercise, administration and regulation of legally recognized exclusivities in the national legal and policy environment. The lack of a consistent, clear and systematic jurisprudence would require a degree of rootedness in actual domestic experience, lest it take on an excessive legalism, and fuel the very kinds of policy uncertainty that Doha declaration was required to deal with.

Trade in IP is an integral component of actual trade: this means that there are real and substantial trade interests engaged when there are perceived failings in adequate IP protection – when "illegitimate" trade is permitted or condoned. This means that there will inevitably be real disputes, founded not on formal notions of TRIPS compliance as an end in itself, but on the true cause of action under TRIPS – the expected benefits arising from an adequate level of IP protection and the creation of measures against illegitimate (infringing or unauthorized) trade. TRIPS sets an upper boundary on retaliation when such benefits are nullified or impaired, thus limiting the effect of trade disputes to a level of objective fairness, based on an assessment of actual damage caused. This brings equity and a symmetrical balance of interests in the international governance of knowledge resources. A systematic jurisprudence should then offer a close reading of the notion of legitimate trade and legitimate interests, built upon on public policy concerns and public international law. This is not a departure, but a return to the principles of IP and cognate areas of law (notably, the law of competition and the regulatory responses, such as the Statute of Monopolies, to privileges obtained "upon misinformations and untrue pretences of public good"). Equally, given the realist interests that gave rise to TRIPS – the identification and concerted advancement of concrete trade interests, and the resort to a multilateral refuge from the unilateral assertion of those interests – it provides the basis for a realist foundation for justice in trade law. If notions of fairness, equity and legitimacy can be brought "behind the border" through trade law, does it entail an unexpected dependency on and deference to the domestic policy and legal

processes to give substance to those notions; or can it unexpectedly foreshadow a fuller conception of fairness in international trade law, based on a richer conception of what it is that makes trade "legitimate"?

Watch this policy space: A tentative conclusion

The legitimacy of IP policy making will depend not on the degree to which a formal, linear balance is struck between polarized interests, but the way in which exclusive rights are defined and deployed as a dynamic means of inducing the production of knowledge goods for the public benefit. The text of TRIPS makes the striking, ostensible, claim that protection of IP can, or at least should, promote the utilitarian goal of public welfare while surpassing a zero-sum trade-off between competing interests to yield *mutual* advantage, and also promoting a sense of fairness in the balancing of rights and obligations. This text may be seen as a negotiating sop; or as a charter for action, as a stimulating challenge for the policy maker. This chapter has not explained in practical detail how this challenge can be met, but is limited to arguing why it must be done.

How to rise above mere compromise between opposed interests is exemplified by the view taken of the treaty text itself. The interpretation and implementation of treaty language should transcend the sectoral impulses that actually structure the dynamics of treaty negotiation. The treaty as a legal regime and policy instrument can be progressively detached from the precise partisan circumstances of its drafting. This detachment is assisted by high-profile political impulses such as Doha (which itself was the outcome of bargaining between opposed sets of interests). But the steady accumulation of a systematic body of TRIPS jurisprudence through dispute settlement, and less directly through the accumulation of enlightened domestic policy making within the treaty framework, provides the potential for a still more solid, broad-based foundation. Yet this wistful invocation of a mythical body of enlightened, enabling and coherent jurisprudence of international IP law would, however, remain mostly an aspiration if the winner-take-all assertion of partisan interests remains a more accurate portrayal of the actual policy process.

PART 2
Science and Intellectual Property

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Chapter 6

Exclusive Property Rights in the Biosciences: An Ethical Discussion

Christian Lenk

What are "exclusive rights"?

The term "exclusive rights" will be used in the present article in the sense that the owner, and only the owner, of a specified property has the right to use, possess and control a specific tangible or intangible entity and that he or she is, in normal circumstances, not obliged to share his or her property with anyone else. One could also argue that the term "property" as such implies the exclusivity of the usage of a specific entity,[1] but this seems to rather be a description of private property, while other forms of property (like public property) exist, and are supposed to be used by all citizens without exclusions. Obviously a clear distinction exists in the case of tangible and intangible property concerning the question of controlling property. While it is one of the typical aspects of the concept of tangible property that the user will control his or her house, car or anything else, such control may produce some problems in the case of intangible property. For example, intangible property, like information, is normally produced for widespread dissemination, and the principle of trying to control access to such property may appear contradictory.

Exclusive rights in intellectual property are traditionally guaranteed by protection mechanisms, such as copyrights, trademarks or – as discussed here – patents. A patent is "the right for the exclusive use of the invention which is under the patent's protection" and "has the effect that only the patent holder is authorized to use the patented invention".[2] Patents secure intellectual property (inventions) and at the same time limit the exclusive use of such property to a specific period of time. The creation of the patenting system seems to be historically connected to the systematic production of knowledge and its application for early industrial use. Patents protect the owner of an invention against espionage and at the same time enable the public to participate in the new knowledge of the patent holder. Without patents, it may be rational for the owner of intellectual property to keep such information secret.

1 For example, the German Dictionary of Law defines property as "the relationship of power of a person (the owner) over a thing by which it is left up to his discretion how to proceed with the thing and to exclude others from exerting influence over it", author's translation, German Dictionary of Law, "property", *Deutsches Rechtslexikon*, 3rd ed. (Munich: Beck Verlag, 2001), p. 1206.

2 Ibid., p. 3186, author's translation.

With the possibility of patenting, the publication of such information is reasonable, and the public profits from the new knowledge, which can be publicly used after the patent's expiry. Therefore, both the public and the private party will in many cases profit from a patented invention: the private party can recoup the investment in research and development, whilst the public acquires knowledge of a new invention and can make use of it without extra investment after the expiration of the patent.

The following exceptions from the exclusive use of patented products and procedures are applied in different countries. First, the possibility of experimental use in the context of scientific research. This is justified with the argument that patents should not obstruct scientific research. Second, and especially relevant in the medical sector, for the preparation of generic products before the expiration of an original product's patent. Such a rule limits the monopoly for a specific product very close to a patent's expiration date. Third, the permission of parallel imports of the same original product, which should regulate the price to a moderate level. This measure prevents high-price strategies of pharmaceutical companies in separate countries. But parallel imports can also produce adverse affects and could give an incentive for pharmaceutical companies to establish equally high prices even in poor countries.[3] Fourth, compulsory licensing as grounds for a company to use a patented procedure against the wishes of the patent holder. Compulsory licensing is normally justified by public interest arguments.[4]

An additional fifth, and probably the most important (and highly relevant) exception is the non-patentability of "essential goods":

> …numerous countries have at times exempted various kinds of invention in certain sectors of industry from patent protection. Often the law has restricted patents on products confining protection to processes for their production. Typically these sectors have been foodstuffs, pharmaceuticals and chemicals, based on the judgement that no monopoly should be granted over essential goods, and that there is more to be gained by encouraging free access to foreign technology, than by potentially stimulating invention in domestic industry.[5]

The decision to not permit the patenting of essential goods obviously has something to do with a balancing of different legal entitlements/rights, that is, essential needs of the population versus property rights of potential patent owners. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) rules out national laws that deny patentability based on the essential-goods argument with the justification that this would be a "discrimination in the grant of patent protection in respect of different fields of technology".[6] This is a confusion of conceptual categories, philosophically speaking, as one can only discriminate against individuals, but not

3 C. Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (2000), p. 65, available at http://www.southcentre.org/publications/publichealth/publichealth.pdf, accessed on March 30, 2006.

4 Ibid., p. 91.

5 Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: IPR, 2000), p. 19.

6 Ibid.

"fields of technology". And it is dubious from the perspective of humanity, because it demands the protection of "fields of technology" against the vital needs of patients in the field of patents on innovative drugs.

Exclusive rights in the context of the liberal state

Private property and the guarantee of private property was one of the central pillars in the rise of the modern civil state. In this context, it is the central goal of the liberal state to protect the property of its citizens. This can be seen as a classic defensive right of citizens as, for example, the right to protection of bodily integrity. But it also can include more active measures of the state, as in the case of the protection of exclusive intellectual property rights. Intellectual property is often widely distributed and disseminated. The author or producer sells copies and allows the user to read and use the knowledge thus embodied. To exclude abuse of intellectual property, especially in a society where nearly everybody has access to photocopiers and computers, which can easily reproduce all forms of electronic content, leads to the establishment of a system of surveillance and of charges for the private or commercial use of intellectual property (see, for example, Lucie Guibault in Chapter 12 of this book).

This clearly collides with other rights of citizens, for example their right to privacy and sometimes even their right to freedom of expression (such as in the cases of teenagers who are sued by international media companies to close down their websites dealing with heroes of teenage stories). It is far from clear if the state, which traditionally has to guarantee the civil defensive rights, also has to build up a system to entitle owners of intellectual property to the exclusive use and the financial exploitation of such information. Although there may be other conclusive arguments to protect intellectual property, such as the incentive for research or public ownership after the expiration of a patent, this is not apparent from the viewpoint of the classic task of the modern state. This task is the protection of property, but not the creation of measures for the exploitation of property. The regulation of property rights therefore has to balance the differing interests of the owners of exclusive property rights, the interests of the state and the legitimate interests and rights of the users of intellectual property.[7]

Implications of exclusive rights in a globalized world

The fact that there are clearly different national traditions in the protection of intellectual property – more liberal and more protective approaches – makes it very difficult to find an international instrument for the protection of intellectual property that is acceptable to all participants or potential members of international treaties like, for example, TRIPS. There also is one important problem in the case of international treaties on property: when the state is the institution that guarantees

7 Ibid., p. 6; Trade Related Aspects of Intellectual Property Rights (TRIPS), Article 7; Universal Declaration of Human Rights, Article 27.

the existence of property, what kind of institution could guarantee property on the international level? State A cannot guarantee its citizens' property rights in state B unless both sides agree to a bilateral or multilateral treaty. And there may be very different interests of state A and B in the case of rights in intellectual property, depending on the extent of their national development and the possibility of their citizens to produce patentable knowledge:

> If you look at the statistics, the statistics for use of the PCT (*Patent Cooperation Treatment*, CL) are that 95.5% of all PCT applications come from nationals of OECD member countries (source: WIPO 2003). And if you include China and Israel, into the mix it goes up to over 99%. So roughly 1% of the world's patents come from everywhere else, from India, from Brazil, from Argentina, from South Africa, from countries many of which have a significant technological capability – Malaysia, Singapore, etc.[8]

In other words, non-OECD countries do not profit from the international patent system in terms of the protection of their own intellectual property. Therefore, if they can realize any profit from the patent system, it must come from patent protection for citizens of foreign countries or from other positive outcomes of the international liberalization of trade. Lehman argues that the protection of intellectual property is one side of a deal whereby developed ("post-industrial") countries profit from safety of their intangible products and developing (or, better put, "threshold") countries profit from the possibility of exporting classic industrial products to the developed countries.[9]

Many of the developing countries are still in a situation where they have serious problems satisfying their citizens' most basic needs. This situation must have an impact on the guarantee of exclusive property rights, when such rights function as a barrier to the access, for example, of patients to life-sustaining drugs. It is questionable whether a state in such a situation should protect intellectual property rights of foreign right holders when those property claims threaten the lives of its own citizens. It is insufficient to justify the protection of property only in terms of the liberalization of international trade, which cannot be an aim in itself. The overall goal of free trade has to be societal welfare and not the protection of singular economic interests. The core functions of a state (the fulfilment of basic needs of citizens of poor countries) should have priority over such international treaties, and it is hardly acceptable that governments of poor countries are threatened with trade sanctions when they try to secure basic needs of their own citizens – which should be one of the main objectives of a functioning state.

The dilemma: Patents, progress and economics

Patents are instruments to secure the intellectual property and the economic investments of people and enterprises that introduce new products and procedures

8 B.A. Lehmann, "Intellectual Property Rights as Trade, Health and Economic Development Issue", *St. John's Journal of Legal Commentary* 17(3) (2003): 417–427, p. 425.

9 Ibid., p. 419.

into markets. From this point of view, patenting makes the future more calculable and predictable for inventors, and gives an incentive to engage in the development of new products. Although this has some disadvantages, it is important to see that these incentives are given solely on a legal level, and taxpayers do not have to give money for the reimbursement of these inventions. The main disadvantage is, indeed, that the incentive consists of a restriction of the right of other people to engage in the same activities.

This is questionable, not only from an economics point of view – because patenting can result in monopolies in specific market areas – but also from a philosophy of rights point of view because in a liberal society people should have as much freedom as possible to do the things they want to do as long as they are not doing harm to others. The protection of intellectual property could equally mean that people should have the right to use their own inventions and establish new products on the market, and does not necessarily include a restriction on preventing competitors from copying such procedures and products. The main argument for the protection of intellectual property by patenting is a consequentialist one, that is, that there would be significantly fewer inventions without patenting and an important loss to society altogether.

In addition, there seems to be some evidence that the incentive to engage in research and investment activities is as strong as the protection of intellectual property. To demonstrate this relationship, one should imagine a situation where we would weaken the right to possess tangible property to, let us say, a sum of €25,000. Every person should have the right to accumulate such an amount of money, and if somebody possesses more money, she or he has to give it to the state. Obviously, such a law would make it pointless (on the private level) to engage in economic activities over and beyond the limit of €25,000. The same goes for the reimbursement of investment in research and development: if the invention of new products and procedures is not rewarded adequately, it is far less attractive to engage in such activities. It follows that protection of intellectual property that is too weak is as harmful for people that could profit from specific new products – for example, drugs – as would be a protection that is too strong.

It is possible that the absence of intellectual property protection is also harmful for potential inventors in developing countries, because without property protection they lack the security (and therefore a sufficient incentive) of being able to recoup potential investments in research and development. Maybe this argument seems unrealistic for the so-called “least developed countries”, but it is clearly an important argument in the case of threshold countries. Those countries will – sooner or later – not only profit from the possibility of copying and “reverse engineering” of industrial products from other countries, but also from patent protection for their own inventors.

Situation in the biosciences

The protection of intellectual property in the biosciences on a global level has to deal with very different contexts and situations. In the following paragraph, two different

settings will be discussed, namely the situation in African countries and the example of India and other Asian countries. The African situation is cited as an example that patent protection alone can hardly count as a decisive obstacle for access to drugs.[10] India is seen as an example for the usefulness of a rather weak patent protection for local industries to encourage research and development activities.[11]

Case 1: Africa, patents and AIDS treatment

The starting point for Attaran and Gillespie-White's study was the earlier discussion on access to HIV/AIDS pharmaceuticals for patients in poor countries and the role of patenting.[12] The authors investigated the patent status of 15 antiretroviral drugs in 53 African countries. They found out that the patent status of the drugs in the concerned countries generally was rather weak (with the exception of the Republic of South Africa) and draw the conclusion "that there is no apparent correlation between access to antiretroviral treatment, which is uniformly poor across Africa, and patent status, which varies extensively by country and drug".[13] According to the arguments of the critics of an extensive protection of intellectual property, one would have expected that weak patent protection would correlate to a better provision of patients with necessary drugs. Hence, one can conclude that it is not the patent status of specific pharmaceuticals, but general poverty, the lack of public health care and the economic situation of Africa's patients that leads to the drastic under-provision of HIV/AIDS pharmaceuticals.

But this line of reasoning does not show that there is no connection at all between access to pharmaceuticals and the patent status of these drugs. So the question remains in which circumstances the authors' main hypothesis of the independence of drug access from patent status would be true. For a general conclusion on the relationship between access to pharmaceuticals and patent status, it would have been necessary to include less-poor countries in the study to see, how this relationship manifests there. It is a plausible supposition that pharmaceutical enterprises will only secure their intellectual property in countries where a market for their products exist and competition between different market actors takes place. It is useless to enforce intellectual property protection in countries where the inhabitants are too poor to buy the product in question. These countries seem to be at a point of economical

10 A. Attaran, L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?" *JAMA* 286(15) (2001): 1886–1892.

11 K. Balasubramaniam, "Access to Medicines and Public Policy Safeguards under TRIPS" (2002), International Centre for Trade and Sustainable Development, available at http://www.ictsd.org/dlogue/2002-04-19/Balasubramaniam.pdf, accessed on March 30, 2006.

12 Oxfam, "Patent Injustice: How World Trade Rules Threaten the Health of Poor People" (2001), available at http://www.oxfam.org.uk/what_we_do/issues/health/downloads/patentinjustice.pdf, accessed on March 30, 2006; B. Pecoul et al., "Access to Essential Drugs in Poor Countries: A Lost Battle?" *JAMA* 281 (1999): 361–367; U.S. President William J. Clinton, "Access to HIV/AIDS Pharmaceuticals and Medical Technologies", 65 *Federal Register* 20521 (2000), Executive Order 13155.

13 Attaran, Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", p. 1890.

development where the existence or non-existence of intellectual property protection does not make a big difference: the patients have no money to buy original or generic drugs, and companies cannot sell drugs. Hence, the conclusion drawn from Attaran and Gillespie-White's study is not that patent protection does not influence the access to essential drugs, but that it does not worsen the drug supply in very poor countries – which is already very poor.

Case 2: India, patenting, pharmaceutical industry and drug prices

The situation and the historical development of drug prices and the pharmaceutical industry in India is widely seen as an example for a possible lower-cost supply of patients in developing countries.[14] India is known for its strong generic pharmaceutical industry, a result of the Indian Patent Law of 1970. The patent law was modelled on the German patent system, which did not permit full product patents, but only process patents.[15] This led to a strong decrease in drug prices in India. A possible additional factor was the fact that India is a rather big market for pharmaceutical products, where real competition between different suppliers takes place.

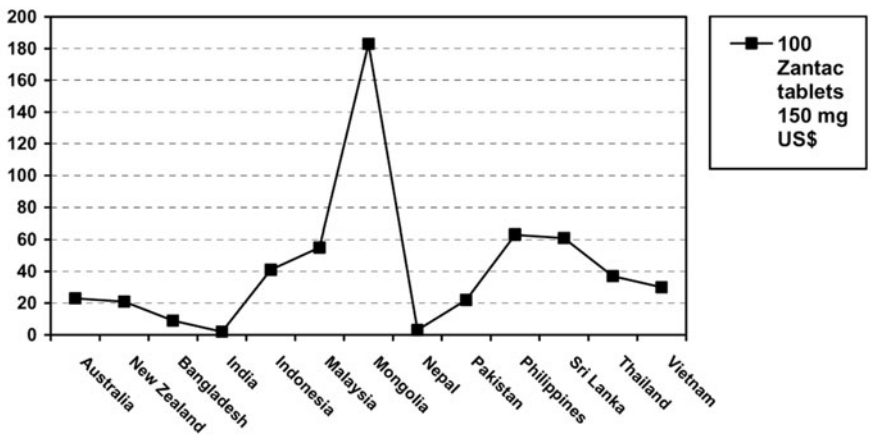

Figure 6.1 Retail prices in U.S.$ for 100 tablets/150 mg Zantac ("Zinetac" in India) in two developed (Asia, New Zealand) and twelve developing countries in the Asia-Pacific region

Source: Balasubramaniam, "Access to Medicines and Public Policy Safeguards under TRIPS", p. 15.

14 Balasubramaniam, "Access to Medicines and Public Policy Safeguards under TRIPS", p. 4; Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy*, p. 36; Oxfam, "Patent Injustice: How World Trade Rules Threaten the Health of Poor People", p. 6.

15 Balasubramaniam, "Access to Medicines and Public Policy Safeguards under TRIPS", p. 4.

The evidence that in such a situation rather weak patent protection results in low drug prices is impressive. First of all, it is a very frustrating discovery that original pharmaceuticals in developing countries are often even more expensive than in developed countries or their countries of origin (see Figure 6.1). This may be due to difficulties in the sale of drugs in those countries (or sales strategies of pharmaceutical companies) and is clearly counterproductive to the aim of general access to drugs. In Figure 6.1, Bangladesh, India and Nepal have the lowest prices for Zantac – and these three countries do not allow product patents. The same working group found out that, from nine important drugs, prices in India were in six cases the lowest.[16]

Taking the findings from the African and the Asian countries together, one can draw the following conclusions. Firstly, the absence of patent protection alone does not grant a good supply of drugs. Comparison of African and Indian situations shows that a certain level of economic and scientific development is necessary to cause a decrease in drug prices.

Secondly, the Indian legislation was successful in enforcing economic development and cutting drug prices. Both factors are important presuppositions for a better general supply of drugs to the population. The comparison of non-developed countries with and without patent product protection shows that weak patent protection is a decisive premise for lower drug prices.

Thirdly, one has to decide how to weigh the interests of the owners of intellectual property in developed countries against the interests of the consumers of pharmaceuticals in developing countries (that is, the patients). It could cause problems to extend the Indian situation to other regions, as this may endanger the return on investment of pharmaceutical companies for research and development. On the other hand, patients in developing countries need effective drugs and their right to life is surely more important than extensive intellectual property rights. A joint approach of pharmaceutical companies, the World Health Organization and governments of non-developed countries could produce a situation that is advantageous both for the patients in poor countries and for pharmaceutical companies, that is, to create a policy framework where patients have access to drugs at affordable prices – even in countries where "affordable prices" are extremely low. This could also be a possibility to avoid the instrument of "compulsory licensing", which is envisaged by the TRIPS agreement to force companies in developed countries to give licenses to other countries to produce essential goods.[17]

The ethical discussion

Globalization and responsibility

It is a widespread perception that the phenomenon of "globalization" changes the ethical evaluation of the international political situation[18] and our relationship

16 K. Balasubramaniam, K. Sagoo (1999), *Patents and Prices*, Table 2, available at http://www.haiap.org/patent_and_prices.htm, accessed on March 30, 2006.

17 Trade-Related Aspects of Intellectual Property Rights, Article 31.

18 Th. Pogge (2003), "What is Global Justice?", Lecture at the Symposium on Global Justice, University of Oslo, Sept. 9–13, 2003.

to individuals in other countries. People in developing countries did not concern most Westerners very much in the past, but nowadays it seems that the economic development in developing and threshold countries becomes more and more important because people from the South are only one phone call or one click on the Internet away. This leads to the familiar situation that employees in developed and developing countries compete with one another for jobs and resources. The fundamental change behind this development is simply that Westerners now have, or could have, a much closer relationship to people in other parts of the world, and this, one could say, means "globalization" in the deeper sense of the word. However, it is not so easy to see how this could have an ethical impact, because from a certain description of our world's state one cannot simply deduce ethical or normative requirements. But there seem to be at least three contexts where the impact of globalization can produce changes in our ethical perception. Firstly, *knowledge*: today Westerners know more about the existential problems of people in other parts of the world than ever before. Knowledge can produce ethical duties, because when we have no idea of somebody's desperate situation, we are not able to decide whether we should help them or leave them to their own devices.

Secondly, *resources and opportunities*: today developed countries possess and produce such a level of resources and have such possibilities in communication and transport at their disposal, that it became merely a normative – no longer a technical – problem to, for example, supply people in developing countries with food and medication. In the past, it would have been simply not possible to produce and transport a sufficient amount of essential goods into developing countries. But this situation has clearly changed in the last twenty-five years. Today it would indeed be possible to, for example, produce a sufficient amount of pharmaceuticals, guided by developed countries, to supply patients in developing countries. Therefore, the real ability exists to safe the lives of patients in such countries, and it is indeed merely a normative decision for us how to deal with this possibility.

Thirdly, known or unknown *relationships*: we are already today part of a multitude of international economical and financial transfers and relationships. Large parts of the electronic equipment, clothing, and so on sold in the West are manufactured in developing and threshold countries, and whether we buy them or not, and how much money enterprises and consumers in developed countries pay for them, is relevant for the producers in the southern factories and sweatshops.[19]

These changes depend on gradual quantitative developments, but seem to result in a kind of qualitative change: globalization reduces the distance between people from different continents and produces a new kind of mutual responsibility. The distinction between "us" and the "others", including its social, cultural, technological

19 As Thomas Nagel puts it, "My relation of co-membership in the system of international trade with the Brazilian who grows my coffee or the Philippine worker who assembles my computer is weaker than my relation of co-membership in U.S. society with the Californian who picks my lettuce or the New Yorker who irons my shirts. But doesn't the first pair of relations as well as the second justify concern about the moral arbitrariness of the inequalities that arise through our joint participation in this system?", T. Nagel, "The Problem of Global Justice", *Philosophy and Public Affairs* 33(2) (2005): 113–147, p. 141.

and economical implications, is becoming more and more questionable. In the words of Thomas Pogge: "Even a mere eighty years ago, the poor and unemployed were still often seen as lazy and delinquent merely on the grounds that others of equally humble birth had risen from dishwasher to millionaire".[20] Maybe we will see one day, that hunger and disease are not obligatory companions of people in the third world.

International equity and the liberal society

Unfortunately, the traditional Western approach to justice in a liberal society seems to be very inappropriate to fit into the framework of a global world order. First of all, in a liberal society one has a primary duty to do no harm to other citizens, but not to help other people. Maybe one should help other people, especially if they have existential problems – but this is, at least in the framework of the liberal society, only a kind of secondary duty. Therefore, there is also no primary duty to help people in very distant places, if there is not even such a duty in the case of the homeless person in front of our very door. Secondly, and due to the Hobbesian contention that justice is dependant on sovereignty,[21] it is questionable whether we have the right or even the possibility to install a fair system of redistributive justice in or for other countries. Citizens of a state have the right to political participation and to achieve a system of fair resource allocation in their own country. But how could they realize the same goal for other countries? This would conflict with the sovereignty and the rights of citizens in this other country. And thirdly, as Thomas Pogge pointed out, Westerners would not accept the present state of the political world order – because it contains the illegitimate use of military forces and tolerates the life and death of millions of people in a desperate economic situation – if Westerners were in the same situation as people in developing countries.[22] This means that we, as citizens of liberal societies, operate double standards on an international level.

The question thus arises: on which approach it is generally appropriate to base an ethical duty towards people in developing countries? The human rights approach remains, but comes with the question of who has the duty to fulfil positive (social) human rights. Human rights are worthless if there is no institutional opposite with the duty to fulfil people's needs. In the end, we are remanded on a general responsibility towards strangers in desperate situations – with the hope that this responsibility becomes more and more evident in the course of diminishing distances, which we

20 Th. Pogge, "What is Global Justice?", p. 3.

21 "The issue of justice and sovereignty was memorably formulated by Hobbes. He argued that although we can discover true principles of justice by moral reasoning alone, actual justice cannot be achieved except within a sovereign state. Justice as a property of the relations among human beings (and also injustice, for the most part) requires government as a enabling condition. Hobbes drew the obvious consequence for the international arena, where he saw separate sovereigns inevitably facing each other in a state of war, from which both justice and injustice are absent." T. Nagel, "The Problem of Global Justice", p. 114.

22 Th. Pogge, "Internationale Gerechtigkeit: Ein universalistischer Ansatz", pp. 31–54 in K.G. Ballestrem (ed.), *Internationale Gerechtigkeit* (Opladen: Leske + Budrich, 2001), p. 35.

call "globalization". It is clear that the institutional allocation of such responsibility could be implemented far better than it is at the moment. But we must also find a pragmatic approach to describing fundamental social and economic rights to secure in a first step the mere existence of people in developing countries. It seems to be very reasonable to choose Amartya Sen's approach of "basic capabilities" or "primary goods" for such a description. In my opinion, this does not mean that one should exclude the possibility of ascribing to people in developing countries a broader "equality of opportunities" in the future. But this is clearly not the task at hand, which ought to be to build a bundle of social and economic rights which secure basic capabilities like, in the words of Sen: "the ability to be well nourished and well sheltered, the capability of escaping avoidable morbidity and premature mortality, and so forth".[23]

Those "basic capabilities" or "primary goods" gain their normative power from their essentiality and meaning for the mere survival of others. This essentiality ensures (in idealized circumstances) that no resources are wasted on useless activities and the givers can be sure that their money is invested in the framework of solidarity, that is, to help people with existential problems. It lies in the universal nature of these primary goods, that everybody should have an equal claim on the fulfilment of basic needs, and that, from an interpersonal point of view, the health of citizens of developed countries counts just as much as the health of citizens of developing countries.

Responsibility for action

From a situation where people in rich countries have the freedom not to take care of the existential needs of people in other countries – a freedom to let other people die who could live longer if they had, for example, sufficient access to pharmaceutical therapy – we have to move towards a new approach to let others participate in resources and medical therapy at least at the level of "basic capabilities". The justification must be the essential character of primary goods, in comparison to the non-essential character of other consumables. It is often argued that free trade, non-regulated markets and the lean state may be the best guarantee for people in developing countries to reach an adequate income level. But it should be clear that very poor people are nearly non-existent from the point of view of economic actors and some kind of positive or negative incentive is needed in order to change this situation. However, the question remains: who should be responsible to take care of people in desperate situations in developing countries?

First of all, it is clear that there is no sole responsibility for individual actors – for example pharmaceutical companies – to solve such a problem. There is, and there must be, international coordination for this task. Second, the moral duty to help others in desperate situations depends on potential capabilities. From an ethical point of view, it is very different whether somebody cannot give another person a specific resource or whether he could give, but withholds it. The potential to help

23 A. Sen, "Capability and Well-Being", pp. 30–53 in M. Nussbaum (ed.), *The Quality of Life* (Oxford: Oxford University Press, 1993), p. 31.

someone is meaningful because without such a potential there can definitely be no duty to help. Third, new ways are necessary for individual and private actors to help people in developing countries. When it is possible today to let people in developing countries economically produce consumer articles for the citizens of the developed world, why is it not *vice versa* possible to organize coordinated help for people in developing countries? What seems to work perfectly in terms of global production and protection of private property should also function in terms of the protection of existential needs of people in developing countries. In other words, it should be possible to use diminishing distances through globalization not only for economic profit but also for philanthropic profit. In a world where we can realize a global protection of intellectual property, it should equally be possible to realize global equity in the distribution of resources.

In a recent article, Molyneux et al. suggested a program to fight the so-called "neglected diseases", that is, tropical diseases which attract only low attention in research and development activities in developed countries.[24] The authors argue that one could control seven different neglected tropical diseases in Africa with only four different drugs, which could be distributed by community-directed approaches or existing programs of the WHO or UNICEF. The costs for this program would be rather low, provided that drug costs were diminished by public–private partnerships. An increasing number of such partnerships in the area of global health are registered and can be found on the Website of the Swiss Initiative of Public–Private Partnerships for Health (IPPPH, www.ippph.org). Such activity could also point the way to the solution to shortcomings in the drug supply for modern pandemics, such as AIDS/HIV, or classical tropical diseases like Malaria. On the one hand, assuming responsibility is the central ethical category for supporting needy individuals – but responsibility is useless and leads to a kind of general paralysis when it is not adequately distributed. Public and private partnerships, coordinated by the WHO, for specific countries or specific diseases could break up this paralysis and lead to effective action.

Conclusion

The protection of intellectual property has had significant influence on the industrial development of Western countries since the 18th century. In the philosophy and law of this time, in the writings of David Hume and Adam Smith, property and wealth did not seem to be rigid concepts, but were in the process of being adapted to the circumstances of modern society. Although intellectual property has not been a very controversial ethical topic in the past decades, the metamorphosis from industry into the so-called information society seems to provoke similar phenomena in the present. The permission to produce a specific product is often of great importance, especially in medicine and the biosciences where access to specific drugs can be crucial to the survival of patients. This shows that questions concerning the protection

24 David H. Molyneux, Peter J. Hotez, Alan Fenwick, "Rapid-Impact Interventions: How a Policy of Integrated Control for Africa's Neglected Tropical Diseases Could Benefit the Poor", *PloS Medicine* 2(11) (2005), DOI: 10.1371/journal.pmed.0020336.

of property are not merely bureaucratic or economic problems, but also questions of participation, distribution of resources and, finally, of political power.

In the past, economic, industrial and scientific differences between developed and non-developed countries prevented the use or misuse of intellectual property for own industrial production. This situation seems to have ended with the economic rise of threshold countries. Whilst many forms of intellectual property were simply useless for non-developed countries, some countries are now in a position to produce generics for their sick citizens. This underpins international initiatives like TRIPS, but also clarifies the ethical dimension and importance of intellectual property. In the history of the classic industrial countries, such as the United Kingdom or the Netherlands, the protection of intellectual property was important to protect inventors and investors and to enable the development of high-quality products and diversified industries. Exclusive rights and monopolies were seen as justified under these circumstances, as long as they did not damage a nation's general welfare.

But present developments in the biosciences shows that traditional concepts from the process of modernization, which were introduced in the framework of national policies, should not be transferred unmodified into the framework of international policy. On the international level, protective policies can represent a barrier to existential needs of people in non-developed countries that developed countries would never accept for their own citizens. Such an approach does not solve the underlying ethical problem that exclusive rights should not damage the welfare of the general public, which consists, on the international level, of the citizens of both developed and non-developed countries. Therefore, the question arises how to produce a balance of interests between those who create innovations and want to earn money and those who have no money and have a crucial need for these innovations.

Regarding ethical priorities, one can only emphasize that the health and life of people in developing countries are more important than property rights – however easily these rights can be justified.

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Chapter 7

Enclosing the "Knowledge Commons": Patenting Genes for Disease Risk and Drug Response at the University–Industry Interface

Bryn Williams-Jones and Vural Ozdemir*

Introduction

Biotechnology and genomics research – while holding the promise of improved pharmaceuticals, medical treatments and foods – is raising concerns about the effects of commercialization on the provision of public health care services (reduced access), the role of commercial influences (industry financing and its effect on academic freedom) and the impact of market forces on the products of research (commercialization of technologies).[1] Some of these concerns have begun to crystallize around the issue of commercial genetic tests for disease susceptibility.[2] Our focus, instead, will be on the effects of strong patent protection on academic research and innovation in the developing field of pharmacogenomics.

Pharmacogenomics is the study of the role of genetics on inter-individual and population-to-population variability in drug effects using a broad survey of the

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1 J. Cohen, "The Genomics Gamble", *Science* 275(5301) (1997), pp. 767–772; M.-H. Parizeau, "Are the Universities and Sciences Subservient to the Economy? A Summary and Analysis", *ISUMA: Canadian Journal of Policy Research* 2(4) (2001), pp. 133–141, available at http://www.isuma.net/v02n04/parizeau/parizeau_e.shtml, accessed on February 23, 2005.

2 For example, there has been significant opposition in Canada and Europe to the Myriad Genetics patents on the BRCA genes and resulting test for hereditary breast cancer. B. Williams-Jones, "History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing", *Health Law Journal* 10 (2002), pp. 121–144. In Canada, provincial governments have simply ignored Myriad's patent claims, while in Europe Myriad's E.U. *BRCA1* and *BRCA2* patents were overturned in 2004. A. Pollack, "Patent on Test for Cancer is Revoked by Europe", *New York Times*, May 19, 2004, p. 3; S. Mayor, "Charity Makes Cancer Gene Freely Available in Europe [news]", *British Medical Journal* 328(7437) (2004), p. 423.

human genome. The case of pharmacogenomics offers a complementary analytical dimension to the more established critique of commercial genetic susceptibility tests, enabling a more nuanced evaluation of how gene patents shape, and are shaped by, a diversity of intellectual property rights, motivations for rapid commercialization of new research findings and the attendant complex web of socio-technical actors.

There is wide consensus that publicly funded not-for-profit research is an essential building block for advances in technology and product development. An open and readily accessible knowledge commons – that is, a space (usually in universities) in which academics and researchers share knowledge without undue restriction – has been a driving force behind many innovations, particularly in the early phases of the 20th century.[3] Less well appreciated are the adverse consequences of gene patents on segments of the knowledge commons.[4] This predicament can be described by the aphorism "eating the seed corn" – literally not saving some corn to use as seed towards next year's crop – where short-term economic returns take precedence over long-term investments for trade as well as sustenance of the knowledge commons. We suggest that the privatization of the commons and enclosure of new genetic discoveries through patents do not necessarily accomplish the technology transfer goals of developing equitable and reasonably priced products that can benefit the society as a whole.[5]

Instead, we argue that the primary purpose of many recent patents is the generation of supplemental revenues for universities, academic researchers and diagnostic industries, though even this "success" is dubious. To this end, we take notice of hitherto disenfranchised viewpoints from the field of science and technology studies to "unpack" the actors and motivations at play in the complex socio-technical network that is university commercialization. Reflecting on the way in which pharmacogenomics research is translated into commercial pharmacogenetic tests, we explore the recently emerging significant trends that challenge the traditional perception that gene patents by pharmaceutical firms and the diagnostic industry are

3 R.R. Nelson, "The Advance of Technology and the Scientific Commons", *Philosophical Transactions: Mathematical, Physical and Engineering Sciences* 361(1809) (2003), pp. 1691–1708.

4 Nevertheless, there has been substantial debate about whether genes and biological materials are the sort of things that should be subject to patent; see for example, G. McGee, "Gene Patents Can Be Ethical", *Cambridge Quarterly of Healthcare Ethics* 7(4) (1998), pp. 417–421; A. Caplan, "What's So Special about the Human Genome?", *Cambridge Quarterly of Healthcare Ethics* 7(4) (1998), pp. 422–424; R.S. Eisenberg, "How Can You Patent Genes?", *American Journal of Bioethics* 2(3) (2002), pp. 3–11. For a broader discussion of the implications of gene patents, see Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (London, 2002), available at http://www.nuffieldbioethics.org/go/ourwork/patentingdna/publication_310.html, accessed on February 9, 2005; Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science* (London, 2003), available at http://www.royalsoc.ac.uk/document.asp?tip=0&id=1374, accessed on February 9, 2005.

5 S. Bruckbauer, "Capitalizing on Commercialization: Should Congress Revisit the Bayh-Dole Act?", *Journal of the National Cancer Institute* 95(19) (2003), pp. 1429–1431.

a uniformly desirable and profitable commodity.[6] In addition, we attempt to dissect the roles played by various stakeholders at the university–industry interface that can importantly influence the adoption or rejection of genetic tests and, by extension, shape the interest in gene patents.

Commercializing university research

The potential public health benefits to be derived from genomics research and biotechnology development are clearly important motivators of the substantial public interest and investment in these fields. American public investment in the Human Genome Project (HGP) over its ten-year life has been estimated at greater than US$3 billion. These levels of funding, however, have been far surpassed by industry investment: in fiscal 2001 alone, the biotechnology industry in the United States spent US$15.6 billion on research and development.[7] Biotechnology is held up by many advocates as a potentially lucrative growth sector for financial markets and industry, and from the perspective of many governments, is an important element for developing "knowledge-based economies".[8] In the U.S. alone, the number of biotechnology start-up firms grew from 1,231 in 1992 to 1,473 in 2004,[9] while revenues from biotechnology more than tripled between 1992 and 2003 (US$8 billion to US$39.2 billion). According to one estimate, by 2000 the U.S. biotechnology industry had created (directly and indirectly) 437,400 U.S. jobs, generated US$47 billion in revenues, and provided US$10 billion in taxes for federal, state and local governments.[10]

Given the large amounts of public and private funds pouring into university-based research, it is not surprising that universities and researchers are increasingly expected (by university administrations, national governments and the private sector) to collaborate with industry, and demonstrate tangible, marketable results from their

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6 G. Anand, "Big Drug Makers Try to Postpone Custom Regimens", *Wall Street Journal*, June 18, 2001, p. B1; R.S. Eisenberg, "Will *Pharmacogenomics* Alter the Role of Patents in Drug Development?", Pharmacogenomics 3(5) (2002), pp. 571–574; A. Smart, P. Martin, M. Parker, "Tailored Medicine: Whom Will It Fit? The Ethics of Patient and Disease Stratification", *Bioethics* 18(4) (2004), pp. 322–342; A. Webster et al., "Integrating Pharmacogenetics into Society: In Search of a Model", *Nature Reviews Genetics* 5(9) (2004), pp. 663–669.

7 Ernst & Young, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*, Biotechnology Industry Organization (2000), available at http://www.bio.org/speeches/pubs/ernstyoung.pdf, accessed on February 9, 2005.

8 Earlier economies clearly were also based on knowledge, but a distinguishing factor of modern economies is the extent of their focus on science and technology as crucial drivers of growth. A. Arora, A. Fosfuri, A. Gambardella, "Markets for Technology in the Knowledge Economy", *International Social Science Journal* 54(171) (2002), pp. 115–128.

9 Biotechnology Industry Organization, "Biotechnology Industry Statistics" (2004), available at http://www.bio.org/speeches/pubs/er/statistics.asp, accessed on February 9, 2005.

10 Ernst & Young, *The Economic Contributions of the Biotechnology Industry to the U.S. Economy*.

research.[11] Nor is commercialization limited to scientific research, but extends to research in other disciplines, as well as to education and athletics.[12]

This view coincides with a shift in the perceived mission of universities, particularly with regards to the applied sciences. In addition to being sites of advanced teaching and research (the university's "first" and "second" missions), universities must now engage in knowledge transfer that leads to technology development and economic growth (the "third mission"), a role that has proven popular with governments, industries and universities world-wide.[13] To facilitate this third mission (and some would argue, to transform universities into "entrepreneurial" institutions), laws and policies have been implemented to ensure strong protection of intellectual property rights and facilitate commercialization and technology transfer.[14]

It is in this climate of commercial science that the field of pharmacogenomics was born. An interdisciplinary research sub-specialty, pharmacogenomics arrived on the heels of the Human Genome Project in the late 1990s by coalescence of traditional methodologies used in human genetics, common complex diseases and clinical pharmacology, together with the impetus provided by genomic technologies developed as part of the HGP that are capable of rapidly generating large volumes of genetic data in short time frames. A glance at leading medical journals now uniformly attests to the vast number of pharmacogenomic studies (in academe and industry) reported in the literature. Forward-looking statements in many commentaries on pharmacogenomics conclude that the recognition of individual differences in genetic make-up may eventually pave the way to customized medicines and additional avenues for commercialization of genetic tests. Diverging views suggest, however, that there is cause for concern over inappropriate use, or the failure to use, pharmacogenomic data that may lead to inequities in access to optimal drug therapy.[15] Some of these concerns, we suggest, are directly related to the way in which intellectual property rights are likely to be handled for the fruits of pharmacogenomics research and subsequent pharmacogenetic tests.

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11 S. Lewis et al., "Dancing with the Porcupine: Rules for Governing the University–Industry Relationship [Commentary]", *Canadian Medical Association Journal* 165(6) (2001), pp. 783–785; Parizeau, "Are the Universities and Sciences Subservient to the Economy? A Summary and Analysis".

12 D. Bok, *Universities in the Marketplace: The Commercialization of Higher Education* (Princeton: Princeton University Press, 2003).

13 H. Etzkowitz et al., "The Future of the University and the University of the Future: Evolution of Ivory Tower to Entrepreneurial Paradigm", *Research Policy* 29 (2003), pp. 313–330.

14 R.M. Cook-Deegan, "National Policies Influencing Innovation Based on Human Genetics", in T.A. Caulfield, B. Williams-Jones (eds), *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), pp. 13–27.

15 Smart, Martin, Parker, "Integrating Pharmacogenetics into Society: In Search of a Model".

Intellectual property rights

The protection of strong intellectual property rights (IPR) – usually framed in terms of patents but also including copyright and trademark protection – has been argued by many in industry, government and academia to be essential both for continued biomedical research and economic development.[16] Without strong IPR, it is maintained, innovators (be they researchers or companies) would not be able to recoup the costs or profit from significant investments made in the long-term research needed to bring a product to market. Further, it is asserted that the broader social and economic impacts of weak IPR (in terms of less technology development, reduced employment and tax base, and so on), would be sufficiently damaging to result in a slow down or even stall of economic growth.

Controversial policy measures, such as the U.S. "Bayh-Dole Act" (Patent Rights in Inventions Made with Federal Assistance, 1980), for example, have been introduced to facilitate (if not actively encourage) universities to commercialize publicly funded research and translate it into patents, products and spin-off companies.[17] "The main intent of the Bayh-Dole Act is to ensure the practical use of inventions made in federally funded research by creating a financial incentive through patent rights.... Transferring technology through patent licensing is a complicated business and has drawn academic research centers into business relations – just as it was intended to do."[18] Following on this and similar enabling policies, by the 1990s most American, Canadian and European research universities had established technology transfer and industry liaison offices to commercialize academic research.[19]

In the case of genetics and biotechnology, commercialization was also supported by a number of controversial legal rulings, in particular the 1980 United States Supreme Court case of Diamond v. Chakrabarty (447 U.S. 303, 1980), which made possible the patenting of biological materials.[20] International trade and patent agreements such as the General Agreement on Trade and Tariffs (GATT) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) extended the influence of this and other cases around the world.[21] By 2000, more than 25,000 DNA-based patents had been granted,[22] with the number of biotech patents granted each year growing from

16 J.J. Doll, "Biotechnology: The Patenting of DNA", *Science* 280(5364) (1998), pp. 689–690; Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper*.

17 Cook-Deegan, "National Policies Influencing Innovation Based on Human Genetics".

18 A. Bar-Shalom, R.M. Cook-Deegan, "Patents and Innovation in Cancer Therapeutics: Lessons from CellPro", *The Milbank Quarterly* 80(4) (2002), pp. 637–676, p. 655.

19 D. Fisher, J. Atkinson-Grosjean, "Brokers on the Boundary: Academy–Industry Liaison in Canadian Universities", *Higher Education* 44(3–4) (2002), pp. 449–467.

20 A.M. Chakrabarty, "Patenting of Life-Forms: From Concept to Reality", in D.Magnus et al. (eds), *Who Owns Life?* (Amherst, NY: Prometheus Press, 2002), pp. 17–24.

21 B.M. Knoppers, "Biotechnology: Sovereignty and Sharing", in T.A. Caulfield, B. Williams-Jones (eds), *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), pp. 1–11.

22 R.M. Cook-Deegan, S.J. McCormack, "Intellectual Property: Patents, Secrecy, and DNA", Science 293(5528) (2001), p. 217.

1,765 in 1990 to 7,763 in 2002.[23] Universities did not lag behind in this patent frenzy; a 1995 study of world-wide patent applications found that 40% of all gene patents had been filed by public institutions or charities.[24] This enthusiasm on the part of universities undoubtedly derives from the hope that patents and licenses will be an effective means of making up for reductions in government funding to academia. Indeed, according to the AUTM Licensing Survey for fiscal 2001[25] – which polled 334 institutions in the U.S. and Canada – nearly US$1.1 billion in royalties and fees were generated from licensed research discoveries made in North American universities, teaching hospitals, and research institutions; the top ten income-earning universities brought in almost US$511 million, most of which was derived from life sciences–related patents. However, it is worth noting that much of this income was generated by a few early blockbuster pharmaceutical patents, and many of these patents are beginning to expire.[26]

To some extent, concerns about inadequate intellectual property protections are borne out in the current funding environment, where protecting IPR is essential for securing venture capital investment in biotechnology companies – patents or patent applications are the *de facto* currency for demonstrating commercial viability, while failure to secure patent protection will "sink" a fledgling biotech company. Patents are markers of innovation and an increase in patents seems to correlate with (or even lead to) an increase in innovation and economic development.[27] But patents do not in themselves guarantee corporate economic success, continued financial support or long-term viability. A patent application may never issue, and even if a patent is eventually awarded, it may be "worked around" by competitors. The process of accumulating large patent portfolios is very expensive, time consuming and requires significant financial and personnel resources to avoid infringement of other patents in the development of a novel technology.

More importantly, the conviction that IPR is a *sine qua non* (Latin for "without which not", referring to an essential element or condition) for economic growth remains largely unsubstantiated; that is, there have been no "control studies" or negative cases to compare in which patents were not allowed (or were removed) with the result that biotechnology development was hindered. In fact, some economists would counter that rapid technological advances have actually occurred in environments without strong IPR protection.[28] For example, while many European countries in the 1860s and 1870s subscribed to an ideology of economic liberalism, they did not share the contemporary belief in the value of patents – the Netherlands

23 Biotechnology Industry Organization, "Biotechnology Industry Statistics".

24 S.M. Thomas et al., "Public Sector Patents on Human DNA", Nature 388(6644) (1997), p. 709.

25 L. Pressman, *AUTM Licensing Survey: FY 2001* (Northbrook, IL: Association of University Technology Managers, 2003).

26 T. Agres, "The Fruits of University Research", *The Scientist* 17(14) (2003), pp. 55–56.

27 P.A. David, D. Foray, "An Introduction to the Economy of the Knowledge Society", *International Social Science Journal* 54(171) (2002), pp. 9–23.

28 R.R. Nelson, *The Sources of Economic Growth* (Cambridge, MA: Harvard University Press, 1996).

even went so far as abandoning its old patent law. The Great Depression of 1873 led to a resurgence of protectionist economic views and the strengthening of patent systems, but until the early 1900s the Swiss Federation and the Netherlands operated successful economies without the protection of patent laws. Contemporary multinational firms such as Philips, Unilever, Novartis and Nestlé trace their origins to this period and some even acknowledge that the lack of patent protection in the late 1800s was important for their early development and success. As van den Belt notes, "the economic history of Switzerland and the Netherlands in the later part of the 19th century shows that, under special circumstances, the refusal to offer legal protection to inventions may be an effective tool for economic development".[29]

Nevertheless, even if one accepts the premise that strong patent protection in the life sciences is critical for continued economic growth (for universities or nations), such patents can still have serious negative consequences for the conduct of academic research and the pursuit of knowledge.

The "knowledge commons"

The results of academic research are circulated through a variety of forums, including informal discussions, research collaborations, scholarly publications and conference presentations; the academe provides a knowledge space in which new ideas and the results of research are objective and dispassionately challenged, accepted or rejected. As an environment predicated on the free flow and sharing of knowledge, academe can be usefully thought of as a "knowledge commons". Clearly this commons is also the site of competition amongst academics, which may result in temporary secrecy and restrictions on the flow of information, while new or contentious knowledge claims may be marginalized by the majority. Some secrecy, competition and conservatism in research are arguably important to the development and consolidation of knowledge. It is only when advocates of a new concept or theory are sufficiently persuasive (that is, their positions are backed by sound argument and detailed evidence) that their colleagues will accept the new ideas, possibly even leading to a "paradigm shift" in the field. This Mertonian[30] vision of the organization of science, and academia more generally, is an ideal to which many – if not most – academics and universities would still ascribe.

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29 H. van den Belt, "Enclosing the Genetic Commons: Biopatenting on a Global Scale", in C. Baumgartner, D. Mieth (eds), *Patente am Leben? Ethische, rechtliche und politische Aspekte der Biopatentierung* (Paderborn: Mentis Verlag, 2003), pp. 229–244, p. 231; Webster et al., "Integrating Pharmacogenetics into Society: In Search of a Model".

30 In the 1950s, the American sociologist Robert Merton studied science as a social institution and proposed that scientists were governed by, or at least ascribed to, a broad set of social norms, specifically universalism, communality, organized scepticism and disinterestedness. "Simply put, scientists should with caution but an open mind treat any knowledge-claim on its merits. They should share with their peers, in a free exchange, ideas that are subject to close scrutiny and free from personal interest or ambition". A. Webster, *Science, Technology and Society, Sociology for a Changing World* (New York: Macmillan, 1991), p. 7.

However, as demonstrated by work in the philosophy of science[31] and science and technology studies,[32] the actual practice of academic science often falls short of the Mertonian ideals. Sandra Harding, a philosopher of science, asserts that the pursuit of scientific knowledge is never entirely a value-free activity,[33] nor should the current perceived breaches in positivist ideals in science be interpreted as a new phenomenon unique to the late 20th century.[34] There is, for example, a long history of university–industry collaboration in the translation of academic research into marketable products, especially in the applied sciences and engineering. As early as the pre-colonial period, pragmatic values markedly shaped the drive for advances in naval sciences for travel to hitherto unexplored distant geographical landscapes to access new natural resources. When viewed through the lens of history, it becomes evident that scholars in both Eastern and Western civilizations were influenced by the intimate and dialectical relationship between knowledge and power.[35] Scientists do not always conduct their research in a disinterested, "objective" manner that is independent from internal or external influences.[36]

State, industry or charity sponsored science funding clearly shapes the directions and foci of research (for example, research into nuclear energy, defense or particular areas of health) – science is necessarily conducted in and is responsive to the larger community.[37] This contextualized nature of science and academia does not, however, undermine the value of aiming for the Mertonian ideals of academic freedom, objectivity and neutrality. These norms form the foundations of modern universities and are strongly defended by academics within these institutions, but there is growing concern that these norms are under threat.

Consultation fees and grant support obtained by industry financing, or income from university-held patents, may lead to real or perceived conflicts of interest

31 S. Harding, *Is Science Multicultural? Postcolonialisms, Feminisms, and Epistemologies* (Bloomington: Indiana University Press, 1998).

32 A.M. Hedgecoe, "Terminology and the Construction of Scientific Disciplines: The Case of Pharmacogenomics", *Science, Technology & Human Values* 28(4) (2003), pp. 513–537; A. Hedgecoe, P. Martin, "The Drugs Don't Work: Expectations and the Shaping of Pharmacogenetics", *Social Studies of Science* 33(3)(2003), pp. 327–364.

33 Harding, *Is Science Multicultural? Postcolonialisms, Feminisms, and Epistemologies*.

34 M. Angell, The Truth About the Drug Companies: How They Deceive Us and What to Do About It (New York: Random House, 2004); J.D. Quick et al., "Ensuring Ethical Drug Promotion – Whose Responsibility?", *Lancet* 362(9385) (2003), p. 747.

35 M. Foucault, "Subjectivity and Truth", in P. Rabinow (ed.), *Michel Foucault Ethics: Subjectivity and Truth Essential Works of Foucault, 1954–1984* (New York: The New Press, 1997), pp. 87–92; E.W. Said, *Representations of the Intellectual: The 1993 Reith Lectures* (London: Vintage Books, 1996).

36 D. Willman, "The National Institutes of Health: Public Servant or Private Marketer?", *Los Angeles Times*, December 22, 2004, available at http://www.latimes.com/news/nationworld/nation/la-na-nih22dec22,0,7519657.story?coll=la-home-headlines, accessed on February 6, 2005.

37 Webster, *Science, Technology and Society*.

and moral ambiguities.[38] In the clinical sciences and pharmaceutical research, for example, industry funded projects in the university settings are, to a large extent, "confirmatory" in nature to facilitate the regulatory registration of drug candidates.[39] By virtue of the revenue flow to universities through these industrial projects, there may be cause for concern over how much weight will be given to such confirmatory research – research that makes relatively little original contribution to the knowledge commons – in evaluation of faculty performance and academic tenure decisions. Considering that the scientists have only so much time to formulate, conduct and supervise original research, the collective consequence of these changes on the type of research executed in the university setting may be inevitably reflected in the quality (less innovative and increasingly confirmatory) and composition of the knowledge commons in the near future.

Tragedy in the commons

One of the classic problems with a commons is when the shared resource becomes overused, resulting in Hardin's well known "tragedy of the commons".[40] If, for example, farmers have unrestricted access to common pasture land for grazing cattle, individual self-interest will lead farmers to maximize their use of the resource at the expense of the collective interest – the pasture's capacity will be quickly exhausted through overgrazing, ultimately harming all farmers. Resolution of this tragedy occurs when the farmers reach an agreement – a moral code as it were – about the fair and appropriate use of the land so that all may benefit. In contrast to a commons field, the knowledge commons of academia is unlikely to be threatened by over-grazing – knowledge cannot be overused, but instead is likely to be improved through free access and sharing.[41] The moral code or agreement that protects this knowledge commons is the Mertonian ideal of academic freedom. The knowledge commons, however, arguably becomes endangered when it is parceled up, "enclosed", and owned by individuals or corporations, that is, when the knowledge becomes proprietary or patented.[42] The fear is that by encouraging researchers to protect their discoveries as intellectual property, other researchers will be restricted

38 J.J. Cohen, "Managing Financial Conflicts of Interest in Clinical Research", *Science and Engineering Ethics* 8(3) (2002), pp. 401–406; C.M. Stein, "Publishing Work Sponsored by the Tobacco Industry", *Clinical Pharmacology & Therapeutics* 76(6) (2004), pp. 517–518; Willman, "The National Institutes of Health: Public Servant or Private Marketer?".

39 L.B. Sheiner, "The Intellectual Health of Clinical Drug Evaluation", *Clinical Pharmacology & Therapeutics* 50(1) (1991), pp. 4–9; L.B. Sheiner, "Learning versus Confirming in Clinical Drug Development", *Clinical Pharmacology & Therapeutics* 61(3) (1997), pp. 275–291.

40 G. Hardin, "The Tragedy of the Commons", *Science* 162 (1968), pp. 1243–1258.

41 David, Foray, "An Introduction to the Economy of the Knowledge Society".

42 P.A. David, "A Tragedy of the public knowledge 'commons'? Global Science, Intellectual Property and the Digital Technology Boomerang", *Electronic Journal of Intellectual Property Rights* WP 04 (2000), pp. 1–34, available at http://www.oiprc.ox.ac.uk/EJWP0400.pdf, accessed on February 9, 2005; J. Kimmelman, "Free the Harvard Mouse", *The Globe and Mail*, December 4, 2002, p. A23.

from accessing and building on this knowledge because it is either kept secret while awaiting patent filing or, once patented, is made prohibitively expensive.

The anticommons

In an academic environment in which the free use of knowledge is restricted, there is genuine concern from a number of commentators that the continued functioning of the knowledge commons will be undermined.[43] We could then have what Heller and Eisenberg have usefully called a "tragedy of the anticommons".[44] Referring to the case of patents on gene fragments, they argue that multiple, overlapping property rights on genetic material – which allows individual owners to exclude others from a resource (the human genome or, we suggest, scientific knowledge more generally) – leads to a situation in which the resource will actually be underused.

In order to conduct both basic and product-oriented research, genetics and genomics researchers use a range of tools such as the polymerase chain reaction (PCR),[45] genes, proteins and gene fragments such as single nucleotide polymorphisms (SNPs) or expressed sequence tags (ESTs). But if basic tools or pieces of genome are patented, then such upstream patents[46] can become tollbooths that increase costs and slow downstream research. Researchers may have to invest significant time and financial resources in legal support to negotiate multiple license agreements. Patent holders may demand high license fees, or "reach through" licenses and a percentage of any profit from downstream products.[47] The transaction costs of accessing patented materials or technologies could be such that academic laboratories (as well as small biotechnology companies) would simply not have the financial or technical

43 David, "A Tragedy of the Public Knowledge 'Commons'? Global Science, Intellectual Property and the Digital Technology Boomerang"; Nelson, "The Advance of Technology and the Scientific Commons".

44 M.A. Heller, R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science* 280(5364) (1998), pp. 698–701.

45 Researchers using this tool must pay a license fee to Hoffmann-La Roche; the patent on PCR continues to be hotly contested. D. Dickson, "Patent on PCR Enzymes may Re-Ignite Old Controversy [news]", *Nature* 372(6503) (1994), p. 212; R. Dalton, "Patent Ruling Could Cut PCR Enzyme Prices [News]" Nature 411 (2001), p. 622.

46 *Upstream patent*: one which is remote from but encompassing of a constitute part necessary for potential applications towards direct clinical or marketable products; *downstream patent*: one with direct practical applications that can be translated into tangible products. R. Eisenberg, "Patenting Genome Research Tools and the Law", *Comptes Rendus Biologies* 326(10–11) (2003), pp. 1115–1120.

47 Heller, Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research"; J. Murray, "Owning Genes: Disputes Involving DNA Sequence Patents", *Chicago-Kent Law Review* 75 (1999), pp. 231–257.

resources to afford such expenses, making certain avenues of basic[48] or applied[49] research overly complicated, unaffordable and not worth investigating.

In conferring monopolies, gene patents increase transaction costs and restrict use, but these costs have been considered acceptable in exchange for continued innovation and economic development. However, in the context of the life sciences, the costs may be unacceptably high. Broad patents can restrict innovation by allowing a company to block development of competing products or services that may be more accurate or less costly. One might nevertheless argue that while this may be a problem for academics, it will nonetheless contribute to the increasing consolidation of research within large biopharmaceutical corporations who can benefit from economies of scale and continue to develop important health care products and services. Yet concerns about the patenting of SNPs and ESTs led to groups such as the Wellcome SNP Consortium (which included both public and industry members), to make new genetic information widely available through public databases in order to prevent or at least minimize the secrecy and cost effects of patents.[50]

Attempts to establish marketing monopolies through the exclusion of alternative product research are evident in clinical trial designs with new blockbuster drug candidates (that is, drugs with projected annual revenues larger than US$1 billion). Comparisons with a positive control (for example, a drug within the same pharmacological class that is already available in the market) are seldom performed in a proactive manner; instead, a placebo control is often chosen, whenever possible, to establish drug efficacy for regulatory registration. The use of placebos in randomized control trials is still common in drug research, and for obvious reasons, is ethically contentious when alternate effective treatments exist.[51] Standard therapies are sometimes used as controls, but usually only on a "reactive" basis, that is, when regulatory agencies request this comparison. In effect, a study designed with a placebo control pre-empts questions on whether and to what extent the drug candidate is similar to existing drugs. Moreover, in the absence of empirical data on

48 P.A. Baird, "Patenting and Human Genes", *Perspectives in Biology and Medicine* 41(3) (1998), pp. 391–408; J.F. Merz et al., "Diagnostic Testing Fails the Test", *Nature* 415(6872) (2002), pp. 577–579.

49 In a study of U.S. genetics laboratories, 30% acknowledged that they had stopped research on or provision of testing for hereditary hemochromatosis due to the restrictive license requirements imposed by the patent holder. J.F. Merz, "Discoveries: Are there Limits on What may Be Patented?" in D. Magnus et al. (eds), *Who Owns Life?*, pp. 99–116.

50 A.R. Williamson, "Creating a Structural Genomics Consortium", *Nature Structural Biology* 7 (Supp.) (2000), p. 953; E. Marshall, "Drug Firms to Create Public Database of Genetic Mutations", *Science* 284(5413) (1999), pp. 406–407. However, it should be noted that industry involvement in the SNP consortium was driven and shaped by multiple motives, some of which were not entirely aimed at non-profit public service.

51 C. Weijer, "The Ethics of Placebo-Controlled Trials", *Journal of Bone and Mineral Research* 18(6) (2003), pp. 1150–1153; P.B. Miller, C. Weijer, "Rehabilitating Equipoise", *Kennedy Institute of Ethics Journal* 13(2) (2003), pp. 93–118.

similarities among drugs, placebo control studies facilitate the direct-to-consumer promotional marketing claims of superior or novel therapeutic efficacy.[52]

Secrecy

While patents would seem to preclude secrecy about new inventions or innovations (by requiring descriptions of the patented product), simply having the potential to patent may increase secrecy and undermine the collaborative nature of biomedical research.[53] Pressure may be brought to bear on researchers from commercial partners or university administrations and technology transfer offices to be more secretive in order to protect against other researchers pre-empting or filing competing patent applications. Along with internal academic restrictions and issues of crediting and authorship, patents are one of the most often cited reasons for restrictions on or delays in scientific publication.[54] Researchers may be required to sign non-disclosure agreements that restrict academic debate and publications, and they may also have financial interests (for example, equity) in the products of research. As such, commercial support may place researchers in a variety of conflicts of interest.[55]

These conflicting interests and constraints have the potential to seriously retard the timely publication of results and threaten the objectivity and credibility of the scientific process.[56] Given the length of time from an original scientific finding to filing and granting of patents (usually on the order of two to five years) and the rapid pace of knowledge development in genetics and genomics, the details of the invention may become available only years after the initial discovery. By this point, the information may have been replicated and published in the academic literature, undermining any value the patent may have had when it was filed.[57]

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52 J. Graham, "Harbinger of Hope or Commodity Fetishism: 'Re-cognizing' Dementia in an Age of Therapeutic Agents", *International Psychogeriatrics* 13(2) (2001), pp. 131–134; Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*.

53 D. Blumenthal, "Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty", *Journal of the American Medical Association* 277(15) (1997), pp. 1224–1228; E.G. Campbell et al., "Data Withholding in Academic Genetics: Evidence From a National Survey", *Journal of the American Medical Association* 287(4) (2002), pp. 473–480.

54 Blumenthal, "Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty".

55 K.C. Glass, T. Lemmens, "Conflict of Interest and Commercialization of Biomedical Research: What is the Role of Research Ethics Review?", in T.A. Caulfield, B. Williams-Jones (eds), *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues* (New York: Kluwer Academic, 1999), pp. 79–100; Lewis et al., " Dancing with the Porcupine: Rules for Governing the University–Industry Relationship [Commentary]".

56 S. Krimsky et al., "Scientific Journals and their Authors' Financial Interests: A Pilot Study", in T.A. Caulfield, B. Williams-Jones (eds), *The Commercialization of Genetics Research: Ethical, Legal and Policy Issues*, pp. 101–110.

57 Cook-Deegan, McCormack, "Intellectual Property: Patents, Secrecy, and DNA".

Academic promotion and tenure decisions in faculties of medicine and the applied sciences are increasingly influenced by the ability of researchers to attract extramural funding from industry or other commercially oriented sponsors, and where possible, to be named on patents resulting from such research. But commercial support or patents may be inappropriate markers of research productivity or knowledge transfer. For example, in a study of patenting in the Departments of Mechanical and Electrical Engineering at the Massachusetts Institute of Technology (MIT), it was found that the majority of faculty members did not engage in patenting (accounting for less than 10% of knowledge transfer), and publication rates far outstripped the number of patent applications. Nevertheless, patents may be uniquely important for researchers involved in genomics and pharmaceutical research.[58] There is also some evidence that patent counts correlate with research "impact" as measured by paper citations, and thus could well complement but not replace existing research activities.[59] Yet as Atkinson-Grosjean demonstrates, while there may be increasing pressure to patent and spin-off research, most scientists continue to be engaged primarily in conducting basic research and have little interest in becoming "merchant scientists".[60]

Overall, the fear is that strong intellectual property rights will inhibit research. As David notes, "[d]iscoveries in many domains are...made in the course of unplanned journeys through information space. If that space is restricted by a host of property rights, then the journeys will become expensive (if not impossible) and the knowledge base itself will suddenly be found to be shrinking."[61] The composition and the size of the knowledge commons are critical for the unhampered evolution of such scientific journeys and discovery efforts.[62] Enclosure of information is a potentially serious threat to knowledge development that is both costly and wasteful; it may be harmful not only to the pursuit of academic science, but also to the translation of academic knowledge into marketable products, blocking downstream research and inhibiting the development of new technologies.[63] It is thus critical to carefully weigh the tradeoffs between protecting innovation and restricting academic freedom and access to knowledge.

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58 Bar-Shalom, Cook-Deegan, "Patents and Innovation in Cancer Therapeutics: Lessons from CellPro".

59 A. Agrawal, R. Henderson, "Putting Patents in Context: Exploring Knowledge Transfer from MIT", *Management Science* 48(1) (2002), pp. 44–60.

60 J. Atkinson-Grosjean, *Adventures in the Nature of Trade: The Quest for "Relevance" and "Excellence" in Canadian Science*, Ph.D. thesis, Individual Interdisciplinary Studies Graduate Program (Vancouver: University of British Columbia, 2002); J. Atkinson-Grosjean, "Merchant Scientists and the Settler Class: Research Cultures in Transition", *Science, Technology and Human Values* (forthcoming).

61 David, Foray, "An Introduction to the Economy of the Knowledge Society", p. 19.

62 Nelson, "The Advance of Technology and the Scientific Commons".

63 J. Borger, "Rush to Patent Genes is Hampering Medical Research", *The Guardian*, December 15, 1999, available at http://www.organicconsumers.org/Patent/rushpatent.cfm, accessed on February 9, 2005.

Pharmacogenomics and gene patents

Pharmacogenomics is predicated on the view that a better understanding of genetic contribution to drug response will help rationalize the choice of drug dosages or the drug itself. A critical look at the forces that created pharmacogenomics and sustain this field of research is essential for a realistic and balanced evaluation of the motivations for genetic testing to customize drug therapy. The idea of genetic influences on drug effects has been formally in existence since 1950s,[64] with the first detailed monograph published in 1962.[65] The application of pharmacogenomics in the pharmaceutical and diagnostic industry, however, is more recent and dates to 1997 when the first official investment and collaborative agreement were announced between the French biotechnology company Genset and the Chicago-based pharmaceutical firm Abbott laboratories. An editorial announcement on the Genset-Abbott alliance in the September 1997 issue of the *Nature Biotechnology* introduced the term "pharmacogenomics" into the research literature.[66]

A common thread in many of the "-omics" technologies (pharmacogenomics, proteomics, metabonomics and so on) is an increase in the scope of scientific inquiry by characterization of *multiple* biological variables (for example, genes), often in the order of tens of thousands, that can allow an integrated "systems biology" perspective on disease or drug response. The decrease in the unit cost of genotyping and the related genomics technologies is another welcome development for many investigators. On the other hand, these enabling technologies also create a statistical conundrum: to attain adequate statistical power and to allow correction for statistical comparisons with multiple genetic factors, researchers require an increasingly larger number of human subjects or biological specimens (for example, tumor biopsy material) to accompany the high throughput genetic data generated by pharmacogenomic technologies. At first glance, this may appear simply a logistical issue concerning the subject recruitment for clinical pharmacogenomic investigations. However, this shift in emphasis in the scientific process from *conception* of new ideas to subject *recruitment* as a critical rate-limiting step invariably affects the nature of stakeholders and the attendant socio-technical networks. The role of clinical scientists as gatekeepers is fundamentally altered. New actors who lack scientific training or merchant scientists become influential in subject recruitment, for example, by virtue of their professional positions in health care institutions and academia or as brokers in university-industry relationships. These actors may further stray from, or not even subscribe to, the Mertonian norms and the first (teaching) and the second (research) missions of the universities.[67]

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64 A.G. Motulsky, "Drug Reactions, Enzymes and Biochemical Genetics", *Journal of the American Medical Association* 165(7) (1957), pp. 835–837; F. Vogel, "Moderne Probleme der Humangenetik", *Ergebn Inn Med Kinderheilk* 12 (1959), pp. 52–125.

65 W. Kalow, *Pharmacogenetics: Heredity and the Response to Drugs*.

66 A. Marshall, "Genset-Abbott Deal Heralds Pharmacogenomics Era", *Nature Biotechnology* 15(9) (1997), pp. 829–830; Hedgecoe, "Terminology and the Construction of Scientific Disciplines: The Case of Pharmacogenomics".

67 Additionally, a new form of postcolonial predicament is slowly emerging as clinical trials are increasingly "off-shored" to developing countries where the subject recruitment

A second and qualitative change intensified by the introduction of pharmacogenomics concerns the mechanistic nature of the genetic biomarker data. This move towards a mechanism-oriented focus in medical therapeutics has bearings on whether, and under what conditions, the pharmaceutical industry may advocate the use of pharmacogenomics and pursue gene patents for prediction of treatment outcomes. Consider, for example, a clinical trial wherein treatment with a new molecular entity (NME) was associated with mortality or a serious adverse event. In such cases, measurement of an elevated NME concentration in the plasma or target organs may provide some insight into patient morbidity or mortality. However, drug safety evaluations based on drug concentration monitoring do not adequately inform on the underlying mechanisms, and hence remain essentially descriptive in nature. By contrast, the knowledge of biological pathways or predisposing mechanisms for drug toxicity may enhance clinicians' ability to draw broader inferences on other patient populations who share the same pathophysiological pathway or mechanism. With the advent of pharmacogenomics, association of elevated NME concentrations with genetic polymorphisms in cytochrome P450 2D6 (*CYP2D6*), a drug metabolizing enzyme, may have far reaching implications for patient safety and the development of rational therapeutics. A pharmacogenomic association of drug toxicity with *CYP2D6* poor metabolizer genotype would additionally inform, for instance, on the vast range of *CYP2D6* inhibitor medications that may lead to drug–drug interactions or safety concerns upon co-administration with the NME under investigation. Because the inter-ethnic[68] differences in *CYP2D6* gene structure and catalytic function are already well established in the literature, this may also suggest the need for additional clinical trials to identify the optimal population specific dose ranges for the NME.[69] Even though this pharmacogenomic data may inform how best to treat patients with newer medications, such broad implications of genetic testing for mechanistically significant biological elements such as *CYP2D6* cause some ambivalence in the pharmaceutical industry.[70] These concerns often focus on

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or the appropriateness of study designs may meet with lesser ethical scrutiny by the local regulatory authorities. S. Shah, "Globalization of Clinical Research by the Pharmaceutical Industry", *International Journal of Health Services* 33(1) (2003), pp. 29–36; A. Hamilton, "Ethical Issues Surrounding the Conduct of Off-Shore Clinical Research", Journal of Clinical Oncology 20(18) (2002), p. 3934. This raises concerns for a financially driven moral relativism that exploits vulnerable populations. O.P. Corrigan, B. Williams-Jones, "Pharmacogenetics: The Bioethical Problem of DNA Investment Banking", Studies in History and Philosophy of Biological and Biomedical Sciences 37 (2006): 549–564.

68 Marked inter-ethnic differences in the prevalence of *CYP2D6* poor metabolizers were noted, for example, among Caucasian (7%) and Asian populations (1%). L. Bertilsson et al., "Molecular Genetics of *CYP2D6*: Clinical Relevance with Focus on Psychotropic Drugs", *British Journal of Clinical Pharmacology* 53(2) (2002), pp. 111–122.

69 Ibid.

70 V. Ozdemir, B. Lerer, "*Pharmacogenomics* and the Promise of Personalized Medicine", in W. Kalow et al. (eds), Pharmacogenomics, 2nd expanded ed. (New York: Marcel Dekker, 2005), pp. 13–52; B. Williams-Jones, O.P. Corrigan, "Rhetoric and Hype: Where's the 'Ethics' in Pharmacogenomics?", *American Journal of Pharmacogenomics* 3(6) (2003), pp. 375–383.

potential delays in financial revenues and introduction of a NME into the market due to new insights gained by pharmacogenomic tests and the need to conduct further research.

Hypothesis-driven research has long been the hallmark of the traditional positivist approach to science. Pharmacogenomics, by contrast, involves a "shotgun" approach that investigates the associations between drug effects and variations across the entire genome. This approach is not biased by our current understanding or perceptions on disease pathophysiology or mode of drug action. As such, the genome wide pharmacogenomic association studies do not need to be based on a particular hypothesis, at least during its initial stages. Observations made with the use of pharmacogenomics, however, may generate new hypotheses and subsequently lead to hypothesis-driven research. Hence, a notable motivation for pharmacogenomics in the industry is upstream applications to discover unprecedented new drug targets and therapeutic candidates, although these may be threatened by the patenting of basic discoveries.

Interest in upstream pharmacogenomic applications is also a direct response to the anticipated expiry over the next several years of a large number of composition of matter patents that ordinarily provide market exclusivity for blockbuster drugs.[71] The pharmaceutical industry is finding it increasingly difficult to develop new blockbusters[72] – current drug targets across all therapeutic areas amount to only about 500 molecules[73] – and even those drugs being developed are often little more than "me-too" drugs. In 2003, of the seventy-two new drug applications approved by the U.S. Food and Drug Administration (FDA), only a mere nine (12.5%) were considered significant improvements compared to already marketed products.[74] The low level of innovation is consistent with a 2002 report of the National Institute for Health Care Management Research and Educational Foundation: in the twelve-year period from 1989 to 2000, 1,035 new drug applications were approved but a sizable percentage (54%) were differentiated from existing drugs primarily on the basis of dosage form, route of administration or as a combination product with another active ingredient.[75] Real innovation in the pharmaceutical industry – as measured by the

71 R.F. Service, "Surviving the Blockbuster Syndrome", Science 303(5665) (2004), pp. 1796–1799; Angell, *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*.

72 D.F. Horrobin, "Innovation in the Pharmaceutical Industry", *Journal of the Royal Society of Medicine* 93(7) (2000), pp. 341–345.

73 J. Drews, "Drug Discovery: A Historical Perspective", *Science* 287(5460) (2000), pp. 1960–1964; J. Drews, S. Ryser, "The Role of Innovation in Drug Development", Nature Biotechnology 15 (1997), pp. 1318–1319; Webster et al., "Integrating Pharmacogenetics into Society: In Search of a Model".

74 Center for Drug Evaluation and Research, "NDAs Approved in Calendar Years 1990–2003 by Therapeutic Potentials and Chemical Type", *Food and Drug Administration, Department of Health and Human Services*, January 21, 2004, available at http://www.fda.gov/cder/rdmt/pstable.htm, accessed on February 6, 2005.

75 National Institute for Health Care Management Research and Educational Foundation, *Changing Patterns of Pharmaceutical Innovation* (Washington, D.C.: NIH, 2002), available at http://www.nihcm.org/innovations.pdf, accessed on February 6, 2005.

number of NMEs approved that were a significant therapeutic advance over existing drugs – has remained consistently low, ranging from 18.8% in 1990, 11.0% in 1995 to 9.2% in 2000.[76] These data are thus at variance with, and do not appear to support the notion that, innovation in the drug industry has been facilitated by the Bayh-Dole Act.

In view of the diversity of human diseases, there is no doubt that novel molecular drug targets[77] will be essential to develop drugs with improved efficacy. At the same time, it is plausible that further clinical development of the specific polymorphic sub-types of new molecular targets with the use of genetic tests may meet with some degree of resistance due to concerns for market fragmentation. Another scenario under which pharmacogenomics testing may be viewed favorably in the industry is early identification of poor drug candidates in phase II proof-of-concept clinical trials enriched for patients with certain genetic sub-types of drug targets previously shown to confer an increased likelihood of response. An inadequate response to a NME in patient samples stratified by genetic testing may facilitate decisions concerning the prioritization of therapeutic candidates for further development. However, unless the pharmacogenomic-guided drug discovery and applications in early phase clinical trials are prospectively continued in late-stage phase III registration trials specifically designed for biomarker validation, genetic data may not be included in drug labels. This is significant because it is uncertain to what extent the undisclosed off-label pharmacogenomic data (from upstream applications) that may remain in pharmaceutical company archives will deliver the much-anticipated new medicines customized by genetic testing.

The experience with genetic tests for disease risk has thus far suggested that gene patents may be an actively and uniformly sought-after commodity by the diagnostic industry. However, a more complex and multifaceted story is unfolding in the case of pharmacogenomics. For the most part, genetic testing for common multifactorial human diseases is a long-term forecast of the composite probability of developing a chronic disease in a far distant future, usually on the order of several decades away. In contrast to this marked *temporal dissociation* between a genetic test for disease risk and the actual occurrence of the disease itself, drug effects are usually acute or sub-chronic in nature; they are elicited in a matter of minutes, days or several weeks following drug administration.

Seen in this light, pharmacogenomic testing in the context of drug therapy requires a precise knowledge of both the genes and the attendant proteins encoded by the genes.[78] This is essential because proteins serve as the "work horses" that actually mediate and determine the final function or clinical relevance of the genes themselves. Moreover, protein function may be influenced by environmental factors

76 Center for Drug Evaluation and Research, "NDAs Approved in Calendar Years 1990–2003 by Therapeutic Potentials and Chemical Type".

77 A *drug target* is a molecular entity, usually an enzyme or receptor protein, to which the drug binds and exerts its molecular effects preceding or underlying the clinically discernible therapeutic effects.

78 D.W. Nebert, L. Jorge-Nebert, E.S. Vesell, "Pharmacogenomics and 'Individualized Drug Therapy': High Expectations and Disappointing Achievements", *American Journal of Pharmacogenomics* 3(6) (2003), pp. 361–370.

through, for example, inhibitor co-medications that can abolish the function of proteins encoded by a gene that does not harbor genetic variants or mutations. Thus, a sound prediction of drug effects may require a dual and complementary strategy involving both genetic and proteomic tests for the same gene and its protein product, respectively. In effect, this may create unprecedented challenges for intellectual property rights and their defense within the legal system. For instance, what are the implications of a proteomics company attempting to develop a protein-based, non-genetic "functional assay" for a gene patented hitherto for genetic tests to predict drug response or toxicity?

Despite the enthusiasm for early applications in drug discovery, prospective stratification of patients using genetic tests in advanced stages of drug development is still rare.[79] In this regard, the fear is that enthusiastic corporate statements on personalized medicines may serve to establish a biohype[80] to attract and secure stockholders' investment or venture capital to be used towards upstream applications (instead of downstream use for drugs in the clinic) that may never deliver personalized therapies. Moreover, if and when drugs are developed against the common polymorphic genetic variants of molecular targets, "therapeutic orphan" populations represented by uncommon or rare genotypes will be created.[81] These pharmacogenetically defined therapeutic minorities are unlikely to benefit from the fruits of genomic technologies in an equitable manner. When viewed from the research portfolios standpoint, there is also the additional potential ethical concern in the future that a small portion of the research investment in the industry may be channeled towards a few select customized therapies – likely adding to and sustaining the biohype noted above – while the remaining larger percentage of research budgets, generated in the name of personalized medicines, are used for upstream genomic applications. In effect, the biohype associated with genetically tailored drug therapies, in its most severe form, may potentially lead to doublespeak and misleading forward-looking statements in press releases and public policy debates, or during the implementation of routine pharmacogenetic testing in the clinic.[82]

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79 Ozdemir, Lerer, "Pharmacogenomics and the Promise of Personalized Medicine"; R. Sanders, "Molecular Diagnostics and Personalized Medicine", *Pharmacogenomics* 4(5) (2003), pp. 541–545.

80 Hedgecoe, "Terminology and the Construction of Scientific Disciplines: The Case of Pharmacogenomics"; N. Brown, "Hope Against Hype – Accountability in Biopasts, Presents and Futures", *Science Studies* 16(2) (2003), pp. 3–21; T.A. Caulfield, "Underwhelmed: Hyperbole, Regulatory Policy, and the Genetic Revolution", *McGill Law Journal* 45(2) (2000), pp. 437–460.

81 Smart, Martin, Parker, "Integrating Pharmacogenetics into Society: In Search of a Model".

82 A. Hedgecoe, *The Politics of Personalised Medicine – Pharmacogenetics in the Clinic* (Cambridge: Cambridge University Press, 2004).

Actors along the university–industry interface

The term "industry" is often used loosely to indicate a single private interest group, where there is, in fact, much heterogeneity in this regard. Therefore, we concentrate our subsequent analysis on gene patents and genetic testing on four elements along the university–industry interface: drug manufacturers comprised of large multinational corporations; mid-size biotechnology firms with a single or limited set of drug candidates or NMEs; small biotechnology firms specializing solely in technology services without a drug discovery pipeline or clinical trial infrastructure; and small biotechnology companies spun out of universities.

To the extent that the larger pharmaceutical firms continue to pursue the blockbuster model with a focus on drugs marketed for the entire patient population while displaying a sub-optimal benefit/risk ratio, it is more than likely that pharmacogenomics will meet with resistance for implementation towards existing drugs in the clinic.[83] However, a frequently overlooked point is that the composition of matter patents that ordinarily offer market exclusivity for new medications do not protect the drug manufacturers against the development of pharmacogenomic tests (that can potentially fragment their market share and exclusivity) by other stakeholders such as university researchers or biotechnology companies. Insofar as the larger drug manufacturers are concerned, in-house development and patenting of genetic tests for their marketed drugs may thus offer the potential for maintaining some level of pre-emptive control on a paradigm-disruptive technology (that is, pharmacogenomics) that can otherwise significantly fragment the pharmaceutical market.[84] The effects of such pre-emptive pharmacogenomic patents are, however, at odds with the conventional views that encourage subsequent commercialization of gene patents by developing genetic tests. Under the pre-emptive business model noted above, drug manufacturers can maintain an inventory of patented genetic tests for prediction of response to their drugs without necessarily proactively pursuing their commercialization, thereby still maintaining a sizable share of the pharmaceutical market without threat from third parties. Oddly enough, this in effect may create additional business ventures for the biotechnology companies who specialize solely in genomic technologies and diagnostic tests, as well as academics with shares in biotechnology firms spun out of universities. Ultimately, the largest pharmaceutical companies may purchase the patent rights from these smaller stakeholders to maintain their market monopoly and blockbuster status.

A frequent argument by pharmaceutical industry leaders is that the Wellcome SNP Consortium (discussed above) is a testament of their commitment to apply the pharmacogenomic technology in the clinic – although little is mentioned exactly where and in what form this commitment is to be realized. Independent experts outside the industry suggest that the Wellcome SNP Consortium has come into existence, in part, by the pragmatic need for a brief and transient period of *pre-competitive cooperation* among several pharmaceutical companies, prior to an

83 Service, "Surviving the Blockbuster Syndrome".

84 Eisenberg, "Will Pharmacogenomics Alter the Role of Patents in Drug Development?"; Smart, Martin, Parker, "Integrating Pharmacogenetics into Society: In Search of a Model".

extensive competitive commercialization process to patent pharmacogenetic tests for prediction of drug efficacy and safety.[85] It should be noted, in this context, that the data on human genetic variation such as SNPs do not constitute a genetic test in and of themselves. Moreover, it is now established that the patterns of SNPs along each chromosome (haplotypes) are more informative than individual SNPs for prediction of drug effects through genetic testing.[86] Thus, patent protections obtained by different interest groups (researchers, universities, industry) on SNPs and other types of upstream genetic variation data may significantly hamper the subsequent phase of research in academia or industry that could lead to patentable pharmacogenomic associations with drug response. This predicament was apparent to a number of large pharmaceutical companies following the launch of pharmacogenomics, which served as a notable driving force for this transient and limited cooperation among the industry leaders prior to the large-scale commercial efforts to develop gene patents for drug targets and other upstream application as discussed previously.

In this complex, interactive and competitive dialogue among the stakeholders within the "industry", moral ambiguities will continue to emerge as some of the pharmacogenetic tests that can prevent drug toxicity or treatment-failure may never reach clinical practice due to patents obtained with pre-emptive motives.[87] While genetics departments within the industry may be sympathetic towards routine pharmacogenomic testing of pharmaceutical products or therapeutic candidates in clinical development, individualization of drug therapy and fragmentation of the market share may be potentially less appreciated by marketing divisions.[88] Conflicting economic pressures related to the implementation of pharmacogenomic tests that are linked to pharmaceutical products (some of which can be blockbuster drugs with sub-optimal efficacy or safety) can also pose challenges for professional integrity and objectivity. Genetics departments within industry or university–industry collaborations on pharmacogenomics may encounter fragmented views and moral dilemmas on how best to balance scientific vigilance, objectivity and Mertonian ideals with demands for short-term economic gain that would accrue with the deployment of blockbuster drugs.

Further complexity may arise from the involvement of insurers (particularly in the U.S., but potentially also in Canada and Europe) since the availability of a genetic test that can predict drug response may allow third party payers to deny reimbursement, or demand a higher co-pay for drug claims in patients who score negative for a pharmacogenomic efficacy test.[89] Collectively, the social and financial downstream benefits of pharmacogenomics will likely accrue to patients, insurers and academic researchers who do not have a vested interest in developing sub-

85 Eisenberg, "Will Pharmacogenomics Alter the Role of Patents in Drug Development?".

86 M.R. Hoehe, "Haplotypes and the Systematic Analysis of Genetic Variation in Genes and Genomes", *Pharmacogenomics* 4(5) (2003), pp. 547–570.

87 Eisenberg, "Will Pharmacogenomics Alter the Role of Patents in Drug Development?".

88 Williams-Jones, Corrigan, "Rhetoric and Hype: Where's the 'Ethics' in Pharmacogenomics?"; Anand, "Big Drug Makers Try to Postpone Custom Regimens".

89 Webster et al., "Integrating Pharmacogenetics into Society: In Search of a Model".

optimal blockbuster "me-too" drugs. Similarly, mid-size biotechnology companies may also actively pursue downstream pharmacogenomic patents and tests, as smaller and more focused clinical trials may complement and benefit their limited clinical trial operational infrastructure.

Conclusions

In view of the growing academic culture of commercialization, epitomized by the Bayh-Dole Act, it is worth reflecting on the social, ethical and policy implications for both continued academic research and the subsequent development of marketable biotechnologies.

- Where are the ethical boundaries with regards to unrestricted financial profits that can accrue from gene patents to individual scientists or particular commercial interest groups from research funded by taxpayers? The issue at hand is not so much if the Bayh-Dole Act (or similar policies elsewhere) is right or wrong, but rather are or should there be limits to commercialization?
- Will there be oversight mechanisms to evaluate the impact of rampant commercialization on innovation (and if so where, in patent offices[90])?
- How would (or should we) avoid the adverse consequences of the *erosion* of the knowledge commons?
- What are the implications of human disease and suffering being perceived as lucrative commercial opportunities to be controlled through the patenting of genetic tests for disease predisposition?

We have, in this chapter, briefly sketched out the nature of these questions, and they continue to pose important challenges for both academics and policy makers; challenges that are in need of further detailed theoretical and empirical analysis. Such analyses would, we suggest, profit from an awareness of the complexity of the actors and socio-technical networks that underpin the process of commercialization in the university and industry contexts. It should be kept in mind, for example, that industry is never a single entity but is instead comprised of many interacting, and often competing elements (large pharmaceutical companies, small to medium biotechs with a NME, or small biotechs with a technology orientation). This industry infrastructure has an important influence on how gene patents will be deployed and will shape future research and technology development. As the academic institutions increasingly move towards serving a dual role as engines for economic growth and as knowledge commons, future public policy debates on pharmacogenomics and personalized medicine will need to be reframed to incorporate these subtle but significant nuances *between* and *within* various actors in industry and academia.

Finally, with the increasingly interdisciplinary nature of scientific inquiries over the past decade, it is likely that a patent on a specific and apparently small

90 E.R. Gold, "Biomedical Patents and Ethics: A Canadian Solution", *McGill Law Journal* 45 (2000), pp. 413–435.

component of the knowledge commons may have far-reaching consequences that may limit instead of facilitate progress in multiple areas and dimensions of research. That is, the interdisciplinary science that is considered so beneficial to society may *multiply* the adverse effects of patents on open scientific progress.

Chapter 8

Reconceptualizing Genetics: Challenges to Traditional Medical Ethics

Heather Widdows

Introduction

This chapter considers the ways in which genetics – broadly conceived – challenges the applicability and effectiveness of the core principles of medical ethics and the assumptions that underlie them. How genetics is conceptualized is fundamental in critiquing current practices and considering more appropriate approaches: when conceptualized as primarily information (as opposed to property or person or a mixture of all three) the challenges posed to medial ethics are particularly prominent. For genetic information carries information not just about the individual but about consanguineous relations and about the wider ethnic group. As a consequence, current assumptions and practices of ethics – intended to protect the individual – are untenable in the genetic era. This chapter argues that the key concepts of medical ethics, those of informed consent and confidentially, upheld by individualism and the primacy of autonomy, are undermined by genetics.

The chapter outlines the status of genetic material, in light of which the individualism of bioethics and the primacy of autonomy are discussed, alongside the "gold standards" of ethical research which derive from these principles. Alternative ethical frameworks are then analyzed, focusing on attempts to expand informed consent – to the family and the group. The chapter concludes by suggesting that, although the inadequacy of individualist models has been recognized, there is little progress in the task of conceptualizing, let alone applying, new ethical models.

Defining genetics

The first question that must be addressed is "what is so different about genetics that it calls into question the long-established practices and principles of medical ethics?". The answer to this is twofold: first, genetic material defies definition and, second – and depending upon which definition is used – it is communal rather than individual. The problem of definition of genetic material is a familiar one and therefore it will merely be touched upon before moving to the more fundamental issue of the potentially communal nature of genetic material.

Genetic material raises new issues because of its unusual nature. At a very basic level it is difficult to define, and thus it poses problems for lawmakers, medical

practitioners and ethicists alike. The difficulty in adequately defining genetic material is apparent in the different legal and ethical approaches adopted by different jurisdictions (or even within the same jurisdiction). For example, in New Jersey in 1996, there was a clear clash between the governor and the legislature when Governor Christie Whiteman vetoed a bill that had been unanimously passed by the legislature because it described genetic information as "personal property";[1] personal property is one of a number of possible definitions, others are "information", "common property", "intellectual property", "person" and "extension of person".[2] The description of "personal property", suggested by the New Jersey legislature, had profound economic and power implications about ownership and property rights. For instance, if it had been passed it would have enforced royalty sharing between researchers and research subjects.[3] This confusion about whether genetic material is "material", "information", "property" or "person" is exemplified in the now-familiar and frequently cited "*Moore* case".[4] In this case property rights were awarded to the researchers and hospital board of regents over the "Mo" cell line developed from Moore's cells. This decision, although arguably in breach of previous legal precedent and therefore perhaps not as significant as it first appears, clearly has implications for the ownership of information and material taken or developed from individuals and indeed from communities.[5] These two examples show that defining genetic material is no easy task and there is, as yet, no consensus regarding which definition should be adopted. This lack of definition, while problematic in itself, compounds the further question of this chapter; that of how genetics should be conceptualized when the discussion moves from definition to that of questioning the individualist assumptions which underlie Western bioethics.

Individualism and autonomy

These difficulties in defining genetics are relevant in addressing how and why genetics challenges the key concepts of medical ethics (informed consent and confidentiality), as how genetics is conceptualized shapes the practices and regulations which are put in place for the governance of genetics. Yet, even though there is no consensus

1 P. Roche, "*Caveat Venditor*: Protecting Privacy and Ownership Interests in DNA", in B.M. Knoppers (ed.), *Human DNA: Law and Policy* (The Hague: Kluwer Law International, 1997).

2 R.E. Gold, *Body Parts: Property Rights and Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996); K. Gottlieb, "Human Biological Samples and the Laws of Property", in R.F. Weir (ed.), *Stored Tissue Samples* (Iowa City: University of Iowa Press, 1988); M.M. Litman, "The Legal Status of Genetic Material", in B.M. Knoppers (ed.), *Human DNA: Law and Policy*.

3 Roche, "*Cavet Venditor*".

4 *Moore v. Regents of the University of California* (1988) 249 Cal. Rptr. 494; (1990) 271 Cal. Rptr. 146, (1990) 793 P.2d 479; cert. denied (1991) 111 S.Ct. 1388.

5 Gold, *Body Parts: Property Rights and Ownership of Human Biological Materials*; D. Dickenson, *Property, Women and Politics: Subjects or Objects?* (Cambridge, MA: Rutgers University Press, 1997).

on which definition should take precedence, however one conceives of genetics, and whatever emphasis one ultimately places on the information element, one must recognize that "DNA is…a repository of information".[6] The crucial fact about genetic information, which makes it different from other medical information, is that it is *identifying* (and continues to be so) and, more importantly, the information it proffers is not only about the individual from whom it was derived but about consanguineous relations and the wider ethnic group. Together these two factors – that genetic information is identifying and that it provides information not only about the individual – threaten the core concepts of medical ethics, those of informed consent and confidentiality. This is because supporting the practices of informed consent and confidentiality are the underlying assumptions of individualism, most obviously evidenced in the primacy of individual autonomy in current bioethical theory and practice.

The bioethical framework is fundamentally individualistic and "has reified the individual and individual autonomy".[7] The individual focus of bioethics is found in its primary methodology of principlism – the application of a small set of principles to any ethical dilemma to determine the "right" or "best" action. Principlism became popular in medical ethics in the 1960s and 1970s in the U.S., applying the four principles of autonomy, non-maleficence, beneficence and justice.[8] Principlism tends to support individualism for two reasons: first, because it is used in the medical setting and therefore is applied by practitioners to individual cases; and, second, and not surprisingly given its American heritage, it has tended to privilege the principle of autonomy over the other principles; hence the "gold standards" of medical ethics of individual consent and confidentiality are clearly linked to autonomy rather than, for example, justice.

The individualism in Western bioethics has been criticized from many quarters, and by both internal and external critics. From external critics, such as the Asian Values movement in bioethics (along with other Western systems of ethics) has been criticized for being too individualistic and presented as a form moral neo-colonialism. [9] The values promoted by the Asian values movement are broadly communitarian, which place the good of the community – the political and religious

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6 V.T. Silva, "In the Beginning Was the Gene: The Hegemony of Genetic Thinking in Contemporary Culture", *Communication Theory* 15(1) (2005), pp. 100–123, p. 106.

7 B.A. Koenig, "Why not Grant Primacy to the Family?", *The American Journal of Bioethics* 1(3) (2001), pp. 33–34, p. 33.

8 A version of principlism was endorsed by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (1979) and in the same year T.L. Beauchamp and J.F. Childress published *Principles of Medical Ethics*, which became the seminal textbook of medical ethics (now in its fifth edition) and established principlism as *the* methodology of medical ethics.

9 The Asian Values movement argues that Western Values (most particularly those implied in human rights) are alien to the values of Asian countries and communities who endorse not Western individual values, but communitarian values which support the political and religious order, emphasize hard work and thriftiness, are linked to business and government and promote loyalty to the family and the wider community. Asian values are especially associated with Noordin Sopiee of Malaysia and Tommy Koh, George Yeo and

order as well as the family – over the good of the individual and conceive of the "good life" as fundamentally rooted in community. The concept of Asian values has spread across the developing world and increasingly non-Western thinkers are rejecting what they consider to be Western, individualist values, in favor of overtly communitarian ethical frameworks. For example Chinese thinkers have turned to Confucianism, which they regard "as the native cultural ground on which to reject human rights concepts as alien, culture-bound, Western impositions".[10] While often the target of such attacks has been human rights as the most obviously individualistic carrier of so-called Western values, bioethics too has suffered similar criticisms. For example, a group of "Developing World Bioethicists" claim to have "produced: an authentic vision of the lifeworld of health care and bioethics in the developing world"[11] from which to reject Western bioethics (especially when it is presented as being universal and global). It is precisely the focus on the individual as the locus of all values that they find so unpalatable: "The focus of Western Bioethics is individual, elsewhere it focuses on social units. Western bioethics often is orientated to principles; Filipino, on the other hand, is not articulated primarily in principles but in lived moral virtues".[12]

The individualism of Western bioethics, most notably in the guise of principlism, is not only under attack from non-Western thinkers, but also from within Western ethics and the principlism of bioethics has been widely critiqued. In particular, principlism has been criticized as being reductionist because it ignores information that does not fit into the principlist "calculator" and therefore ignores morally relevant perspectives and approaches. As Evans notes, "many feel that the use of principles does not capture the moral life quite properly".[13] Such criticisms echo those of the so-called "developing world bioethicists" that an individualist ethic is not a comprehensive ethic but one which privileges individual choice to the exclusion

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Kishore Mahbubani of Singapore, although they have also been endorsed more broadly in the non-Western world by thinkers and politicians across Asia and Africa.

10 Such thinkers insist that "the West's conception of human rights is too individualistic, and out of keeping with China's communitarian traditions based on Confucianism" as well as with other more communitarian value systems. Cf. W.T. de Bary, *Asian Values and Human Rights: A Confucian Communitarian Perspective* (Cambridge, MA: Harvard University Press, 1997), p. 6.

11 A.T. Alora, J.M. Lumitao, *Beyond a Western Bioethics: Voices from the Developing World* (Washington, D.C.: Georgetown University Press, 2001), p. xii.

12 Alora, Lumitao, *Beyond a Western Bioethics*, p. 4.

13 J.H. Evans, "A Sociological Account of the Growth of Principlism", *Hastings Centre Report* 30(5) (2000), pp. 31–38, p. 37. There are other criticisms of principlism relating to its supposed simplicity. Critics claim that principlism is not as simple as it is claimed, as the principles contain strands from many different moral theories and the individual has to decide for him/herself the key elements of the principles, and then, having defined the principles, they have to be "weighed" against each other (K.D. Clouser, B. Gert, "A Critique of Principlism", *Journal of Medicine and Philosophy* 15 (1990), pp. 219–236; B. Gert, C.M. Culver, K.D. Clouser, *Bioethics: A Return to Fundamentals* (New York: Oxford University Press, 1997)). However, for the purposes of this chapter it is the individualism that is of particular relevance.

of social, economic and communal concerns. This is blatantly true in the ascendancy of autonomy – a fundamentally individual concept – to the extent that autonomy has become "the" moral value, rather than simply one of four equally valid principles, and the practices it supports, those of informed consent and confidentially, have become "the" practices of bioethics (as least as it is conceived in the West).

Genetics challenges the individualism inherent in bioethics as it questions the place of the individual as the locus of ethical concern, for "the fact that genetic information about one person can be of value to others poses an important challenge to the primacy of respect for the principle of autonomy in medicine".[14] As a result the traditional mainstays of medical ethics (informed consent and confidentiality), supported by the assumptions of individualism, are brought into question as adequate guarantors of good ethical practice,[15] as "disclosure of genetic information by individual DNA donors also exposes information about others with similar genetic profiles".[16] Given the central importance of informed consent and confidentiality in medical ethics, and prior to considering possible models which move beyond the individual, these key concepts and the manner in which they are problematized in the genetic era will be addressed in a little more detail.

Confidentiality

Confidentiality "has long been regarded as one of the most important principles of medical ethics" and indeed is "prominent in Hippocratic Oath".[17] Confidentiality is held to be such an essential principle of medical ethics that it has been termed the "central ethical pillar of clinical practice".[18] Confidentiality is owed by the practitioner to the individual patient (irrespective of whether this information impacts upon others, and whether the health care professional has a duty of care to other genetically related family members). Thus, confidentiality is concerned only with the individual and is strongly dependent upon the principle of autonomy: "if we look with a strictly "autonomous eye", the other family members are irrelevant".[19]

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14 M. Parker, A.M. Lucassen, "Genetic Information: A Joint Account", *British Medical Journal* 329 (2004): 126.

15 J. Husted, "Autonomy and a Right not to Know", in R. Chadwick et al. (eds), *The Right to Know and the Right not to Know* (Aldershot: Ashgate, 1997); B.M. Knoppers (ed.), *Human DNA: Law and Policy*; B.M. Knoppers, "Who Should Have Access to Genetic Information", in J. Burley (ed.), *The Genetic Revolution and Human Rights* (Oxford: Oxford University Press, 1999); they continue to be the focus of medical ethics, as evidenced in *Tomorrow's Doctors* (GMC, 1993), which highlights these two key issues of confidentiality and informed consent, in sections 29 and 30 on "Medico-legal and ethical issues".

16 G.R. Mitchell, K. Happe, "Informed Consent after the Human Genome Project", *Rhetoric and Public Affairs* 4(3) (2001), pp. 375–406, p. 376.

17 J. Harris, *The Value of Life: An Introduction to Medical Ethics* (London: Routledge, 1985), p. 225.

18 K.M. Boyds, R. Higgs, A.J. Pinching (eds), *The New Dictionary of Medical Ethics* (London: BMJ Publishing Group, 1997), p. 51.

19 D.J. Doukas, J.W. Berg, "The Family Covenant and Genetic Testing", *The American Journal of Bioethics* 1(3) (2001), pp. 2–16, p. 4.

However, in the genetic era such individually biased confidentiality quite simply cannot be guaranteed, as genetic information is identifying and continues to be so when compared to a database. Thus the possibility of identifying the individual from whom the information was derived, or their genetically related family members, at any time in the future is a real possibility – and one that becomes increasingly likely as number of people who have their information stored (particularly on large-scale databases) continues to grow and the use of genetics in clinical practice likewise becomes more common. How this is to be addressed has been seen as "among the most important challenges identified by a group of nurses, physicians, and genetic councilors who were asked what ethical and professional challenges they faced when they saw patients with genetic concerns".[20] Thus the problems genetics poses to the effectiveness of confidentiality are already impacting upon current medical practice.

The question then is not only how to continue to enforce confidentiality but rather the deeper question of whether individual confidentiality should continue to be guaranteed, or whether in the genetic era other ethical duties should take precedence. Dan Brock suggests that the assumption that "underlies and supports the general practice of medical confidentiality is that medial information is first and foremost about the patient, and so the patient has the greatest interest in that information and in controlling who has access to it".[21] However, this long-held assumption may no longer be true in the genetic era. For example, if an individual tests positive for a genetic condition, such as Huntington's disease, or as a carrier of the BRCA1 or BRCA2 (indicators for breast cancer) or cystic fibrosis gene, this information has relevance for family members (consanguineous relations may wish to be tested themselves, and sexual partners may desire the information when making reproductive decisions). Therefore it is not only that confidentiality is difficult to maintain in practice (because of the identifying potential of genetic material) but there is the underlying question of whether confidentiality should continue to be paramount. Clearly, at the very least there needs to be a reassessment of the primary place of confidentiality and a thorough "rethinking…(of the)…paramount position of the individual in ethics".[22] This chapter considers some of the suggestions for more appropriate ethical practices in the genetic era after informed consent has been considered in a little more detail.

Informed consent

In addition to confidentiality, the other key guarantor of ethical practice, and very much connected to confidentiality, is that of informed consent. Informed consent does not have the longevity of confidentiality as a cornerstone of good ethical

20 D.M. Bartels, "Family Covenants and Confidentiality within Families", *The American Journal of Bioethics* 1(3) (2001), pp. 15–16, p. 15.

21 D.W. Brock, "Genetics and Confidentiality", *The American Journal of Bioethics* 1(3) (2001), pp. 34–35, p. 34.

22 B.M. Knoppers, R. Chadwick, "Human Genetic Research: Emerging Trends in Ethics", *Nature* 6 (2005), pp. 75–79, p. 75.

practice, however, it has become its second pillar. Consent then is the means by which "the law protects and preserves a patient's bodily integrity"[23] and in some areas of science and medicine it has become almost the only concern, for example, in the areas of research voluntary informed consent is absolutely essential.[24] Consent is fundamentally intended to protect individual autonomy, indeed so much so that it has been stated that "respect for the person requires a patient's autonomous consent be obtained before any treatment or procedure involving the patient can be carried out, and…no consent will be autonomous unless it is fully informed".[25]

The ascendancy of informed consent is related to the horrors of Nazi research practices and the wish to prevent such atrocities occurring again. Thus, "ethically the post-war consensus – from Nuremberg to Helsinki to the Common Rule – is that, to the greatest extent possible, people should not be exposed to the risks of human subjects research without their informed consent".[26] Informed consent is regarded as the final ethical guarantee for the individual and this is the "tool that is intended to safeguard autonomy and promote the freedom to choose".[27] Accordingly, and understandably given the historical context in which informed consent became prominent, informed consent focuses by definition on the individual and, as it is currently implemented, it is fundamentally individualistic.

However, as with confidentiality, the appropriateness of current practices are brought into question as "of course the key feature of genetic information is that it is typically information about a family, or even…about a larger community not just about an individual patient".[28] Therefore the question is whether the individual should continue to be the ethical focus as "one-to-one models of informed consent give…genetic bystanders no say in decisions about whether to proceed with potentially harmful research, since such normative frameworks invest individual research subjects with the sole power as agents of consent".[29] Arguably individuals should not be able to make decisions or consent to use of their genetic material in any sense, as the material reveals information not only about themselves, but also about those genetically related to them. Thus it has been claimed that genetic information does not belong to the individual and therefore the individual should not be able to consent to its use. For this reason genetics is "challenging ethical and social issues that overshoot traditional models of informed consent".[30] No longer can the individual be considered the only locus of concern, however, given the almost

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23 It is the "legal obligation to volunteer sufficient information to the patient so that the patient understands what is being done, why it is being done and what its likely consequences will be": Boyd, Higgs, Pinching, *The New Dictionary of Medical Ethics*, p. 57.

24 A. Goldworth, "Informed Consent Revisited", *Cambridge Quarterly of Healthcare Ethics* 5 (1996), pp. 214–220.

25 Harris, *The Value of Life*, p. 205.

26 H.T. Greely, "Human Genomics Research: New Challenges for Research Ethics", *Perspectives in Biology and Medicine* 44(2) (2001), pp. 221–229, p. 223.

27 F.A. Castillio, "Limiting Factors Impacting on Voluntary First Person Informed Consent in the Philippines", *Developing World Bioethics* 2(1) (2002), pp. 21–27, p. 22.

28 Brock, "Genetics and Confidentiality", p. 34.

29 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 376.

30 Ibid.

unquestioned dominance of the individual in current models of western ethics such a reassessment will not be easy. For not only are "new ways of thinking…more difficult as the primacy of the individual becomes enshrined in law and bureaucratic procedures such as the common rule",[31] but particularly in the West, as pointed out by the developing world critics, the pre-eminence of the individual is assumed to the point where even conceiving of and conceptualizing alternative models is most difficult.

Beyond the individual to the family

For these reasons it clear that the "gold standards" of ethical practice, those of confidentiality and informed consent, and the premises they derive from, those of individualism and individual autonomy, are no longer adequate in the genetic era. Thus it has been questioned "since testing one person provides information about others within a family must we modify our traditional model of informed consent, one focused exclusively – some would argue excessively – on the individual?".[32] Likewise, and in a similar manner, "confidentiality arises as an ethical issue when information that is relevant to others emerges in a consultation and the patient is unwilling for this information to be shared".[33] Accordingly, alternative, non-individual models of consent and confidentiality have been sought, which consider the family and the wider ethnic group – the ethical locus, rather than the individual. Two such models are that of the "joint account" and the "family covenant". The joint account model sees genetic information as belonging to, and available to, all family members. While there may be cases where information could be withheld (for example in situations where serious such disclosure would seriously harm the individual) the "default" position would be that genetic information is familial and not individual.[34]

The "family covenant" is perhaps the most discussed model of family consent, where the family and not the individual is the "unit of care". The family covenant is suggested as a model that dictates the manner in which results from genetic tests are to be shared with family members; as such it "offers the individual, family and physician a mechanism to help resolve competing claims for confidentiality and disclosure".[35] It was intended to pre-empt questions of when and how to disclose potentially distressing information about the genetic status of individuals within families. The thinking behind this approach is the "bonds that hold families together

31 Koenig, "Why not Grant Primacy to the Family?", p. 33.

32 Ibid.

33 M. Parker, "Confidentiality in Genetic Testing", *American Journal of Bioethics* 1(3) (2001), pp. 21–22.

34 The "joint account" model is put forward by Michael Parker, who is critical of traditional models of consent on the grounds that they assume that the individual has the right to refuse to share such information (Parker, "Genetic Information: A Joint Account").

35 Doukas, Berg, "The Family Covenant and Genetic Testing", p. 3.

may not survive such dynamic tension unless there is some framework constructed to allow for balancing of individual and family interests".[36]

The family covenant has be praised as being "a significant step by recognizing that in genetics the family plays a significant role in genetic counseling and testing, and the family, not simply the individual is the patient".[37] Thus, the convent model focuses on a group and "claims to move beyond a strictly autonomy-driven paradigm".[38] However, while going some way to redressing the problems of the individual bias of confidentiality and informed consent, the family covenant model continues to have problems, for example, the "effectiveness of a covenant depends upon the possibility of reaching agreement within families about a range of questions in addition to those about genetics".[39] Questions about who should be included as a family member may cause difficulty and, as has been pointed out, if questions about how and when to disclose are likely to become problematic the family covenant will not be adequate as it cannot be enforced.[40] Moreover, the family covenant does not, in fact, question the underlying individual premises, and consent and confidentiality remain important. For even in this model confidentiality remains a key concept and is "promoted within the boundaries agreed to by all parties".[41] Moreover, the authors of the model assert "when the family covenant is used in genetic testing, healthcare would continue to be directed toward the individual patient. The covenant applies only to the extent that the physician (and the patient) must consider the impact of genetic test results on other family members to the extent agreed upon a priori by the family".[42] Thus the individual bias remains and individual autonomy is held to be an untouchable premise and consequently the covenant is not binding as the "the ethical accounting of individual autonomy and family benefit claims must be based on the concept of voluntary promise rather than a right".[43] Indeed, this is acknowledged by the authors who recognize that "the family covenant could be seen as a faint nod to the obligations to those other family members, as it potentially can be revoked if the patient decides to keep genetic information private".[44]

Therefore while attempting to incorporate a wider ethical locus, and to take into account the shared nature of genetic material, the family covenant does not actually move very far from the usual individual models. In particular it continues to uphold individual consent and confidentiality as primary ethical premises. Individual consent and confidentiality are in fact the mechanisms by which the family covenant is negotiated: the boundaries of confidentially are gradually expanded by virtue of individuals consenting to future sharing of information. Thus, while attempting to

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36 Ibid.

37 W.H. McKellin, "Clinical Ethics and Family Morality", *The American Journal of Bioethics* 1(3) (2001), pp. 31–32, p. 31.

38 Koenig, "Why not Grant Primacy to the Family?", p. 33.

39 Parker, "Confidentiality in Genetic Testing", p. 21.

40 Conversely if there are no difficulties about who to disclose to and how this should be done then the need for a family covenant is obviated.

41 Doukas, Berg, "The Family Covenant and Genetic Testing", p. 7.

42 Ibid.

43 Ibid., p. 6.

44 Ibid., p. 7.

reckon with the problem of genetic information belonging not only to the individual the family covenant could be said to actually support the primacy of the individual (something which is less true of the "joint account" model, which assumes that the information belongs to the family and not the individual). However, even this very slight movement away from the individual model has been criticized, as potentially "undermining the rights of the individual" and of being "a slippery slope toward revealing genetic information to a variety of third parties with some moral claim".[45] Accordingly it would seem that moving away from the individual model and conceptualizing alternative ethical frameworks is no easy task.

Beyond the individual to the wider community

Unsatisfactory as attempts to move towards a family model appear, it is even more difficult to include within the ethical framework those who belong to the wider community or ethnic group. Genetic information is relevant not only to the family, but to the wider community, and there is a need to address "the ethical and logistical challenges presented by the fact that genomic research impacts whole population groups as research subjects, even when just a few individual DNA donors contribute tissue samples for analysis".[46] Here the issue goes beyond how to communicate the results of potentially important genetic tests and raises issues of who owns and who has the right to use genetic information derived from individuals but potentially belonging to a community – an increasingly important issue as the new genetics, stem cell technologies, and other advances lend commercial importance and value to the tissues and genomes of populations in developing countries.[47] This has become a particularly pertinent issue for groups, such as indigenous populations, with relatively homogenous genetic makeups. Such relatively homogenous groups are valuable subjects for researchers, and research on such groups "that are, or are perceived as being, closely genetically connected has implications for all members of those groups, whether or not they decided – or even were asked – to take part in the research".[48] Thus, even if current individual ethical standards are met the effects are likely to be far wider and "will land on many group members who did not give their informed consent after weighting the foreseeable benefits and risks".[49] As a result it has been suggested that "the ramifications of genomic research can ripple quickly throughout human populations, with potentially dire consequences for social groups linked to the individual human research subjects who donate tissue samples".[50]

This issue came to the fore most notably with the launch of the Human Genome Diversity Project (HGDP), in instances in which the inadequacy of individual informed consent was dramatically demonstrated. For example, the Hagahai people

45 Ibid., p. 8.

46 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 386.

47 D. Dickenson, "Commodification of Human Tissue: Implications for Feminist and Development Ethics", *Developing World Bioethics* 2(1) (2002), pp. 55–63.

48 Greely, "Human Genomic Research: New Challenges for Research Ethics", p. 222.

49 Ibid.

50 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 376.

of Papua New Guinea were the subject of a patent application filed by the U.S. National Institute of Health (NIH) and an anthropologist, Dr. Carol Jenkins, who was doing research on the Hagahai. The Hagahai are a tribe of about 260 persons who only came into consistent contact with the outside world in 1984. A patent was granted on a cell line containing unmodified Hagahai DNA and several methods for its use in detecting HTLV-1-related retroviruses in 1994. Under the "benefit-sharing" agreement, the Hagahai were entitled to 50 per cent of any royalties accrued by the researcher. However, the patent itself made no concrete provision for the Hagahai to receive any compensation for becoming the property of the U.S. government. The patent was "disclaimed" in 1996, however the Hagahai cell line remains in the public domain and is now available to the public at the American Type Culture Collection as ATCC Number: CRL-10528 Organism: Homo Sapiens (human) at a cost of $216.

Unfortunately this is not the only example and in addition to the Hagahai, at around the same time there were patent applications filed by "US federal health agencies on genetic samples derived from indigenous peoples in the Solomon Islands and Panama".[51] The situations surrounding these applications were not dissimilar to the Hagahai. In the Solomon Islands example, patents were filed by the U.S. Department of Commerce on two T-cell lines; one from a 40-year-old woman and one from a 50-year-old man.[52] Although under pressure the patent claim was withdrawn, as with the Hagahai, the cell-lines remain on deposit at the American Type Culture Collection. One further cell-line on deposit in the same place is one derived from a 26-year-old from Guyayami, Panama.[53] Again the patent claim was withdrawn due to the pressure of advocacy groups and concerned parties, however, given situations like these it is not surprising there is increasing mistrust of scientists and researchers. And the National Research Council "expressed concerns about how the samples might be used against donors and their communities, and the possible implications of the HGDP for human rights abuses".[54]

Such extreme cases, along with the theoretical considerations regarding the inadequacy of informed consent, have lead to a crisis in the research community as "research into human genetics has stretched current regulations of human subjects beyond the [*sic*] breaking point".[55] The lack of group protection and what has been seen by many as the exploitation of vulnerable groups has lead to images of biopiracy, for example, and perhaps not surprisingly in light of examples such as that of the Hagahai people:

> In several early writings about the HGDP by indigenous peoples and advocacy groups, the HGDP and its participants were characterized as blood sucking vampires swooping down into remote villages, sucking the blood of unsuspecting victims and callously leaving them to die while flying off to far away labs and patent offices where monsters and biological

51 J. Barker, "The Human Genome Diversity Project: 'Peoples', 'Populations' and the Cultural Politics of Identification", *Cultural Studies* 18(4) (2004), pp. 571–606, p. 595.

52 Ibid.

53 Ibid.

54 Ibid., p. 598.

55 Greely, "Human Genomics Research: New Challenges for Research Ethics", p. 221.

> weapons were being designed in the dark and under-the table financial deals were being made in secret.[56]

As a result of such bad practice and the increasing suspicion of research populations, research councils have "proposed the adoption of "group consent" as a normative rule governing genomic research to alleviate this ethical blind spot in traditional informed consent doctrines".[57] Such attempts at some kind of group consent in the form of "prior consultation and communication with these specific communities and populations are emerging as ethical prerequisites".[58] For example, following the initial bad practice connected to the HGDP, the North American Regional Committee put together a "Proposed Model Ethical Protocol" which explicitly recognizes the communal nature of genetic information. Thus it states that "the Project intends to study populations, not individuals. As a result, we believe that the populations, as well as the individuals, must give their free consent to participate".[59] Such a starting principle represents a fundamental shift away from the individual model and the document continues, "we believe…that the population-based nature of this research requires population-based consent and we will insist on it".[60]

This said, asserting that genetic information belongs to groups rather than an individual is one thing; finding ways to put this into practice is another. For example, who is capable of granting communal consent? The National American Research Council suggests that consent should be sought from the "culturally appropriate authority", whatever or whoever that might be. There are also additional problems with consent, particularly when working with vulnerable populations. For example, whether groups or individuals, the ability to consent freely depends on many other issues, such as economic and social power, for instance, "poor people who are sick and chronically marginalized and who have faith in the benevolence and expertise physicians when asked to participate in a drug trials do not have real options".[61] Issues of exploitation and coercion remain if the locus is a group rather than an individual (although arguably less so as the group has more power to negotiate with the researchers than do individuals).[62] Moreover, even when group consent is sought

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56 Barker, "The Human Genome Diversity Project: 'Peoples', 'Populations' and the Cultural Politics of Identification", p. 583.

57 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 377. For an example see the Nuffield Council on Bioethics document *The Ethics of Research Related to Healthcare in Developing Countries*.

58 Knoppers, Chadwick, "Human Genetic Research: Emerging Trends in Ethics", p. 76.

59 National American Research Council, *Model Ethical Protocol for Collecting DNA Samples* (1999), available at http://www.stanford.edu/research/mrcbl/nbac/pubs.html.

60 Ibid.

61 Castillo, "Limiting Factors Impacting on Voluntary First Person Informed Consent in the Philippines", p. 24.

62 These issues are not limited to genetics and obviously apply to those conducting research in the developing world. In this context researchers have been criticized for continuing to focus on consent (whether group or individual) when other issues for instance access to health care, inducement to participate or trial after care, could arguably be claimed to be more important. For such reasons "when evaluating research protocols, reviewers should not just limit themselves to the prescribed forms, but should be mindful of the complex contextual

it is generally seen as an addition to informed consent rather than adequate consent in itself and thus individual informed consent remains "the" necessary guarantor of ethical research.[63]

Furthermore, as difficult as it may be to achieve group consent with genetically homogenous populations – and here one tends to think of indigenous populations as the model, it is even more problematic in culturally diverse populations. Wider, less-definable populations are needed for broader research that "seeks associations between genetic variations and human health in vast populations through the development of vast databases of phenotypic and genotypic information",[64] as, for example, the DeCODE Icelandic resource and U.K. Biobank. Attaining group consent in such contexts is even more problematic than with indigenous groups, for who is the "culturally relevant authority" in these cases, thus "the problems of defining the group membership and then determining who can legitimately give consent on its behalf"[65] are further exacerbated. Those who contribute to these broad database projects are not obviously connected, and in fact "genetically linked persons who share a common stake in the outcome of a particular research project may not live near each other, or share overlapping moral, social, and deliberative ties that would be important ingredients of any meaningful group consent discussion".[66] Therefore, even if the non-individual nature of genetic information is recognized, the means to ethically accommodate this recognition does not yet seem to be available.

However, even if effective practice is not yet established, the recognition that genetic information belongs to groups rather than to individuals represents a paradigm shift in ethical thinking (albeit that consent and individual consent continues to be primary). Thus, in the simple fact that in "the implementation of processes that respect the need for public consultation and debate…[have]…come to prominence, particularly in relation to population databases such as the proposed UK biobank and the Quebec CARTaGENE project",[67] a step away from the individual has begun. Thus, however ineffectively, the dominance of the individual is being questioned and alternative practices sought.

Reconceptualizing

In the attempts to attain group consent a move away from individualism is evident. As noted in this chapter the challenge of genetics to the traditional individualist concepts of medical ethics applies not only in research, but also in clinical questions

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issues involved in 'informed consent'" (Castillio, "Limiting Factors Impacting on Voluntary First Person Informed Consent in the Philippines", p. 27).

63 Nuffield Council on Bioethics, *The Ethics of Research Related to Healthcare in Developing Countries* (2002), available via http://www.nuffieldbioethics.org; National Commission on Bioethics 2001.

64 Greely, "Human Genomics Research: New Challenges for Research Ethics", p. 221.

65 Ibid. p. 222.

66 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 389.

67 Knoppers, Chadwick, "Human Genetic Research: Emerging Trends in Bioethics", p. 77.

about sharing information within families (an issue likely to be increasingly important as genetic tests and treatment expand). The fact that genetics has raised questions at every level has been described as a "kind of genetic domino effect…[that]…has prompted ethicists, scientists, and policymakers to rethink the basic categories undergirding traditional informed consent norms".[68] Yet, despite the turn to group consent, as evidenced by this discussion, there has not been a radical rethinking, but merely an expanding of the consent model (indeed, group consent is presented as an additional rather than an alternative model). Such expansion of current models is not enough to address the challenges of genetics, and truly new approaches are needed. Thus it has been suggested that "rather than simply beginning with the individual in a reflexive, knee-jerk way, we could systematically examine other ways of instituting respect for persons, means of truly honoring the importance of social groups such as the family".[69] However, such reconceptualizing has yet to be begun in earnest and the new questions which genetics raises are only beginning to be defined clearly, let alone addressed.

However, although adequate conceptualizing of genetics is only just begun and the full impact of the challenges that genetics poses to traditional ethical concepts and principles is only just being recognized there are movements which suggest conceptual reassessment is beginning, for example in the trends in ethical thinking identified by Ruth Chadwick and Bartha Maria Knoppers.[70] They suggest that an underlying shift from individual to more communitarian models can be identified – as evidenced by the five general trends they outline, namely those of reciprocity, mutuality, solidarity, citizenry and universality.[71] This communal turn may simply be linguistic, encouraged by the almost mythical rhetoric which has surrounded the HGP and the uncovering of the "book of life", for instance, "the human genome is said to be, in a collective sense, shared by all…Often expressed as the common heritage of humanity and justifying obligations to future generations, it highlights and reinforces the approach of benefit-sharing".[72] However, as has become all to obvious in this discussion, recognizing the non-individual nature of genetic information and finding ethical models and practices which can accommodate this insight, without sacrificing the clearly valid insights which led to the establishment of informed consent and confidentiality, are two very different things.

Therefore although there is recognition that genetic information undermines traditional concepts of medical ethics, there is as yet little new thinking and few alternative models. Even with regard to the development of large databases "the individualist approach…persists, as can be seen in the continuing debate not only about informed consent, but also about access to feedback on findings that relate to individual samples".[73] Perhaps this is inevitable given the almost total dominance of the individual in Western ethics, and it will take some time to begin to even

68 Mitchell, Happe, "Informed Consent after the Human Genome Project", p. 276.
69 Koenig, "Why not Grant Primacy to the Family?", p. 33.
70 Knoppers, Chadwick, "Human Genetic Research: Emerging Trends in Bioethics".
71 Ibid.
72 Ibid., p. 77.
73 Ibid.

conceptualize new ethical models which still protect individuals and yet recognize groups. For now then, perhaps it is enough that "genetic research is forcing a public and therefore a political examination of personal and social values"[74] and ethicists should grasp this opportunity to propose new ethical models that are more appropriate to the reality of human being and human beings in the genetic era.

74 Ibid., p. 75.

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Chapter 9

Lack of Access to Essential Drugs: A Story of Continuing Global Failure, with Particular Attention to the Role of Patents

Sigrid Sterckx*

Introduction

One-third of the world's population has no access to essential drugs.[1] In the poorest regions of Africa and Asia, one out of two persons lacks such access.[2] The extent of the crisis is clear from the following examples (to give but a few).

Malaria

According to the Roll Back Malaria program, an international group of ninety organizations set up in 1998, between 350 and 500 million people worldwide became ill with malaria in 2003. The World Health Organization (WHO) reports that malaria

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1 I do not use the concept of "essential drugs" in the sense the World Health Organization currently uses it. The concept was officially launched by the WHO in 1975. The original definition was: "[drugs] that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms". See World Health Organization, *The Use of Essential Drugs. Report of a WHO Expert Committee* (Geneva: WHO, 1983). In 1977, the WHO published the first *Model List of Essential Drugs*. In 1999, an element was added to the definition of "essential drugs": "and at a price that individuals and the community can afford". See World Health Organization, *The Use of Essential Drugs. Ninth Report of the WHO Expert Committee (November 1999)* (Geneva: WHO, 2000). Hence the fact – often mentioned by proponents of strong drug patents – that about 95% of the drugs on WHO's *Essential Drugs List* are not patented (anymore) is not surprising, as patented drugs are often not "affordable". The WHO definition is highly susceptible to criticism: whether or not a drug is considered essential must not depend on its price. What matters is whether the drug substantially affects the life/functioning of patients.

2 See the website of the World Health Organization: www.who.int.

continues to kill an estimated two million people each year. Ninety per cent of these are African children younger than five years.[3] Every thirty seconds, a child dies of malaria in Africa. No infectious disease takes more lives of children in Africa than malaria – three times as many lives are lost to malaria than from HIV/AIDS.[4]

In view of the fact that malaria is cheap and easy to cure, this is an intolerable situation. Many of the older malarial drugs have become useless, as the most virulent forms of malaria have become resistant to these drugs. The good news is that recently developed artemisinin-based combination therapy (ACT) *does* work. The price of this type of treatment, which only takes three days, is US$0.60 for a child and US$2 for an adult.[5] However, many of the countries which are hit most hardly by malaria lack the money to make this treatment available to their extremely poor citizens. Moreover, there is an acute shortage of ACTs.

Tuberculosis (TB)

Each year, almost nine million people develop TB. The disease kills up to two million people a year and its toll is rising. Ninety-nine per cent of TB deaths occur in developing countries. Health care providers in developing countries lack diagnostic tools that are adapted to local conditions. As a result, almost half of the people who need treatment are not detected! For children, the available tool – sputum microscopy, developed 123 years ago – does not work at all. Yet, as reported by MSF, "most existing efforts to develop more effective TB tests are technology-driven and focus on the more lucrative Western markets".[6]

HIV/AIDS

Worldwide, forty million people are infected with HIV. Ninety-five per cent of these people live in developing countries. In 2004 alone, 3.1 million people died from AIDS. Women are particularly vulnerable. The percentage of women living with HIV/AIDS has increased progressively (from 41% in 1997 to 50% by the end of 2002). In Southern Africa young women are four to six times more likely to become infected with HIV than young men.

Since 1996 it has been possible for the disease to be treated with so-called "antiretroviral drugs" (ARVs). Although many patients have access to AIDS drugs in industrialized countries, this is rarely the case in poor countries. At the end of 2003, six million people in developing countries needed ARVs, but only 8% of them actually received treatment. By December 2004, the number had risen to 12%. In Africa, where four of those six million patients live, the figure was still only 8%.

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3 Médecins Sans Frontières (MSF). See www.msf.org.

4 Ann Veneman, Executive Director of Unicef, quoted in BBC News, May 3, 2005, "'Too Early' for Malaria Verdict", available at: http://news.bbc.co.uk/go/pr/fr/-/1/hi/health/4508883.stm.

5 MSF. See www.msf.org.

6 MSF, *World TB Day 2005: Development of Simple and Rapid Diagnostic Tools Key for Fighting Tuberculosis.* Press release, March 22, 2005. Available at www.accessmed-msf.org.

Obviously, providing drugs alone is not enough – prevention is also very important. But without drugs, treatment of the people who have developed AIDS is simply impossible. A few years ago, after generic AIDS drug manufacturers could start to compete with manufacturers of brand drugs, the drugs became significantly cheaper. According to MSF, treatment now costs US$140 per patient per year, compared to US$10,000 four years ago. Nevertheless, several million patients still don't have access to treatment.

In Brazil, the government, pushed by NGOs, has been successful in reducing drug prices thanks to generic production by state companies and bulk purchases of imported drugs. Generic production of seven ARVs saves the country 400 million dollars per year! Combined with prevention efforts and follow-up of patients, this has resulted in a 54% decrease of mortality between 1995 and 1999.

In reaction to excessive prices of patented ARVs, the government has repeatedly threatened to override the patents by granting compulsory licenses (see below) if the companies did not reduce their prices. This approach has had a significant impact on prices.

Sleeping sickness

Sleeping sickness (human African trypanosomiasis), which is transmitted by infected tsetse flies, threatens sixty million people, only 7% of whom have access to diagnosis and treatment. An estimated 300,000 to 500,000 people are currently infected, a figure which appears to be rising. If left untreated, the disease is 100% fatal.[7]

Melarsoprol, a remedy against sleeping sickness, was developed some seventy years ago but can be described in lay terms as "arsenic in antifreeze".[8] Five to ten per cent of the patients treated with melarsoprol die as a result of the toxicity of the treatment, and just as many experience extremely adverse side effects. The drug is injected intravenously and corrodes the veins of the patient. There are, however, no other remedies available for treating late-stage sleeping sickness.[9] Production of eflornithine, the only existing alternative, was abandoned because of lack of profit (see below). Meanwhile it appears that a melarsoprol-resistant form of sleeping sickness is spreading rapidly: about one in four patients are suffering from this resistant form.

Leishmaniasis

Leishmaniasis currently affects an estimated twelve million people in eighty-eight countries,[10] particularly in very poor and remote communities. Each year some two million people become ill with the disease. In humans leishmaniasis exists in

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7 See www.accessmed-msf.org.

8 D.G. McNeil, Jr., "Drug Makers and 3rd World: Study in Neglect", *The New York Times*, May 21, 2001, pp. 1 ff.

9 In the first stage of the disease, the parasite is only found in the blood; in stage 2, the brain is also infected by the parasite.

10 Mainly Bangladesh, Brazil, India, Nepal and Sudan, but the disease also occurs in Europe, particularly in HIV-infected people.

different forms, the most severe of which is visceral leishmaniasis or *kala-azar* (Hindi for "black fever"), affecting 500,000 people each year. If untreated, *kala-azar* is 100% fatal.

The most common treatment of *kala-azar* was discovered around 1930. It is known as SSG, a derivative of antimony. The brand form of this drug – marketed by GlaxoSmithKline – is highly expensive: $US150 per treatment course (one month). In African countries where generic SSG is not authorized,[11] the majority of people with *kala-azar* do not have access to treatment.

Moreover, SSG treatment causes very severe side effects in 10% of cases. There is also a growing problem of resistance, particularly in India, which is very badly affected by *kala-azar*. The more the parasite's resistance to SSG spreads, the less effective the treatment becomes. A few other drugs exist, but those are either toxic or extremely expensive.

Currently, most research and development money for leishmaniasis is invested in drugs for animals rather than humans! As MSF explains:

> Dogs in developed countries can be infected by the type of leishmaniasis that also infects people in Southern Europe, and people in rich countries are willing to pay considerable sums for pet health care. This treatment of pets may actually compromise the treatment of humans: in Europe, dogs are sometimes treated repeatedly with SSG, which can induce drug resistance in the parasite. It may then become much more difficult to cure humans infected by the same parasite.[12]

Clearly, research and development of effective, safe and affordable drugs for human leishmaniasis patients is needed very urgently.[13]

Causes of the crisis

Lack of research and development of drugs for tropical diseases – skewed research priorities

The 'non-priorities' Of the 1,223 molecules that were sold worldwide between 1975 and 1996, less than 1% was intended for tropical diseases.[14] Moreover, only

11 Generic SSG is marketed in India. The generic used by MSF costs 1/14 of GlaxoSmithKline's brand product. See www.accessmed-msf.org.

12 See www.accessmed-msf.org.

13 In April 2005, some good news was announced: results from a large clinical trial conducted by the Institute for OneWorld Health (the first not-for-profit pharmaceutical company in the U.S.) show that paromomycin –an antibiotic that is off-patent – is effective for the treatment of visceral leishmaniasis. In the mid-1990s researchers at the WHO conducted small clinical trials to test an injectable form of paromomycin. The trials showed that the drug was safe and effective. But the WTO did not find a sponsor for a large-scale clinical trial, so the "pipeline" ended there, until the Institute for OneWorld Health conducted a trial in 2001, funded by the Bill and Melinda Gates Foundation.

14 B. Pécoul et al., "Access to Essential Drugs in Poor Countries – A Lost Battle?", *Journal of the American Medical Association* 281(4), (1999), pp. 361–67 [hereinafter Pécoul et al. (1999)].

four (!) of the eleven products in question were the result of research done by pharmaceutical companies. Most drugs for tropical diseases are either accidental discoveries "retrieved" from veterinary medicine, or molecules discovered by government institutes or universities, and later acquired or sold by pharmaceutical companies.

The pharmaceutical industry claims that companies put in great efforts in the field of neglected diseases.[15] An enquiry lead by the Harvard School of Public Health and an international group of experts (the Drugs for Neglected Diseases Working Group) in 2002 provided data that pull these claims to pieces.[16] Hardly any investments are being made, and few products are in the pipeline. The experts sent written questionnaires to the CEO and/or the head of research and development of the world's top twenty pharmaceutical companies to assess the level of research and development activity in several neglected diseases (sleeping sickness, leishmaniasis, Chagas disease, malaria and tuberculosis). A distinction was made between three types/stages of research and development activity: screening (to find useful chemical compounds); pre-clinical or clinical development; and the bringing to market of a product within the last five years. Of the twenty companies, thirteen companies responded, eleven of which completed the questionnaire. One company indicated no reportable research activities in infectious disease. Another company said that time constraints prevented completion of the survey. The eleven companies who responded include at least six of the world's top ten pharmaceutical companies. The survey demonstrated that none of the companies invested in research and development in the field of sleeping sickness. As to Chagas disease, only one company seemed to invest in pre-clinical or clinical development of a compound. The same was the case for leishmaniasis. Two companies reported investments for malaria: one of them reported screening and each stated that it had products in pre-clinical or clinical development or had brought a product to market within the last five years. And finally, for tuberculosis, the situation seemed to be less harrowing: out of the eleven companies, five seemed to make investments in this field, four of which reported screening activities, three reported pre-clinical or clinical development, and one company had brought a product for treating tuberculosis to market within the last five years.

In other words, there is a very serious lack of private investment in research and deveopment of drugs for tropical diseases: tropical diseases are examples *par excellence* of neglected diseases.[17] Moreover, as the examples in the introduction

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15 See, for example, the assertion of the Pharmaceutical Research and Manufacturers of America, that "Companies are conducting extensive research on malaria". PhRMA, *2002 Industry Profile*, Chapter 1 (Value of medicines), p. 8.

16 The survey is available at www.accessmed-msf.org.

17 A distinction should be made between "neglected" and "most neglected" diseases. See the "Fatal Imbalance" report, p. 11, available on www.msf.org. Malaria and tuberculosis are examples of *neglected* diseases. The pharmaceutical industry has only marginal interest in these diseases. Although also affecting people in wealthy countries (for example, a specific group of travelers), these illnesses primarily affect people in developing countries. Thanks to the fact we've just mentioned, neglected diseases still play a role in the global pharmaceutical market. Examples of *most neglected* diseases are Chagas, sleeping sickness, dengue, lepra,

show, of the few drugs for tropical diseases that exist, many are out of date, toxic and non-effective.

The 'priorities' In 2003 – the most recent year for which data are available – worldwide pharmaceutical sales grew 9%, to reach US$491.8 billion.[18] North America, the EU (with then still only fifteen members) and Japan together accounted for 88% of (audited) worldwide pharmaceutical sales in 2003. Sales in North America represented 49% of all global sales! European sales outside the EU-15 represented 3% of global sales; sales in Latin America represented 4% and sales in Asia, Africa and Australia together represented 8%.[19] Generic drugs represented only 4 to 5% of worldwide pharmaceutical sales (a figure which has remained the same for the past several years).

The five leading therapy classes in 2003 were (in order of importance): cholesterol and triglyceride reducers (up 14% compared to 2002); anti-ulcerants (+9%); antidepressants/mood stabilizers (+10%); antirheumatic non-steroidals (+6%) and antipsychotics (+20%). For the first time in fourteen years, cholesterol and triglyceride reducers replaced anti-ulcer drugs as the leading therapeutic class worldwide. The best selling drug in the world was, again, Pfizer's Lipitor, which accounted for US$10.3 billion or 39% of sales of cholesterol and triglyceride reducers. Another statin, Merck & Co's Zocor, remained second.

The number of so-called "blockbuster drugs" also clearly continues to increase: sixty-four products had more than one billion dollars in sales in 2003; twenty-three of these had over two billion dollars in sales.

More money is invested in health-related R&D than ever,[20] but a major problem lies in the selection of the targets of these investments.

The 1990 Commission on Health Research for Development made the first attempt to estimate global spending on health-related research and development. It discovered what became known as the "10/90 gap": less than 10% of the total health-related research and development budget is devoted to the world's major health problems representing 90% of the global disease burden.[21] The "10/90" concept is about fifteen years old and has penetrated the theoretical views of the problem rather

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schistosomiasis and leishmaniasis. These diseases only affect people in developing countries. The patients are so poor that they have virtually no purchasing power. In other words, there is no "market" for these diseases; they fall outside the global pharmaceutical market. Consequently, the industry's interest in the development of drugs for these diseases cannot be stimulated through the implementation of *market*-based mechanisms.

18 IMS Health, annual world review (tracks sales of approximately 90% of all prescription drugs and over-the counter-products in more than 80 countries). See www.ims-global.com//insight.

19 IMS Health does not give separate figures. In 2002, sales in the whole of Africa represented just 1% of the global pharmaceutical market.

20 See, for example, PhRMA's yearly Industry Profiles, available at www.phrma.org. In the most recent version, the figures can be found in Chapter 4 ("R&D investments, disease targets"). Important note: we have no other sources with which to compare these figures, so it is not clear how reliable they are.

21 See Global Forum for Health Research, *10/90 Report 2000–2001*.

well, but those who suffer from the inflictions in question see little change. The gap persists.

Moreover, as regards the health needs of developing countries, research priorities are skewed in favor of HIV/AIDS, malaria and tuberculosis – which can be called "neglected" diseases, in contrast with "most neglected" diseases such as sleeping sickness and leishmaniasis and many other lethal diseases a great majority of people in rich countries have never even heard of, but which kill millions of people in developing countries.

As noted earlier, the pharmaceutical industry claims that it *is* concerned about health problems in developing countries. In the most recent Industry Profile published by Pharmaceutical Research and Manufacturers America, for example, it is stated that:

> U.S. pharmaceutical companies support and conduct research on diseases that are uncommon in this country but major public health problems in other nations around the world.[22]

Four examples are then provided: malaria, blinding trachoma, dengue fever and TB. As to malaria, *PhRMA* only mentions that Bayer is working with the WHO to develop a new drug for patients in developing countries and that GlaxoSmithKline is working with WHO to develop a fixed-dose combination therapy drug. Apart from the fact that this seems rather meager in terms of effort, it can be noted that neither of these companies is an American company – yet this research is labeled as "American-funded research". Concerning blinding trachoma, only twenty-three "research grants" by Pfizer "to study this disease" are mentioned. In the case of dengue fever, the American effort is allegedly represented by Novartis's funding of the Institute of Tropical Medicine in Singapore, which is said to work on the development of therapies for dengue fever and TB. Finally, as far as TB is concerned, Astra Zeneca's new laboratories for TB research in India are mentioned. It is hard to avoid the impression that these efforts are rather poor.

In reality, pharmaceutical companies are investing most of their research and development money on so-called "me-too" drugs and lifestyle products. The industry develops profitable drugs for the wealthy regions in the world and makes its biggest profits from hair tonics, anti-impotency drugs, drugs for cholesterol, ulcers, depressions, allergies and high blood pressure. More money is invested in research of drugs against baldness than in research of all tropical diseases combined!

Moreover, the greater part of pharmaceutical R&D budgets is spent on "me-too" drugs – drugs that are slightly altered (and hence not innovative) versions of existing success products. The American Food and Drug Administration (FDA), for example, classifies the applications it receives either as "priority drugs" (which are considered a significant improvement in relation to the existing drugs and are therefore subjected to a prompter and faster assessment procedure) and "standard

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22 PhRMA, *Pharmaceutical Industry Profile 2005 – From Laboratory to Patient: Pathways to Biopharmaceutical Innovation*, Chapter 4, (2005), p. 21. Available at www.phrma.org.

drugs" (similar to existing products). Of all drugs approved by the FDA between 1997 and 2003, 80% belong to the standard drug category.

Of the 1,035 drugs approved by the FDA between 1989 and 2000, two-thirds were altered or even identical versions of the (active ingredients of) drugs already available on the market. The rest (only 35% or one in three) consisted of so-called "new chemical entities": drugs based on new chemical substances forming a new treatment. Of the above-mentioned 1,035 drugs, only 24% were categorized by the FDA as significant improvements, while the remaining 76% were designated as "standard drugs".

Representatives of the pharmaceutical industry answer criticism that they spend a considerable part of their budgets on "me-too" drugs with a story about the mechanisms of the free market and their responsibilities towards their shareholders: no profits means no shareholders, which in turn means no research. This makes some sense, but a big difference between the pharmaceutical market and other markets is that – so-called "lifestyle" drugs left aside – the pharmaceutical market is a free market only for manufacturers and not for consumers (patients). After all, patients do not choose to be ill.

Quality problems

The quality of the available drugs is sometimes extremely poor. The majority of the developing countries do not have the resources required for the application of the so-called good manufacturing practices to their production.

In many countries in West Africa there are many black markets for drugs where counterfeit products are sold (often by the piece!) that are much cheaper than the branded products (or even generic products) and in some cases contain only a fraction of the required dosage of the active ingredient or even nothing at all.

The extensive field experience of MSF teams has borne out that:

> [O]rganized illegal circuits seem [more] inclined to manufacture copies with the appearance of known trademark drugs (counterfeit) than comparatively less-expensive generic products, whereas nonorganized illegal circuits (small production) increasingly manufacture drugs that are substandard or inadequate, including generic drugs.[23]

Discontinuation of drug production

When a new product for treating a tropical disease is found or it is discovered that an existing product (developed for a different purpose) can also be used in this field, the manufacturer almost automatically decides not to market the drug. Due to the absence of a profitable market, it is highly unlikely that investments can be recouped. In some cases, companies can be persuaded (under pressure from WHO, a national government, or a NGO) to make the product available, possibly by donations. But in most cases production is abandoned for good. One example which illustrates this sad reality is the case of eflornithine (to treat sleeping sickness).

23 Pécoul et al. (1999), p. 363.

The production of eflornithine, the best drug against melarsoprol-resistant forms of sleeping sickness, was discontinued for therapeutic purposes because there was no profit to be made from it. This drug was originally developed as a cure for cancer. Its utility for treating sleeping sickness was discovered by accident in the 1980s.[24] The results of administering eflornithine to last-stage patients were so spectacular that the remedy was named "the resurrection drug". The American manufacturer, a U.S. subsidiary of Aventis, decided in 1995 to stop production. It had been known for quite some time that the remedy was ineffective against cancer. In January 2000, Aventis sold its last supply of eflornithine to MSF. This supply ran out by the middle of 2002. In December 2000, the company assigned the patent rights on eflornithine to the WHO, which agreed to look for a third party manufacturer (and which according to some commentators has not put in much effort to find a solution).

In September 2000, Bristol-Myers Squib, in co-operation with Gillette, introduced Vaniqa, an eflornithine cream, for removing facial hair in women. Bristol-Myers Squib estimated that every week some twenty million women in the U.S.A. remove their facial hair. The market for this cream represents at least six billion dollars. The active agent is the same as would be required for the treatment of sleeping sickness. However, the sleeping sickness market is not being supplied. Is it perhaps the case that the possibility of any occasional negative event being reported on the low profit usage causing loss of market in the high profit usage is too great a commercial risk?

Inertia of international organizations and national governments

The ultimate responsibility for securing people's basic needs in terms of health care does not rest with the private sector, but with governments. It has been clear for some time that the failure of the pharmaceutical market is becoming increasingly distressing (and that, under such circumstances, governments have the moral obligation to intervene), we see that governments often fail in their duties. While it is wonderful to see what organizations such as the Bill and Melinda Gates Foundation are doing to improve access to drugs, governments and international organizations should be more serious about addressing the problems. In particular, they should recognize the shortcomings of the patent system, as well as pressure the pharmaceutical industry to spend part of their research and development budgets on diseases which have been neglected so far. Given the enormous profits characterizing this industry,[25] that would be perfectly possible.

In countries where neglected diseases are endemic, public health budgets (and supporting infrastructure) are generally insufficient. For example, in Uganda, a country badly hit by sleeping sickness, the budget per patient per year is less than the price of one trap for tsetse flies. The WHO's Commission on Macroeconomics and Health estimates that an increase in donor assistance for health to $35 billion per year by 2015 (up from $5 billion per year in 2001), if properly spent and combined

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24 F. Doua, et al., "Treatment of Human Late-Stage Gambiense Trypanosomiasis with α-Difluoromethylornithine (Eflornithine)", *American Journal of Tropical Medicine and Hygiene* 37 (1985), pp. 525–533.

25 See the *Fortune 500* rankings of the last 20 years: www.fortune.com.

with greater spending on health by national governments, would prevent eight million deaths per year.[26]

Other factors also play a role in the inadequacy of government measures, such as improper administration, corruption and sometimes a blatant lack of interest in the fate of the general population.

Lack of infrastructure

In many developing countries, health care infrastructure is very meager. The same holds for transportation infrastructure. This is obviously an important determinant of lack of access to drugs. However, the pharmaceutical industry frequently seems to suggest that this (together with corruption and misgovernment in developing countries) is the major problem (rather than prices and patents) in preventing access to drugs.

In the months preceding the WTO Ministerial Meeting in Doha in November 2001, the U.S. pharmaceutical industry lobby organization *PhRMA* widely circulated a paper intended to "prove" that patents are not a barrier to access to drugs – the notorious Attaran/Gillespie-White paper.[27] The authors of this paper assert that patents are *not* an important barrier for access to antiretroviral drugs in African countries. According to them, the real barriers are poverty and limited public and donor spending on health care. Of course no reasonable person will deny that poverty is an enormous problem and that donor aid is necessary to improve access to drugs.[28] But the claim that patents are no barrier to access is simply wrong.[29]

Drug prices

Another important barrier to access to drugs is of course the fact that the prices of many drugs are very high. Perhaps shockingly, some drugs are nowhere as expensive as in Africa.

In their attempts to justify high prices, spokespersons of the pharmaceutical industry always refer to the high cost of research and development. Undoubtedly, pharmaceutical research and development is expensive and financially risky. However, there is uncertainty about the cost of bringing new drugs to market. According to an analysis from 2003 by the Tufts Center for the Study of Drug Development, the cost to develop a new drug, including post-approval research, averages US$897 million.[30] But how are these figures computed and can they be taken seriously?

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26 See www.cmhealth.org.

27 A. Attaran, L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?", *Journal of the American Medical Association* 286 (15), (2001), pp. 1886–1906.

28 See, for example, the recommendations of the WHO's *Commission on Macroeconomics and Health*. See www.cmhealth.org.

29 See Consumer Project on Technology, Essential Action, Oxfam Treatment Access Campaign and Health Gap, *Comment on the Attaran/Gillespie-White and PhRMA Surveys of Patents on Antiretroviral Drugs in Africa*, October 16, 2001. Available at www.cptech.org.

30 Tufts Center for the Study of Drug Development "Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, Is $897 Million [News Release]", May 13, 2003.

In 1991, an article written by Joe A. DiMasi and colleagues was published putting the cost of developing a new drug at US$231 million.[31] In subsequent studies the figure became US$312 to US$359 million. Adjusted to 2000 dollars this amount became US$473 million. Two years later, at the end of 2002, there was already talk of US$802 million. However, the original study of DiMasi and colleagues, which served as a basis for subsequent adaptations, shows some inherent flaws, which we cannot elaborate here.[32]

One of the major drawbacks to DiMasi's study is that it is by no means representative of "the average drug". The goal was to calculate the average development cost of drugs developed entirely by transnational pharmaceutical companies. However, many drugs result from considerable public funding (for example, for both basic research and clinical testing).[33] In the United States, for instance, the National Institutes of Health (NIH) (subsidized by the federal government) are great (maybe even the greatest) benefactors of the pharmaceutical industry.[34] As Bernadine Healy, former senior executive of the NIH, puts it:

> There's no other industry in which you have so much public investment in the fundamental knowledge that enables … the development of the commercial industry itself.[35]

Yet the figures reported by the Tufts Center are mentioned in just about any report by pharmaceutical lobby groups, and they are not only used to attempt to justify high drug prices, but also strong drug patents.

Developing countries, pharmaceutical patents and the WTO-TRIPS Agreement

Background

A WTO Agreement concluded in 1994 – the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS,[36] has globalized strong patent protection in all fields of technology, including pharmaceuticals.

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31 J.A. DiMasi et al., "Cost of Innovation in the Pharmaceutical Industry", *Journal of Health Economics* 10 (1991), pp. 107–142.

32 For a very concise discussion of this topic, see the MSF report "Fatal Imbalance", available at www.msf.org, p. 17. See also Public Citizen, *America's Other Drug Problem: A Briefing Book on the Rx Drug Debate* (Washington, D.C.: Public Citizen, 2002) [hereinafter Public Citizen (2002)]. See also Goozner, Merrill, *The $800 Million Pill. The Truth Behind the Cost of New Drugs* (Berkeley: University of California Press, 2004) [hereinafter Goozner (2004)].

33 See ibid.

34 National Institutes of Health, "NIH Contributions to Pharmaceutical Development", administrative document, February, 2000, quoted in Public Citizen (2002), p. 51.

35 Cited in ABC News, Peter Jennings Reporting, "Bitter Medicine: Pills, Profit and the Public's Health", May 30, 2002, see http://abcnews.go.com/onair/ABCNEWSSpecials/pharmaceuticals_020529_pjr_feature.html.

36 GATT Secretariat (ed.), "Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights", in *The Results of the Uruguay Round of Multilateral Trade*

When the developing countries became independent, most of them had patent laws made by their former colonial masters. Some of them soon deemed these laws – which, generally, provided strong patent protection – inconsistent with the level of their economic development. In the course of the 1970s, various developing countries weakened their patent legislation, especially in the domain of pharmaceuticals – *inter alia* by only allowing *process* patents and excluding pharmaceutical *products* from patent protection.[37]

No more room for a 'selective' patent granting policy

In the context of the topic that concerns us, one of the most important provisions of TRIPS is Article 27(1), which implies that patents must be granted "for any inventions, whether products or processes, *in all fields of technology…"*, and that patent rights must be enjoyable "*without discrimination* as to…the field of technology". This provision was referred to by the pharmaceutical multinationals, which initiated a lawsuit against the government of South Africa in 2001, alleging that South Africa's Medicine Act (1997) – which allowed the government to import generic versions of drugs which were still under patent in South Africa – amounted to a violation of their patents.[38]

The allegation of discrimination was also used against Canada in the WTO dispute, brought by the E.U., regarding exceptions in Canadian law to patent rules for testing generic drugs for registration purposes.[39]

In its decision, the WTO argues, *inter alia*, that one of the reasons why Article 27(1) was included in the TRIPS Agreement was to stop countries from passing laws on compulsory licensing dealing specifically, and hence discriminatingly, with drugs.[40] As James Love states:

Negotiations. The Legal Texts (Geneva: WTO, 1994), pp. 365–403. Also available at docsonline.wto.org.

37 In the pharmaceutical sector a product patent protects the actual drug, regardless of how it was manufactured and of the purpose it serves. Not surprisingly, a product patent is the most coveted form of protection. Process patents offer protection for the way in which the product is made. A process patent offers a "strong" form of protection, only if there is no other (financially sound) way of producing the product in question, other than through the process covered by the process patent. In the pharmaceutical sector, this is rarely the case.

It is often forgotten that, also in many industrialized countries, the granting of pharmaceutical product patents is a recent phenomenon. In Germany and in France, such patents weren't granted until 1967. Japan has only granted them since 1975, Switzerland since 1978, Italy since 1979, Canada since 1987 and Spain since 1992. These exclusions were said to be motivated by a concern for the public interest.

38 *Pharmaceutical Manufacturers' Association of South Africa, et al. v. The President of the Republic of South Africa, the Honourable Mr. N.R. Mandela N.O., et al.*, High Court of South Africa, Case number 4183/98. Ultimately, after realizing the public relations disaster they had created, the companies would withdraw the case.

39 *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, March 17, 2000.

40 Ibid., p. 87. Ultimately the WTO Panel ruled that the contested provisions were not in violation of Article 27(1) TRIPS.

> The current thinking is for countries to adopt laws that provide for compulsory licensing in broad areas like 'health', and make the argument that health isn't a field of technology. But at a certain level it becomes ridiculous to argue that countries cannot fashion laws that have the express mission of expanding access to medicines.[41]

Indeed, this line of argumentation is ridiculous, unjust and unacceptable.

It is highly unlikely that the quasi-worldwide implementation of strong patents "*à la*" TRIPS will incite pharmaceutical companies to invest in the research and development of drugs for tropical diseases because the majority of the patients have little or no purchasing power, which makes the market totally uneconomic. The reason why pharmaceutical lobbies are such great advocates of strong patents in developing countries, it seems, is not that it would encourage them to develop drugs for neglected diseases, but rather that it would allow them to hinder competition from local drug manufacturers in more technologically advanced developing countries which seek to supply both their own markets and/or the markets in less developed countries. This will have a negative impact on the wellbeing of patients in those countries.[42]

Most developing countries are technology importers rather than exporters, so they have little incentive to provide patent protection – they can hardly be expected to consider having to pay more royalties to foreign patent owners as an incentive.[43]

Compulsory licensing

The granting of a compulsory license implies that, after an administrative or judicial procedure, the government forces a patent holder to grant a license to one or more third parties for the use of his patented product or process. The rights of use ensuing from the possession of a compulsory license are similar to those ensuing from the possession of a patent, except for the fact that compulsory licenses (as permitted by TRIPS) have to be granted to supply the domestic market of the country that grants them.[44]

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41 Love (2002), p. 88.

42 See, for example, Fink, Carsten (s.d.), *How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries*, Discussion paper (Washington, D.C.: World Bank).

43 In the 1999 Human Development Report, the following data were reported, *inter alia*: the industrialized countries own 97% of all patents worldwide; in 1995 one single country, the U.S., received over 50% of the global royalties and licensing fees paid to owners of patents; ten industrialized countries controlled 95% of the U.S. patents of the past two decades; these ten countries captured more than 90% of cross-border royalties and licensing fees; 70% of global royalties and licensing fee payments were between parent and affiliate in multinational corporations; more than 80% of patents that have been granted in developing countries are owned by residents of industrialized countries. See United Nations Development Project, *Human Development Report 1999. Globalization with a Human Face* (1999), p. 68. Available at http://hdr.undp.org/reports/.

44 See Article 31(f) TRIPS.

In the context of the patent system, compulsory licenses play a double role: on the one hand, to force the patent owner to allow society to benefit from his or her invention, and on the other hand to boost the industrialization of the country.[45]

The TRIPS Agreement is rather lenient as regards authorizations to third parties to use patents without the patent holder's consent (see Article 31 of TRIPS). The most fundamental obligation seems to be the compensation of the patent owner (Article 31(h)). But a clear gap exists between what is allowed by TRIPS and what happens "in the field" (that is, in national contexts).

Compulsory licenses, or the threat of granting such licenses, can play a very important role in improving access to drugs. As noted earlier, the Brazilian government has, over the past years, repeatedly announced that it would issue compulsory licenses for ARVs if the companies holding the patents on the drugs would not lower their prices. In some cases this has produced very positive results.

Data exclusivity protection

Data exclusivity implies that, for a specified period of time, drug regulatory authorities prevent the use of registration data – test data and other data relating to the safety and efficacy of the drug provided by an originator of a pharmaceutical product – in the process of registration of a generic version of the same product. Data exclusivity is separate from patents, although it can have the effect of artificially extending the period of monopoly protection of a drug or of creating a monopoly in a country where the drug is not even patented.

Article 39(3) TRIPS concerns such data exclusivity:

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

According to the International Federation of Pharmaceutical Manufacturers and Associations:

> A brief review of the negotiating history of the TRIPs Agreement reveals that the drafters of Article 39.3 envisioned "unfair commercial use" to be any direct or indirect reliance by a country's regulatory authority on the innovator's dossier and accompanying test, clinical and pharmacological data, in the review of a subsequent generic application for a health registration on the innovator's product. A further review of the negotiating history of TRIPs Article 39.3 reveals that the drafters envisioned the period of protection at a minimum of five years (the United States model) to 10 years (the European Union model) from the date of marketing approval of the innovator's product.[46]

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45 J. Voyame, Préface, in J.-M. Salamolard, *La licence obligatoire en matière de brevets d'invention. Etude de droit comparé* (Geneva: Librairie Droz, 1978), p. 7.

46 See www.ifpma.org.

However, these specific requirements are not expressed in Article 39(3) of TRIPS. It is only mentioned that data should be protected, but not *how* this should be done or *for how long*.

The provision is interpreted differently in different countries. In the view of the U.S., it implies that manufacturers of generics are not allowed to use scientific publications or regulatory approvals by foreign governments without permission from the "owners" of the data. Hence, clinical trials must be repeated. First of all this is medically unethical – the subjects involved are exposed to totally unnecessary risks. Secondly, it does not only imply that money is be wasted on trials which have been conducted already, but also that patients who desperately need access to affordable drugs have to wait even longer before generics can get authorization to come on the market. As we explained earlier, generic competition is very important in order to bring prices down.

Data exclusivity protection is pushed by big manufacturers of branded pharmaceuticals, in order to delay generic competition so that they can continue charging artificially high prices. In the absence of data exclusivity protection, generic drugs could be marketed immediately after conducting bioequivalence tests and after patent expiry or compulsory license grant. There seems to be no reason why proving bioequivalence should not be sufficient to allow generic manufacturers to put their products on the market. When a drug regulatory authority is presented with bioequivalence data by a generic manufacturer, the regulator need not make any disclosure in order to decide whether the generic gets approval. As drug regulatory authorities are not commercial operations, they cannot make any (unfair or other) "commercial use" of data. And the generic manufacturer would not get to see the data provided by the originator company, so there can be no unfair use on the part of the generic company as it does not get access to the data. Moreover, the concept of "unfair use" can only reasonably be said to mean the use of data relating to a branded product with the aim of increasing the chances of success on the market of a *different* product.

In the scenario outlined in the previous paragraph, a problem may still arise when the drug regulatory authority does not have the data because the originator company/patentee never sought regulatory approval in the country in question. However, there seems to be no reason why the regulatory body could not decide to accept regulatory approval by another regulatory body (for example, the FDA or EMEA) and thus *only* require proof of bioequivalence (also possibly as approved by another regulatory authority).

To argue that Article 39(3) of TRIPS implies a requirement for a specified period of exclusivity (for example, five years) is self-defeating. If using the data provided by the originator company after two years is "unfair commercial use", then it must equally be after six years.

As if TRIPS is not yet enough: "Adequate" intellectual property protection according to the U.S.

For decades, the U.S. has been preaching to the world about "adequate" intellectual property protection. This preaching has been combined with both unilateral and

bilateral actions to move other countries in the "right" direction. (Interestingly, it has been well reported how the U.S. and other now-industrialized countries only offered weak patent protection during the period that their domestic industries were developing.)

Although membership in the WTO – and before 1994, membership in the GATT– implies a commitment on behalf of countries that they will take a *multilateral* approach to the solution of trade conflicts, even in the post-TRIPS era the U.S. continues to apply the unilateral and bilateral measures described below.

The unilateral approach

The "Special 301" provisions of the U.S. Trade Act of 1974 provide that the U.S. administration can take action against inadequate protection of intellectual property rights occurring in other countries and against trading partners who engage in "unfair competition". The term "unfair" was not defined in this Act, but a preparatory report of the House of Representatives from 1973 defined "unjustifiable" actions as "restrictions which are illegal under international law or inconsistent with international obligations".[47] (Later on, inconsistency with international law would cease to be a criterion – see below.) Hence, after the entry into force of the 1974 Trade Act, access to U.S. markets would be used as a leverage to obtain "adequate" protection for intellectual property rights by other countries.

In 1979 section 301 was again amended:

> [The 1979 *Trade Agreements Act*] established the right of private petitioners to seek government redress and made Section 301 "a potentially powerful weapon for a US industry aggrieved by foreign trade practices".[48]

Indeed, in the context of a section 301 investigation, the USTR must consult not only the petitioner but also other relevant private sector actors, who thus get the opportunity to directly influence trade policy.

The first case which resulted in trade retaliation under section 301 was a case initiated by the Pharmaceutical Manufacturers of America against Brazil, because Brazil did not allow product patents for pharmaceuticals. As a result of Brazil's refusal to amend its patent law, the U.S. imposed a $39 million tariff on imports of Brazilian pharmaceuticals. In 1990 Brazil agreed to change its policy and the sanctions were lifted.

In 1988, two years after the start of the Uruguay Round of multilateral trade negotiations, the Omnibus Trade and Competitiveness Act was enacted, which contained a 'Super 301' provision granting authority to the Office of the United States

47 See M.A. Moyer, "Section 301 of the Omnibus Trade and Competitiveness Act of 1988: A Formidable Weapon in the War against Economic Espionage", *Northwestern Journal of International Law & Business* 178 (1994), p. 192.

48 S. Sell, *Private Power, Public Law – The Globalization of Intellectual Property Rights* (Cambridge: Cambridge University Press, 2003) [hereinafter Sell (2003)], p. 78, with reference to B. Fisher, R. Steinhard, "Section 301 of the Trade Act of 1974", *Law and Policy in International Business* 14 (1982), p. 599.

Trade Representative (USTR) to determine which countries should be subjected to investigation and trade retaliation. As noted by Susan Sell:

> The 1988 amendments effectively transferred substantial authority from the president to the USTR. This change was intended to enhance USTR's position as the lead trade agency and reduce the possibility that trade retaliation would be waived for foreign policy or defense considerations.[49]

> [1988] was a watershed year in the quest to strengthen a trade-based approach to IP protection. The private sector secured the changes that it sought, and proceeded to use these new weapons in its arsenal – swift retaliation and a more credible threat – particularly against newly industrializing and developing countries.[50]

Moreover, the involvement of industry associations in the decision-making process became more and more institutionalized.

The new act was perceived by many countries as a standing incitement to *unilateral* action, in breach of the United States' commitments to a *multilateral* approach under the General Agreement on Tariffs and Trade (the predecessor of the World Trade Organization). It has even been compared to "the economic equivalent of civilian bombing".[51]

In the meantime, several countries have experienced what this implies in practice:[52] trade retaliation in the form of increased tariffs. Of course, trade retaliation is only possible if the country in question is economically dependent on the U.S. Thanks to the so-called Generalized System of Preferences – ironically enough, a mechanism which was originally set up by the United Nations Conference on Trade and Development (UNCTAD) to help developing countries – the U.S. has made many developing countries dependent on the U.S. market. The USTR, apparently preferring the term "encourage" over "retaliate", reported in 1996 that:

> The [USTR] Administration has…used the 'Special 301' provisions in U.S. trade law to improve intellectual property protection in more than fifteen major markets, and has used the benefits of the Generalized System of Preferences program to encourage several developing countries that benefit from that program to improve intellectual property protection …[53]

In 1995 Bruce Lehman, former U.S. Commissioner of Patents and Trademarks, had explained to the members of the House of Representatives that:

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49 S. Sell, *Power and Ideas. North–South Politics of Intellectual Property and Antitrust* (New York: State University of New York Press, 1998) [hereinafter Sell (1998)], p. 134.

50 Sell (2003), p. 94.

51 See R.A. Cass, "Velvet Fist in an Iron Glove: The Omnibus Trade and Competitiveness Act of 1988", *Regulation* 14(1) (1991), pp. 1–10, p. 2 (no sources cited).

52 See, for example, Sell (1998), p. 196.

53 USTR, Identification of Trade Expansion Priorities (Super 301) pursuant to Executive Order 12901 (1996).

> The nature of the world today is that we can't send the marines into a country that we may have an intellectual property dispute with …[54]

Hence, Special 301 is used. Moreover, this section of the Trade Act was amended in 1994, explaining that:

> A foreign country may be determined to deny adequate and effective protection of intellectual property rights, *notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights*…[55]

Raghavan rightly remarks that the "definition is so wide that it can be used to take any action the U.S. wants against any country that is likely to emerge as a competitor".[56]

In 1997 and 1998 the USTR, on behalf of the Pharmaceutical Research and Manufacturers of America, threatened Thailand with trade sanctions because Thailand intended to produce a generic version of the AIDS drug ddI. As a result of the threats, Thailand dropped its plan. Indeed, although TRIPS allows compulsory licensing, until now any country wanting to use this mechanism "has been handcuffed by U.S. trade negotiators".[57]

In the USTR's annual *Special 301 Reports*, those countries that are considered by the U.S. to deny "adequate" and "effective" protection are put into one of the following categories: (1) Priority Foreign Country; (2) Priority Watch List or (3) Watch List. The label of "Priority Foreign Country" is reserved for the worst "offenders": countries which have "the most onerous and egregious acts, policies, and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products" and which are "not engaged in good faith negotiations or making significant progress in negotiations to address these problems". Countries identified as Priority Foreign Countries can be subjected to an investigation and trade sanctions.

Countries are put on the "Priority Watch List" if they "do not provide an adequate level of IPR protection or enforcement, or market access for persons relying on intellectual property protection". Those on the "Watch List" "merit bilateral attention to address IPR problems".[58]

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54 U.S. Government Printing Office, Patents legislation. Hearings before the Subcommittee on Courts and Intellectual Property of the Committee on the Judiciary, House of Representatives. 104th Congress, 1st Session, June 8 and November 1, 1995 (Washington, D.C.: GPO, 1996), p. 47.

55 Section 182(4), *Uruguay Round Agreements Act* (1994) (that is, the act implementing *inter alia* the TRIPS Agreement into U.S. law) (emphasis added).

56 C. Raghavan, *Recolonization. GATT, the Uruguay Round & the Third World* (London/Penang: Zed Books & Third World Network, 1990), p. 87.

57 K. Vick, "African AIDS Victims Losers of a Drug War", *The Washington Post*, December 4, 1999, p. A1, quoted in Sell (2003), p. 151.

58 In its 2005 Special 301 Report, released on April 29, 2005, the USTR makes its annual comments on the "adequacy" and "effectiveness" of intellectual property rights protection around the world (available at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301asset_upload_file195_7636.pdf). The Report lists 1

The bilateral approach

In addition to this unilateral strategy, the U.S. also uses the strategy of bilateralism. In the Free Trade Agreements it has negotiated with several countries, and is currently negotiating with many others, much emphasis is placed on the protection of intellectual property rights. In this context, the U.S. aims at what some commentators call "TRIPS-plus" protection – provisions that go far beyond what is required by the TRIPS Agreement.[59] This may seriously threaten access to drugs in the countries in question.[60] Moreover, they clearly contradict the Doha Declaration on the TRIPS Agreement and Public Health, the outcome of the WTO Ministerial Meeting in Doha (Qatar) in November 2001.

The Doha Declaration on TRIPS and Public Health

A group of eighty countries, led by Brazil, India and the African group of countries, pushed for a legally binding declaration that TRIPS can and should be read as allowing countries to take measures to promote access to essential drugs without needing to fear retaliation by WTO or national governments. The U.S. and Switzerland totally rejected this proposal, arguing that patents are not a barrier to access to drugs. But in the end the bloc of developing countries achieved their goal.

The 4th Session of the WTO Ministerial Conference, held at Doha, Quatar, on November 9–14, 2001, resulted, *inter alia*, in the so-called Doha Declaration on the TRIPS Agreement and Public Health.[61] The essence of the Declaration is worded in paragraph 4:

> We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly…we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
>
> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

According to the fifth paragraph:

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country (Ukraine) as a "Priority Foreign Country". In January 2002 the U.S. imposed $75 million worth of trade sanctions on Ukrainian imports. These sanctions are still in effect. Fourteen countries figure on the Priority Watch List (Argentina, Brazil, China, Egypt, India, Indonesia, Israel, Kuwait, Lebanon, Pakistan, the Philippines, Russia, Turkey and Venezuela). Thirty-six countries or economies, including the European Union, are on the "Watch List".

59 See F. Abbott (2004), *The Cycle of Action and Reaction: Latest Developments and Trends in IP and Health*. ICTS-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, October 12–16, 2004.

60 See, for example, MSF, *New Guatemalan Law and Intellectual Property Provisions in DR-CAFTA Threaten Access to Affordable Medicines*, press release, March 11, 2005. Available at www.accessmed-msf.org.

61 WTO document WT/MIN(01)/DEC/1, November 20, 2001.

> (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.…

Subparagraph (b) is important because developing countries that are planning to issue compulsory licenses are sometimes put under great pressure, primarily by the U.S., not to do so. However, the system of compulsory licenses enables a country to factor national interests into its patent system and allows it to achieve a better balance between the rights and the obligations of patent holders. Therefore it should be used to the full, especially in "vital" sectors such as drugs.

Subparagraph (c) is important in that it stresses that every member state has the sovereign power of decision to proclaim a (national) state of emergency.

The sixth paragraph of the Doha Declaration reads:

> We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

According to Article 31(f) of TRIPS, compulsory licenses must be used predominantly for the supply of the domestic market of the member state that issued the compulsory license and can, therefore, only be used to a limited extent for export. If a country has insufficient or no manufacturing capacities and the drugs offered by foreign manufacturers are too expensive, the country should be allowed to look elsewhere for a suitable supplier. Until recently, this did not really pose a serious problem because a number of developing countries – with India as the most prominent example – have a good production capacity and are able to export their drugs, even when these are patented in other countries.

Per paragraph 7 of the Doha Declaration, the *least developed* countries have been allowed a transition period until 2016 to conform their drug-related patent provisions to the WTO-TRIPS Agreement, but now that the *developing* countries (for example, India) that can export drugs to them must acknowledge drug patents, since 1 January 2005, the least developed countries are sure to encounter serious problems. In this context, compulsory licenses that permit export will become increasingly vital.

The discussions in the TRIPS Council concerning export strategies went off the rails during a debate about the question for which diseases the export of drugs under compulsory license should be allowed. When the president of the TRIPS Council proposed a draft in December 2002 stating that the Doha Declaration was *not* limited to HIV/AIDS, malaria and tuberculosis, the U.S. (as the only among the then 145 WTO members) refused to accept this draft and negotiations were broken off.

On August 30, 2003, an agreement on the implementation of paragraph 6 of the Doha Declaration was adopted by the WTO General Council.[62] The agreement involved a temporary waiver from the obligation, laid down in Article 31(f) of TRIPS, to use compulsory licenses primarily for the supply of the domestic market. Meanwhile, this agreement has been made permanent.

The waiver allowed countries producing patented pharmaceutical products under compulsory license to export those products to eligible importing countries, provided that numerous conditions are met. Unfortunately, as those conditions are particularly onerous, the agreement can hardly be called an "expeditious solution" (as called for in paragraph 6 of the Doha Declaration).

Moreover, very few countries have implemented the waiver in their national laws. Only Norway, Canada, the EU[63] and India have done so. China is reported[64] to have implemented a limited version of the waiver, which came into force on January 1, 2006. However, the Chinese order refers only to "infectious diseases", while the WTO agreement applies to all diseases.

Some of the conditions that are being imposed are the following:

- an entity in the importing country must seek a voluntary license from the patent holder;
- if efforts to obtain a voluntary license fail, a compulsory license must be applied for and be obtained in the importing country;
- the importing country, unless it is a Least Developed Country, must show that it has insufficient capacity to produce the drug locally;
- the importing country must notify the TRIPS Council that it has decided to use paragraph 6;
- the interested importing country or entity must identify a potential exporter;
- the potential exporter must first try to obtain a voluntary license on commercially reasonable terms for a commercially reasonable period of time;
- if such a license is refused by the patent holder, the potential exporter must seek a compulsory license from its own government;
- if a compulsory license is granted, the exporter must then formulate the drug and investigate the shape, coloring, labeling and packaging of the patent holder's product in the importing country, so as to differentiate the product for export;
- the exporting country must notify the TRIPS Council of the grant of the license and its conditions;
- the exporter must seek product registration and prove bio-equivalence, when required by national law in the importing country;
- if in the importing country data exclusivity is granted, the exporter will need to obtain authorization from the owner of the data to use them, or he will have

62 See document IP/C/W/405.

63 Regulation (EC) No 816/2006 of the European Parliament and of the Council of May 17, 2006. See Official Journal of the EU L 157/1, June 9, 2006.

64 See the IP-related website of the World Health Organization (www.ip-watch.org), under the section "Public Health".

to develop his or her own toxicity and efficacy studies (unless the use of the data is included in the compulsory license);
- before shipment of the drug starts, the holder of the compulsory license for exportation must post information on a website about the quantities that will be supplied and the distinguishing features of the product.

These steps must be repeated time and time again, as each time a country registers as an eligible importer, new voluntary licenses must be sought and if refused, new compulsory licenses for export need to be obtained. Clearly, these conditions are so burdensome for potential suppliers that they will hardly be encouraged to use the system.

The temporary waiver approved in August 2003 was made permanent on December 6, 2006, when the decision was taken to amend the TRIPS Agreement. The amendment will become part of TRIPS once it is ratified by two-thirds of WTO member states. The deadline is December 1, 2007.

NGOs have heavily criticized the amendment, arguing that it makes a flawed agreement permanent. As Doctors Without Borders (MSF) put it in their briefing note for the WTO Hong Kong Ministerial Meeting:

> To date there is no experience using the mechanism – not one patient has benefited from its use – despite the fact that newer medicines, such as second-line AIDS drugs, are priced out of reach of poor patients. Delaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice. The amendment…does not take into account the fact that economies of scale are needed to attract interest from manufacturers of medicines.

According to Ellen ‘t Hoen, Director of Policy Advocacy for the MSF Access to Essential Medicines Campaign: “Since 2003 we have tried to place drug orders under the ‘August 30’ decision. But these attempts have not yet been successful”.

The pharmaceutical industry has welcomed the amendment.

The need for a new approach

As we have attempted to show, for many serious diseases no or hardly any drugs exist, and where drugs do exist, they are often not available to the patients who need them. As to the lack of access to *existing* drugs, more thinking is needed to find ways in which the patent system can be reformed to help solve this problem. In this context, provisions on compulsory licensing and government use of inventions, *inter alia*, should be focused on. Policy makers urgently need to commit themselves to study proposals for reform rather than to copy the discourse of the pharmaceutical industry.

As to the lack of research and development, we need to recognize that the patent system clearly fails to create incentives for research and development of drugs for tropical and other neglected diseases. Meanwhile, as noted earlier, more than two billion people have no access to essential drugs.

Some commentators claim that our current approaches to the encouragement of pharmaceutical research and development must be fundamentally rethought. James Love, Director of the Consumer Project on Technology (an American NGO) and Tim

Hubbard from the Sanger Institute (Cambridge, U.K.) have recently proposed a "New Global Medical R&D Treaty". They start from the observation that the current global framework for encouraging medical research and development is profoundly flawed. The current policies, they say, "focus nearly exclusively on measures that expand the scope and power of intellectual property rights, or reduce the effectiveness of price negotiations or controls".[65] Thus, the mechanism used to increase medical research and development is to increase drug prices. This has a number of undesirable effects, such as limiting access to drugs and hindering follow-on research. A new framework is therefore needed "that has the flexibility to promote both innovation and access", and "is consistent with efforts to protect consumers and control costs".[66]

They propose a draft international treaty. Each party to this treaty would be obliged to make minimal investments in medical research and development. The level of this financing would depend on the country's national income. Moreover, a mechanism would be established for the assignment of credits for socially important projects.[67] These credits, which would be tradable, could be used by member states to satisfy their obligations under the treaty.

"Open access" research would be promoted, and results of publicly funded research would have to be accessible in open access archives.

On May 27, 2006, the World Health Assembly adopted a resolution to establish an intergovernmental study group to develop a global plan on research and development for diseases predominantly affecting developing countries. This group will report back at the 2007 World Health Assembly.

The draft "New Global Medical R&D Treaty" has been completely rejected by the International Federation of Pharmaceutical Manufacturers and Associations, which argues that the Treaty is anti-innovation. It is interesting, to say the least, that proposals to solve the crisis of research and development of drugs for tropical diseases should be labeled "anti-innovation", while there are so many indications that it is the current functioning of the patent system that has "anti-innovation" effects. Already in 1944 eminent scholar Michael Polanvyi made the following observation in an article in *The Review of Economic Studies*:

> It cannot be doubted that patents are not infrequently being used to-day for the consolidation of the very kind of purely restrictive monopoly to which patents for inventions were originally meant to stand in definite contrast.[68]

Today, this diagnosis seems ever so accurate!

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65 J. Love et al., *Request to Evaluate Proposal for New Global Medical R&D Treaty* (Letter to the World Health Assembly Executive Board and the World Health Organization Commission on Intellectual Property, Innovation and Health, February 24, 2005), available at http://www.cptech.org/workingdrafts/24feb05WHOen.pdf, p. 1.

66 Ibid.

67 Such projects could include, for example, R&D for neglected diseases, projects that involve the transfer of technology and capacity to developing countries, and the preservation and dissemination of traditional medical knowledge. See ibid., p. 2.

68 M. Polanvyi, "Patent Reform", *The Review of Economic Studies* 11 (1944), pp. 61–76, p. 63.

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Chapter 10

Out of Touch: From Corporeal to Incorporeal, or *Moore* Revisited

Nils Hoppe*

Introduction: *Moore* once more

It is almost inevitable that the case of *Moore v. The Regents of the University of California*[1] (UCLA) should feature prominently when one seeks to illustrate some of the more challenging questions of proprietary interests in human biological material. Fifteen years after the decision, *Moore* still has the advantage of being both an outrageous background story and an interesting evolutionary history through the courts. Further, it lends itself as a good example to illustrate new perspectives on individual entitlements to human biological material.[2]

One particularly engaging problem is the one faced by the courts in cases involving such material where what I would term a "sublimation of the legal interest" has occurred: the value lies no longer in the tangible tissue but in the intellectual property derived from the tissue. In order to address the issues arising from this process of sublimation, I propose to deploy some of the mechanics of the law of equity to fairly reflect the differing entitlements in the tissue and the intellectual property. Initially, I briefly outline the background to the Moore case and move on to the question of disenfranchisement, which plays an important role in Moore. After that, I address the question whether the outcome is equitable in terms of justice before reaching the core of my argument, where I show a different way of looking at the possibilities afforded by the law of equity. Considering the underlying concepts of the separation of legal and beneficial ownership of property in terms of estates of land in relation to human biological material, it is submitted, opens up new possibilities of definition whilst taking into account some of the more complex ethical objections to commodification. The scope of this chapter does not permit an in-depth analysis, but some notions and concepts can be outlined and further debate on this idea may be encouraged.

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* I am very grateful for the feedback and criticism of Christian Lenk (Göttingen), Ryan Morgan (Cork) and Asim Sheikh (Dublin). As ever, all remaining inaccuracies are my own.

1 249 Cal. Rptr. 494 (1988); 271 Cal. Rptr. 146 (1990), 793 P2d 479 (1990); cert. denied 111 S.Ct. 1388 (1991).

2 A more substantial work on this topic is in the process of being completed as part of this author's doctoral thesis and will shortly be published.

Moore v. The Regents of the University of California et al.

> "No one can give a better title than he himself possesses."[3]

To outline the case in all brevity, a patient, plaintiff, whose leukemia had gone into satisfactory remission was asked back to UCLA, joint defendant, at the expense of UCLA, between November 1976 and September 1983 for the extraction of bodily substances (serum, bone marrow and sperm). In April 1983, Moore was asked to provide written consent for research to be carried out on that material. The physicians treating Moore had established early on that his spleen produced a protein which can be used to treat some forms of cancer. DNA extracted from his spleen was developed into a cell line, first named "Mo Cell Line" and later "RLC Cell Line", which was infinitely reproducible and could be turned into a pharmaceutical product with high commercial value.

In 1984, the physicians in question, David Golde and Shirley Quan, patented the cell line thus created.[4] Sandoz and Genetics Institute Inc. were given licenses to commercially exploit the cell line in return for 75,000 stock options in Genetics Institute Inc. and $330,000 in cash. Moore jointly sued Golde, Quan, UCLA, Sandoz and Genetics Institute Inc., alleging the tort of conversion. Conversion is essentially wrongful interference with another's property in a case where, usually, the original property is unavailable for recovery purposes.[5] Conversion being a form of trespass to property, the plaintiff – in our case, Mr. Moore – needs to show cause for a number of aspects of the claim. First, that a duty of care was owed to him by the defendants and that this duty was breached. He also needs to show that he sustained detriment from this breach.

As outlined, the injured party usually either claims damages amounting to the value of the property or the defendant opts to pay for the value of the goods rather than return them. However, the injured party can waive the tort and bring an action for money in relation to any benefit which may have accrued to the tortfeasor resulting from the wrongful act.[6]

> The point is not whether a definite something was taken away from plaintiff and added to the treasury of defendant. The point is whether defendant unjustly enriched itself by doing a wrong to plaintiff in such manner and in such circumstances that in equity and

3 The magnificent Denning LJ in *Bishopsgate Motor Finance Group v. Transport Brakes Ltd*, [1949] 1 KB 332.

4 U.S. Patent No. 4,438,032: "Unique T-Lymphocite Line and Products Derived Therefrom" (issued March 20, 1984).

5 In England the defendant can opt to pay for goods wrongfully detained, rather than return them. Cf. Torts (Interference with Goods) Act 1977, s. 3. This is the subject of some criticism leveled by contemporary commentators. Cf. N. Curwen, "The Remedy in Conversion: Confusing Property and Obligation", *Legal Studies* 26(4), December 2006, pp. 570–583.

6 For a critical view of the doctrine of waiver of tort, see S. Hedley, "The Myth of 'Waiver of Tort'" 100 *Law Quarterly Review* (1984), 653.

> good conscience defendant should not be permitted to retain that by which it has been enriched.[7]

Moore stated that his property was misappropriated and no longer recoverable, hence the profit from the misappropriation should be his. Whilst the doctrine of waiver of tort remains controversial, it appears clear that it does not constitute an action in its own right but merely a path to a remedy on the basis of a tort having been committed (as the name clearly suggests, if nothing else since no real waiving is going on). The requirement of the commission of a tort thus leads back to the initial point – the one which Moore's counsel tried so passionately to obscure: the question of damage. In order to show this damage, there needs to have been some sort of detriment, a wrongful interference or trespass to Moore's property actually resulting in damage. Clearly, the kernel of the argument – and the point that made *Moore* so interesting – was that the California Supreme Court felt that it had to explicitly address the issue whether Moore's spleen cells were indeed property capable of being owned. The majority in this case found that to establish a proprietary reach-through between the original source of the material and the subsequent exploitation of such material would prove detrimental to medical research per se.[8] An interesting question does remain: can a waiver of tort not also be based on a trespass to the person, thereby eliminating the requirement for the proprietary quality of the human body? Scholarly opinion tends to suggest that it cannot,[9] though it seems that some case law exists where waiver of tort was successfully deployed to recover benefits having accrued from enticing a servant away from his master.[10] Assuming for the sake of the following line of reasoning for one moment that Moore's cells really were property, the crux of *Moore* is that the Court felt that it had to address the issue of conversion of both the tangible property (the cells) as well as the intangible property (the information they contained which led to the patentable invention). This is a slight departure from California's own Appeals Court's reasoning in 1977, where it held that producing bootleg copies of a music record could be a conversion of the intangible property, no interference with any tangible property having occurred.[11] Would the Court in *Moore* have had quite the same problems with quantifying value if they only had to consider the value of the information gleaned from Moore's cells rather than of the cells themselves? It is submitted that they would not have, though for public interest reasons they would probably have found another path to the same result.

Having considered the tangible and intangible as merged for the purposes of conversion, the Court felt it was inappropriate to consider the question of whether his cells were property and how much they were worth. It did in its judgment suggest

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7 *Federal Sugar Refining Co. v. United States Sugar Equalization Board Inc*., 268 Fed. 575 (S.D.N.Y. 1920), cited by Cullity J in *Serhan v. Johnson & Johnson* (2004), 132 A.C.W.S. (3d) 221 (Canada: Ontario Superior Court), paras. 34–35.

8 Cf. D. Price, "From Cosmos and *Damian to Van Velzen*: The Human Tissue Saga Continues" 11 *Med Law Rev* (2003), 1.

9 J.H. Baker, *An Introduction to English Legal History* (London: Butterworths, 2002), p. 374.

10 *Lightly v. Clouston* (1808), 1 Taunt. 112.

11 *A&M Records, Inc. v. Heilman*, 75 Cal. App. 3d 554 (1977).

to Moore that he might be more successful if he tried to claim compensation on the basis of the physicians' failure to obtain appropriate consent for their actions. This unsolicited legal advice from the Supreme Court never came to be tried in the courts, unfortunately, as Moore's thirst for justice was quenched by an out of court settlement which ranged somewhere between $200,000 and $400,000 – most of which was soaked up by Moore's legal expenses bill.[12] It does suggest, however, that the Court is perfectly happy to offer a remedy in cases of dishonest appropriation whilst declining to answer the question of property. Had Moore's counsel offered them a way of achieving this result, avoiding the controversial questions, they may have succeeded.

The English judiciary is, incidentally, in no way more forthcoming with an answer to the question of property rights in human tissue. Despite some particularly high-profile opportunities we are no nearer to solving the problem.[13]

Intangible and disenfranchised?

This refusal to construe a proprietary interest of the original source (the word "donor" would clearly be inappropriate) in effect leads to a total disenfranchisement of the original source of the material in relation to any downstream profit accrued – in the interests of the advancement of science. This is, without doubt, a laudable aim but, in the case of *Moore*, we recognize that there is a substantial, personal pecuniary interest of the scientists involved in the extraction and subsequent invention. If Golde and Quan had not personally gained anything from the illegal extraction and had created a wonder drug, it could be argued that the public outcry at their behavior would have been less voluminous and that the Court's line of reasoning would have been readily accepted. In terms of an economic exploitation chain, severing the original source of the "product" from any profit seems to make this person the field/cow/chicken and the physicians into the farmers who need not compensate their crop or livestock for their produce. Indeed this would follow from the logic in *R v. Kelly*,[14] mentioned above, in that the cells extracted from our livestock are not capable of ownership.

12 R. Cairney, "Venting His Spleen (Doctor Patented Quirk in Patient's Unusual Genetic Code)", *Canadian Medical Assoc. Journal*, December 12, 1998, p. 1451.

13 See, for example, *R. v. Kelly*, [1998] 3 All ER 741, where an artist who had permission to sketch human anatomical samples misappropriated these samples from the Royal College of Surgeons with the help of an "inside man". The court relied on a Lockean fruit-of-one's-labor philosophy to construe property rights in the samples, given that considerably artful work had gone into preparing them for display. It appears clear that *au naturel*, the samples would not have been capable of ownership.

By way of a fascinating anecdote it is interesting to note that in the run-up to the proceedings in *R. v. Human Fertilization and Embryology Authority, ex parte Blood*, [1996] 3 WLR 1176, the complainant, Diane Blood, first sought legal advice on the question of the exportability of her deceased husband's sperm from a barrister: "I found myself at a barrister's chambers in Nottingham. He thought he'd found the only answer. The sperm was mine as a piece of property. He advised me to write and ask for it, then I could take it abroad. End of problem." D. Blood, *Flesh and Blood* (Edinburgh: Mainstream Publishing, 2004), p. 63.

14 Ibid.

Golde and Quan put some considerable, artful work into preparing a cell line which – by virtue of the work invested – suddenly becomes capable of ownership.

Whilst this logic clearly holds true for a number of reasons, it disregards one very important aspect of *Moore*: the real value of the claim lies in the intangible property that was extracted from the cells. In terms of conversion, the Courts have moved from allowing conversion for money only to goods and then from goods to intangible property. Given this transformation in the application of the doctrine, it is disappointing, if not surprising, that the Court failed to extend doctrine to encompass new elements of life – the pecuniary facet of biomedical research and the autonomous role that should be played by the patient/research subject: why accord full autonomy to patients in therapy and deny it in situations of monetary gain from research participation?

This failure, it could be submitted, would also be in crass contrast to modern developments in biomedical ethics. It would be a step back from seeing the patient as an autonomous individual who needs to be taken into account when decisions are made and whose say is final. It would convey a shocking level of disrespect for the patient's right to decide what happens – and does not happen – with his or her body. If Moore had been asked whether he wanted to participate in research he may, out of gratitude for being cured, have agreed. Did Golde and Quan not ask him because they feared he may say "no"? This leads to patient autonomy being a farce that is only ever deployed when the circumstances lead the physicians to assume that they will get their way even with the patient's participation in the decision-making process.

The counter-argument is often that of exploitation: if we allow research subjects to benefit financially from harvesting their biological material, we create the possibility that the less well-to-do amongst them start selling parts of themselves in order to repay their credit card debt or finance their children's education. But can the possibility of exploitation really prohibit the implementation of a system? This is certainly not the place to outline the arguments for and against illegalizing cannabis or prostitution compared to regulating them, but the point is clear. The mere possibility of abuse or exploitation ought not lead to a complete prohibition as this would interfere with our autonomy. We cannot seriously prefer having our rights restricted absolutely rather to finding a normative approach for preventing exploitation and abuse.

As mentioned at the outset, the Supreme Court justices gave Moore a helpful hint on how to tackle the problem of obtaining compensation without forcing them to answer the complex question of ownership in human tissue. They focused on the fact that Golde and Quan had failed to obtain proper consent for the extraction of the tissue. Bearing in mind the points on autonomy made above and the principle of patient inclusion in decision-making processes, this is clearly the point that this case hinges on – the illegality of the extraction, aggravated by the subsequent generation of personal profit on the part of the healers-turned-scientists. We have also seen that the Court was perfectly willing to suggest a remedy based on the wrongful quality of the interference. They did not go as far as seeing a tortious interference with property, tangible or intangible but, despite the fact that the judges' lamentable lack of courage keeps us waiting for the next opportunity to judicially nail down the

exact proprietary status of extracted human biological material, the case still – for the reasons given – raises an interesting point: can we trace some sort of entitlement from the original source to a profit generated from a product resulting from the extraction? In particular we need to bear in mind that Moore's original material (if we are to use this proprietary terminology) has been harvested and the important information has been extracted. It is no longer the original material (sperm, urine, spleen tissue) that we are interested in – it is the information encoded on it, the value inside the tissue that we are interested in.[15] The fact that this new interest of ours cannot be handled as the original cells could, the fact that it is now intangible makes the process of establishing a sustained entitlement to it all the more difficult.

Moore clearly had an interest of his own – or entitlement – in his cells. The Supreme Court is of the firm opinion that to recognize a legal interest in one's own cells represents an encumbrance of medical research. If not a legal interest – what then?

Let us accept as true that faulty consent or even a lack of consent at the time of extraction does indeed render the extraction a wrongful act on the part of the extractors, should we try the *Moore* approach of using the law of tort to recover damages or profit in lieu of recovering our original material, or ought we not also look at the tools that the common law's virtuous twin, equity, has in store for us?

Equity is not justice

Remedies: Equitable or medical?

Let us first clear up a couple of misapprehensions about the term *equity*. In medical ethics literature, the term is frequently used denoting "justice", "fairness", "right" and the like. For common law jurisdiction lawyers, the term tends to rather refer to the rule sets inherited from the Lord Chancellor's Court of Chancery, which responded to citizens' petitions on behalf of the Crown. Where the undeviating application of narrowly defined law would lead to manifestly unfair (inequitable) results, the person "attacked" or detrimentally affected by such an application[16] was able to petition the Crown and invoke equity. The rules of equity meant the application of moral decision-making processes to achieve an equitable result. Initially, the monarch would take these decisions individually and personally, but, with time, the number of petitions increased to a level where he had to delegate such decisions to the Lord Chancellor. The Lord Chancellor was the Crown's spiritual adviser, and in this capacity, of course, a cleric. He established the Court of Chancery and started applying the same decisions to cases of the same kind. Despite this systematic

15 I have addressed this particular point elsewhere comparing it to a *chose in action* – the abstraction of proprietary interest in the paper a check is printed on and the face value of the check. See N. Hoppe, "Bodycheque: Assignment of Rights in Human Tissue", *Journal of Academic Legal Studies* 1(1) (2005), pp. 14–17.

16 "Equity is a shield and not a sword": equitable doctrine cannot be used to invoke a legal measure but only to defend against one. See *Coombe v. Coombe*, [1951] 1 All ER 767.

approach to precedent, some contemporary commentators fretted at the occasionally arbitrary application of the rules.[17]

Equity set out to protect the moral rights of the monarch's subjects and achieved this by seeking collision with common law. Two sets of courts developed over time, one applying the law, the other applying equity (the Court of Chancery). By virtue of the Supreme Court of Judicature Acts 1873, the court structures were joined in 1875. This meant that the same civil courts would apply the rules of equity as well as the rules of common law. The important point, which ought not be underestimated, is this: the legislation joining the two court structures expressly provided that, in case of conflict between equity and common law, equity prevails:

> Subject to the provisions of this or any other Act, every court exercising jurisdiction in England or Wales in any civil cause or matter shall continue to administer law and equity on the basis that, wherever there is any conflict or variance between the rules of equity and the rules of the common law with reference to the same matter, *the rules of equity shall prevail*. [Emphasis added by author.]

This is significant, as it underlines the role of equity in the English legal system. It is clear that rules founded on morals, common sense and fairness are thought more appropriate in cases of collision. Is it equity then, one of the more ancient doctrinal concepts in the common law jurisdictions, that best addresses issues in relation to tracing entitlements from the donor to vendor, from Moore to Sandoz? If Moore had an equitable interest in his cells and Golde and Quan wrongfully interfered with this interest without consent, we may well be able to trace an equitable entitlement from the extraction of the material, via the isolation of the relevant DNA structure and the combination (or mixing, as will be of relevance below) of that DNA with that of *Escherichia coli* bacteria to form the *Mo Cell Line* which is then commercialized to generate a medical product recently estimated to be worth some three billion U.S. dollars.[18]

An illustration: Tracing in equity

What, then, does equity have in store for us that cannot be accomplished using common law principles? I would like to show the potential of applying equitable principles in relation to the dishonest appropriation[19] of another's cells by looking at the mechanism of tracing. This method enables us to follow proprietary interests in things that have been misappropriated.

We have the options of tracing at law and tracing in equity at our disposal. After a conversion, that is, the misappropriation of the property in tort, as Moore tried to

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17 "Equity varies with the length of the Chancellor's foot", attributed to 17th century jurist John Selden.

18 J. Bentley, P. Thacker, "The Influence of Risk and Monetary Payment on the Research Participation Decision Making Process", *Journal of Medical Ethics* 30 (2004), p. 293. See also C. Grady, "Payment of Clinical Research Subjects", *J. Clin. Invest*. 7 (115), pp. 1681–1687.

19 For the avoidance of doubt, this chapter of course only looks at civil law aspects.

show, tracing in law requires that the entitlement in property we intend to follow[20] has not been mixed with other property; once the property has been mixed, the claim is frustrated. This is, in our example, clearly problematic as we have seen that the finished product (*Mo Cell Line*) is a mixture of a number of different things, including the DNA of *E.coli* bacteria, the owner of which would be difficult to establish,[21] and in all likelihood a number of other products to fix the product in a vessel for the purposes of further analysis (the owner of which was probably UCLA). To add insult to injury, the property which all of the attention is focused on then detaches from its natural medium and vests in the information that forms the basis of patentable and licensable data, sublimating from tangible to intangible. Tracing at law presents virtually insurmountable problems in this context.

Tracing in equity, however, has other requirements. A fiduciary relationship needs to exist between the parties,[22] the entitlement needs to be traceable and there needs to be an element of fault (not dishonesty) in the appropriation of the entitlement which the original interest-holder has been deprived of.[23] An interesting aspect is that we are able to refer to it as an "entitlement" rather than as "property", which may serve to pacify some of those focusing on terminological aspects of commodification ethics.

The California Supreme Court has, helpfully, already answered the question of whether Golde and Quan had a fiduciary duty towards Moore when the justices suggested a claim for breach of fiduciary duty as an alternative course of action for recovering damages. Even in its normal dictionary meaning, fiduciary means "a person…who holds a position of trust or confidence with respect to someone else and who is therefore obliged to act solely for that person's benefit." Who, if not a doctor, satisfies these requirements? Some scholars insist that it is precisely the relationship between doctor and patient that has been held not to represent a fiduciary duty, citing *Sidaway*.[24] In *Sidaway*, the Court was primarily concerned with the extent as to which the "medical man's" duty to provide full consent should lead to liability. The Court certainly did not decide that there was no fiduciary duty between doctor and patient

20 This is an important linguistic aspect: we ought not speak of following the property, as this leads to confusion. The actual tangible original (source) property is no longer – it has been converted into something else. I therefore use the term "entitlement in property" at this stage to make clear that we are following an entitlement from one kind of property to another. This is particularly significant as, as I will show later, some ethical quandaries in relation to commodification of human tissue are isolated if we can speak of "entitlement in human tissue" as opposed to "property in human tissue".

21 No owner at all, in all likelihood, until U.S. patenting laws are further diluted in their efficacy and genetic structures that exist naturally become patentable.

22 See *Re Goldcorp Exchange Ltd*, [1995] 1 AC 74; *Westdeutsche Landesbank Girozentrale v. Islington London Borough Council*, [1996] 2 All ER 961, per Browne-Wilkinson LJ, p. 996.

23 See P. Birks, "Restitution and Resulting Trusts", in S. Goldstein (ed.), *Equity and Contemporary Legal Developments*, (Jerusalem: Hebrew University of Jerusalem Press, 1992). Essentially, where the party attacked is "Equity's darling" (a bona fide purchaser for value without notice), the element of fault is missing.

24 *Sidaway v. Board of Governors of the Bethlem Royal and the Maudsley Hospital*, [1985] AC 871; [1985] 2 WLR 480; [1985] 1 All ER 643.

per se, merely that the degree of disclosure of risks merited special consideration. *Sidaway* is not uncontroversial, not least because it rejects the notion of informed consent.[25] It is, for the purposes of the instant construal, firmly submitted that the doctor/patient relationship is one characterized by a fiduciary duty.

In order to pin down the other requirements that we may have to satisfy in order to have the possibility of tracing an entitlement in human cells from extraction to medical product, let us look briefly at the helpful dictum of Lord Justice Millett in the case of *Boscawen v. Bajwa*:[26]

> Equity lawyers habitually use the expressions 'the tracing claim' and 'the tracing remedy' to describe the proprietary claim and the proprietary remedy which equity makes available to the beneficial owner who seeks to recover his property in specie from those into whose hands it has come. Tracing properly so-called, however, is neither a claim nor a remedy but a process. Moreover, it is not confined to the case where the plaintiff seeks a proprietary remedy; it is equally necessary where he seeks a personal remedy against the knowing recipient or knowing assistant. It is the process by which the plaintiff traces what has happened to his property, identifies the persons who have handled or received it, and justifies his claim that the money which they handled or received (and if necessary which they still retain) can properly be regarded as representing his property. He needs to do this because his claim is based on the retention by him of a beneficial interest in the property which the defendant handled or received. Unless he can prove this, he cannot (in the traditional language of equity) raise an equity against the defendant or (in the modern language of restitution) show that the defendant's unjust enrichment was at his expense.

Orienting ourselves on the words of Lord Justice Millett, we can see how this may help us in our quest to find a different approach to our example. Moore tries to trace what has happened to his property (for want of a better word – for the time being). Let us call that property the "original entitlement" for ease of reference. He identifies Golde and Quan (who have handled the cells), Sandoz and Genetics Institute (who have received the intellectual property derived from the cells), and back to Golde and Quan again (who have received money from the licensing of the intellectual property).

We encounter a number of problems at this stage of our reflections on Equity and Moore: first of all – thanks to Lord Justice Millett – we are still stuck using the term "property". Secondly, it is beyond dispute that Golde and Quan invested a considerable amount of time and energy into the production of the *Mo Cell Line* (after all, it took them seven years of regular coaxing to get Moore to return to California to give samples). If we assume that we may substitute the term "entitlement" for "property" (and, it is submitted, nothing speaks against it) we still have to look at the work invested by others. One reason why we trace in equity rather than at law is, after all, because the original entitlement has been mixed with other parties' entitlement.

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25 Subsequent cases from common law jurisdictions have opted not to follow *Sidaway* instead applying the ratio of *Reibl v. Hughes* (1980), 114 DSLR 3d 1 (cf. *Rogers v. Whitaker* (1992), 175 CLR 479). Both *Rogers* and *Reibl* are very persuasive.

26 *Boscawen and others v. Bajwa and another; Abbey National plc v. Boscawen and others*, [1995] 4 All ER 769, per Millett LJ, at 334D–E.

Two possible solutions to this final obstacle come to mind:

- apportioning entitlement in the destination property in relation to the amount of work invested in its creation; and
- apportioning 100% of the destination property to Moore on the basis of the dishonest appropriation of the original entitlement.

Much seems to be in favor of the second proposition. It solves a number of follow-on difficulties caused by having to specify the actual value of the original work invested by Moore, much in the same way that there can be no real compensation for Moore if he were to follow the Supreme Court's advice to try and recover any.

In order to adequately compensate him for the damage he has sustained through the misappropriation of his cells, we would need to quantify this damage. Looking outside our fish bowl of equitable entitlements at the ocean of tortious and criminal liability outside for one minute, and assuming that we are looking at the damage in analogy to claims for compensation for physical harm, English law uses a catalogue in order to quantify damages.[27] The misappropriation of serum, sperm and other bodily substances does not in any way leave sustained harm upon Moore that he needs to be compensated for. The extraction of material from him by Golde and Quan, under the pretence of its therapeutic and diagnostic purpose, clearly represents a battery:

> It is only if the consent is obtained by fraud or misrepresentation of the nature of what is to be done that it can be said that the consent is not a true consent.[28]

The fact that he clearly sustained grievous bodily harm during the procedures does not entitle him to meaningful compensation either. This leads to the interim conclusion that we ought not try to reach some meaningful level of compensation for actual loss.

If the wronged party is permitted to recover the entirety of the profit generated from the unlawful appropriation, it solves our primary problem in that it does not require us to attempt to quantify the value of human tissue. This unhinges some of the more persistent ethical objections to rights in human tissue and carries with it a clearly punitive character to deter scientists from leapfrogging the requirement of adequate consent in the interests of advancing their research.

Concluding thoughts

A reasonable question to ask at this point would be "how can we apply ancient doctrine to current problems in bioethics?". Initially, one could plausibly argue the core of the medico-legal problem is that we attempt to legislate for medical progress

27 W. Norris, C. Cory-Wright et al. (eds), *Kemp & Kemp: The Quantum of Damages* (London: Sweet & Maxwell, 1975).

28 *Sidaway v. Board of Governors of the Bethlem Royal and the Maudsley Hospital*, [1984] 2 WLR 778, per Sir John Donaldson MR, p. 790.

and are always several steps behind. The ambit of medical research moves at a pace that the legislator cannot envisage. Hence, we have some brand-new law which can either only approximate reality in the life sciences or has been abstracted to a level at which its application depends entirely on the understanding of those unlucky enough to be asked to construe it in individual cases – unsuitable for a system depending on precedent. The law of equity provides an elegant option to include notions of fairness, justice and moral decision making in instances where the law fails to do justice to the whole set of facts underlying an individual case. What needs to be done is to move the concepts of equity from their dusty setting in the law of real property and trusts into the focus of new challenges such as the life sciences, where the development of the common law limps behind current changes.

Whilst equity prevails where it collides with common law, the two should not be seen as competitors. Equity merely steps in where common law produces unequitable results. It is therefore complementary to common law. In the case of human tissue we have a case where, as I mentioned at the outset, the original source of the material (John Moore, in our example) is completely disenfranchised once the material is extracted. He is excluded from the downstream profit of his own material (and I use the terminology "his own material" fully aware of the linguistic limitations). This is equitable if he is asked for his consent and his consent contains a waiver of participation in downstream profit. If he does not waive the downstream profit and – as in the case of Moore – he is even misled in relation to the exact use his tissue was extracted for, there is a wrongful act, an interference, a misappropriation. In this case, the use of his material for scientific research and for the creation of downstream profit is unequitable and there should be an equitable remedy for Moore. It is clear that the remedies tort had in store for Moore could not easily have been applied, though the separation of the merged tangible and intangible property may have held the key to permitting the court to help Moore recover what they clearly felt he was entitled to. An equitable entitlement, however, approximates what is thought to be Moore's interest much more closely.

The advice given by the Supreme Court justices may have been sound in the sense that it pointed out a way for Moore to recover some of the material profit that he was abstractly morally entitled to. He had been disenfranchised and even the judges felt he ought to be compensated for this disenfranchisement. What it failed to address is one important point: in the modern life sciences the borderline between tangible and intangible is extremely fluid. Once the intangible assets are extracted from the carrier tissue – the tangible part of the property – and reproducible and capable of being licensed for reproduction to third parties, the tangible part of the equation becomes worthless. It has been sucked dry of its value, which now lies in the intangible property; the genetic makeup, the information contained on the medium that is the cell line, a copy of which is sufficient to start a new, infinitely reproducible cell line. If we are to not disenfranchise the original source, we need to realize that the entitlement in the property has to pass with the value of the property: from tangible to intangible. If our source has not validly waived this entitlement, we need to ensure that this means traceability of this entitlement to the very end of the exploitation chain. The debate in relation to commodification and commercialization of human tissue ought to move in the direction of equity; questions of a trust in relation

to human tissue have already been touched on but not really explored sufficiently,[29] the notion of a constructive trust is, it could be submitted, entirely sequitur in cases such as *Moore* and the law of bailment holds a number of fascinating concepts which ought to be discussed in detail.[30] The question of rights in tangible and intangible aspects of human tissue is by no means answered – the law has a number of concepts in store which may yet provide satisfactory answers provided that the courts find the courage to extend them to some of the new challenges provided by commercial exploitation in the life sciences.

29 M. Boyes, P. Ward, "Brain Donation for Schizophrenia Research: Gift, Consent, and Meaning", 29 *Journal of Medical Ethics* (2003), 165–168.

30 I am grateful to Asim Sheikh (University College Dublin) for pointing out the law of bailment as an interesting possibility and for providing stimulating debate of the question in relation to human tissue.

PART 3
Distribution, Licensing and Protection of Intellectual Property

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Chapter 11

Knowledge and Information – Private Property or Common Good? A Global Perspective

Rainer Kuhlen

Introduction

Central to this chapter is the controversy over how far knowledge and information should be primarily an object of development (in the public interest) or an object of commercial exploitation (in the interest of private people). In this vein, the fundamental question "who owns knowledge" is addressed. This chapter also discusses whether the hypothesis of the "tragedy of the commons" can justifiably apply to knowledge and information. We do not think so. The expansion of intellectual property regulations (IPR) worldwide is highlighted, including its critical aspects. Some of the current worldwide dominant arenas are analyzed with respect to the question whether knowledge and information should be public or private property: the WTO, in particular the TRIPS contract, in the framework of GATT and GATS; WIPO with its current debate on a Development Agenda; WSIS with new strategies for a Digital Solidarity Fund and for Internet Governance, with consequences for an IPR regime; UNESCO with its recent Convention for the Protection and Advancement of Cultural Diversity. This chapter also addresses the current amendment of copyright law in Germany and focuses on its consequences for education and science and the provision of information through libraries. The demand for an economically driven information society, in particular when supported by politics (law) and by GATS, does present a threat to the libraries' ability and mission to provide information and documents for the public. Finally, a suggestion is made on how the classical three-step test of copyright law, which is increasingly becoming overly restrictive and counter-productive, even for the economy, can be replaced in the public interest by a reversed test which is more appropriate for the electronic environment and a development agenda.

Who owns knowledge?

The conflict regarding which conditions lead us to view knowledge and information as public or private property has become increasingly heated in recent years. The reason for this is obvious: knowledge and information are decisive resources for

development of any nature, be it personal, scientific, social, economic or political. This is what defines the information and knowledge society. The following questions are raised accordingly:[1]

> Who owns knowledge and information, who can access knowledge, who can use knowledge for what purposes? Who should and who may make knowledge public as information products?

No other element of our social order seems to be more unclear than the concept of "intellectual property". The liberal idea of possession of (material) property and its fundamental relevance for the development of civil society and free economy has been directly and mostly without any further consideration transferred to property objects of an immaterial nature.

For this reason, the history of the last two hundred years and in particular of the last twenty years is also the history of progressive privatization and commercialization of knowledge and information, that is, the conversion of public property to private property. As private property it dominates the markets. Information markets are currently the driving power of the economy in general, both because information is increasingly important for all types of industry production and for all services – investments in information are at least as high as those in labor, raw materials and operations in practically all branches – and because knowledge and information are directly traded as information products on commercial markets.

However, counter movements are not to be ignored. Doubts with regard to even the validity of the term "intellectual property" are on the increase.[2] Thus, sections of civil society, in particular from the free software and human rights movement, attempt to avoid the expression "intellectual property rights" in the debates, for instance at the World Summit on the Information Society (WSIS) and to instead highlight the developmental potential of intellectual works rather than the ownership and the right to exploitation.

One can indeed speak of a Renaissance of the idea of the "commons", in which knowledge and information are an example of public property. This explains the intensity of the conflict regarding knowledge and information in the present day. The positions have radicalized precisely because of the progressive digitalization of all objects and processes of the intellectual world we "live in" (in our *Lebenswelt*). On one hand, the procedures to protect knowledge and information (in the technical and legal sense) have intensified. On the other hand, it is precisely the electronic space

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1 R. Kuhlen, "Universal Access – Wem gehört Wissen?", in A. Poltermann (ed.), *Gut zu Wissen. Links zur Wissensgesellschaft* (Muenster: Verlag Westfaelisches Dampfboot, 2002), pp. 164–197.

2 T. Hoeren, "Urheberrecht und Verbraucherschutz: Überlegungen zum Gesetz über Urheberrecht in der Informationsgesellschaft", *Arbeitsberichte zum Informations, Telekommunikations- und Medienrecht*, vol. 10 (Muenster: LIT Verlag, 2003); J. Boyle, "The Second Enclosure Movement and the Construction of the Public Domain", *Law and Contemporary Problems* 66 (1, 2) (2003), pp. 33–74; L. Lessig, *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity* (New York: Penguin, 2004).

that provides the potential to make knowledge and information freely accessible and usable for everyone.

Can the "tragedy of the commons" also be applied to knowledge and information?

According to the prevailing opinion of the economic sciences, a restoration of knowledge and information to the domain of public property would mean that a successful high-yielding exploitation of knowledge and information would no longer be possible. To put it another way: should a commodity be completely seen as a public commodity, as part of the "common", its destruction is thereby virtually pre-programmed. This premise was justified for a long time with the hypothesis of the "tragedy of the commons".[3]

This hypothesis ("Freedom in a common brings ruin to all" – Garret Hardin) means that public commodities would be overused and then destroyed if they were available for the free use of all. This could only be prevented by transferring them to private property, which would ensure that these commodities would be in sufficiently short supply in the interests of their long-term use and exploitation, so that they could regenerate and further yield profit. In addition, public control (by government regulation) could, according to the hypothesis, prevent over-use of public commodities. Today, the leading schools of economics prefer the market answer to the tragedy thread.

However, this hypothesis, particularly when applied to the "common" knowledge and information has recently been the subject of harsh criticism.[4] Intellectual works, especially in their digital form, are commodities which, unlike material commodities, are not consumed in use, but rather gain value through their use and can at least continuously create new uses. They are therefore considered to be *non-rival* (and in principle also non-excludable) in their use – one use does not affect another use. Millions of users can have access to an electronic server or to a public website without negatively impacting each other. Furthermore, considerable (technical and legal) efforts and enforcement are necessary to exclude users from such commodities, especially when these are available in digital form.

The main conclusion that economics and politics nevertheless draw from the "tragedy of the commons" hypothesis (namely to privatize and thereby limit availability), is a situation where, without private incentives to gain profit from existing products, no new knowledge and no new information products would be created.

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3 G. Hardin, "The Tragedy of the Commons", *Science* 162 (1968), pp. 1243–1248.

4 Boyle, "The Second Enclosure Movement and the Construction of the Public Domain"; C. Hess, E. Ostrom, "Artifacts, Facilities and Content: Information as Common-Pool Resource", paper presented at the Conference on the Public Domain, Duke Law School, Durham, North Carolina, November 9–11, 2001, pp. 44–79; Lessig, *Free Culture: How Big Media Uses Technology and the Law to Lock Down Culture and Control Creativity.*

Protection of private property in the public interest?

This line of argument is followed by legislators worldwide: that, on the one hand, privatization and limited availability is the only possible way to create sufficient incentives for new development. On the other hand, only through privatization and limited availability can the part of information economics vital for the political economy be sustained or further developed.

Clearly the first argument for protection does not apply for all production of knowledge and information. In science, widely financed by public resources, the incentive for productivity is not driven directly by monetary recognition, but rather by a quest for reputation or the sheer curiosity of discovering something new and the satisfaction of being able to share this new knowledge with others.

Further, the aim of being able to take note of newly produced knowledge by making this knowledge public does not have to necessarily conform to commercial forms of management in an electronic environment. Workable models to publicize immaterial commodities without intent of commercial exploitation have been developed (similar to open access usage) that also incorporate the traditional quality assurance provided by science in the past.[5]

Combining scientific production with the protection of its commercial exploitation therefore hardly makes any sense in an electronic environment. In fact, we can recognize more than just initial indications that state funding and support programs aim to push forward the open access approach and no longer leave informational safeguards in education and science exclusively to their fate on the markets.

In the general public markets, in which we include the media of the broadcasting services or the entertainment industry, the picture is somewhat different. Authors/originators/artists primarily produce their intellectual or cultural objects simply because they are creative, but they very often have no alternative source of income to secure their livelihood and are therefore dependent on receiving monetary recognition for their work. In culture there is a clear responsibility on the part of the state to protect the rights of the creative artists to their work. However, this does not necessarily mean the protection of the rights of commercial exploitation through a third party, at least not when this protection results in business and organizational models for exploitation no longer being appropriate for the electronic environment, and the public being restricted in access to cultural objects.

Counter measures

The information industry is resisting the newly recognizable perspective of re-transformation of private commodities to the public domain, not only with theoretical arguments (tragedy of the commons), but primarily with practical (technical and legal) measures.

5 H. Andermann, "Entwicklung von alternativen Publikationsstrukturen in Europa und den USA", *Bibliotheksdienst* 37(6) (2003), pp. 731–739.

Considering the defensive strategies of the technical measures (for example, copy protection, in general all forms of digital rights management – DRM)[6] against "abuse" by free reproduction and easy available distribution technology, we must conclude that these aggressively fought battles against uncontrolled free use of intellectual objects have yet neither been won, nor indeed can be won. This is primarily due to the fact that, on one hand, the costs for the enforcement of technical measures (DRM) have the effect of increasing the cost of transaction higher than that of open access and availability forms, meaning that a reasonable yield is no longer possible. On the other hand, consumer do not accept strict protection measures, and tend to abandon this type of protected product and turn to new products or new distribution procedures on the open markets or to file share and exchange services.[7]

Nevertheless, legal protection and regulation of intellectual property rights in the interest of the commercialization of all areas of science and information have been increasingly strengthened through the following measures, amongst others:

- temporal extension of the duration of international property rights (IPR) protection;
- extension of IPRs to living objects (knowledge about these) and occurrences in nature;
- attempts to extend IPRs to software (in a by all means still controversial debate);
- introduction of special *sui generis* regulations, for example, for databases (as a compilation of data of any particular nature which, according to the respective EU Database directive[8] does not have to necessarily be IPR worthy itself) or for semi-conductor developments;
- reduction of originality claims and levels of standard requirements for intellectual work;
- extension of IPRs to new objects such as business models and procedures;
- intensification of global harmonization of international conventions such as WTO/TRIPS[9] or WIPO requirements[10] (with the consequence that IPR regulations were forced to be introduced in those countries where the concept of IPR was so far unknown, and which therefore scarcely had the infrastructure to secure IPR measures and where acceptance among the population was not to be expected);
- expansion of the exclusive publication/availability rights of the author/user;
- trends to diminish the exemptions (*Schranken*, that is, the restrictions of the exclusive publication/availability rights of the author/user), which have been

6 E. Becker et al. (eds), *Digital Rights Management: Technological, Economic, Legal and Political Aspects* (Berlin: Springer, 2003).

7 R. Kuhlen, "Napsterisierung und Venterisierung – Bausteine zu einer politischen Ökonomie des Wissens", *PROKLA – Zeitschrift für kritische Sozialwissenschaft, Sonderheft Wissen und Eigentum im digitalen Zeitalter* 32(4) (2002), pp. 57–88.

8 Directive 96/9/EC of the European Parliament and the Council of March 11, 1996 on the legal protection of databases.

9 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

10 WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty.

incorporated in most copyright laws in favor of the public interest in education and science, but also for allowing private copies for one's own use and other exemptions;
- reinforcement of the protection mechanisms through technical procedures and, simultaneously, protection of these technical measures within the IPR laws against circumvention under threat of civil and criminal consequences.

Global arenas

Globally, we can currently identify four main areas in which new behavioral forms, new legal regulations and new organizational models for contact with knowledge and information are being developed:

1. WTO (World Trade Organization) with TRIPS (Trade-Related Aspects of Intellectual Property Rights), initially in the framework of GATT (General Agreement on Tariffs and Trade), and now increasingly looking towards GATS (General Agreement on Trade and Services), has the aim of accelerating the liberalization of world trade for information, media-based and cultural commodities of all natures and of fostering its importance on the markets and the information markets by protecting intellectual property rights.
2. WIPO (World Intellectual Property Organization), a UN organization entrusted with the task of providing valid regulations worldwide for handling of intellectual property, and is currently encouraged by countries like Brazil and Argentina, in the process of refocusing on the developmental potential of intellectual works instead of solely concentrating on the protection of intellectual property.
3. WSIS, the UN World Summit for the Information Society, whose first stage took place in 2003 in Geneva and was finalized in 2005 in Tunisia, attempted, among other aims, to develop a strategy to overcome "digital divides", for example, through a Digital Solidarity Fund and a new strategy for Internet Governance.
4. UNESCO, the UN organization for Education, Science, Culture and Communication, was finally successful (against the vote of the U.S.A. and Israel) in getting the Convention on the Protection and Advancement of Cultural Diversity adopted by the General Conference in Fall 2005 and thus attempted to find a counterbalance against the rigorous commercialization of cultural objects, including those related to knowledge and information.

Many additional international organizations are involved to a great extent in all of these arenas, for example, the IFLA, the international library association in the WSIS context, but also recently in the attempts of a re-organization of the WIPO by supporting the Geneva Declaration on the Future of the World Intellectual Property Organization.[11]

11 Available at http://www.ifla.org/III/Clm/CLM-GenevaDeclaration2004.html.

With respect to the general debate about the goods character of knowledge and information, it is particularly noteworthy that a *multi-stakeholder* approach seems to prevail worldwide, especially in the UN context. According to this approach, not only representatives from the private sector and from international organizations, in addition to the official government delegates, will be heard in inter-governmental meetings and committees, but groups from civil society as well. These groups do not always have direct involvement in decisions, but are involved in discussions in which subject-relevant arguments of specialists from civil society often influence questions about the information society. It is clear that the majority of people in civil society stand up for an expansion of the realm of the "commons", including (non-rival and non-excludable) knowledge and information, and view strong or even exclusive private control over knowledge and information as obstructive and counter-productive for development of any nature in all areas (individual, social, cultural, educational, scientific and also economic).

The impact of the WTO

The initiative and position of power for intellectual property regulations in the last ten years have been primarily occupied or at least initiated by the WTO,[12] in particular through the TRIPS agreements, which pushed forward the worldwide intensification of the protection of commercial exploitation interest under pressure from the demand for liberalization, commercialization and privatization, including that of knowledge and information. In the framework of the Doha round, and also within the GATS action, the service industries, including the information services, have been affected. GATS aims at full liberalization in 160 different service sectors.[13] Only services with direct relevance to states' sovereignty and security are exempt. Services within the civil service are also affected, as are all music and audiovisual sectors (including radio and all music and film/video),[14] training and information services and, in this way, libraries. Critically, information services in a broader sense highlight a dichotomy in the positions, which characterize the contradictions in the regulation of intellectual property.

There is a strong indication that strong IPR regulations regarding patent rights, but copyright as well, present a considerable barrier to overcoming the various manifestations of global North–South divides, as they protect existing privileges and user rights rather than making knowledge available for free development and, in this way, helping to overcome North–South divides.[15]

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12 P. Wittgenstein, *Die digitale Agenda der neuen WIPO Verträge. Umsetzung in den USA und Europea unter besonderer Berücksichtigung der Musikindustrie*, dissertation (Zurich, 2000).

13 H. Brügger, "Liberalisierung der Dienstleistungen. Gefährliche Dynamik", *Medienpolitik* 2 (2005), available at http://www.klartext.ch/detail.php?id=KT2005-04-20-001314.

14 V. Wiedemann, "Gesamtziel: Vielfalt. Audiovisuelle Medien in den GATS Verhandlungen", epd medien 92 (November 23, 2002) pp. 3–38.

15 Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London: IPR, 2002).

Global, uniform directives for PR regulations are not in the interest of all countries. Instead, much speaks for a dynamic, more flexible handling of IPR directives. This should involve consideration of the various political economies as well as differences in knowledge and information sectors. Weak IPR that allow the possibility of free copying and reverse engineering must be accepted for a controlled period of time and not defamed as piracy. Reverse engineering is the transfer of knowledge and not the theft of information products. Software patents promote monopolies, which inhibit innovation rather than innovative developments. Generous exemptions for exclusive exploitation rights are also necessary for areas of knowledge which are indispensable for the development of knowledge infrastructures, and for the social and political infrastructure of countries and thus for knowledge production (science and culture), which transfers to education, media and health in the broader sense.

UN World Summit for the Information Society (WSIS)

At WSIS II in Tunis in 2005, WSIS was not able or not willing to produce – let alone agree on – innovative solutions for the existing regulations for the protection of rights to intellectual works (in particular copyright and patent rights) in its final documents (Tunis Commitment and Tunis Agenda 2005). In Geneva at WSIS I in 2003, in the conclusion of the (first) WSIS Declaration a compromise formulation was found under paragraph 42 which, on the one hand, emphasizes incentive as a motive for the protection of intellectual works and as a condition for creativity and innovation but, on the other hand, recognizes the significance of broad (more open, more free) distribution and sharing of knowledge for exactly these processes of creativity and innovation:

> Intellectual property protection is important to encourage innovation and creativity in the information society; similarly, the wide dissemination, diffusion, and sharing of knowledge is important to encourage innovation and creativity. Facilitating meaningful participation by all in intellectual property issues and knowledge sharing though full awareness and capacity building is a fundamental part of an inclusive Information Society.[16]

At WSIS II in Tunis in 2005, the concept of IPR, not to mention the challenge to reformulate the concept of intellectual "property" at all, was not even mentioned in the official documents. However, the basic question (posed by the UN-appointed Working Group for Internet Governance – WGIG – in its discussion about the extension of property rights also to intellectual electronic products) still remains whether "the greatest overall economic and social benefit will be achieved by simply extending the IPR rules developed for the off-line world into the very different 'space' created by the Internet, or whether achievement of these benefits in the 'global information society' will require significant modifications to the IPR regime" (WGIG, WG IPR).

On the one hand, the WSIS texts emphasize that development is dependent on access to knowledge and that the Internet holds the potential to expand this access for all, in particular for the developing countries. On the other hand, the interests of

16 WSIS I Declaration, para. 24.

those who, in precisely the same electronic environment, can witness the constantly increasing economic significance of knowledge, need also be considered. WSIS was hardly in the position to dispel this tension by itself.[17]

A new alignment in WIPO?

WIPO is also involved in the international debate about the goods character of knowledge and information. What kind of a commodity are they? WIPO has primarily followed the parties in favor of strict IPR regulations in recent years and up to the present day[18] and emphasized the importance of IP for economic growth.[19] However, by the beginning of October 2004 at the latest, a revision of this previous policy can be detected in the WIPO. On October 4th at the general meeting of the WIPO, the suggestion made by Brazil and Argentina, and supported by many developing countries, regarding the establishment of a "Development Agenda for WIPO" was accepted.[20]

The Development Agenda emphasizes that "development should be a central dimension in any negotiation involving IP systems". It queries the correctness of the policy, previously also represented by WIPO, that only strict IPR regulations can promote development:

> It is important to promote a critical examination of the implications for developing countries of the adoption of increased IPR protection, rather than to seek to approach this highly controversial issue as if it were governed by absolute truths, solely under the one dimensional perspective of the private rights holders, ignoring the broader public interest. (no. 5 of the proposal)

> Now, more than ever before, it has become clear that in the increasingly global, knowledge economy, access to knowledge and technology is indispensable for social and economic development and for the well-being of peoples in all countries. Consequently, any policies and international norm-setting, particularly in relation to intellectual property protection, which may have an impact on access to knowledge and technological development, pose a serious development concern for developing countries and LDCs. (no. 13 of the proposal)

The UNESCO Convention on Protection and Advancement of Cultural Diversity

As expected, the UNESCO Convention on Protection and Advancement of Cultural Diversity did not take an explicit position with regard to IPR issues. However, several

17 W. Kleinwächter, *Macht und Geld im Cyberspace. Wie der Weltgipfel zur Informationsgesellschaft (WSIS) die Weichen für die Zukunft stellt* (Hanover, 2004).

18 WIPO Copyright Treaty; WIPO Performances and Phonograms Treaty.

19 WIPO, Intellectual Property – A Power Tool for Economic Growth (2003), available at http://www.wipo.int/about-wipo/en/dgo/wipo_pub_888/index_wipo_pub_888.html.

20 Cf. J. Boyle, "Manifest on WIPO and the Future of Intellectual Property", *Duke Law and Technology Review* 9(8) (2004); also see *The Geneva Declaration on the Future of WIPO* (2004), available at http://www.cptech.org/ip/wipo/genevadeclaration.html.

UNESCO member countries, Switzerland in particular with the Berne Convention on Cultural Diversity and North–South Relations (June 2004) among others, are lobbying to have not only cultural production and the arts, but also the approaches and systems of rights of social groups, counted among public commodities. This does not necessarily disqualify the economic function of culture, but is intended[21] to prevent culture from becoming entirely reduced to a trade commodity of commercial markets.[22] Politically the relationship between the WTO and UNESCO is somewhat unclear, which therefore makes it problematic, as, in principle, the same governments are in fact responsible for the signing of WTO treaties and also for the ratification of the UNESCO Convention, binding under international law.[23] Therefore, it remains to be seen whether the WTO, with its strong economic interests, considers the UNESCO Convention to be compatible with the WTO treaties or whether it sees a fundamental conflict between the two international contracts. For example, the right of a state to take regulatory and financial measures to protect the cultural expression of its jurisdiction, under the Convention, could be interpreted by the WTO as conflicting with WTO regulations.

It will be one of the major challenges for UNESCO to transfer the central idea of the adopted Convention – namely, that public investment in cultural goods is not a bias in market activities, but is a necessary precaution in the public interest – to the general domain of IPR regulations.

Naturally, the legal relationship between both these treaties (UN-external WTO treaties and the UN-internal UNESCO Convention) is particularly controversial. Article 20 of the Convention attempts in a quasi-Salomonian fashion to regulate the relationship of the Convention to other treaties:

> **Article 20 – Relationship to other treaties: Mutual supportiveness, complementarity and nonsubordination**
>
> 1. Parties recognize that they shall perform in good faith their obligations under this Convention and all other treaties to which they are parties. Accordingly, without subordinating this Convention to any other treaty,
>   (a) they shall foster mutual supportiveness between this Convention and the other treaties to which they are parties; and
>   (b) when interpreting and applying the other treaties to which they are parties or when entering into other international obligations, Parties shall take into account the relevant provisions of this Convention.

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21 J. Pérez de Cuéllar, *Our Creative Diversity*, Report of the World Commission on Culture and Development (Paris: UNESCO, 1996).

22 D. Kröger, "Geistiges Eigentum im Netz. Zwischen Industrierecht und Kulturgut", in C. Schulzki-Haddouti, M. Redelfs (eds), *Informationsfreiheit als Demokratisches Prinzip. Mehr Transparenz durch mehr Informationen Globalization* (Bonn: Bundeszentrale fuer Politische Bildung, 2003), pp. 210–226; J. Smiers, *Arts under Pressure: Protecting Cultural Diversity in the Age of Globalization* (London: Zed Books, 2003).

23 M. Krajewski, S. Bormann, C. Deckwirth, "Auswirkungen des GATS auf Instrumente der Kulturpolitik und Kulturförderung in Deutschland", *Expert Evidence to the German UNESCO Commission* (2004), available at http://www.unesco.de/c_arbeitsgebiete/kkv_gutachten.pdf.

2. Nothing in this Convention shall be interpreted as modifying rights and obligations of the Parties under any other treaties to which they are parties.

The Convention should in no way be subordinate to GATS, as favored by the USA, but the Convention should also not be superior to GATS, as favored by the advocates of cultural freedom (previously known as "exception culturelle") such as, among others, France and Canada. Both treaties should rather be seen as equal, so that any conflicts arising can be negotiated and solved in individual cases.

The current situation of intellectual property rights in Germany

German intellectual property rights law (UrhR) was adapted and formally initiated by the EU-Copyright directive of May 22, 2001 (EU 2001) to cover the digitalization of intellectual works, and has affected authors, exploiters and users. The first implementation of the EU Directive became legally binding under the German intellectual property rights law as of September 13, 2003. With the following so-called "Second Basket" (*Zweiter Korb*), the Ministry for Justice (BMJ) in charge of IPR was confronted with many unsolved problems and conflicts in interests in regulation measures for intellectual property rights and necessary exemptions.

The politically debated and certainly most interesting question for the public in the course of the reform is in how far the rights regarding *private copies* established for the analogue media can be accepted by the law in the electronic environment. Amazingly the BMJ has seen a certain element of flexibility regarding private copies in the jungle of commercial entitlements and has attempted, if with considerable conditions, to retain this for consumers. Private copies should remain a possibility – at least, that is the theory. It is expected, as is already the case in the games sector, that electronic products are protected by technical measures, and the principle entitlement to a private copy can longer be redeemed. If the technical measures do not permit private copies, then private copying by breaking DRM codes will be illegal. The music industry is certainly outraged following the suggestion by the BMJ that private downloads from exchange servers within a certain limit should not be liable for prosecution. In addition, the wording that copying and downloading of music items is only prohibited when it is obvious for the user that the item is an illegal copy seems to be insufficient for the industry.

In this context of this article we are more interested in the consequences of the enforcement of intellectual property rights in education and science.[24] The interests of these sectors were until now barely considered in the adaptation of intellectual property rights. There was no real representation of interest for science and education, notably compared with the powerful lobbying *Börsenverein*, the German interest group of publishers and booksellers. This has meanwhile changed decisively with the foundation of the Coalition for Education and Science (*Aktionsbündnis*

24 R. Kuhlen, "Wie öffentlich soll Wissen für Wissenschaft und Unterricht sein? Anmerkungen zum Urheberrecht in der Informationsgesellschaft", *Festschrift für Jürgen Krause* (in press 2005), text available at http://www.inf-wiss.uni-konstanz.de/People/RK/Publikationen2004/rk_urh_in_D-fuer_ie-buch.pdf.

Urheberrecht für Bildung und Wissenschaft, see http://www.urheberrechtsbuendnis.de/links.html), whose "Göttingen Declaration"[25] was signed by the six large scientific organizations, including the Science Council (*Wissenschaftsrat*); by more than 250 professional societies (*Fachgesellschaften*), including most library and information organizations; and by more than 3,500 individuals (as of November 2005). Two especially critical points, also relevant for libraries, follow.

For the use of electronic media in universities a so-called "on the spot consultation" has been formulated in §52b of the draft German intellectual property rights law. In accordance with this, use of electronic materials is only possible on the premises of and at special workstations in libraries. This regulation is inadequate in both its range – why only libraries and not also educational establishments, museums and non-commercial archives? – and in its limited possibilities for simultaneous use. To restrict the number of works which can be made available simultaneously to the number of examples purchased simply mirrors existing regulations within the framework of the analogue world, instead of benefiting from the possibilities of new technology to allow a more comprehensive and flexible use in the interests of education and science. This would mean that science and education, which have meanwhile been equipped with online access area-wide, would be sent back to the "stone age". In other jurisdictions, such as the UK, the Scandinavian countries, the Netherlands and the U.S.A., this would be an unimaginable restriction, which additionally would run contrary to all plans of the Federal Ministry of Education and Research (BMBF) for the networking of science and education in the framework of the e-Grid initiative. Here, the lack of understanding for the elementary information requirements of science and education in practice shown in the drafts to date can be clearly seen. Time will tell whether the future process of the "*Zweite Korb*" can take these requirements into account.

The suggested regulations in the draft version of §53a of the German copyright law reform, which concede the information industry a quasi monopoly in electronic document delivery and in this way prohibit the libraries from being active in this area should the market provide an appropriate opportunity (as publishers increasingly do in addressing retail markets), would have virtually catastrophic consequences. This suggestion neither meets the practical demands of the scientific and educational establishments nor the conclusions of the Federal Court of Justice in a decision in 1999. In this way, German intellectual property regulations strangle the scientific system and put Germany at a disadvantage in comparison with countries such as the U.K., where the British Library has by far more freedom in its actions – higher fees are only requested in the case of a direct commercial use. In addition, the transfer in electronic form is possible. As long as the user gives his or her confirmation to the British Library that the copy will be only used for personal non-commercial research or private study, the user does not have to pay the additional intellectual property rights fee, which the British Library in all other cases collects in the name of the holder of the rights.

25 Göttinger Erklärung zum Urheberrecht für Bildung und Wissenschaft of July 5, 2004.

Public documentation, meta-information, search and delivery systems such as *vascoda* (http://www.vascoda.de/) and *subito* (http://www.subito-doc.de/), which currently receive comprehensive financial support from the public resources of the BMBF, and which are widely used and in demand among the scientific community and in education environments, would then be prohibited from using their electronic capacity. The threat of a scientific two-class system looms on the horizon in which, due to a lack of economic "relevance", certain sectors would not be able to raise the funds for the use of commercial services and would doubtlessly "fall by the wayside". In particular, students, who more strongly rely on the public services of the libraries, would be adversely affected. To reduce their information requirements to the provision of paper versions, as almost cynically suggested by the BMJ, would create a backward situation for education and training. But, again, the regulation according to §53a is still a draft proposal, not yet binding law.

Inconsistencies in the domain-specific information policy (Fachinformationspolitik)

As in other countries, differences in governmental policy in Germany can be seen, for example, in the policy of the Ministry of Justice (stronger protection in the interest of economic exploitation) and that of the Ministry for Research (BMBF). This contradiction will very likely continue to exist in the new government. The BMBF relies on the responsibility of the state for a functional provision of information in science and education. Not only did the BMBF, together with the German scientific community, lobby extensively with a considerable amount of funding for virtual specialist libraries and the development of powerful documentation, meta-information, search and delivery systems, such as the already mentioned *vascoda* and *subito* and many nation-wide information centers, but also very recently initiated the project eSciDOC as a publication platform for research.

ESciDOC is a joint project of the Max Planck Society and the *Fachinformationszentrum Karlsruhe*, in which the political intent of the so-called "Berlin Declaration" for open access to knowledge in science and humanities[26] is put into practice and which has found wide support from leading German and international research organizations. eSciDOC will serve science with the development of a multidisciplinary publications and communications platform on an open access basis and is in this way a part of the general e-Science program, which declares public and free use as a major political aim.

If we were to compare the open publications policy represented by the federal government though the BMBF with the aims and wording of the currently valid intellectual property rights and a fortiori with those from the "*Zweiter Korb*", we can only be amazed or shocked by the level of inconsistency of the German, but naturally also of the European and international information policy in general.

This inconsistency is a fundamental one. One part of scientific and information policy, together with an important part of general policy for the regulation of the handling of intellectual property or with intellectual and electronically represented works, is based on the fact that invention and, in particular, innovation (that is, the

26 Berliner Erklärung über den offenen Zugang zu wissenschaftlichem Wissen, 2003.

economic conversion of inventions into marketable products, production processes and services) is only possible when strong protection measures are established in the interest of the author and the user involved in the investment in information products, which should secure the ownership of knowledge and information. Partly in contradiction to the current existing possibilities of new media surroundings for unreserved usage, the legislator follows strategies of limitation and legal protective measures to secure these strategies, preferably using software-technical measures (DRM).

In contrast, an understanding of knowledge and information is increasingly articulated, even in the economic sciences, which, on the one hand, allows for a difference in character between immaterial and material commodities and, on the other hand, assesses the consequences of the significance of knowledge and information for invention and innovation in a completely different way.[27] What is assured for the production of knowledge in science (and in art or cultural commodities in general), namely that the production of new knowledge, is hindered or made practically impossible through limited access to existing knowledge. As a general rule, we can say that the production of knowledge becomes all the more creative and intensive, also in a quantitatively measurably scope, when more freedom is guaranteed for scientific communication. This is also valid for the innovation ability of the economy.

The challenge for libraries

Regarding information policy, the international library association, IFLA, has commented on various occasions and in various places on the open conflict regarding the character of information as a public or private commodity. Here, we will mention only the involvement of IFLA, coordinated with UNESCO, in the context of the World Summit for the Information Society and, most recently, with regard to its signing of the Geneva Declaration on the future of the WIPO.[28]

> The IFLA proclaims the fundamental right of human beings both to access and to express information without restriction. IFLA and its worldwide membership support, defend and promote intellectual freedom as expressed in the United Nations Universal Declaration of Human Rights. This intellectual freedom encompasses the wealth of human knowledge, opinion, creative thought and intellectual activity. IFLA asserts that a commitment to intellectual freedom is a core responsibility of the library and information profession worldwide, expressed through codes of ethics and demonstrated through practice.[29]

27 J. Cortright, "New Growth Theory, Technology and Learning: A Practitioner's Guide", *Reviews of Economic Development Literature and Practice* 4 (2001), text available at http://www.impresaconsulting.com/ngt.htm; Hess, Ostrom, "Artifacts, Facilities and Content".

28 The Geneva Declaration on the Future of the WIPO.

29 Committee on Copyright and other Legal Matters (CLM), *The IFLA Position on the Geneva Declaration on the Future of the WIPO*, September 28, 2004, available at http://www.ifla.org/III/clm/CLM-GenevaDeclaration2004.html.

Lobbying for the freedom of information belongs to one of the central values, obligations and aims of the IFLA, entirely in accordance with Article 19 of the Universal Declaration of Human Rights:

> people, communities and organizations need universal and equitable access to information, ideas and works of imagination for their social, education, cultural, democratic and economic well-being.[30]

In particular, the task of the libraries is also to maintain open access to knowledge from the past and present for future generations, as it is only in this way that the generation of new knowledge can be possible. The IFLA distances itself here from a strategy of limitation for the benefit of private (commercial) availing of knowledge and information, in particular because, from a global perspective, this strategy of limitation not only shows itself to be obstructive for innovation in the developed countries of the West and the North, but also leads to a widening of the digital division (*digital divide*) between the North and the South and has shown to and continues to show a deterioration of the economic situation of threshold and developing countries.

In general, the role of the libraries is threatened in their service function by strict IPR regulations and the advancing commercialization of knowledge and information. With the increasing liberalization of trading, also in relation to information-related services, the market will, with support from GATS, assert a claim to look after the security of information for scientific and educational requirements. Should it become reality, the attempt in Germany with the introduction of §53a to reduce or even prohibit the responsibility of libraries for the provision of information and the delivery of documents and also for electronic material in the case of a comparative offer from the open market, would further restrict the public character of knowledge and information. The attempt made on the part of Google to digitalize large libraries and also their own stocks of books, can also be considered in this context. If the markets is in a position in the future to provide not only articles from journals and conference volumes electronically, but also the full texts, and retrospectively the stocks from the past, then the book bastion of the libraries would no longer apply and this could be the end of the public role of libraries. This, of course, must not necessarily mean a public catastrophe – it is not the first time that a technical or media revolution has made established structures obsolete. But if so, there must be a fair chance for new structures and institutions that do not follow stakeholders' interests in the first instance, but act with full responsibility for the needs of science and education for open and free access to knowledge and information. It cannot be possible that information supply in electronic environments designed to ease access to knowledge and information becomes worse than it was in analogue environments.

30 Ibid.

A somewhat subversive suggestion

From the Berne Convention to the present TRIPS treaty, and the WIPO treaties of 1996 to the U.S. DMCA (Digital Millennium Copyright Act)[31] and the E.U. Directive of 2001,[32] the so-called *three-step test* has played an important role.[33] In a manner of speaking, it represents the benchmark for the formulation of compromises between the private and public interests; or to put it another way, in how far private commodities of knowledge and information can partly be given the character of public commodities. The test says that exceptions to the exclusive exploitation (a) can only be made in certain special cases when they (b) do not conflict with a normal use or exploitation and in this way (c) do not result in any unacceptable disadvantages for the creators.

This *three-step test* (Article 9 of the Berne Convention), through which the validity of exceptions to the exclusive right of exploitation should be demonstrated, is in a similar way to the Anglo-Saxon "fair-use principle", not an empirically quantifiable test, but rather limits the scope of flexibility, which appear in concrete cases in the form of barriers (of the exclusive right of exploitation) and which then must be balanced. According to Beger (2004)[34] the current exemption rules for science in §52a of the German copyright law (*Urheberrecht*) is fully compatible with the three-step test.

The three-step test is similar to the sacred cow of intellectual property rights. However, as with many other sacred cows, this test could be "slaughtered", or in this case, reversed to the original objective of IPR regulations (namely to foster public welfare) and thus take into account new and fundamentally altered media and technological conditions. Accordingly, in such a way a renewed three-step test suggests that a commercial exploitation of intellectual works (a) is only permitted in special cases when (b) it is ensured that the original works are freely available and accessible for everyone and useable under the reference of the authorship and (c) when the scope of the public availability lies within the full responsibility and informational autonomy of the author of the respective work.[35]

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31 Text available at http://www.eff.org/IP/DMCA/hr2281_dmca_law_19981020_pl105–304.html.

32 Directive 2001/29/EC of the European Parliament and of the Council of May 22, 2001 on the Harmonization of Certain Aspects of Copyright and Related Rights in the Information Society.

33 M.R.F. Senftleben, *Copyright, Limitations and the Three-Step Test. An Analysis of the Three-Step-Test in International and EC Copyright Law*, dissertation (Amsterdam, 2004).

34 G. Beger, "Hält §52a UrhG dem urheberrechtlichen Dreistufentest stand?", in R. Hammwöhner, M. Rittberger, W. Semar (eds), "Wissen in Aktion. Der Primat der Pragmatik als Motto der Konstanzer Informationswissenschaft, Festschrift für Rainer Kuhlen", *Schriften zur Informationswissenschaft* 41 (Konstanz: Universitaetsverlag Konstanz (UVK), 2004), pp. 131–140.

35 R. Kuhlen, J. Brüning, "Creative Commons (CC) – für informationelle Selbstbestimmung, gegen den Trend des Urheberrechts/Copyright als Handelsrecht; oder: Chancen für einen Innovativen Drei-Stufen-Test?", *Information – Wissenschaft & Praxis* 8 (2004), pp. 449–454.

Conclusion

One does not need to fully agree with media theorists such as McLuhan to recognize that the media reality has a stronger effect, at least in a mid-term perspective than the inertia of business and organizational models, which, by all means, have been practical in analogous surroundings and have proved themselves to be acceptable for the authors and users and profitable for the exploiters. Even the protective hand of the legislator will not be able to favor and secure the barriers to innovation for much longer. As long as the many information economy organizations remain in their defensive attitude and waste their energies in fighting wars against what they call information pirates rather than developing new business models appropriate to electronic environments, the old dinosaur argument may apply: not being able to adjust to and thus survive in a radical changing environment which, nowadays, promote and reward knowledge sharing and free access.

It is perhaps not necessary to worry too much about currently obsolete legal regulations and the effect of technical restrictions means – market and civil society, although from different perspectives and with different interests, will certainly find ways out from the dilemma of existing regulations, for example: open/free software is asserting itself as an alternative production model.[36] Open access is also proving to be an alternative model to the strategy of limitation of commercial publishers.[37] *Creative Commons* has shown itself worldwide to be a possibility for creative people to regain their informational autonomy through the imparting of self-determined licensing rights.[38] Collaborative forms of publication, such as Wikipedia (http://www.wikipedia.org/) show alternatives to individualistic understanding of authorship and creativity. Even commercial ventures such as Google advocate that the access to information and the information itself can be free (by all means in the sense of free of charge, not necessarily in the sense of freedom) and nevertheless profits of billions can be achieved. Current business models in the music industry, for example, in Germany *Vitiminic* (http://www.vitiminic.de/main) or *Dorfdisco/ Potato* (http://www.dorfdisco.de/index.pho; http://potatosystem.com/info/Ger/), suggest that music platforms in the interest of creativity are possible without the input of big music labels, which work with high transaction costs and aim for large profit margins; and that digital music can also be used without strict DRM.[39]

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36 V. Grassmuck, *Freie Software. Zwischen Privat- und Gemeineigentum* (Bonn: Bundeszentrale fuer Politische Bildung, 2002); R. Stallmann, *Free Software, Free Society* (Boston: GNU Press, 2002).

37 Andermann, "Entwicklung von alternativen Publikationsstrukturen in Europa und den USA"; D. Prosser, "On the Transition of Journals to Open Access", *ARL Bimonthly Report* 227 (April 2003), available at http://www-arl.org/newsltr/227/openaccess.html.

38 Kuhlen, Brüning, "Napsterisierung und Venterisierung"; R. Kuhlen, "Creative Commons. Im Interesse der Kreativen und von Innovation", in K. Lehmann, M. Schetsche (eds), Die Google-Gesellschaft. Wissen im 21. Jahrhundert (Transcript-Verlag, 2005).

39 R. Kuhlen, "Die Digitale Kopie: Wie frei ist der Nutzer im Internet? Oder: IPR – nicht nur im Handelsrecht. Potenziale wissenschaftlicher, sozialer und wirtschaftlicher Entwicklung", 2. Leipziger Dialog zum Welttag des geistigen Eigentums, Leipzig, May 3,

WIPO is on the right track with the revision of its previous policy and its current conception of open forms of usage of knowledge and information as a chance for development. The UNESCO Convention is also heading down the right path with its Convention on the Protection and the Advancement of Cultural Diversity and its demand that cultural commodities are, in principle, public commodities. As soon as the information industry understands, paradoxical though it may sounds for them, that they can hardly make any profit with the information itself, but rather through value-added offers accompanying them, then the legislator will no longer have to create laws which simply do not represent the normative behavior and ethical expectations of creators and the users in an electronic environment. Then libraries will be able to continue to expand their policy of free access to knowledge and information, together with their information work towards the advancement of creativity, innovation and development and the sustainability of information for future generations.

2005, available at http://www.inf-wissen.uni-konstanz.de/People/RK/Vortraege04-Web/welttagIPO030505-vortrag-rk.pdf.

Chapter 12

The Limit of Balancing Interests Through Copyright Levies

Lucie Guibault*

Introduction

When devising the structure and content of the copyright regime, the legislator normally tries to establish a balance between the interests of authors in protecting their works, and those of the general public in using such works. The recognition of statutory limitations on copyright is but one tool in the hands of lawmakers for defining the scope of a rights owner's exclusive rights. Statutory limitations take different forms in the legislation, ranging from an outright exemption from the rights owner's prerogatives to a statutory license, or levy system, where certain uses are allowed to take place without authorization from the rights owner but against the payment of an equitable remuneration.[1] The form of a particular limitation normally reflects the legislator's assessment of the need and desirability for society to use a work against the impact of such a measure on the economic interests of the rights holders. Statutory licenses, rather than outright exemptions, have become over the last few decades a popular solution for legislatures grappling with the inevitable conflicts of interests that arise as technology allows new forms of use of copyrighted material. Although very efficient from the users' perspective, the drawback for rights owners is that, contrary to negotiated licenses, the amount of remuneration to be paid under a statutory license is generally fixed by the legislator or by some regulatory authority and does not necessarily reflect the market price for their works. The home taping regime is one such statutory limitation that has been adopted in reaction to technological developments.[2] Today, most continental European countries grant authors, publishers, performers, and phonogram and video producers a remuneration

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* The text of this chapter is based on P.B. Hugenholtz, L. Guibault and S. van Geffen, The Future of Levies in a Digital Environment, report prepared for the Business Software Alliance, March 2003, available at http://www.ivir.nl/publications/other/DRM&levies-report.pdf, accessed on March 30, 2006.

1 S. Dusollier, *Droit d'auteur et protection des oeuvres dans l'univers numérique* (Brussels: Editions Larcier, 2005), p. 423.

2 L.M.C.R. Guibault, *Copyright Limitations and Contracts: An Analysis of the Contractual Overridability of Limitations on Copyright* (The Hague: Kluwer Law International, 2002), Information Law Series – 9, p. 24; and P. Goldstein, "Copyright and its Substitutes" *Wisconsin Law Review* (1997), pp. 865–871.

right for the private use of their works, which takes the form of a levy either on recording equipment, blank media support or both.

But technology has continued to evolve, once again upsetting the delicate balance reached with regard to private use, making this limitation as controversial and as complex as ever. Digital technology now not only makes the reproduction of copyrighted material easier, cheaper and of better quality than ever, but it also allows for an unlimited distribution of copies without any loss of quality. Depending on the future development of digital technology, the private copying levy regime may find itself at a crossroad: either it will have to be phased out, or it will have to be extended to the digital environment. On the one hand, with the advent of digital rights management (DRM), the assumption that copyright levy systems are premised on the idea that private copying of protected works cannot be controlled and exploited individually must be re-examined.[3] In the digital environment, technical protection measures and DRM systems make it increasingly possible to control how individuals use copyrighted works. Rights holders are now in a position to apply such systems to identify content and authors, set forth permissible uses, establish prices according to the market valuation of a particular work, and grant licenses directly and automatically to individual users. Unlike levies, DRM makes it possible to compensate rights holders directly for the particular uses made of a work, according to the prevailing market price for that work. Where such individual rights management is available there would appear to remain no need, and no justification, for mandatory levy systems. On the other hand, it has been argued that the uncontrolled use of peer-to-peer file sharing programs and the unauthorized exchange and distribution of protected material could justify extending the levy system into the digital environment.[4]

The question arising in the context of the private use exemption is whether a statutory license regime, according to which users are allowed to make reproductions of protected works for private purposes in exchange for the payment of a levy on blank supports or recording equipment, is the most suited instrument to balance the interests of both rights owners and users of copyright protected material. Is the home taping regime always justifiable from the point of view of the rights owners, and of the users? In which circumstances would this regime no longer be legitimate for either one or both parties? How does the advent of the digital technology affect our perception on this issue? Taking the example of the home taping regime, what conclusions can be drawn regarding the legitimacy of a statutory license system as an instrument of Internet governance?

This chapter is divided into two sections. The first section concentrates on the notion of private use. We first present an historical overview of the recognition of

3 See N. Helberger (ed.), 1st State of the Art Report: Digital Rights Management and Consumer Acceptability. A Multi-Disciplinary Discussion of Consumer Concerns and Expectations, INDICARE, December 2004.

4 D.J. Gervais, "The Price of Social Norms: Towards a Liability Regime for File-Sharing", *Journal of Intellectual Property Law* 12 (2004), pp. 39–73; N. Netanel, "Impose a Noncommercial Use Levy to Allow Free Peer-to-Peer File Sharing", *Harvard Journal of Law & Technology* 17 (2003), pp. 1–84.

a limitation allowing users of copyright protected works to make reproductions for private purposes, as well as the reasons behind the transformation, in several European member states, of an outright private use exemption into a statutory license. We then examine the private use exemption as it is laid down in the European Directive on Copyright and Neighboring Rights in the Information Society,[5] where the European legislator attempted, with respect to the digital networked environment, to reconcile the irreconcilable. This leads us, in the second section of this chapter, to consider the limits of the statutory license regime as an instrument to balance the interests of rights owners and users in the digital networked environment. To this end, we examine the statutory license system first from the rights owners' perspective, before examining it from the users' perspective. While doing so, we discuss the different factors that should, in our opinion, be taken into consideration when deciding whether to extend the home taping regime into the new environment. Among these are the need to provide a "fair compensation" to the rights owners for the legitimate use made of their work, while avoiding to impose double payment obligations on the users, for example in the case where DRM makes it possible to compensate rights holders directly for the particular uses made of a work.

Notion of "private use"

Traditionally, copyright owners have never held absolute control over the use of their works. Everyone has therefore always been free to read, listen to, or view a work for his or her own learning or enjoyment. In theory, copyright did not extend to acts of consumption or reception of information by individuals.[6] In fact, nowhere in the international instruments or the national legislation dealing with copyright or neighboring rights is there a definition of the notion of "private use" or "private copying". Some national laws do give a hint as to the extent of the exemption, but it is usually left to the judge to decide whether a particular use of a copyright protected work falls within the scope of the statutory exemption or not. In the following pages, we briefly examine how the private use exemption has been considered through the years and how it has been recently regulated inside the European Directive on Copyright and Neighboring Rights in the Information Society.

Historical development

The view that copyright protection did not extend to the private sphere of the individual was well accepted by most early continental European copyright scholars.[7] In fact, some early commentators believed that legal provisions confirming that private

5 O.J.C.E. L 167, June 22, 2001, pp. 10–19.

6 Guibault, *Copyright Limitations and Contracts: An Analysis of the Contractual Overridability of Limitations on Copyright*, p. 48.

7 J. Kohler, *Urheberrecht an Schriftwerken und Verlagsrecht* (Stuttgart: Enke, 1907), p. 178; R.-P. Lepaulle, *Les droits de l'auteur sur son oeuvre* (Paris: Dalloz, 1927), p. 7; F. Leinemann, "Die Sozialbindung des 'Geistigen Eigentums'", *UFITA-Schriftenreihe* (Baden-Baden: Nomos Verlagsgesellschaft, 1998), p. 112.

use was outside of the rights holders' exploitation monopoly was pointless, since private use was the indispensable corollary to the bequest of the work to the public through publication. Eventually, however, the common view evolved to hold that the regulation of private use inside the copyright act had become necessary because changes in society had blurred the line between public acts and private acts. Early 1900s versions of the Dutch and German copyright statutes did include exemptions for the reproduction of a work in a limited number of copies for the sole purpose of private practice, study or use of the person making the copies, whereas a specific provision regarding private use was introduced in French law only in the Act of 1957. It was always understood however that these "private" reproductions must be neither put into circulation nor reach the public in any way. As Ricketson reports:

> Essentially, private use exceptions in national laws at that time were predicated upon the basis that these copies were made by hand or with the use of a typewriter, and that the quantity of such copying could scarcely conflict with either the normal exploitation of the work or the legitimate interests of the author.[8]

By the 1950s, the considerations at the root of the exemption allowing a user to make single copies of a work were put to the test with the development of more sophisticated techniques of reproduction. At the time of the Stockholm Conference for the revision of the Berne Convention in 1967, reprography of literary works and home taping of sound recordings were becoming wide spread among the population. And although no consensus could emerge on the introduction of a specific limitation on private use, delegations agreed to the adoption of the "three-step test" of Article 9(2) and to specify, in Article 9(3), that "any sound or visual recording shall be considered as a reproduction for the purposes of this Convention". The Main Committee I of the Stockholm Conference has interpreted these provisions, both as a justification for the existence of the private use exemption and as the basis for adoption of home taping levy regimes:

> This clearly envisages that exceptions under Article 9(2) may take the form of either absolute exceptions or compulsory licenses, depending essentially on the number of copies made....As a matter of language, it also makes sense. The power under Article 9(2) is to permit the reproduction of works in certain special cases, and there is nothing in the wording of the provision which forbids the imposition of conditions on the grant of such permission, such as an obligation to pay for it (or to acknowledge the source of the work reproduced, for that matter).[9]

According to Ricketson, it also seemed clear from the Report of Main Committee I that "unreasonable prejudice to the legitimate interests of the author" could be avoided by the payment of remuneration under a compulsory license.

The introduction in 1965 of a levy system in Germany was triggered by two seminal decisions of the German Federal Supreme Court (BGH), rendered in 1955 and

8 S. Ricketson, *The Berne Convention for the Protection of Literary and Artistic Works: 1886–1986* (London: Centre for Commercial Law Studies, Queen Mary College, 1987), p. 486.

9 Ibid.

1964 respectively, both of which involved the sale of sound recording equipment.[10] In the latter case, the German collecting society, GEMA, asked the Federal Supreme Court to order that producers of recording equipment be obligated, upon delivery of such recording equipment to wholesalers or retailers, to request from the latter that they communicate the identity of the purchasers to the GEMA.[11] First, the Supreme Court considered the question of whether the producers and retailers of recording equipment could also be held liable for copyright infringement, even if they did not realize the reproductions themselves, but only provided individuals the necessary means for doing so. The Court answered this question in the affirmative, pointing out that producers of recording equipment took express advantage of the popularity of private home taping. It decided however that the GEMA could not force vendors of home-taping equipment to oblige their customers to reveal their identity so as to enable the society to verify whether these customers engaged in lawful activities. In the opinion of the Court, although home taping formed an infringement of copyright, such measures of control would have undeniably conflicted with each individual's right to the inviolability of his home, as guaranteed by Article 13 of the German Basic Law (GG).

With respect to sound and audiovisual recordings, the German Copyright Act was modified again in 1985 in order to introduce a levy on blank tapes, in addition to the long-standing levy on the sale of recording equipment. The main argument for the introduction of a levy on blank tapes in 1985 was that the remuneration collected on the sale of recording equipment no longer equaled the dimensions assumed by the legislator when the provision was enacted in 1965. The decrease in remuneration obtained from the sale of recording equipment could be explained by the fact that the average factory price in 1985 was far lower than in 1965. The collecting societies had stressed that, at the same time, this decrease of remuneration collected per unit contrasted sharply with the rapid increase of private home taping.[12] Contrary to the position that had prevailed until then, the legislator agreed with the collecting societies that some legal responsibility for infringement of copyright by private home taping could be assumed not just by the producers of recording equipment but also by the producers of blank tapes and cassettes. The argument put forward in 1965, according to which it would be unjust to put a levy on blank material because no distinction

10 Note that the German Federal Supreme Court had examined the question of the reproduction of sound recordings in an earlier case, but not in the context of a private use, see BGH, decision of November 21, 1952 – Aktz.: I ZR 56/52 (*Überspielen von Schallplatten auf Magnettonbänder*) in *GRUR* 03/1953, p. 140.

11 BGH, May 29, 1964 – Aktz.: Ib ZR 4/63 (*Personalausweise*), in GRUR 02/1965, p. 104; see K. Koelman, L. Bygrave, "Privacy, Data Protection and Copyright: Their Interaction in the Context of Electronic Copyright Management Systems", in P.B. Hugenholtz (ed.), *Copyright and Electronic Commerce* (The Hague: Kluwer Law International, 2000), pp. 59–123, p. 101; and D.J.G. Visser, "Coyright Exemptions Old and New", in P.B. Hugenholtz (ed.), *The Future of Copyright in a Digital Environment* (The Hague: Kluwer Law International, 1996), Information Law Series – 4, pp. 49–56, p. 50.

12 T. Collova, "Über die Entwicklung der gesetzlichen und vertraglichen Regelung der Vervielfältigung zum persönlichen Gebrauch (private Überspielung) in der Bundesrepublik Deutschland", UFITA 125 (1994), pp. 53–102, p. 86.

can be made between blank material used for purposes affecting copyright and those used for other purposes, was simply put aside.

Today, most continental European countries have followed the German model and have granted authors, publishers, performers, and phonogram and videogram producers a remuneration right for the private use of their works, either under the home taping regime or the reprography regime. Only three EU member states have not implemented a levy system for reprographic reproduction and home taping: Ireland, Luxembourg and the United Kingdom. Since then, however, further technological developments have once again upset the delicate balance reached with regard to the private use and have made this exemption as controversial and as complex as ever. Digital networked technology now offers users the possibility to reproduce a work at low cost in countless numbers of perfect copies and to transmit these to an unlimited number of people across the globe, thereby posing a threat to the economic interests of rights owners.

Private use under the EC Copyright Directive

Before the adoption of the EC Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the Information Society,[13] the private use exemption was regulated at the European level only with respect to computer programs and databases.[14] In fact, the two Directives expressly exclude any possibility to make a private copy of a computer program or an electronic database. At the time, the motive of the European legislator behind this decision was twofold. First, reproductions made under the private use exemption of computer programs and electronic databases had gained economic significance for rights owners, who considered private uses as a primary form of exploitation of copyrighted material. Consequently, such reproductions should, to the greatest extent possible, be licensed directly to end-users. Second, encryption technology could already be used to reduce the traditional symptoms of market failure encountered in the analogue world, by making it possible to license and enforce copyright even in cases of mass distribution of copyrighted works. As a small concession to users of computer programs and electronic databases, both directives allow the lawful user to use the product "in accordance with its intended purpose".[15] The Computer Programs Directive also

13 O.J.C.E. L 167, June 22, 2001, pp. 10–19.

14 Council Directive of May 14, 1991 on the legal protection of computer programs (91/250/EEC), O.J.E.C. no. L 122, 17/05/91 p. 42, Articles 5 and 6 [hereinafter "Computer programs directive"]; and Directive 96/9/EC of the European Parliament and of the Council of March 11, 1996 on the legal protection of databases, O.J.E.C. of 27/3/96 no L 77 p. 20, Article 6.

15 Council Directive 91/250/EEC of May 14, 1991 on the legal protection of computer programs, Official Journal L 122, 17/05/1991 p. 42, Article 5(1); and Directive 96/9/EC of the European Parliament and of the Council of March 11, 1996 on the legal protection of databases, Official Journal L 077, 27/03/1996 p. 20, Article 6(1).

permits the making of a single back-up copy of a lawfully acquired computer program.[16]

With the adoption of the EC Copyright Directive, the European legislator dealt with the issue of private use with respect to the remaining categories of works, in both analogue and digital form. This provision was one of the most hotly debated items of the entire Directive. Article 5(2)(b) of the Directive finally gives member states the possibility to adopt an exception or limitation to the reproduction right:

> In respect of reproductions on any medium made by a natural person for private use and for ends that are neither directly nor indirectly commercial, on condition that the rights holders receive fair compensation which takes account of the application or non-application of technological measures referred to in Article 6 to the work or subject-matter concerned. (Emphasis added)

The requirement that reproductions be made "by a natural person for private use and for ends that are neither directly nor indirectly commercial" clearly excludes any form of commercial copying, be it for legitimate business-related purposes or ordinary "piracy". Moreover, Article 5(2)(b) does not permit member states to adopt exemptions allowing "private" copying by or within business enterprises or other legal persons, even if such copying has no commercial purpose. Consequently, the scope of any exemption permitted by Article 5(2)(b) is fairly limited, as must be any system of private copying levies directly associated with it.

Legal literature now generally agrees that levies, as a form of "fair compensation" prescribed by Article 5(2)(b), cannot serve to compensate rights holders for losses incurred by acts not exempted pursuant to this provision, such as intra-company uses, or acts of piracy. Member states are mandated by the Directive to tailor the form and level of "fair compensation" to "the particular circumstances of each case". When determining the "possible" level of such compensation, member states must consider the "possible harm to the rights holders resulting from the act in question" or the "prejudice to the rights holder". The notion of fair compensation is thereby inherently linked to the notion of harm (damage), that is, the prejudice suffered by a rights holder due to acts of private copying. Consequently, one might argue that member states are under an obligation to provide for compensation only if the likelihood of such harm can be reasonably established.[17] Recital 35 of the Directive establishes a *de minimis* rule, by stating that "in certain situations where the prejudice to the rights holder would be minimal, no obligation for payment may arise." Examples of such *de minimis* use are "time shifting" (the recording of broadcasts for later perusal) and "porting" (copying legally acquired content to other platforms, such as PCs, car stereos or portable media).

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16 Computer Programs Directive, Article 5(2); cf. Koelman, Bygrave, "Privacy, Data Protection and Copyright: Their Interaction in the Context of Electronic Copyright Management Systems", p. 105.

17 Hugenholtz, Guibault, van Geffen, *The Future of Levies in a Digital Environment*, report prepared for the Business Software Alliance, March 2003, available at http://www.ivir.nl/publications/other/DRM&levies-report.pdf, p. 36, accessed on March 29, 2006.

Another requirement set out in Article 5(2)(b) of the Directive concerns the payment of a "fair compensation" to the rights holder, while "taking the application or non-application of technological measures into account". Article 6(4) of the Directive governs the relationship between the application of technological protection measures and the exercise of the limitations on copyright. It provides that, in the absence of voluntary measures taken by rights holders, member states must take appropriate measures to ensure that rights holders make available the means of benefiting from a certain number of limitations, to the extent necessary to benefit from these limitations and where that beneficiary has legal access to the protected work or subject-matter concerned. However, member states are given the option, and not the obligation, to adopt similar measures with respect to the private use exemption. Whenever the reproductions made for private use have already been made possible by rights holders to the extent necessary to benefit from the exception or limitation concerned, member states may not take any additional "appropriate measure". In addition, the whole effect of this provision may be further undermined by the fourth indent of Article 6(4) of the Directive. It provides as follows:

> the provisions of the first and second subparagraphs shall not apply to works or other subject-matter made available to the public on agreed contractual terms in such a way that members of the public may access them from a place and at a time individually chosen by them.

This means that any condition of use set by the rights holder in a contract has precedence over the user's right to make a private copy, even if most contracts concluded in the digital environment take the form of "take it or leave it" licenses.[18]

Copyright levies and digital technology: The challenge

The establishment of statutory licenses has never gathered unanimity. In the eyes of some commentators, such licenses are only the result of a compromise between the traditionally protected interests of creators and the pressures exercised by representatives of the new copyright industries and that these licenses ultimately only benefit economic intermediaries.[19] Is the standardization of non-voluntary licenses an illustration of the socialization of copyright law? Are statutory licenses anything else than a rough justice solution from the standpoint of economic efficiency?[20] Do the considerations at the root of such a regime justify in all cases the slow erosion of the principle of exclusive rights? In the following pages, we consider the legitimacy of the copyright levies from respective position of the rights owners and the users.

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18 Guibault, Copyright Limitations and Contracts: An Analysis of the Contractual Overridability of Limitations on Copyright, p. 203.

19 A. Strowel, *Droit d'auteur et copyright – Divergences et convergences* (Paris: Editions Larcier, 1993), p. 286.

20 A. Peukert, "DRM: Ende der kollektiven Vergütung?", sic! – *Zeitschrift für Immaterialgüter-, Informations- und Wettbewerbsrecht* 10 (2004), pp. 749–757, p. 752.

Statutory licenses from a rights owners' perspective

From the perspective of the copyright owners, a statutory license allowing users to make reproductions of their works for private purposes would appear justified under essentially two conditions: (1) if the exclusive right of authorizing or prohibiting such acts cannot effectively be controlled or exercised and (2) if the remuneration received in exchange for the loss of revenue due to the legitimate use of their works can be qualified as fair. With respect to the first criterion, the historical survey of the previous section in fact shows that, with the advent of the home taping technology, rights holders were for all relevant purposes unable to control the use made of their works by private individuals without violating the latter's right to privacy. As a result, rights holders suffered an unreasonable prejudice to their legitimate interests, which could be avoided by the payment of remuneration under a statutory license. However, this is no longer the case in the digital networked environment. With the advent of DRM, the assumption that private copying of protected works cannot be controlled and exploited individually must be re-examined. In the digital environment, technical protection measures and DRM systems make it increasingly possible to control how individuals use copyrighted works. Rights holders are now in a position to apply such systems to identify content and authors, set forth permissible uses, establish prices according to the market valuation of a particular work, and grant licenses directly and automatically to individual users. Unlike levies, DRM makes it possible for rights holders to directly license the particular uses made of a work, at its regular market price. Where individual rights management is available, there would appear to remain no need, and no justification, for mandatory levy systems. Why, indeed, should rights owners be legally forced to forego their exclusive right to authorize or prohibit the making of reproductions of their works, if there are no more obstacles preventing them from effectively exercising their exclusive right?[21]

In our opinion, a statutory license is justified, from the rights owners' point of view, if the remuneration received in exchange for the loss of revenue due to the legitimate use of their works can be qualified as "fair". How should the "fairness" of the compensation under a statutory license regime be evaluated? Pursuant to Article 5(2)(b) of the European Directive, the level of the compensation is inherently linked to the notion of harm (damage), that is, the prejudice suffered by a rights holder due to acts of private copying. As mentioned above, levies cannot serve to compensate rights holders for losses incurred by acts not exempted under the private use exemption. Levies are not intended, as sometimes mistakenly believed, to compensate rights holders for acts of illegal copying. "Fair compensation" is due only in cases of legitimate private copying.[22] Of course, no "fair compensation" is due at all for the vast quantity of on-line content that is not or no longer protected by copyright law or that can be downloaded with the implied or express consent of the content providers, and therefore fall outside the scope of any private copying regime

21 P. Sirinelli, "Reproduction et dissémination sur les réseaux numériques du point de vue de la loi française", in Hungarian ALAI Group (ed.), *Creators' Rights in the Information Society – Proceedings of the ALAI Congress* (Budapest: ALAI Group, 2003), p. 273.

22 Dusollier, *Droit d'auteur et protection des oeuvres dans l'univers numérique*, p. 425.

in the first place. In fact, a substantial amount of copies that end users of copyrighted works produce in practice, either on digital media or digital equipment, are likely either to cause no more than minimal harm to the rights holders, or to fall outside the scope of Article 5(2)(b) of the Directive altogether.[23]

What is a "fair compensation" in a world where rights owners make use of digital rights management systems? On this point, the European Copyright Directive has taken a rather ambivalent approach. Article 5(2)(b) of the Directive attempts to reconcile the existing system of private copying levies with a future of individual digital rights management, by prescribing that in calculating the amount of "fair compensation" for acts of private copying the "application or non-application of technological measures" be taken into account. Why, indeed, should rights owners be legally forced to settle for the "fair compensation" fixed by the public authorities, if technology allows them to reap the real profits generated by the exercise of their exclusive right to authorize the making of reproductions of their works? A recurring objection to the establishment of statutory licenses has always been that not only the amount of remuneration established by the competent authority is generally too low to reflect the real value of a use, but that rights owners thereby lose all negotiating power to obtain a "more reasonable" remuneration.[24]

Arguably, as digital rights management systems enable content owners to control private copying, and set conditions of private use at their discretion, levies on digital media or equipment should gradually be phased out. When and how should the phase-out take place? How should one take "account of the application or non-application of technological measures"? Whereas the language of Article 5(2)(b) of the European Copyright Directive and its corresponding recitals offer little guidance in establishing the true meaning of the phase-out provision, it is important to come up with a sensible and practicable interpretation, which might be suitable for implementation by the member states. One option could be to measure the actual "application or non-application of technological measures" or "degree of use" of such measures. Such an undertaking could prove to be a fruitless and frustrating exercise, in view of the non-linear relationship between content, technical protection measure, media, equipment and levy, and absent any baseline to measure the "degree of use" against it. Instead, a more sensible and workable interpretation should be favored, inspired by economical and practical considerations, and supported by the recitals of the Directive. Levies could be phased out not in function of actual use, but of availability of technical measures on the market place. The phasing-out of levies should be a decision based on technology assessment. Technological protection measures could be deemed "available" if and to the extent that they can be realistically, and legally, applied in the marketplace. Factors to be assessed might include: upfront costs to producers and intermediaries; incremental costs or savings for consumers; consumer friendliness and acceptance, as reflected, for example, in

23 Hugenholtz, Guibault, van Geffen, *The Future of Levies in a Digital Environment*, p. 34.

24 F.K. Fromm, W. Nordemann, K. Vink, *Urheberrecht: Kommentar zum Urheberrechtsgesetz und zum Urheberrechtswahrnehmungsgesetz* (Stuttgart: Kohlhammer, 1998), p. 380.

market share; incorporation of Privacy Enhancing Technologies in DRM systems; accessibility of DRM protected content by disabled users and users with special needs and so on.[25]

For similar reasons, we believe that from the rights owners' perspective, the extension of a levy regime into the digital networked environment to cover peer-to-peer activities would ultimately undermine the development of digital rights management systems without necessarily offering an economically efficient alternative. Not only would the preservation of a levy regime discourage rights owners from implementing workable DRM solutions, but the application of a statutory license regime to the digital networked environment would bring about substantial costs, from both administration of the royalty regime and losses incurred because of shortcomings in the rate-setting process. The registration and tracking of the usage of copyrighted works accessed on peer-to-peer networks may be expensive, while the process of fixing the tariff may be costly and time-consuming. In addition, the collection and allocation of copyright revenues under a statutory license could, in practice, prove inequitable for certain rights owners. Indeed, it is unclear whether the usage of each copyrighted work could be tracked accurately enough for many copyright owners, particularly those offering relatively few creative works, to receive applicable royalty payments.[26] In such circumstances, the compensation paid to these less successful or less prolific authors could hardly be qualified as "fair". Through the gradual substitution of exclusive rights through rights of compensation, exclusive rights would effectively cease to exist. Rights holders would instead become totally dependent on remuneration rights collected by collecting societies.[27]

Finally, one should not lose sight of the fact that an all-encompassing levy scheme applicable to peer-to-peer or similar activities could be perceived by many users as an "unlimited license to copy". The users' inevitable misconception regarding the legitimacy of peer-to-peer activities derives to a large extent from the ambiguity prevailing among judges and lawmakers on the issue. It is now generally accepted that downloading a work from the Internet for private use purposes falls under the private use exemption, while the uploading of that work onto the server for sharing purposes constitutes an infringement of the copyright in that work. How must this distinction be reconciled with the application of a levy regime? Won't users be fooled in thinking that, because of the payment, not only the downloading but also the uploading of the work is permissible?[28] This expected social impact from the application of a statutory license to the digital networked environment would contribute to a large extent in undermining the development of digital rights management.

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25 Hugenholtz, Guibault, van Geffen, *The Future of Levies in a Digital Environment*, p. 42; Peukert, "DRM: Ende der kollektiven Vergütung?", p. 754.

26 Peukert, "DRM: Ende der kollektiven Vergütung?", p. 755.

27 Hugenholtz, Guibault, van Geffen, *The Future of Levies in a Digital Environment*, p. 42.

28 Sirinelli, "Reproduction et dissémination sur les réseaux numériques du point de vue de la loi française", p. 278.

Statutory licenses from a users' perspective

Even if they have the great advantage of permitting users to make an unspecified amount of reproductions for private purposes, statutory licenses are legitimate from a users' perspective only if they meet the following criteria: (1) an adequate causation must exist between the act of making a reproduction of a copyrighted work, the media or equipment used to make the reproduction and the harm done to the interests of the rights owner; and (2) the imposition of a levy on blank media or equipment must take "account of the application or non-application of technological measures". Regarding the first criterion, the decisions of the German Supreme Court (BGH) in the GEMA cases established that levy schemes should be rooted in the notion of contributory liability of equipment manufacturers and traders.[29] For this reason, most levy schemes are and should be limited to equipment or media the primary use of which is to reproduce copyrighted works. In a report entitled Copyright Issues in Digital Media, the United States Congressional Budget Office considered that the application of levies on general-purpose digital equipment was not desirable for the following reasons:

> From an equity point of view, levying a fee on computers and other equipment used to access certain creative works could also impose a tax on the use of that equipment for activities unrelated to the copyrighted materials in question. For example, taxing purchases of computers or other digital media to compensate recording artists for Internet downloads would force individuals who use computers for other purposes to subsidize the online music consumption of others.[30]

Hence, lawmakers should be extremely wary of expanding existing analogue levies to digital media or equipment.[31] Applying levies to such general-purpose machines as PCs, printers or scanners would be unjustified and might have unwanted economic and social consequences. Levies raised on PCs or hard disks do not reflect the contributory liability rationale on which the levy system is based. Where would the list of digital devices subject to the payment of a levy stop? Would mobile telephones, radio and television sets, digital cameras, digital video units, car stereos, automobile information systems, watches, all at some point in the future also be subject to the payment of a levy?

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29 K.J. Koelman, P.B. Hugenholtz, "Online Service Provider Liability for Copyright Infringement", Study prepared for WIPO, Geneva 1999, OSP/LIA/1 Rev.1, p. 8: "Adequate causation is found if an act or omission has, in a general and appreciable way, enhanced the objective possibility of a consequence of the kind that is the subject of the case. In deciding this, account is taken of all the circumstances recognisable at the time the event occurred." In the five "*Tonbandgerät*" cases decided by the Federal Supreme Court, the unlawfulness of manufacturing, selling or advertising tape recorders was based in on §1004 of the German Civil Code ("Störung", that is, interference with property rights), and/or §823 ff. (unlawful conduct).

30 Congressional Budget Office, *Copyright Issues in Digital Media* (Washington, D.C.: CBO, 2004).

31 Hugenholtz, Guibault, van Geffen, *The Future of Levies in a Digital Environment*, p. 37; Peukert, "DRM: Ende der kollektiven Vergütung?", p. 756.

In our opinion, a statutory license is justified, from the users' point of view, if the copyright levies apply only to blank media and equipment the primary purpose of which is to make private copying of copyrighted works, and only as long as copyright owners do not license their work directly to users. Following the wording of Recital 35 of the European Directive, no compensation may be required "in cases where rights holders have already received payment in some other form, for instance as part of a license fee". Therefore, no levy is due for files copied by users of proprietary online services or (other) digital rights management systems. Also, insofar as a work or phonogram is distributed in copy-protected form, and the accompanying end-user license allows for private copying, no compensation is in order. Any legal system that allows for digital private copying subject to levies is in fact difficult to reconcile with a legal regime aimed at protecting and promoting digital rights management systems. The co-existence of levies and DRM lead to the undesirable effect of obliging users to pay twice for the same service: first by paying a license fee for the use of DRM-controlled content, second by paying a levy on media or equipment.[32] Consumers may end up paying twice for the right to make a private copy of a work – once by paying the levy, and once again by paying the rights holder for the right to copy the work.[33] In such circumstances, copyright levies should be phased out as soon as DRM technology is available so that the legitimacy and the integrity of the copyright levy system are preserved.

As mentioned earlier in this chapter, some arguments have been put forward in favor of the extension of a levy regime into the digital networked environment to cover peer-to-peer activities. According to the main proponents of the implementation of a levy regime to cover peer-to-peer activities, such a system would be an important mechanism for ensuring that authors and copyright holders continue to receive adequate remuneration for the creation of "sustained works of authorship." No less importantly, it would in Netanel's opinion confer on non-commercial users an unhindered entitlement to copy, share and modify the music, movies, stories and art that populate our culture.[34] However, lawmakers should be very cautious with the introduction of a statutory license applicable to peer-to-peer activities.[35] In addition to the reasons given in the section above, we consider that a general levy raised on a subscription to broadband Internet access or on the sale of PCs, for example, would certainly not possess the adequate causation between the act of making a private copy, the medium used to perform it and the prejudice caused to rights owners, since they would be assessed on individual equipment purchasers and Internet subscribers

32 Helberger (ed.), 1st State of the Art Report: Digital Rights Management and Consumer Acceptability, p. 68.

33 Peukert, "DRM: Ende der kollektiven Vergütung?", p. 752.

34 N. Netanel, "Impose a Noncommercial Use Levy to Allow Free Peer-to-Peer File Sharing", p. 84; see also K. Koelman, "P2P Music Distribution: a Burden or a Blessing?", paper presented at the IViR – BUMA/STEMRA Conference "Copyright and the Music Industry: Digital Dilemmas", Amsterdam, July 4–5, 2003.

35 M. Lemley, "Reducing Digital Copyright Infringement Without Restricting Innovation", Boalt Working Papers in Public Law, April 2004, Paper 62, available at: http://repositories.cdlib.org/boaltwp/62, accessed on March 30, 2006.

regardless of their actual use of peer-to-peer technology and level of copyright infringement. As Blackmore explains:

> Effectively, they [the levies] penalize those who do not infringe copyright and may encourage copyright infringement amongst consumers who consider that they have already paid for the right to infringe copyright. They may either discourage copyright owners from pursuing chronic copyright infringers with legal action or provide copyright owners with a windfall when they succeed against such infringers.[36]

As Helberger observes, there is reason to believe that any levy regime applied to peer-to-peer activities would not just seek compensation for private copying, but also for copyright infringing practices. Such systems do not just try to tackle the restrictions DRM may impose on consumers, but also for acts considered illegal under current copyright law.[37] Moreover, the implementation of a levy system would tromp any effort to find other solutions to cope with the problem of peer-to-peer file sharing and on-line copyright infringement. One possible solution would be to follow the Scandinavian model of the "extended collective license"[38] and another, to encourage rights owners to make their works available subject to a Creative Commons license.

Concluding remarks

As the home taping regime illustrates, statutory license systems may not be the best suited instrument to serve as a model of governance in the information society, in replacement of the prevailing neo-liberal concept of property. Statutory license regimes represent at most a rough justice measure, that is, one that is entirely satisfactory neither from the perspective of the rights owner nor from the perspective of the user. From the rights owners' point of view, a levy regime is advantageous only if the exclusive right of authorizing or prohibiting acts of private use cannot effectively be controlled or exercised. With the advance of technology, the notion that content cannot be controlled and exploited on an individual basis has changed: through DRM, rights owners can control the use that is made of their works and are able to charge individually for the use of content through individual licensing

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36 N. Blackmore, "Peer-To-Peer Filesharing Networks: The Legal and Technological Challenges for Copyright Owners", New South Wales Society for Computers and the Law, March 2004, §5.1, available at http://www.nswscl.org.au/journal/55/Blackmore.html, accessed on March 30, 2006.

37 Helberger (ed.), 1st State of the Art Report: Digital Rights Management and Consumer Acceptability, p. 69.

38 The extended collective license combines a voluntary assignment with a *legal extension of the repertoire* to encompass non-represented rights holders, thus accelerating the acquisition of rights, see D. Gervais, *Application of an Extended Collective Licensing Regime in Canada: Principles and Issues Related to Implementation*, report to the Minister of Canadian Heritage, Ottawa, 2003; and P. Schønning, "Chronique des pays nordiques", *Revue internationale du droit d'auteur* 173(136) (1997), p. 168. See also Gervais, "The Price of Social Norms: Towards a Liability Regime for File-Sharing", p. 72.

schemes. Private copying may be prevented altogether or offered only subject to certain conditions by the rights holder. In such circumstances, a statutory license regime no longer appears justified. Moreover, to form an acceptable alternative to the copyright owner's exclusive rights, the sums received in exchange for the loss of revenue due to the legitimate use of copyrighted works must be fair. In practice, it is very difficult to determine first what is a fair compensation for private uses, and second, which medium or equipment should be subject to the payment of the levy.

From the users' point of view, the implementation of a levy regime is legitimate provided that there exists an adequate causation between the act of making a reproduction of a copyrighted work, the media or equipment used to make the reproduction and the harm done to the interests of the rights owner. The extension of a general levy regime into the digital networked environment in the form of a fee on a subscription to broadband Internet access or on the sale of PCs, for example, would certainly not possess the character of adequate causation, since it would be assessed on individual equipment purchasers and Internet subscribers regardless of their actual use of peer-to-peer technology and level of copyright infringement. Moreover to be justified, the preservation of a levy on blank media or equipment should take "account of the application or non-application of technological measures". This is a clear indication of the European legislator's intention to phase out levies as soon as technological measures are available on the market as a viable means of distributing copyright protected works.

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Chapter 13

The Institutional Nature of the Patent System: Implications for Bioethical Decision-Making

Sivaramjani Thambisetty

The relationship between law and morality is particularly fraught in the sphere of patent law. There is reluctance to concede that morality and patentability intersect, and a number of legal scholars have argued that patent law was not intended to encompass moral or ethical judgments on inventions.[1] Although it is possible to historically trace moral concerns within legal doctrine, for example in the controversy over patenting playing cards in the 19th century, and more recently over the protection of contraceptives,[2] patent systems in Europe and the United States[3] remain largely unreceptive to bioethics. In a European context this remains true, despite the existence of the Biotechnology Directive. On the one hand specific exclusions from patentability in the Directive seems to deflect meaningful bioethical debate on the interpretation of the more general prohibition against the patenting "of inventions the exploitation or publication of which would be contrary to ordre public or morality" under Article 53(a) of the European Patent Convention (EPC). On the other hand, the bright line exclusions are closed categories and make it harder to reopen or question established interpretations in patent law that fall under the rubric of bioethics.

Bioethical decision-making[4] in the patent system is a subset of the normal process of change, transition and reform. Unearthing the dynamics of the general process of

1 In the present context I use the two terms "morality" and "ethics" interchangeably. For a discussion see R. Brownsword, "The Ethics of Patenting: A Legal Perspective", paper presented at the Roundtable on the Bioethical Issues of Intellectual Property Rights, March 28–29, 2003, University of Cambridge. Available at http://www.shef.ac.uk/ipgenethics/roundtable/papers/RBrownsword.pdf, accessed on March 30, 2006.

2 See S. Thambisetty, "Understanding Morality as a Ground for Exclusion from Patentability under European Law", *Eubios J Asian and Intl Bioethics*, March 12, 2002, pp. 48–53.

3 In the U.S. there is no equivalent statutory exclusion for patentability on ethical grounds.

4 I use the term "bioethical decision-making" to refer to a range of circumstances where ethical and moral concerns generated by biotechnological inventions are addressed. This includes substantial patent examination at the patent office, opposition proceedings at the European Patent Office (EPO), and litigation.

change and shifting legal doctrine in patent law provides clues as to why the system is so limited in its approach to bioethics. The circumstances under which moral questions are raised by the research on biological material and the application of that research impinges on patent matters can and has been varied. It includes "inherent patentability" issues about naturally occurring substances such as proteins and cells,[5] concerns about the monopolization of subject matter "essential" for biomedical advances,[6] the questionable ethics of patenting higher life forms as products,[7] and the international distributional effects of the patentability of biotechnological inventions including agricultural biotechnology.[8]

There are at least two characteristics common to all such debates. Firstly, the cases are framed by decision-making bodies such as patent offices and the courts as a question between competing forces – the pressure to increase the scope of "inherent patentability" and allow new biological subject matter, and the contrary and restraining force of a cautious (risk averse) and value laden approach to scientific research and development. Secondly, resolution of the controversies requires critical discussion and debate. Typically, bioethical controversies in patent law have been "resolved" by incorporating additional subject matter. Thus the animal and plant variety, and gene patentability debates have all been settled in favor of the granting of expansive patent rights. Furthermore, in most cases (with one notable exception[9]) the controversy has been "settled" with little purposive debate about patentability and bioethics in patent law itself. What are the features within the patent system that load the dice in favor of expansive patent rights rather than a more measured approach? Are there any systemic factors that undermine the level of debate, or influence the responsiveness of the system to bioethical concerns?

The patent system today is a configuration of complementary institutions in which the behavior of each is affected by the existence and performance of the other, often in ways that are poorly understood. It is submitted here that complex causal reasons within the institutional nature and function of the patent system often undermine assessments based on social optimality. With respect to bioethical concerns, it elicits a standard response, framing and resolving the problem in favor of expansive patentability. Without judging the outcome on its ethical content, it is possible to evaluate the existence of endemic factors within the system that favor more property rights over fewer, and undermine the possibility of informed debate about alternative

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5 *Howard Florey/Relaxin*, [1995] EPOR 541.

6 See S. Basheer, "Block Me Not: Are Patented Genes 'Essential Facilities'?" *ExpressO Preprint Series*, April 3, 2005, Working Paper No. 577, available at http://law.bepress.com/expresso/eps/577'; see also M. Heller, R. Eisenberg, "Can Patents Deter Innovation: The Anticommons in Biomedical Research", *Science* 1280(5364) (1998), pp. 698–701.

7 See T 0315/03 Transgenic animals/HARVARD (July 6, 2004) and *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45.

8 See Commission on Intellectual Property Rights, Chapter 4, and S. Thambisetty, "Human Genome Patents and Developing Countries", Study Report 10, Commission on Intellectual Property Rights, U.K. Government (2002), available via http://www.iprcommission.org/.

9 *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45 (see discussion below).

intellectual approaches. Based on illustrative examples form the European and U.S. legal systems, and an institutional approach to bioethical decision-making,[10] I submit that the normal and general course of change in patent systems lead inevitably to increased patentability irrespective of deontological concerns.

In the first and second sections, I discuss the "reformed" role of patent offices and courts in modern legal systems and how they impact on the general process of change and transition in the law. In the third section, I explore an institution that is not normally regarded as being part of the patent cluster. Research funding bodies such as the National Institutes of Health (NIH) in the U.S. act as powerful "norm-setting" institutions that play an effective role in the exploitation of intellectual property. The absence of an equivalent entity in Europe is a significant factor for the patent system that has so far been inadequately explored. In the final section, I conclude that the institutional inter-relationships in the patent this cluster reveal latent aspects that may have a credible impact generally on the social optimality of inventions and specifically on bioethical decision-making.

Patent offices

Administration

In order to maintain the integrity of the patent system and avoid political interference in individual applications, the "statutory person" model for patent offices is quite popular, especially in commonwealth countries. A "comptroller" appointed by the government usually heads the statutory office.[11] The United States Patent and Trademark Office, a federal agency under the Department of Commerce, *de facto* adheres to this model; the actual appointments are political. In the U.K. the patent office is an executive agency of the department of trade and industry and became a self-financing trading fund in 1991.[12]

Since the late 1980s and 1990s patent offices in a number of countries have changed their status, role and functions remarkably. Most of them now have executive agency status with greater powers over their finances, personnel and other operations. Self-funding offices, including in the U.S. and U.K., have been

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10 "Institutionalism" includes a variety of theoretical strands. I refer here to an approach that emphasizes patterns of group behavior and recognizes the need for political intervention to change entrenched habits. Although the institutional approach is uncommon in legal scholarship it can be used very effectively to explain complex causal relationships. As an illustration see R. Fujikawa, "Federal Funding of Human Stem Cell Research: An Institutional Examination", *Southern California Law Review* 78(1075) (2005).

11 As is the case in Ireland, for example. See http://www.patentsoffice.ie/About-us.html.

12 A trading fund is part of government established by means of a Trading Fund Order under the Government Trading Fund Act 1973. Trading Funds in the U.K. include the Land Registry Office, Meteorological Office and the Queen Elizabeth II Conference Centre. See http://www.hmtreasury.gov.uk/spending_review/spending_review_2000/associated_documents/spend_sr00_ad_ccrappd.cfm.

transformed from inward-looking and isolated entities[13] into nimble customer oriented agencies, with unexpected repercussions. The notion that paying customers, in the form of applicants rather than the public, are the intended beneficiaries of the patent system is an indefensible position for a quasi-judicial administrative agency entrusted with issuing patents in the public interest. According to Mark Lemley, this has resulted in greater numbers of patents in the U.S. without regard to quality of the subject matter.[14]

The pressures of revenue-raising for patent offices can also lead to changes in the social benefits of intellectual property. Patent renewal fee structures are an integral part of patent offices as revenue-generators.[15] The life of a patent is the patentee's choice in return for fees. Since it is not worth paying renewal fees on a patent that is not being used, renewal fees can ensure that patents of lesser social value are valid for a reduced length of time.[16] However, distortions can arise in a self-funded patent office, due to conflict between the fee structure that would optimize the social value of innovation and that which would maximize revenue for the patent office.

One study theoretically predicts that a financially constrained, self-funded patent office can be expected in course of time, to reduce renewal fees and increase initial application fees in a bid to increase revenue. If the patent renewal fees do not rise steeply enough, more inventors will be encouraged to renew their patents. Reducing renewal fees also increases the inventor's expectation of profits that can then be appropriated through initial high application fees[17]. The model predicts that over a period of time the rebalancing of fees by self-funded patent offices could result in two unforeseen detriments to social welfare: it will discourage the filing of some patents while extending the effective life of others.

The U.S. Federal Trade Commission has reported that a patent examiner in the U.S. spends 18 hours on average per application reading a patent application, searching for and reading prior art, writing one or more provisional rejections,

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13 B. Doern, "Global Change and Intellectual Property Agencies" (London: Pinter Publishers, 1999), p. 31.

14 M. Lemley, "Rational Ignorance at the Patent Office", Berkeley Olin Program in Law and Economics, *Working Paper Series 1021* (Berkeley: Olin Program in Law and Economics), fn 3, p. 2.

15 Renewal fees have been in operation in European countries now for over forty years. See U.K. Patents Act 1977, s. 25 (as amended). All U.S. patents issued on patent applications filed after December 1980 must be maintained by payment of renewal fees in increasing amounts at varying intervals. Failure to pay is effective abandonment of the patent, as the patent holder can no longer sue: 35 USCA, s. 41. Canada also requires payment of "maintenance fees" as defined in s. 46(1) of the Patents Act. The Canadian Intellectual Property Office is a "revenue generating agency…financed…entirely by intellectual property services rendered": CIPO, *Intellectual Property – Innovation on a Global Scale*, Annual Report 2001–2002, p. 2.

16 S. Scotchmer, "On the Optimality of the Patent Renewal System", *RAND Journal of Economics* 30(2) (1999), pp. 181–196.

17 J. Gans, S.P. King, R. Lampe, "Patent Renewal Fees and Self Funding Patent Offices", *Legal Studies Research Paper* No. 64 (Melbourne: University of Melbourne Faculty of Law, 2004), p. 14. Also see discussion at p. 9, available at http://ssrn.com/abstract=515162.

reviewing responses and amendments, often conducting an interview with the applicant's attorney and writing a notice of allowance. Against this backdrop there are constant demands to increase productivity, often issuing from the patent office itself, such as the 2004 USPTO Annual Report, which set the goal of accelerated processing times through "more focused examination".[18] While it is the job of the patent office to grant patents for suitable inventions, it is also to weed out unsuitable inventions. Robert Merges notes that in the U.S. requiring examiners to write up reasons for rejection but not allowance gives them psychologically more incentive to allow rather than reject a patent. The volume of patent applications that arrive also mean that an examiner is more likely to be rewarded for getting quantity rather than quality correct.[19]

Patent quality problems have also been experienced in the European Patent Office (EPO). Recently, according to staff surveys, examiners at the EPO are losing confidence in its ability to ensure the quality of the patents that it issues. In a devastating indictment to have two-thirds of the 1,300 patent examiners state that productivity demands within the EPO did not allow them "to enforce the quality standards set by the European Patent Convention".[20] One can safely say that this translates into more patent rights for questionable inventions rather than fewer.

Policy role

Explicit policy-making roles and opportunities have also been structured into the new institutional incarnation of patent offices. For example the United States Patent and Trademark Office (USPTO) Corporate Plan undertakes to perform a "leadership" role in policy development; the primary performance goal being to "help protect, promote and expand intellectual property rights systems throughout the United States and abroad".[21] The United States Trade Representative also uses regional and multilateral trade initiatives such as the North American Free Trade Agreement to "promote and *extend* (emphasis added) the protection of intellectual property".[22]

The Intellectual Property Policy and Innovation Directorate of the U.K. Patent and Trade Mark Office works to "facilitate and improve the international competitiveness of British industry".[23] In 2001 a new body, the Intellectual Property

18 http://www.uspto.gov/web/offices/com/annual/2004/0402_performance.html.

19 R.P. Merges, "As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform", *Berkeley Technology Law Journal* 577(14) (1999).

20 The survey also noted that 90% of the patent examiners did not have time to keep up to date with advances in their scientific field. See A. Abbott, "Pressured Staff 'lose faith' in Patent Quality", *Nature* 429 (2004), p. 423.

21 U.S. Patent and Trademark Office, *Corporate Plan* (2000), p. 17; *Corporate Plan* (2001), p. 71. Also see U.S. Patent and Trademark Office, *Corporate Plan* (2001), p. 66.

22 http://www.ustr.gov/Trade_Sectors/Intellectual_Property/The_Work_of_USTR_-_Intellectual_Property.html.

23 http://www.patent.gov.uk/about/ippd/whatwedo/index.htm.

Advisory Committee (IPAC) was set up in the U.K.[24] to meet the needs of the patent office for external advice on "policy making" at a variety of levels, provide a forum for consultation with interest groups, and provide the government with high-level "independent" advice on intellectual property issues.[25] There are *prima facie* at least a couple of problems with this set up.

Firstly, this committee is sponsored by the patent office – a body that is widely perceived to be supportive of and hospitable to the strengthening of intellectual property rights. A review of the IPAC was instituted in October 2004 due to concerns about the ambiguous remit of the organization. The provisional recommendations include considering whether the patent office should continue to be the sole sponsor of this body given the need to avoid the perception of conflict of interest between the Patent Office's Policy Role and its relationship with IPAC.[26]

Without going into the legitimacy of these roles taken on by the patent office, it is obvious that this represents an expansion of institutional capacity. In the United States and the United Kingdom there has been no political debate on whether the patent office prejudices its statutory obligations by positioning itself as an advocate for expanding intellectual property systems.[27] It seems obvious that a real conflict of interest is created by such an expansion of institutional capacities. It is also questionable whether patent offices truly have the dynamic ability to adapt lessons learnt from their "expanded" role, given other pressures that emanate from their revenue generating work.

The second, more generic, concern is the proliferation of "interest group" politics in intellectual property. Clearly the last few decades have seen a net expansion in all types of intellectual property rights. Landes and Posner analyze some of the reasons for this hospitable climate from the perspective of public choice theory.[28] Using this rubric they argue convincingly that there is an inherent asymmetry between the value that creators of intellectual property place on having property rights and the value that would-be users place on the freedom to use without obtaining a license

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24 The IPAC replaced The Standing Advisory Committee on Industrial Property (SACIP) following a review in the context of patent office consultation. See *Review of the Standing Advisory Committee on Industrial Property (SACIP) in the Context of Patent Office Consultation.* Available at http://www.intellectual-property.gov.uk/ipac/pdf/sacip.pdf.

25 http://www.patent.gov.uk/about/ippd/ipac/index.htm. Particularly on the strategic policy questions about the proper scope of IP rights in areas such as biotechnology, computer software and business methods. Recommendation contained in the Quinquennial Review of the Standing Advisory Committee on Industrial Property, p. 2; available at http://www.intellectual-property.gov.uk/ipac/std/about.htm.

26 See Provisional Conclusions and Emerging Recommendations No. 12, available at http://www.patent.gov.uk/about/ippd/ipac/review-summary.htm.

27 See B. Kahin, "The Expansion of the Patent System: Politics and Political Economy", *First Monday* 6(1) (2001), p. 7.

28 Public choice theory sees legislation and political processes generally from the point of view of demand and supply. Legislations are "non excludable" goods in that everybody can enjoy them without having contributed to their creation. The theory focuses on the role of interest groups in solving the resultant free rider problem. See D.A. Farber, P.P. Frickey, *Law and Public Choice: A Critical Introduction* (Chicago: University of Chicago Press, 1994).

from the patent holder. This makes it easier to organize interest groups to demand an expansion of intellectual property rights than it is to get would-be users to oppose such an expansion.[29]

When patent and trademark offices avow the expansion of intellectual property rights explicitly or implicitly as part of their functional responsibilities, they in effect function as a powerful interest group that drives up the demand for greater and stronger intellectual property rights. The "technical" and often opaque nature of the subject matter also means that patent offices or advisor bodies associated with them are less likely to be interfered with by other government agencies, further strengthening their *de jure* and *de facto* independent status. Given that patent offices are at the forefront of the application of patentability standards during examination of applications, and additionally in the case of the EPO, of litigation,[30] an accurate appreciation of the role of the patent office has to include consideration of the distinctive interests the office promotes.

Conflicting institutional competencies

The question of institutional competencies in a European context is often more complicated than in the United States. Illustratively this can be seen in the awkward co-existence between the European Commission (EC) and European Patent Office (EPO), which is a non-European Union (EU) organization. The Biotechnology Directive[31] is a EU document and has no direct legal basis under the European Patent Convention, although some of the patentability standards were clearly based on EPO practice and Board of Appeal decisions. Soon after the Directive was legislated the EPO stated that it would use the Directive as a supplement to interpretation of the European Patent Convention (EPC).[32]

This apparent symbiosis is not uncontroversial. The failed Directive on Computer Implemented Inventions initiated by the European Commission[33] was widely perceived as little more than consolidation of the tortured legal interpretation

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29 Absence of serious opposition to the bill that became the Sonny Bono Copyright Term Extension Act is provided by the authors as evidence of this persistent asymmetry. W.M. Landes, R.A. Posner, *The Political Economy of Intellectual Property Law* (Washington, D.C.: AEI-Brookings Joint Center for Regulatory Studies, 2004), available at http://www.aei.brookings.org/admin/authorpdfs/page.php?id=985.

30 As per s. 91 (1) of the U.K. Patent Act 1977, U.K. courts are required to take judicial notice of the EPC and any decision of a "relevant convention court", a phrase that is defined in s. 130 of the Patent Act 1977. The definition includes any department of the EPO that has jurisdiction under the EPC, and includes EPO Boards of Appeal.

31 Directive for the Legal Protection of Biotechnological Inventions No. 98/44/EC.

32 After some amendments made by the EPO Administrative Council, the Directive was introduced into the Implementing Regulations of the EPC in 1999. See C. Baldock, O. Kingsbury, "The Biotechnology Directive and its Relationship to the EPC", July 2000 (Boult Wade Tennant), available at http://www.boult.com/information/ArticleDetails.cfm?ArticleID=31.

33 European Union Directive on the Patentability of Computer Implemented Inventions (2002/0047/COD).

on computer-related inventions adopted by the EPO.[34] The Economics and Social committee (ESC) of the E.C. noted that it would be preferable for the EC to take the initiative away from the EPO and develop it in other intellectual directions. The reason for this is that the EPO is only competent in one area of intellectual property and "is naturally attempting to extend its own area of competence and sources of revenue".[35] According to the ESC, the E.C.'s proposal was unsound as it incorporated the view of the EPO, which lacked an appreciation of the overarching complexity of intellectual property rights. A legislative proposal should ideally take advantage of greater flexibility and variety in the legal arrangements for new technologies, as well as entertain the possibility of multiple intellectual positions regarding key questions of patentability. This is an approach that cannot emanate from a body with a relatively limited mandate such as the EPO.

"Stickiness" and convergence in legal interpretation

Patent statutes are the obvious centerpiece of the patent system, and choice of approach to legal interpretation often has unrecognized systemic consequences. Interpretative theories are often debated at a high level of abstraction and generality that allows for a number of different reasonable approaches. Institutional assessments of legal rules in contrast take note of external pressures on interpretation that affect how these statutes are read and applied. The indifference of major interpretive approaches to institutionalism and their resultant failing has only recently received greater attention.[36]

Patent offices apply an incremental and technologically specific approach to patent law. Formally patent law operates a "one size fits all" system. All inventions, irrespective of technological field, must satisfy the same patentability criteria and all applications have to fulfill the same requirements. But patent doctrine is rife with different industry-specific sub-cultures of interpretation. Instances of industry- and technology-specific interpretations of patent doctrine abound, even if they are not explicitly articulated thus. Such "technological exceptionalism"[37] is really a way of using past experience to modify current doctrine and practice marginally to adapt the law to new technologies.

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34 In 2002, the European Economic and Social Committee described the doctrinal premise of the European Patent Office's interpretation of Article 52(2) of the EPC as "the product of legal casuistry". See J. Pila, "Dispute Over the Meaning of 'Invention' in Article 52(2) EPC – The Patentability of Computer Implemented Inventions in Europe", *International Review of Industrial and Copyright Law* 36 (2005), pp. 173–191.

35 See ESC Opinion, COM (2002) 92 Final – 2002/0047 (COD) (September 19, 2002) 5.4. This is noted by J. Pila, ibid., p. 191.

36 See C. Sunstein, A. Vermeule, "Interpretation and Institutions", *John M. Olin Law and Economics Working Paper* No. 156 (Harvard: The John M. Olin Center for Economics, Law and Business). The authors argue for an "institutional turn" in legal interpretation based on institutional capacities and dynamic effect.

37 The term itself was introduced at length by Dan Burk and Mark Lemley. For a critique see P. Wagner, "Of Patents and Path Dependency: A Comment on Burk and Lemley", *Berkeley Technology Law Journal* 18 (2004), p. 1341.

The classic case of such incremental development specific to a technology is the use of the patent offices' considerable experience with chemical compounds as an analogy to characterize biotechnological inventions which turned out to be problematic in many ways.[38] More recently, when the EPO had to consider what the scope of the exclusion of "animal varieties" from patentability should be for the first time, it immediately referred to the familiar regime for protection of plant varieties. Plant varieties are protected by another form of industrial property right called plant variety rights[39] (PVR), as well as patent protection of limited scope. The existence of such additional protection for plant varieties and the lack of it for animal varieties led the EPO to interpret the exclusion narrowly to make up for the lack of parity in protection. This is an example of incremental adaptive change that characterizes vast tracts of the patent system.

Technologically specific interpretations may not be a problem except that fact-based and case-based interpretations tend to get converted into long-term doctrinal rules. The technical terminology and approaches to interpretation make patent law an unusual branch of legal interpretation where technology-specific applications of the rules tends to "stick", often due to institutional dynamics, rather than substantive merit.[40] As per the reasoning in the US case *Re Deuel*,[41] a novel chemical is non obvious if there is no structurally similar compounds in the prior art. Proteins are not structurally similar to the DNA molecules. The fact that a person skilled in the art could have used known methods to isolate the DNA sequence from amino acid sequence was, according to the court, irrelevant to the enquiry of whether the DNA sequences themselves were non obvious.[42] This interpretation leaves the notional standard of "the person skilled in the art" contemplating the gap between scientific possibilities and legal improbabilities.

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38 See S.A. Bent et al., *Intellectual Property Rights in Biotechnology Worldwide* (New York: Stockton Press, 1987), pp. 6–12 for a detailed discussion.

39 See M. Llewellyn, "From Outmoded Impediment to Global Player: The Evolution of Plant Variety Rights", in R.C.D. Vaver, L. Bentley (eds), *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish* (Cambridge: Cambridge University Press, 2004).

40 Polk Wagner argues that technological specificity is not a problem because the patent system is not path dependent, so any "errors" in interpretation of application of the rules will be gradually set right by the system. However he ignores the "stickiness" in the patent system created by institutional dynamics. P. Wagner, "Of Patents and Path Dependency: A Comment on Burk and Lemley", p. 1341.

41 51 F 3d. 1552 (Fed. Cir., 1995).

42 "Unfortunately the reasoning in *Deuel* leaves a biotechnologist of ordinary skill in the art in an awkward position. On the one hand, based on prior art knowledge, the biotechnologist knows that sequencing around twenty amino acids is sufficient to obtain the cDNA sequence that codes for a particular protein, absent unforeseen difficulties. On the other hand, under current law, the expected product of this scientifically obvious manipulation is legally unobvious and thus patentable. Such a convoluted result is unsettling". A. Varma, D. Abraham, "DNA is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market", *Harvard Journal of Law and Technology* 9(53) (1996), p. 78.

Remarkably, this interpretation has sustained in the 2001 Utility Examination Guidelines[43] despite the well-recognized rift in scientific and legal perception. The Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation of the U.S. National Research Council makes a telling observation on the institutional nurture of this outcome. "[b]ecause it makes it easy for patent applicants to get past the nonobviousness hurdle, they have no incentive to challenge the rule, and after being repeatedly reversed on this point, the USPTO seems to have little interest in raising it again, even though advances in the art may culminate in a different result".[44]

In contrast to other bodies that make decisions involving scientific advancements, including courts, the patent office has no recourse to the judgment of contemporaneously active technological practitioners. This sort of disinterested input in the early stages of patent application examination could take the form of a "peer review" model. Such a step would, particularly for applications that herald new subject matter, help to avoid errors.[45] In the absence of any technical input, patent offices often mimic the practice of patent offices in other countries in particularly difficult areas. Such close associations can lead to proliferation of "similar" standards or convergence,[46] even though this in itself does not guarantee accuracy or optimal standards of patentability. One may characterize such convergence in a number of ways – as a preoccupation with legitimacy or as an inevitable part of risk-averse human behavior on the part of patent examiners.

Convergence is a more contained phenomenon than harmonization[47] and recently has been engineered primarily by domestic patent offices including those in the U.S., Europe and Japan.[48] To illustrate, in direct response to concerns that overly broad patent scope in genetics threatened future innovation, the USPTO in 2001 issued new

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43 66 Fed. Reg. at 1095 (Jan. 5, 2001). The Guidelines cite *In re Deuel* and state "As the non obviousness requirement has been interpreted by the US Court of Appeals for the Federal Circuit, whether a claimed DNA molecule would have been obvious depends on whether a molecule having the particular *structure* (emphasis added) of the DNA would have been obvious to one of ordinary skill in the art at the time the invention was made".

44 Committee on Intellectual Property Rights in Genomic and Protein Research Innovation, National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation and Public Health* (National Academies Press, 2006), p. 70. Interestingly, even this restrictive approach to structural obviousness in the Utility Examination Guidelines is likely to lead to rejections as more DNA sequences become available on public databases.

45 See R. Eisenberg, "Obvious to Whom? Evaluating Inventions from the Perspective of PHOSITA", *Berkeley Tech Law Journal* 19(885) (2004).

46 Harmonization allows for a certain degree of competition within common standards, while convergence indicates movement towards identical standards. Some commentators use the terms interchangeably. See, for example, in J. Hughes, "Political Economies of Harmonisation: Database Protection and Information Patents", *Cardozo Law School Burns Institute for Advanced Legal Studies, Research Paper Series* No. 47 (2002).

47 The international harmonization of intellectual property standards is not new or restricted to a post TRIPs world. See Hughes, ibid., pp. 7–8.

48 See the "Trilateral Project" website, available at http://www.uspto.gov/web/tws/sr-3-b3b-ad.htm.

guidelines for the utility requirement.[49] The Guidelines represent the understanding of the USPTO and are important tools in planning patent applications and litigation of genetic patent cases. A year after the Guidelines were issued a decision by the EPO opposition division[50] adopted the standard used in the 2001 Utility Examination Guidelines of the USPTO, namely the "specific, credible and substantial" (SSC) standard.

The standard was adopted on the basis of implicit assumptions about similarities between interpretation of "utility" under U.S. patent law and the understanding of "industrial applicability" under the EPC. Although both criteria in the different legal systems incorporate an idea of "use" of the invention, it was commonly understood prior to this decision that the emphasis on "use" was in the U.S. and in Europe.[51] There are specific institutional reasons for such remarkable convergence including institutionalized "cooperation" between European, Japanese and U.S. patent offices to explicitly enhance the mutuality of standards of search and examination of biotechnology patents.[52] Such accelerated transformation of patentability standards can have unsettling systemic effects and should ideally be preceded by a thorough exploration of the implications.

Courts

Specialist courts

Patent courts more than others often have their own, sometimes unusual, trajectories of development because of the specialist nature of the subject matter and the increasing court space given to intellectual property litigation. The United States Court of Appeals for the Federal Circuit (CAFC), for example, occupies a unique role as an appellate body jurisdictionally demarcated by subject matter rather than by geography. The specialist nature of such courts has a number of implications for the general expansion in patent rights.

Many have noted and analyzed the "pro patent attitude" of the CAFC which, according to Landes and Posner, is to be expected as "a patent court is more likely to take the pro-patent side…simply because a court that is focused on a particular government program, like an administrative agency (invariably specialized), is more likely than a generalist court to identify with the statutory scheme that it is charged

49 Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

50 *ICOS/seven transmembrane receptor* OJEPO 2002, 293. The patent was revoked in the proceedings on the grounds that the disclosure of a *predicted* function of a protein is not adequate disclosure of the function of the protein.

51 See M. Llewelyn, "Industrial Applicability/Utility and Genetic Engineering: Current Practices in Europe and the United States", *EIPR* 11(473) (1994), p. 474.

52 Such projects have resulted in a comparison of biotechnology patent application examination procedures. See M. Hewlett, A. Christie, "An Analysis of the Approach of the European, Japanese, and United States Patent Offices to Patenting Partial DNA Sequences (ESTs)", *IIC* 34(6) (2003), pp. 581–710.

with administering",[53] In the U.S., the creation of the court seems to have had a positive and significant impact on the number of patent applications, the number of patents issued, the success rate of patent applications and the amount of patent litigation, but all of these have not necessarily had a positive effect on technological progress.[54] They note that what has also increased is the demand for patent lawyer services. Given that the patent bar had pushed strongly for the creation of the court, the authors conclude that

> the creation of the court, whose specialized character and resulting 'mission' orientation enabled a prediction that it would favor patents more than generalist federal appellate courts, may thus have been a consequence largely of interest group politics.[55]

So are specialist patent courts a boon or a burden? The basic premise behind establishing the appeals court distinct from the twelve regional circuits, each of which has a United States Court of Appeals, was that centralization of authority would lead to clearer, more predictable patent law. A recent study indicates, however, that whether or not the court is fulfilling its mandate is a question that remains remarkably open.[56] In this context it is worth comparing two decisions on the OncoMouse laboratory mouse (also known as the Harvard mouse), one given by the Technical Board of Appeal at the EPO,[57] which may be regarded as a specialist court for, *inter alia*, its Article 99 EPC jurisdiction[58] and the decision given by the Supreme Court of Canada.[59]

Although based on very different statutory wording, the EPO in its decision focused on a literal application of the law to evaluate whether the "invention" of genetically modified rodents was patentable. To evaluate whether the exploitation or publication of this invention "would be contrary to ordre public or morality",[60] the EPO adopted a balancing test to see whether the animal suffering in this case was balanced by evidence of substantial medical benefit. The EPO cut down the scope of

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53 W.M. Landes, R.A. Posner, "An Empirical Analysis of the Patent Court", 71 *University of Chicago Law Review* 111 (2004), p. 112.

54 See Landes, Posner, *The Political Economy of Intellectual Property Law* (Washington, 2004), pp. 26–27, available at http://www.aei.brookings.org/admin/authorpdfs/page.php?id=985.

55 Landes, Posner, "An Empirical Analysis of the Patent Court", p. 27.

56 Wagner and Petherbridge do not suggest that the court is an unqualified success in bringing additional consistency, uniformity or predictability to patent law, although the results suggest that the institutional picture of the court is one of broad transition and movement in the right direction. P. Wagner, L. Petherbridge, "Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance", 152 *University of Pennsylvania Law Review* 1105, p. 1111.

57 T 0315/03 Transgenic animals/HARVARD (July 6, 2004).

58 Article 99 of the EPC allows for "any person" to file an "Opposition" to any patent within nine months of its grant. Most of the ethically controversial biotechnology patents were subject to a number of "Oppositions" under this rule. If convinced, the EPO can revoke a patent it has already granted.

59 *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 SCR 45.

60 Article 53(a), EPC.

the patent from transgenic rodents to transgenic mice, on the grounds that there was no correspondence between animal suffering for all rodents, including squirrels and porcupines that may be so genetically modified, and substantial medical benefit that was only established in the case of mice. In contrast to this formal and tunnel vision, the Supreme Court of Canada, a generalist appellate court, embarked on a broad and eventful exploration of "inherent patentability" concluding that higher animals cannot be classified as a "method of manufacture" or "composition of matter" although this may apply to micro-organisms. Calling on Parliament to intervene, the Court gave a decision that was purposive in its approach to the law. Although it would not be prudent to draw a conclusion about the merits and demerits of specialist courts based on this one example, the scope of the Canadian decision is illustrative of the standing of higher generalist courts.

There are other peculiarities that are relevant for an institutional appraisal of specialist courts. For example, the apparent uniformity of technological views in a difficult area like biotechnology may be illusory because of the small number of judges who decide these cases.[61] In the U.S., a single federal judge, Judge Lourie, authors most of the cases identified by commentators as relevant to the technological issues for biotechnology inventions in the U.S.[62] Patent matters in the U.K. High Court, much like in U.S. federal cases, are heard by a limited number of judges. Justice Laddie, until he stepped down in early 2005, Justice Pumfrey and more recently, Justice Kitchin[63] preside over patent matters. The association of patent matters with a limited number of senior judges at the court of appeals is very significant as the House of Lords rarely hears patent cases.[64]

Awareness of the strengths and limitations of specialist patent courts and the composition of generalist appellate courts with jurisdiction over patent matters is likely to be of increasing importance in the future, particularly internationally. For those who would like to see the spread of intellectual property legislation, *convergence* in judicial practice is as important, as is getting appropriate legislation drafted under the TRIPS agreement in place. The World Intellectual Property Organization (WIPO) and the EPO sponsor parties of judges, or about-to-be-judges, from various countries of the undeveloped or semi-developed world to go on tours to see how western countries' judicial systems operate, with a view to implementing

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61 See P. Wagner "(Mostly) Against Exceptionalism", *Public Law Research Paper* No. 7 (Philadelphia: University of Pennsylvania Law School), p. 5.

62 Wagner, Petherbridge, "Is the Federal Circuit Succeeding? An Empirical Assessment of Judicial Performance", pp. 1117–1118.

63 The U.K. patent office often consults "patent judges" in the context of proposed legislative or procedural amendments; it is notable that only three judges, Justices Laddie, and Pumfrey and Lord Justice Jacob, appear to have responded. For example, see patent office consultation on "Should Patents be Granted for Computer Software or Ways of Doing Business?", http://www.patent.gov.uk/about/consultations/responses/comsoft/gtom/

64 This is generally true, although in the two years three important appeals made their way to the House of Lords; *Kirin Amgen Inc and Others v. Hoechst Marion Roussel Ltd and Others*, [2004] UKHL 46, *Sabaf SpA v. MFI Furniture Centres Ltd and Others*, [2004] UKHL 45, *Synthon BV v. Smithkline Beecham plc*, [2005] UKHL 59.

TRIPS in their own countries. This is part of the spate of initiatives on the part of WIPO to bring greater substantive harmonization between countries' patent laws.

Advocates of judicial convergence are supported by the idea of a "global patent system" which, as an idea, is underpinned by two main substantive arguments: first, that the sophistication of technological achievements make it impossible for small patent offices in developing countries to examine patent applications effectively,[65] and second, that there is already a significant level of sharing of the results of substantive examination. In this context the tendency of the harmonization efforts is to gravitate towards the procedures and methodologies of the patent offices and courts in developed countries. This of course begs the question of whether such entities function in a manner that lends methodological, substantive and normative credibility to the patent system.[66] Reconsideration of the institutional design of the patent system anywhere in the world should incorporate a more sophisticated understanding of the unintended consequences of current specialist courts, and the advantages of the appellate authority of higher non-specialist courts.

Research funding bodies

Political and legislative opinion in Europe identifies the biotechnology sector as one of dynamic growth and potential for Europe.[67] Yet in Europe the industry lags behind the U.S. in significant ways.[68] Many different variables make up a more supportive institutional arrangement in the U.S.[69] Since access to finance is crucial for innovation in biotechnology, what power if any, do public agencies that give grants for research and development have on patent protection?[70] It is submitted

65 Lord Justice Robin Jacob of the U.K. Court of Appeals questions the possibility of countries with limited scientific resources setting up an "effective" patents court, suggesting that if TRIPS is to be implemented, some sort of international resolution of patent litigation would have to be devised. R. Jacob, "Intellectual Property in the New Millennium", available at http://www.law.ed.ac.uk/script/newscript/noframes/nfonline.htm.

66 See B. Dhar, "Will Global Patent Courts Work?", *Economic Times*, March 23, 2004. Available at http://economictimes.indiatimes.com/articleshow/575999.cms.

67 Opinion of the advocate general in *Kingdom of the Netherlands v. European Parliament and the Council of the European Union*, C-377/98 (2001). Also see European Commission Green Paper COM (95) 688 Final, and the Recitals of the Directive for the Legal Protection of Biotechnological Inventions 98/44/EC (hereafter Directive).

68 The turnover of the biotechnology industry in U.S. is double that of European industry (31,808 million euros compared to 15,327): Ernst and Young, *Beyond Borders: The Global Biotechnology Report*, 2002.

69 The greater availability of venture capital is noteworthy. Pisano, Mang, "Collaborative Product Development and the Market for Know How: Strategies and Structure in the Biotechnology Industry", in Burgelman, Rosenbloom (eds), *Research on Technological Innovation, Research and Policy* (Greenwich: JAI Press, 1993), pp. 109–120.

70 Public funding of research is particularly significant in the context of biotechnology due to the research-intensive nature of the industry. See Kroll et al., "Tracing the Influence of Basic Scientific Research on Biotechnology Patents: A Case Study of Signal Transduction and Transcriptional Regulation (STTR)", *Patent World*, March 1998, pp. 38–46.

here that strong, centrally positioned research funding bodies have expanded the institutional cluster of the patent system and added to our repertoire of tools when dealing with patentability and patent exploitation in a manner that is significant for social optimality.

The NIH is part of the U.S. Department of Health and Human Services, and is the primary federal agency for conducting and supporting medical research. More than 80% of the NIH's annual $28 billion budget for medical research is awarded through almost 50,000 competitive grants to researchers at over 2,800 universities, medical schools and other research institutions in the U.S. and abroad.[71] NIH funding has doubled since 1992, a growth that exceeds inflation.[72] In contrast, and as highlighted by the Lambert review, in 1981 the U.K.'s total spending on research and development as a proportion of its gross domestic product in 1999 was lagging behind Germany, the U.S., France and Japan and only just keeping pace with Canada.[73] In the U.K., public funding for basic research is channeled through seven different U.K.-wide research councils, in addition to the charity sector led by the Wellcome Trust. Generally, universities own intellectual property that arises out of public funding that is channeled through a peer review process.

A strong single research council that has some ability to specify how public money should be used in exploiting research results can modify patenting behavior among a large population of scientists. The presence of federal agencies like the National Institutes of Health (NIH) and National Science Foundation that fund research in American universities, and the absence of a corresponding central agency in the U.K. is therefore highly significant. Even in the European Union there is no entity with comparable clout to the NIH. Currently, the European Commission is in the process of setting up a European Research Council to manage a research fund for European universities and research institutes. This is expressly fuelled by concern that the funding for basic research in Europe is far from optimal.[74] Plans for this council include complementing or even replacing national funding mechanisms.[75] Whether it can evolve into a sophisticated "norm-setting" institution like the NIH remains to be seen.

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71 http://www.nih.gov/about/NIHoverview.html.

72 See presentation to the Association for Independent Research Institutions 2003 at http://www.grants.nih.gov/grants/award/awardtr.htm.

73 Lambert Review on Business-University collaboration, December 2003 (www.lambertreview.org.uk), p. 3 (hereafter Lambert Review).

74 As per the Lisbon Declaration of March 2000 and the Barcelona Summit of March 2002, that aim is for Europe to become the most competitive and dynamic knowledge-based economy by 2010. See http://europa.eu.int/comm/research/press/2004/pr1803en.cfm. According to one leading scientist the possibility of meeting the 2010 goal and surpassing the U.S. in research funding did not amount to "a snowball's chance in hell". R.M. May, "Raising Europe's Game: How to Create a Research Council that is a Champion's League for Science", *Nature* 430 (2004), pp. 831–832.

75 *European Research Council: A Cornerstone in the European Research Area.* Final report of the European Research Council Expert Group, December 2003, Annex 1, Explanatory Comments. Available at http://www.ercexpertgroup.org/finalreport.asp.

Promoting the institutional goals of science

The economic structure of research has undoubtedly changed considerably in the U.S., owing significantly to the explicit U.S. policy of allowing grantees to seek patent rights in government-sponsored research results. The policy, codified during the 1980s with the passage of the Bayh Dole Act[76] and the Stevenson Wydler Act,[77] has made universities keen players in the patenting arena. Concern about this issue has also been expressed in the U.K., even in the absence of a specific policy similar to that of the U.S.. The Royal Society observed that, although patenting rarely delays publication significantly, it could encourage a climate of secrecy that does limit the free flow of ideas and information that are vital for successful science.[78] Both in the U.S. and the U.K., academic norms of sharing and building on each others' work has, according to many observers, been replaced with territorial behavior that threatens to deplete the common pool of knowledge essential for further innovations.[79]

Institutional economics prominently includes an analysis of formal and informal norms as part of the constraints that shape human behavior.[80] Norms are distinct from legal rules, the violation of which is typically punished by private actors.[81] The NIH's power to set formal and informal rules backed by law is, from this perspective, of critical importance to maintain and where necessary, reform norms of behavior

76 35 U.S.C. 200–212 (1994). The policy has a number of converging goals including saving federally funded research from "publication oblivion". See R. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government Sponsored Research", *Virginia Law Review* 82(1663) (1996), pp. 1664–1665. See also P. Mikhail, "*Hopkins v. CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is not Always in the Public Interest", *Harvard Journal of Law and Technology* 13(375) (for a critique of the policy with specific reference to biology).

77 Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. 3701–3714.

78 The Royal Society, *Keeping Science Open: The Effects of Intellectual Property Policy on the Conduct of Science*, April 2003. Also see *Annual Survey on University Technology Transfer Activities, Financial Year 2002* (Nottingham: Nottingham University Business School, 2003).

79 A. Kaur Rai, "Regulating Scientific Research: Intellectual Property Rights and the Norms of Science", *North Western University Law Review* 94(77) (1999). Also see R.S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research", *Yale Law Journal* 97(177) (1987); R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review* 56(1017) (1989); but see S. Kieff, "Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg", *Northwestern University Law Review* 95(691) (2000).

80 D.C. North, *Institutions, Institutional Change and Economic Performance* (1990).

81 The "law and norms" theory is part of legal scholarship where moral persuasion may be more effective than legal authority such as in international law and "cyber-governance". But in the final analysis Internet norms generally rely on supreme legal authority, initial property entitlements and contractual arrangements that govern the net. See M. Lemley, "The Law and Economics of Internet Norms", *Chicago-Kent Law Review* 73 (1989), pp. 1257–1294. Similarly, the NIH is a governmental body backed ultimately by the law.

within academic institutions.[82] The NIH's exercise of its institutional capacity by way of intramural regulations on access to research tools to ensure that the institutional goals of science are met is an interesting case in point.

Access to patented research tools is a significant problem resulting from the science-based nature of biotechnology.[83] In the U.S., research tools developed using federal government funds present a unique problem. In 1997, the NIH convened a working group to study access to unique research platforms that concluded that access to research tools was severely constricted and suggested regulating NIH grant recipients.[84] The working group explored ways of including wide dissemination of research tools developed with federal money as preconditions of funding. From October 2004, the NIH requires grant applicants to include a specific plan for sharing of model organisms and other materials[85] that result from funded research. Applicants' track record of sharing will be taken into account when their grants are up for renewal. The application for funds, as per the new policy, should also include a sharing plan on how intellectual property rights will be exercised while making the research resources available to the broader scientific community.[86]

These guidelines hit squarely at the inherent tension between the NIH, which seeks to maximize the impact of the research it supports, and universities that are entitled to patent and profit from inventions made with government money. NIH policies clearly have the potential to modify behavior, including the post-grant enforcement of patent rights, as non-compliance may result in loss of funding.[87] Putting pressure on patent holders funded by the NIH to share the outcome of publicly funded research also has the potential to rectify the weakening of the experimental use exemption in U.S. patent doctrine.[88] This institutional picture is significant as it shows relocation

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82 See Robert Merton's work in identifying the overriding institutional goals of science. R. Merton, "The Puritan Spur to Science" in *The Sociology of Science* (Chicago: University of Chicago Press, 1973), pp. 228–253, cited in R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research", *Yale Law Journal* 97(177) (1987), pp 182–183.

83 For a succinct description of the problem see Cornish, Llewellyn (eds), *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (London: Sweet & Maxwell, 2003), pp. 842–843.

84 Report of the National Institutes of Health (NIH) Working Group on Research Tools (June 4, 1998), http://www.nih.gov/news/researchtools/.

85 Termed in general as "biomedical research resources". See NIH Policy on the Sharing of Model Organisms for Biomedical Research, May 7, 2004, available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html.

86 The new policy was enforced by the NIH in making stem cells produced by the Wisconsin Alumni Research Foundation (WARF) using NIH funds available for academic research. For more information see http://www.nih.gov/news/stemcell/WicellMOU.pdf.

87 See C. Jennings, "Universities Unnerved by Revised Rules for Sharing NIH Research", *Nature* 430 (2004), p. 953. Realistically however it is likely to be a last resort. Ruiz Bravo of the NIH is quoted as saying "We don't want to use a hammer to swat flies". See also "Share Issues", *Nature* 430 (2004), p. 951.

88 A recent comprehensive paper by Mathew Rimmer uses a comparative approach to study the research use exemption and concludes that it is imperative that the narrow U.S. law does not become the international standard. M. Rimmer, *The Freedom to Tinker: Patent Law and Experimental Use*, Expert Opinion (London: Ashley Publications, 2005).

or sharing of responsibility to maintain the science base of technology between the courts (in the U.S., the research exemption is judge-determined)[89] and the executive arm of the government.

Meeting public interest needs

The Bayh Dole Act also includes certain provisions to protect the public interest. One such, called "march in" rights, allows for mandatory licensing of patents under certain conditions.[90] Among other reasons, the NIH can exercise "march in" if the contractor or assignee has not taken, or is not expected to take within reasonable time, effective steps to achieve practical application of the subject invention. It can also be exercised to alleviate health and safety needs which are not reasonably satisfied by the contractor, assignee or their licensees.[91] This power is not used often. The following case illustrates the dynamic created by this power between courts, inventors and the NIH.

CellPro appealed to the NIH's "march in" power to obtain a mandatory license to practice stem cell separation technology that was invented by a researcher at Johns Hopkins University under a grant from the NIH.[92] CellPro failed to obtain a license from Johns Hopkins and its sublicensee, Baxter Healthcare Corporation, and was subsequently found by the CAFC to be in willful infringement of the patents.[93] However, Cellpro was not required to immediately cease marketing its device. The CAFC allowed it to make, use and sell the device as until such time as an alternative device was approved for therapeutic use in the United States.

Sometime before their appeal to the federal circuit, CellPro complained to the NIH that allowing Johns Hopkins and Baxter to enforce their full patent rights and exclude CellPro from making, using or selling its cancer treatment device would create a public health need.[94] After a fact-finding enquiry, the NIH decision was made a few days after the federal circuit court's determination. The NIH refused to exercise

89 Under U.S. law, the extremely narrow scope of the exemption was clarified in *Madey v. Duke University* 307 F. 3d 1351 (Fed. Cir., 2002) with the effect that the exception is confined to private study and may not include even un-sponsored university research. In the U.K. the statutory research exemption has a closed definition that on the one hand provides certainty to users but on the other hand can be too inflexible. It does not apply to the use of research tools as methods or subjects for further investigation, for example. *Monsanto v. Stauffer*, [1985] RPC 515. Furthermore the EPC in this context is interpreted differently in different countries. Cornish (1998), 29 IIC 735.

90 35 U.S.C., s. 203(1) authorizes a federal agency in limited circumstances to ensure that a federally funded invention is available to the public.

91 35 U.S.C., s. 203(1)(a)–(b) (1994).

92 The technology involved a method of purifying stem cells and had potential application in the treatment of cancer. CellPro had obtained regulatory approval to use a device incorporating an associated technique before John Hopkins or Baxter Healthcare.

93 *Johns Hopkins Univ. v. CellPro, Inc.*, 931 F. Supp. 303 (D. Del. 1996).

94 H. Varmus, Office of the Director, *Determination in the Case of Petition of CellPro, Inc., Aug. 1, 1997* (National Institutes of Health), available at http://www.nih.gov/news/pr/aug97/nihb-01.htm.

"march in" rights as Hopkins and Baxter had already produced another device that was awaiting regulatory approval. The NIH in its determination concluded that "it would be inappropriate for the NIH, a public health agency, to exercise its authority under the Bayh-Dole Act to procure for CellPro more favorable commercial terms than it can otherwise obtain from the Court or from the patent owners. CellPro's commercial viability is best left to CellPro's management and the marketplace".[95]

In this case NIH's determination was directly complementary to the federal circuit court's decision to allow CellPro to continue to market its device. If the court had not filled the gap that would have been created by a full exercise of the Baxter patent, the NIH determination may well have gone the other way.[96] Tempering the exclusive rights of the patent holder in the public interest is an equitable measure that can also be taken by the courts.[97] However, given the recent patent friendly posture of the Federal Circuit Court,[98] NIH power to temper the exercise of patent rights over inventions made with public money is significant. Not unlike the specter of compulsory licensing, the real power of "march in" rights may reside in deterrence rather than actual use.[99] Additionally, under U.S. law, the patentee's absolute right to exclude is subject to the government's power of eminent domain that can be exercised by the NIH.[100]

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95 Ibid., p. 8.

96 For a criticism of the NIH determination see P. Mikhail, "*Hopkins v. CellPro*: An Illustration that Patenting and Exclusive Licensing of Fundamental Science is not Always in the Public Interest". The author believes that the NIH feared the chilling effect of "march in" rights on future investment and erred on the side of caution.

97 In the U.S. there is dated precedent for not enforcing full patent rights when the public interest is at stake.

Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation, 146 F.2d 941 (9th Cir., 1944) (discussing suppression of patents against the public interest, in this case, in connection with a patent for irradiated margarine used to treat rickets); *City of Milwaukee v. Activated Sludge*, 69 F.2d 577, 592–93 (7th Cir., 1934) (denying injunctive relief when the requested relief would have closed the city's sewage treatment plant thereby causing public health concerns). Also see B. Mcgarey, A. Levey, "Patents, Products and Public Health: An Analysis of the Cellpro March In Petition", *Berkeley Technology Law Journal* 14(1095), p. 1107.

98 Studies have linked an upsurge in patenting in the U.S. to the so-called "Patent Friendly Court Hypothesis". See J.L. Turner, "In Defence of the Patent Friendly Court Hypothesis", available via http://ssrn.com/abstract=713601 (April 2005).

99 Article 31 of the TRIPS Agreement allows for compulsory licensing in certain specified circumstances.

100 28 USCA §1498 (West Supp., 2001); and Exec order no. 10, 789, 3 CFR 426 (1954–1958 Comp). K. Murashige, "Patents and Research – An Uneasy Alliance", *Academic Medicine* 77(12) (2002), pp. 1329–1338, p. 1331 (arguing for a change to the patentees absolute power to exclude in the context of access to research tools). For an early case that applies the doctrine of eminent domain to patents in the U.S., see *Crozier v. Fried Krupp Aktiengesellschaft*, 224 US 290 (1912).

Conclusion

Bioethical decision-making is a subset of the general method of change and transition in the patent system. Legal change in the patent system has been greatly compressed, and the conventional stages of transition by which new technologies are accommodated have in some cases been bypassed altogether.[101] Hence it is even more important that we understand the institutional nature of the patent system and study the inertias, the competencies, and the dynamics within the system that thwart debate on the social optimality of patenting certain kinds of subject matter.

Complex institutional relationships within the patent system make it difficult to implement changes to patentability rules and doctrine that are not directly related to or adapted from past experience. There are at least three conclusions that can be drawn from the discussion here. Firstly, the present nature of patent offices and specialist courts clearly indicate an institutional trend towards expansive patent rights. Thus, successful objections to the social optimality of a certain class of inventions, including bioethical implications, will have to surmount the institutional dynamics in addition to the substantive and often formal legal requirements. Secondly, norm-setting mechanisms backed by law can provide a more comprehensive intellectual position than what is currently possible among patent offices and courts. Thirdly, the incremental advance of the rules react uneasily to "policy overhaul" type of arguments[102] that are often required when debating ethical implications of unprecedented subject matter as in the case of biological material in the early years of the biotechnology revolution. The long-term projection of this process of change is further complicated by institutional "stickiness" that can make it hard to reverse undesirable or simply inaccurate interpretations of the rules.

The virtual inevitability of incrementalism may come as a disappointment to some idealists. However the appeal of incrementalism in policy formulation in general and in the patent system in particular is high because "overhaul" type of reform introduces formidable legal and political risk. "Satisficing",[103] rather than

101 R. Merges, "One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000", *California Law Review* 88(2187) (2000).

102 Often incrementalism or "muddling through" is portrayed as antithetical to the rational comprehensive model which might be an overly rigid of looking at it. Charles Lindbloom depicted the two as mutually exclusive. Regarding the rational comprehensive or "root" method he observed "starting from the fundamentals anew each time, building on the past only as experience is embodied in theory, and always prepared to start completely from the ground up". The branch in comparison "continually building out form the current situation, step by step in small degrees". C. Lindbloom, "The Science of Muddling Through", *Public Administration Review* 19 (1959), pp. 79–88.

103 "Satisficing" is the strategy of choosing the first reasonable option – this may not always be the best option, but it maybe the best strategy given that unlimited resources maybe required to search for the elusive "best" option. Overwhelmed by the complexity of the problems they confront, decision makers lean heavily on pre-existing policy frameworks, adjusting only at the margins to accommodate distinctive features of a new situation.

goal maximizing, is the preferred criterion and slight improvement compared to past performance is favored.[104]

Prof. Cornish notes that

> inevitably, patent systems have been shaped over time by the technologies for which their aid has been sought. In large measure this impact on the system has been interstitial, a matter of remark only to its specialists'.…Judges and patent offices have accepted a variety of stratagems, which only patent specialists comprehend; *they,* of course come soon enough to believe in the devices as necessary categories of thought. It is from these strange games that much of the new upset about biotechnology patents originates.[105]

Incremental tweaks here and there conclusively shape the patent system, often leading to a case of the tail wagging the dog.

104 See W. Hayes, "Policy Formulation: An Introduction", The Public Policy Web http://www.geocities.com/~profwork/pp/formulate/.

105 W. Cornish, *Intellectual Property: Omnipresent, Distracting, Irrelevant,* Clarendon Law Lectures (Oxford: Oxford University Press, 2004), pp. 10–12.

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Chapter 14

Why People Give Information Freely: Internet Architecture and the Rebirth of Folkloric Culture

John Cahir

Introduction

The fact that people freely donate information in the Internet environment is one of the most fascinating features of cyberspace. The emergence of an "information commons" in the Internet environment contradicts predictions that law and technology would combine to create a "second enclosure movement"[1] while also raising interesting questions as to nature of and rationale for intellectual property rights.[2] Well-known examples of the phenomenon include the Open Source Software (OSS) movement,[3] the Wikipedia encyclopedia project[4] and the various open access academic journals.[5] In truth, the Internet information commons covers all those instances where persons create and make information available without restriction for access and use by others.

This chapter seeks to identify the reasons why people give freely to the information commons, and explains in particular why the Internet's communicative architecture is a significant causal factor behind the emergence of the phenomenon. The information commons has sparked considerable interest across a number of different academic disciplines including economics, sociology and computer science. In this chapter, I show that, while explanations from these disciplines may each

1 J. Boyle, "The Second Enclosure Movement and the Construction of the Public Domain", *Current Legal Problems* 33(66) (2003).

2 J. Cahir, "The Withering Away of Property: The Rise of the Internet Information Commons", *Oxford Journal of Legal Studies* 24(4) (2004), p. 619.

3 OSS is computer software that is produced by volunteers and distributed on a non-commercial basis The explosion in OSS projects has paralleled the Internet's own growth; see K. Healy, A. Schussman, "The Ecology of Open Source" (working paper, April 25, 2003), available at: http://www.u.arizona.edu/~kjhealy/drafts.php3.

4 Wikipedia is a volunteer produced free online encyclopedia containing (as of May 2007) over 5,300,000 individual articles: http://wikipedia.org.

5 Open access initiatives for academic journals include the Public Library of Science project (http://www.publiclibraryofscience.org) and the NAJ economics journal (http://najecon.org). Lund University Library hosts a directory of open access academic journals: http://www.doaj.org.

offer many interesting insights, they fail individually to capture the whole picture. So as to remedy the situation, a complete explanatory framework is offered. The chapter argues that the Internet's communicative architecture is a key causal factor contributing to the emergence of the information commons because its decentralized structure facilitates the unleashing of material and social forces, which had no equivalent facility in pre-Internet mass media. I conclude by comparing culture in the Internet information commons to culture in folklore-based societies.

Outline of the explanatory framework

This chapter attempts to answer a difficult question: why has the information commons come about? In order to answer that question, it is first necessary to identify the type of social phenomenon with which we are dealing. The most incontrovertible statement that one can make is that, in order to come into existence, the information commons requires that an individual or group engage in productive activity that leads to the creation of an informational object. We are therefore first and foremost discussing a *productive phenomenon*. This section, by drawing on the existing literature in this field, will attempt to put forward a comprehensive theoretical framework for explaining why individuals and groups engage in this type of productive activity.

Before proceeding with this inquiry, a distinction between two separate issues will be made. This chapter addresses one question: why has the information commons come about? A closely related, though distinct, question is: how does it come about? The latter question requires one to analyze the *process* of commons-based information production, whereas the former requires one to identify the *a priori* conditions that facilitate the process coming into being. The latter question entails, *inter alia*, analyzing the way in which unpaid volunteers co-ordinate their actions when creating a complex product like the Linux operating system. It examines the role of decentralized organizational structures and when or whether hierarchical commands are needed. The organizational literature has already recognized the process of commons-based production as a *sui generis* organizational phenomenon. This chapter will not deal in any detail with the question of organization.[6] It is accepted that it overlaps with the question of causation in some respects, but it is secondary to the overriding purpose of locating the Internet's communicative architecture within an explanatory framework.

The bulk of existing explanatory literature on the information commons focuses on one particular manifestation of the phenomenon – Open Source Software (OSS). The reason why OSS has attracted such abundant attention is because of the economic importance of its product and the conscious ideological orientation of some of its adherents.[7] The OSS movement has, by any standard, had some

6 Save for a brief explanation of how the Internet's communicative architecture has facilitated the co-ordination of volunteer production.

7 The acknowledged godfather of the OSS movement is the Free Software Foundation founder, Richard Stallman, a brilliant former MIT computer scientist. See S. Williams, *Free as in Freedom: Richard Stallman's Crusade for Free Software* (Sebastopol, CA: O'Reilly,

remarkable achievements. It has produced, *inter alia*, Linux, which has acquired 25% of the server operating system market; Apache, which has 65% of the web server market; and Sendmail, which routes at least 42% of all Internet mail.[8] Each of these complex software programs has been produced by unpaid volunteers and has matched, and often surpassed, the offerings of commercial software producers. This chapter maintains that OSS is but one aspect of a wider phenomenon. However, the theoretical explanations for its emergence (in general) apply equally to the entire field of informational objects that are in the information commons.

The OSS movement has recently inspired a flood of academic papers.[9] The hacker guru, Eric Raymond, presaged many of these academic contributions in two late 1990s articles published in the online magazine *First Monday*.[10] In "Cathedral and the Bazaar" he used the cathedral metaphor to refer to the organization of software production that takes place in a commercial software firm, and the bazaar metaphor to refer to the manner in which OSS is produced by volunteers. Cathedral building requires a centralized *a priori* approach involving commands by managers to workers. A bazaar is a decentralized "bottom-up" form of organization, in which self-selected volunteers, rather than a "top-down" management, determine the nature and direction of the productive enterprise.

Raymond hypothesized that the reason why the Linux operating system had proved to be such a success was because it was organized on the bazaar rather than the cathedral model. In "Homesteading the Noosphere" Raymond addressed the issue of why individual volunteers participate in OSS projects. He argued that a *de facto* gift culture existed in computer programming communities. Gift cultures tend to emerge in societies that do not have significant material scarcity problems, like the advanced industrial economies of the west. Under such conditions, one's social status is determined not by what one controls, but by what one gives away. In the computer programming community, the skilled programmer who contributes an especially useful piece of code to the common enterprise attains a higher social status within the community than the programmer who pursues personal aggrandizement. According to Raymond, a reputation game propels individuals to forego earning opportunities in favor of OSS participation.

Raymond's articles introduced some of the main puzzles about OSS that continue to trouble academic commentators. OSS has proved to be particularly perplexing for economists, as it seems to undermine their assumptions about rational choice. Sociologists in contrast are generally content with describing it in terms of gift

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2002) for a history of Stallman's role in the OSS movement and for an outline of his political/software philosophy.

8 Figures are from M. Osterloh, S. Rota, B. Kuster, "Open Source Software Production: Climbing on the Shoulders of Giants", (2002) available at: http://opensource.mit.edu/online_papers.php.

9 MIT hosts a large online database of academic papers on OSS: http://opensource.mit.edu/online_papers.php.

10 E. Raymond, "The Cathedral and the Bazaar", *First Monday* (1997), available at: http://www.firstmonday.org/issues/issue3_3/raymond/index.html; and E. Raymond, "Homesteading the Noosphere", *First Monday* (1997), available at: http://www.firstmonday.org/issues/issue3_10/raymond/index.html.

cultures and the like. What the existing literature lacks is an overarching explanatory framework for the existence of the phenomenon.[11] Economists and sociologists are at odds with each other in asserting the primacy of each other's discipline. I contend that no single causal factor can account for its existence, but that *it is the product of numerous different causal factors operating at different levels*. Accordingly, economic and organization theory and sociology jointly contribute to the explaining the existence of the information commons. The individual underlying causal factors, which in combination have given rise to OSS and other information commons manifestations, can be classified as falling within one of these three categories: (a) the individual level, (b) the social level and (c) the structural level. In order for a commons project to succeed there must, it is submitted, be a convergence of a sufficient and necessary number of causal factors at each of these levels.

The individual level

The individual level is concerned with identifying the personal reasons why any given individual is motivated to participate in an information commons project. Even if social structures are present that facilitate volunteerism, there must still be a sufficient number of individuals with the matching motivational drive. Economic theory assumes that individual human behavior is rational. We each have preferences and must order those preferences; in microeconomics it is assumed that in relation to economic decisions, individuals seek to maximize their own self-interest, which generally entails material wellbeing.[12] At first blush, the widespread volunteerism evinced by skilled computer programmers that participate in OSS and other commons projects seems to defy rational choice theory. It has led one author to suggest that non-material explanations for this type of activity are untenable.[13] Can the donative behavior of information producers be reconciled with economic theory?

There is no necessary contradiction between donative behavior and rational choice theory. Firstly, there is ample empirical evidence of volunteerism in the charitable and non-profit sectors of the economy. Economic theory does not deny the possibility that non-material motivations can attract people to the activities run by such organizations.[14] Secondly, studies by behavioral economists have shown

11 One partial attempt is S. Weber, "The Political Economy of Open Source", *Brie Working Paper* 140 (2000), available at: http://e-conomy.berkeley.edu/publications/wp/wp140.pdf. Weber stresses the distinction between the "set of microfoundations – the motivations of individual humans that choose freely to contribute – as well as on macrofoundations – social and collective structures that channel these contributions to a collective end." (p. 19).

12 R. Cooter, T. Ulen, *Law and Economics*, 3rd ed. (Boston, MA: Addison-Wesley, 1999), Chapter 1; and R. Posner, *Economic Analysis of Law*, 5th ed. (New York: Aspen Law, 1998), Chapter 1.

13 D. Lancashire, "Code Culture and Cash: The Fading Altruism of Open Source Development", *First Monday* (2001), http://www.firstmonday.dk/issues/issue6_12/lancashire/index.html.

14 H. Hansmann, "The Role of Non-profit Enterprise", *Yale Law Journal* 835 (1980).

that in practice it is rare for individuals to act wholly rationally.[15] There are a number of plausible cognitive explanations for why individuals often act non-rationally. Thirdly, it is possible to interpret individual reasons for participating in OSS projects as being guided by *indirect* self-interest. The computer programmer who contributes to a project with a view to enhancing his or her reputation in the paid-for job market can be said to fit this profile.[16]

The reason why many thousands of talented individuals are motivated to donate their time and skill to producing a product that benefits society at large is definitely a question deserving of an answer. As a matter of empirical truth, it cannot be denied that volunteerism is widespread in the computer programming community. It is futile, however, for classical economists to seek to explain their motivation by reference to material self-interest alone.[17] There are probably some individuals who participate for selfish reputational purposes; however, it seems unlikely that this reason alone accounts for all, or even a majority, of individual actors' reasons. In many respects it is best to view participation in information commons projects as a sphere of non-market productive activity. Many areas of social life, for example, family life and hobbies, by definition operate outside of the framework of strict economic rationality. When the social structures and culture exist to support these types of activity, standard rational considerations simply do not come into play. The reluctant father will play football with his son, even if his son does not offer any monetary benefit in exchange. The interesting feature about OSS development is that it represents a sphere of non-market production in a field in which state/market organized production has traditionally dominated. Economic history proves, however, that there are no fixed boundaries between what may be produced under the auspices of market and non-market organizational structures. If the market can subsume productive activities that were once performed outside of market structures (for example, the transition from home child rearing to paid-for crèche care), it is plausible that a reverse transition may also occur.

Economic theory is still of relevance because it reminds us that all individual and collaborative productive activity must have a microfoundational basis.[18] A more generous rational choice approach accepts that, given the appropriate social structure, a mix of both monetary and non-monetary motivations can account for individual decision-making. In this regard, a developing branch of economic

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15 See C. Sunstein (ed.) *Behavioural Law and Economics* (Cambridge: Cambridge University Press, 2000).

16 J. Lerner, J. Tirole, National Bureau of Economics, Working Paper (2000), available at: http://opensource.mit.edu/online_papers.php.

17 Some economists have already conceded this point: E. Franck, C. Jungwirth, "Reconciling Investors and Donators – The Governance Structure of Open Source", University of Zurich, Working Paper Series (2002), available at: http://opensource.mit.edu/online_papers.php.

18 Lerner, Tirole, *The Simple Economics of Open Source*, represent the individual decision to volunteer in an OSS project as a simple cost/benefit analysis, between on the one hand the programmer's psychological and material gains that arise from volunteerism (for example, creative pleasure, reputation enhancement) and, on the other, the opportunity costs associated with that activity.

literature recognizes the existence of both *extrinsic* and *intrinsic* motivations.[19] Extrinsic motivation refers to where productive activity is carried out in order to satisfy a desire that is not directly contingent on the particular productive activity itself. This type of motivation is obviously quite common and typically includes the situation where a person dislikes his or her job, but appreciates receiving a salary at the end of the month: the worker is motivated to work because of the promise of an extrinsic monetary reward. Given the necessity of money for non-subsistence material enjoyment, it is likely that most paid-for labor entails, to a greater or lesser extent, a measure of extrinsic motivation. When economists speak of rationality, it is this type of motivation that they have in mind. In information commons projects, the individual who participates in the expectation of a future indirect monetary benefit can be said to be extrinsically motivated. However, because the programmer's extrinsic motivation does not require payment for his or her contribution to the information commons project, it can be satisfied within its productive dynamic.[20]

Intrinsic motivation refers to where productive activity is carried out in order to satisfy an individual's immediate desires. Two subclasses of intrinsic motivation have been identified.[21] Firstly, *enjoyment-based* intrinsic motivation covers the pleasure-seeking activity of individuals. We normally associate this type of motivation with leisure time pursuits; however there is no reason why it could not also include activities that result in the production of socially useful informational objects. If we accept that intellectually challenging and creative activities have high felicific counts, it is reasonable to assume that intrinsic motivations will suffice for attracting volunteers to interesting information commons projects. Secondly, *obligation-based* intrinsic motivation covers the duty serving activities of individuals. The existence of this type of motivation is closely linked to the formation of social bonds (see next subpart). In other words, an obligation-based intrinsic motivation will generally only arise in a social context. A common example of this type of motivation is the sense of duty that motivates an offspring to voluntarily care for an ailing parent. In the context of information commons projects, this type of motivation can arise when the existence of an online community or similar social institution, and its attendant social norms, motivates individuals to reciprocate. The ethnographic literature on OSS projects records strong evidence of persons who participate out of a desire to "give something back".[22]

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19 See R. Benabou, J. Tirole, "Intrinsic and Extrinsic Motivation", Princeton University Working Paper (2002); B. Frey, *Not Just for the Money: An Economic Theory of Personal Motivation* (Cheltenham: Edgar Elgar, 1997).

20 Osterloh, Rota, Kuster, "Open Source Software Production: Climbing on the Shoulders of Giants". Empirical evidence suggests, however, that the chances of being able to convert reputational gain into a monetary benefit are slim: E. Von Hippel, G. Von Krogh, "Exploring the Open Source Software Phenomenon: Issues for Organisation Science", *Organisation Science* (forthcoming), at http://opensource.mit.edu/papers/removehippelkrogh.pdf .

21 S. Lindenberg, "Intrinsic Motivation in a New Light", *Kyklos* 54(317) (2001).

22 For example, S. Faraj, M. Wasko, "The Web of Knowledge: An Investigation of Knowledge Exchange in Networks of Practice", Florida State University, Working Paper (2001).

To summarize, the individual level refers to the microfoundational motivation that stimulates individuals to voluntarily participate in information commons projects. Individual motivation is a necessary causal factor for the existence of the information commons. By now, ample empirical evidence exists to prove that, as a matter of fact, there are a significant numbers of individuals out there who are prepared to donate to information commons projects. From a theoretical perspective, we can reconcile this phenomenon with rational choice theory by expanding the set of individual preferences to include actions that satisfy intrinsic motivations and certain non-contingent extrinsic motivations. No one but the most romantic would suggest that an entire economy could function on the basis of volunteer-based production. By the same token, few economists maintain that all productive functions can be performed exclusively by the state or the market. The so-called "third sector", that is, charitable, religious and voluntary organizations, plays an important role, in terms of net contribution, in modern economies. In addition, it has been shown in other contexts that where an activity inspires donative behavior, volunteers often best provide for the good in question.[23] The instrumental vision of a "mixed economy" sees a role for market, state and the third sector according to which institutional form is best suited to providing the good or service in question. The information commons is entirely consistent with that vision.

The social level

The social level is concerned with the *social practices* that explain the emergence of the information commons. The existence of these practices will often result in a positive feedback into the pool of individual motivations discussed above. Most information production involves the productive efforts of more than one individual and is therefore, by definition, a social practice. The archetypal socio-economic institutions for organizing socially produced information are the market and the firm.[24] Benkler has lucidly argued that "commons-based peer production" represents an alternative institution for organizing information production.[25] At the social level, we can explain the emergence of this institution by reference to social practices that have formed in volunteer information-producing communities.

Raymond paid particular attention to these social practices is his early articles. As noted previously, he hypothesized that a "gift culture" accurately characterizes the social interactions that take place in OSS projects.[26] The importance of gift giving to

23 See K. Healy, "Embedded Altruism: Blood Collection Regimes and the European Union's Donor Population", *American Journal of Sociology* 105 (2000), p. 1633, suggesting that the opportunity to sell blood plasma reduces the likelihood of a person donating.

24 R. Coase, "The Nature of the Firm", *Economica* 4(386) (1937). Coase hypothesized that economic organization takes place within the hierarchy of a firm structure when using the price system alone to guide economic decisions proves too costly.

25 Y. Benkler, "Coase's Penguin, or, Linux and the Nature of the Firm", *Yale Law Journal* 112(369) (2003).

26 Raymond, "The Cathedral and the Bazaar". See also R. Ghosh, "Cooking Pot Markets: An Economic Model for the Trade in Free Goods and Services on the Internet", *First Monday* (1998), available at: http://dxm.org/tcok/cookingpot.

society has long been recognized and analyzed by sociologists and anthropologists alike.[27] The donation of a gift in human society generally gives rise to a reciprocal obligation on the part of the donee. Thus, there is really no such thing as a "free gift". The gift culture analogy has been developed in subsequent literature on OSS.[28] Within the community of software programmers who use OSS, a sufficient number who know that their colleagues elsewhere have voluntarily contributed to the project feel that they too should contribute. This social practice helps explain why popular OSS applications attract by far the largest pool of volunteers:[29] in a gift culture there is a greater likelihood of reciprocity when the pool of users is large. One failing of this hypothesis is that it does not explain why an individual instigates an OSS project in the first place. It has been suggested that one must assume that there are a sufficient number of risk-takers and/or idealists who are prepared to be proactive, rather just than reactive, in their voluntary activity.[30] Another interesting sociological analogy is the notion of kinship or community amity.[31] Within the family, as has already been noted, strict rational calculations do not normally influence economic decisions. The powerful social force of the family unit overrides market logic. Amity is particularly strong at the family level, but it is not limited to it. Amity explains why individuals are generally prepared to donate more readily to members of their community, whether it be one based on geography, profession or other interest group, rather than to unrelated strangers. The social ties that bind members of the computing programming community can help explain why they evince a willingness to volunteer in OSS projects.

A great deal more could be said about the causal factors at the social level that result in the existence of the information commons. For present purposes it is sufficient to note that because nearly all productive activity takes place within a social context, we must analyze social practices as much as individual motivation if we are to fully understand why volunteer information production occurs in the Internet environment. The gift culture and community ethic analogies help explain why the productive dynamic of the information commons continues to flourish.

The structural level

The structural level is concerned with identifying the macrofoundational structures that *facilitate* the individual motivations and social practices that constitute the

27 M. Mauss, *The Gift: Forms and Functions of Exchange in Archaic Societies* (London: Cohen and West, 1954), is the original authoritative work on this subject.

28 D. Zeitlyn, "Gift Economies in the Development of Open Source Software: Anthropological Reflections", University of Kent, Working Paper (2003), available at: http://opensource.mit.edu/online_papers.php.

29 Healy, Schussman, "The Ecology of Open Source", surveyed the 45,000 OSS projects hosted by http://www.sourceforge.net and discovered that only a small fraction of very popular OSS applications have attracted a significant number of developers.

30 Franck, Jungwirth, "Reconciling Investors and Donators – The Governance Structure of Open Source".

31 See Zeitlyn, "Gift Economies in the Development of Open Source Software: Anthropological Reflections".

productive dynamic of information commons projects. A structural feature operates by ordering and patterning individual and social behavior. Individual motivations and social practices explain why persons and groups are prepared to voluntarily co-operate for the purpose of producing commonly shared information goods. The structural level refers to both physical and abstract organizational models that unleash and support the continuation of those productive forces. Most economics and sociology literature overlooks this level; however, its importance as a causal factor cannot be denied.[32] By way of analogy, one can say that productive forces at the individual and social level resemble potential energy, and that they remain in that form until such time as macrofoundational structures facilitate their transformation into a kinetic form. In market economies, private property and contract are the two principal institutional forms for facilitating market inspired production and distribution of goods and services. In state-run economies the state's bureaucratic command structure performs a similar function.

At the structural level, one can place two separate factors that have contributed to the emergence of the information commons: (a) the Internet's communicative architecture, and (b) the governance structures that regulate individual behavior in volunteer information-producing communities. The first factor will be discussed in detail in the section that follows. It is sufficient here to recognize that the Internet is a communication platform that has facilitated both the *production* and *distribution* of informational objects that enter the information commons. It is a structural phenomenon because it orders the way in which communicative exchanges take place, rather than contributing to the specific content of informational objects. The second factor refers to the formal and semi-formal norms that regulate individual behavior that impinge on the integrity and sustainability of information commons projects. Spontaneous social practices are sometimes, but not always, sufficient for regulating collective behavior. When they prove to be insufficient, an external objective source of norms can reduce the likelihood of anti-social behavior and/or mitigate its deleterious effects.

Following Benkler, governance structures are analyzed in terms of their signaling properties.[33] Norms and prices both send signals that have predictable effects on individual action.[34] The tendency of norms and prices to reduce uncertainty regarding future events is what makes them useful for coordinating collective action. The passing of traffic regulations by a law-making authority signals to each

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32 K. Kuwabara, "Linux: A Bazaar at the Edge of Chaos", *First Monday* (1999), available at: http://firstmoday.org/issues/issue5_3/kuwabara; characterization of the development of the Linux operating as akin to a blind evolutionary process seems to deny the role of objective norms in facilitating commons-based production. However, his thesis is weakened by the fact that Linux kernel was issued under the GPL from its early days. His thesis might stand up to scrutiny if it could be demonstrated that Linux would have developed without adopting the license.

33 Benkler, "Coase's Penguin, or, Linux and the Nature of the Firm".

34 The idea that price is a signal is normally attributed to F. Hayek, "The Use of Knowledge in Society" *American Econ. Rev.* 35 (1945), p. 519. The semiotic theory of law explains norms in terms of their signalling properties: see R. Kevelson, *Law and Semiotics* (New York: Plenum Publishers, 1990).

individual driver to take particular courses of action (for example, stopping at red lights). The combined effect of individual drivers taking predictable actions is a functioning and safe traffic system for all. Likewise, when the coffee crop fails in Brazil, the price mechanism will signal to the coffee drinker in England to reduce his or her consumption. Rules and prices are both in the words of Joseph Raz, "practical reasons to act".[35] Price signals differ from legal norms in that they do not emanate from any identifiable authority, but instead are the product of dispersed individuals acting independently of each other in accordance with economic logic. If it were not for effective governance structures many collective activities would not be able to take place, even if individual motivations and social practices were conducive to achieving particular results. The matter under consideration here is the type of governance structures that feature in volunteer information-producing communities.

It should first be pointed out that many information commons projects do not rely on any formal governance structure. As noted above, spontaneous individual actions and social practices will often suffice for small-scale volunteer production of information. The self-publicizing author or musician will not generally operate in accordance with any formal governance structure. Furthermore, because information commons projects do not entail any allocation problem in relation to either profits or shares in the finished product itself (information being a non-rival good), the governance structure need only address a small number of collective action problems at the provisioning side of the equation. Thus even complex information commons projects can function effectively within minimal governance structures.

The principal governance structure for large-scale collaborative commons projects is the "copyleft" license.[36] The GPL is the best known of these licenses, though many other variants exist. Common features of copyleft licenses are the permissions to make non-commercial distributions and/or adaptations of copyright works. A crucial additional element of the GPL is its "viral" quality, that is, it stipulates, as a condition of use, that all altered versions of the binary code must also be released under the GPL.[37] Operating systems like Linux are free for all to use and distribute; however, the drawback from a profit-orientated individual's point of view is that all enhancements and additions to the code must also, as a matter of contract law, be donated to the commons. The drafters of copyleft licenses have cleverly used a mixture of property and contract law to institutionalize an effective commons regime. Thus the governance structure of volunteer information producing communities is primarily a creature of private law.

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35 J. Raz, *Practical Reasons and Norms*, 2nd ed. (Princeton, NJ: Oxford University Press, 1990).

36 Franck, Jungwirth, "Reconciling Investors and Donators – The Governance Structure of Open Source". See P. Lambert, "Copyright, Copyleft and Software IPRs: Is Contract Still King?" *EIPR* 23(165) (2001) for an overview of the legal issues relating to the main copyleft licenses.

37 See R. Hawkins, "The Economics of Open Source Software for a Competitive Firm", *Netnomics* 6(2) (August 2004), available at: http://slytherin.ds.psu.edu/hawk/research/opensource/opensource.pdf. See Chapter 5, Pt. II.C for an evaluation of "viral licences".

In comparison to the complex organizational apparatus of the commercial firm, the copyleft governance structure is exceptionally minimalist. It is, however, sufficient for maintaining the integrity and sustainability of volunteer information production. To understand why, we must once again make the distinction between motivation and co-ordination. When voluntary labor is the only productive input of an enterprise, the most important objective of a governance structure is to prevent anti-social behavior that undermines volunteer motivation. The co-ordination of productive activities can be arranged on an *ad hoc* basis so long as the vital component of volunteer motivation is allowed to flourish. The copyleft license is therefore an exemplary device: it is silent on how productive activity should be coordinated, but capable of generating the signals needed for unleashing volunteer motivation.

Franck and Jungwirth have argued that the copyleft license achieves the goal of (a) attracting volunteers who participate in OSS projects for the purpose of advancing reputational gains (extrinsic motivation), and (b) attracting volunteers who participate for donative purposes (intrinsic motivation). The copyleft license facilitates the reputation seeker because it signals to that person that they, rather than a manager or impersonal legal entity, will be acknowledged for the contribution they have made to the collective enterprise.[38] Furthermore, because there is no question of a direct monetary payment, the copyleft license signals that the amount and quality of the code, as assessed by that person's peers, will be the sole measure of his or her contribution. If the same software were to be produced by a commercial firm, the reputation seeker would have to apply for a job, submit him or herself to a formal bureaucratic structure, and accept monetary payment in lieu of reputational ego-satisfaction.

The copyleft license facilitates the donative volunteer through a different type of signaling device. It is generally recognized that intrinsic motivations are likely to fail if the donor has reason to fear that his or her donation will enrich a residual claimant, like a shareholder, rather than the intended beneficiary or, in the case of a public good, the public at large.[39] This explains why charitable organizations are almost universally incorporated on a non-profit basis. A pre-requisite for any enterprise that taps into the productive resources of intrinsically motivated volunteers is the "non-distribution constraint" – a device that signals to volunteers that their donations will not be distributed to residual claimants.[40] The different copyleft licenses embody this device to varying degrees. The fact that an information good is made freely available, by definition, undermines the ability of anyone else to extract economic rents from it. The viral nature of the GPL makes it a particularly powerful non-distribution constraint. Not only are recipients prevented from extracting rents from the informational object itself, they are also contractually obliged not to demand economic rents from downstream enhancements or additions that they themselves make. The GPL therefore sends two important signals to the volunteer. First, it tells the volunteer that his or her donation will benefit only the public at large; secondly it

38 A feature of nearly every OSS project is a credit list of contributors.

39 Hansmann, "The Role of Non-profit Enterprise".

40 Ibid.

tells the volunteer that future contributions that build on his or her donation will also only be used for that purpose.

The Internet's communicative structure and the information commons

Having already located the Internet's communicative structure at the structural level of causal factors, we can surmise that it *facilitates* the unleashing of individual motivations and social practices that are responsible for the actual production of informational objects donated to the commons. This section describes precisely the causal relationship between Internet architecture and the information commons.

The communicative structure of the Internet patterns the flow of information between Internet users. The point can be illustrated by recalling the manner in which a hierarchical communication system patterns information flows. In television, radio, book and music publishing, the flow of information is unidirectional – the role of information sender is clearly distinguished from the role of information recipient. These early mass communication systems are marked by a scarcity of *information transmission capacity*, which gave rise to a communicative structure that is conducive to proprietary control (that is, copyright protection). Conversely, it is contended here that the decentralized communicative structure of the Internet is conducive to an information commons because: (a) it facilitates the organization of volunteer information producers on a global scale; and (b) it favors open over closed access of informational resources. The former relates to the manner in which volunteer production of information takes place. The latter refers to the manner in which distribution occurs.

Organization of production

The extent to which the information commons is actually *realized* is largely dependent on the organization of volunteers towards productive ends. A central element of any organizational strategy, in respect of a collaborative project, is the way in which individual producers manage to make connections with each other. Benkler's thesis is that commons-based peer production is a form of self-selection of productive functions, which in turn leads to an efficient co-ordination of individual actions. The idea is that, when the set of possible agents is large and dispersed, the individual engaged in extensive communication and feedback exchanges is best positioned to adjudge his or her suitability for a particular task.[41] Decentralized communication systems are also an efficient mechanism for providing information on what tasks need to be performed, their relative importance, what are in fact being performed and whether or not an individual's contribution is of value.

This author would add to Benkler's thesis by holding that the capacity of volunteers to self-select in this fashion is a direct consequence of the Internet's communicative

41 Benkler, "Coase's Penguin, or, Linux and the Nature of the Firm". Central to Benkler's hypothesis is the notion that human intellectual capital is highly variable and individuated. While we may all be prone to overestimating or underestimating our abilities, no one else is any better position to come to a more accurate estimation.

architecture. This productive phenomenon would not have taken place *but for* the fact that every Internet user is an end node in a decentralized broadcast enabled communication system. It is through this communicative mechanism that the co-ordination of volunteer production of information is made possible. Once a person is connected to the Internet, he or she becomes not just a spectator or consumer, as one is with the traditional mass media, but also a potential producer of a new information good. The interactive nature of the Internet allows individuals to search and make connections with like-minded individuals for the purpose of engaging in an information commons project. Once those connections have been established, communication can be sustained via both email and the World Wide Web. Thus, all the communicative pre-requisites for forming an information producing community from a pool of dispersed volunteers are provided for by the Internet's communicative structure.

There are a number of unique features to this model of organization that distinguish it from traditional economic structures. The human intellectual resources of a firm are, by definition, limited to a set of bounded agents, that is, its employees and/or contractors. The formation of these economic relationships acts like a fence in two respects. Firstly, the employee is contained within the firm – he or she must generally devote his or her efforts to pursuing the objectives set by the firm's management. Secondly, and more crucially, all non-employees are in effect excluded from participating in the firm's productive activities. The nature of the firm is such that if you are not tied to it economically, you are unlikely to donate your labor to it. The information commons model, in contrast, is an open house – anyone can come and go when they want. The disadvantage of this model is that there is less certainty as to the likely long-term commitment of a volunteer compared with an employee. The advantage is that an information commons project can draw on the enormous pool of unbounded agents that constitute the global Internet community. No commercial firm has access to a comparable resource. The Internet's communicative structure has harnessed this resource by providing pathways through which connections can be made; it is therefore one of the principal causal factors behind the information commons.

The logic of open access

The decentralized, broadcast-enabled structure of the Internet embodies what I term *the logic of open access*. By this phrase it is meant that the Internet supports a tendency in human nature to engage in free communicative exchanges, which in practice means that access to informational resources is open and therefore in a commons. If I am correct in this contention, the changes to our cultural and informational landscape that the Internet has precipitated are of a magnitude equivalent to those that resulted from the invention of the printing press and other technologies of hierarchical mass communication. This hypothesis will be defended by reflecting on the historical role played by mass communication technologies in framing the copyright doctrine, and by drawing on the evolutionary property theories of David Hume and Friedrich Hayek.

For present purposes, one can divide the history of communications into three different phases: (a) the period before the invention of the printing press; (b) the era of hierarchical mass communications and (c) the Internet age. There is scant historical evidence of any notion of copyright, or "information property", prior to the invention of the printing press.[42] The reasons for this are obvious – literacy levels were low and the task of copying manuscripts was painstaking. Until the invention of the printing press, formalized knowledge and education was confined within a few specialist institutions, principally the Church and the medieval universities. The masses were illiterate and, by virtue of this incapacity, largely excluded from having direct access to the existing body of formal learning. For them, the practice of communicating knowledge and sharing in cultural experiences was through the oral medium. The folkloric traditions of Western Europe remind us of what cultural expression was like prior to the invention of mass communications.[43] Recent scholarship on "traditional knowledge" in current day indigenous communities also underlines how the process of creating and sharing cultural expression, and practical knowledge in general, in such communities is a gradual collective process, in which the notion of individual authorship and ownership is alien.[44]

We can explain, in part at least, this pre-printing press antipathy towards information property by reference to the structure of purely oral communication systems. In an oral community, each member has an equal capacity to be both a sender and receiver of information, that is, there is a decentralized communicative structure. Furthermore, if it is a close-knit community with strong communal norms, the distinction between broadcast and point-to-point transmission is largely redundant; cultural expression is by its nature a shared experience. Given such a communicative structure, it is easy to understand why the idea of a single individual having a right to control the transmission by others of cultural or technical expression is anathema to the way in which the society functions. A property right in oral expression would require a prohibition on speaking – a repugnant idea. It seems reasonable to conclude that the natural state of affairs prior to the invention of the printing press was the existence of an information commons. Certainly, there were no property rights in information in the sense that we understand them today.

The invention of the printing press altered fundamentally the way in which cultural expression and technical knowledge were communicated in society.[45] The

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42 R. Bowker, *Copyright Its History and Its Law* (Boston: Houghton Mifflin, 1912), pp. 8–9, cites some isolated evidence of recognition in classical and early Christian times of protean copyright protection. According to Bowkler there was is no evidence of literary property in Greek or earlier literatures. In Roman times, there is reference in Justinian's Institutes to an artist's right to a tabula on which he painted – certainly a rather minimal concept of information property.

43 See N. Chadwick, *The Celts*, 2nd ed. (London: Penguin, 1998).

44 See P. Yu, "Traditional Knowledge, Intellectual Property and Indigenous Culture: An Introduction", *Cardozo International and Comparative Law* 11(239) (2003).

45 See M. Rose, *Authors and Owners: The Invention of Copyright* (Cambridge, MA: Harvard University Press, 1993); K. Eden, *Friends Hold All Things in Common: Tradition, Intellectual Property and the Adages of Erasmus* (New Haven, CT: Yale University Press, 2001).

ability to make multiple copies of a book, and to distribute them, gave rise to a hierarchical communication system. The publisher, at the top, was the transmitter of information and the reading public, at the base, the recipients. With the increase in literacy, this means of disseminating knowledge replaced the decentralized oral tradition and the scrivener's art. For obvious economic reasons, the printing business had to operate on a commercial basis – how else were the sunk costs of a printing press to be recouped? Printing became a trade, like any other, and in England and elsewhere was organized into an anti-competitive guild system. The first copyright statute – the Statute of Anne 1710 – was passed, not out of a desire to protect authors and promote new literature, but because of the Stationer's Company's fear of competition.[46] The scarcity in communication channels meant that publishers were insulated from competition by the communicative acts of the public; however, amongst themselves and potential newcomers to the business, some form of regulation was needed to protect against mutually destructive competition. A regulated trade could be achieved in two ways: either through a public licensing system that limited the number of printers, coupled with an internal mechanism that permitted collusive arrangements; or through a statutory provision that granted the exclusive right to print a particular work to a given individual. The licensing model had fallen out of favor by the early 18th century, so the latter option was pushed by the Stationer's Company and ultimately succeeded with the passing of first copyright statute.[47] Only in the 18th century did the idea of a literary property, in the legal sense, take hold.[48] What is important to understand is that the very idea of owning information, that is, controlling how it is disseminated, is a direct consequence of the hierarchical communicative structure of the publishing business.

The invention of more recent hierarchical mass communication systems such as cinema, radio and television, were each in their turn assimilated into the information property paradigm first established by the printing business. These technologies further entrenched the divide between senders and recipients of information. Culture, and information in general, once an organic part of social life, became a product to be purchased and consumed. For the newly literate consumer this system of production and distribution made available a range of cultural and educational resources of unimaginable quantity and variety. Furthermore, regulation through copyright law proved uncontroversial in the public eye, as it was in effect a means for producers and distributors to divide, amongst themselves, the spoils of the new entertainment and information industries.

The invention of the Internet has, in a sense, taken us full circle. Its decentralized, broadcast-enabled communicative structure resembles the communicative structure of earlier oral cultures. The Internet's global reach and the diversity of digital expression, whose communication it facilitates, means, however, that it is a radically more pervasive system for disseminating information. Despite these significant differences, it shares with oral cultures the logic of open access. The fact that everyone with a connection to the Internet is now able to both receive

46 J. Feather, *A History of British Publishing* (London: Routledge, 1988), Chapter 6.

47 Ibid., pp. 74–75.

48 Rose, *Authors and Owners: The Invention of Copyright*.

and send information means that the natural human tendency to engage in dialogic communicative *exchanges* has once more been realized, but this time on a global scale. The volunteer producer has been provided with the simplest and most efficient means in which to distribute his or her informational output – the unregulated posting, linking and transfer of HTML pages. When commercial intermediaries exclusively controlled communication channels there was simply no outlet for the volunteer producer to donate his or her information to the commons. By facilitating donative behavior of this type the Internet has led to the creation of the information commons. This obviously places the commercially minded information producer in a difficult position. If a person wants to exercise his or her property rights and retain control over communication in the digitally networked environment, he or she must impose technical restrictions on access to and use of informational resources. Such a course of action contradicts the logic of open access. By so doing, this commercially minded person risks creating a "dark space" for him or herself in an otherwise free and open information environment. Of course, some commercial information services have overcome this difficulty; nevertheless, those who attempt to resurrect the property paradigm in the digitally networked environment are by definition limiting the communicative capacity of the Internet.

One way of explaining this movement from commons to property and back to commons again is through the "evolutionary property" theory initially proposed by David Hume[49] and since developed by, *inter alia*, Friedrich Hayek.[50] Hume's explanation for, and ultimate defense of, private property rests on the idea that there was a gradual historical transition from an unordered commons in respect of material resources to an ordered regime of private property. Hume does not attempt to justify any initial allocation, in the manner of Locke, but regards private property simply as a convention that "bestows stability on the possession of…external goods".[51] It is in the common interest that this convention be established, irrespective of the distributional consequences, because without it neither human society, material wellbeing, nor justice could survive. We are therefore obliged to respect individual holdings recognized by the law, because to flout them would undermine the foundations on which prosperous societies are built. Furthermore, we can explain the existence of this convention as being the result of an evolutionary historical process in which humans gradually restrained their passions in return for the benefits that stability of possession confers. In a like manner, Hayek argued that through the "slow selection of trial and error"[52] private property emerged as a system of rules for delineating individual spheres of control over limited resources. The very fact that

49 D. Hume, *Treatise on Human Nature*, 1739 (Buffalo, NY: Prometheus Books, 1992). For a good evaluation of Hume's theory see J. Waldron, "The Advantages and Difficulties of the Humean Theory of Property", in E. Frankel Paul (ed.), *Property Rights* (Cambridge: Cambridge University Press, 1994).

50 F. Hayek, *The Fatal Conceit: The Errors of Socialism*, W. Bartley (ed.), (London: Routledge, 1988). See also J. Buchanan, *The Limits of Liberty: Between Anarchy and the Leviathan* (Chicago: University of Chicago Press, 1975).

51 Hume, *Treatise on Human Nature*, Book III, Part I, Section II.

52 Hayek, *The Fatal Conceit: The Errors of Socialism*, p. 36.

private property is an evolved institution captivated Hayek, because of his belief in evolutionary epistemology.[53]

What underlies the Hume/Hayek methodology is the idea that social and legal institutions are the product of an evolutionary process that guides human society towards a position of common benefit and accord. The empirical proof of an established social arrangement – for example, the practice of respect for each other's possession – is both an explanation for, and justification of, a *de jure* recognition of the arrangement. Social practices and the norms that regulate them are not, however, immutable.[54] In particular, the opportunities provided by new communication technologies create new possibilities for the way in which our relationship with socially valuable informational resources are ordered. In reflecting on the history of communications, we can say that prior to the invention of the printing press the social practice regarding the production and distribution of information in society was one that favored a commons. With the movement into the era of mass communications, the hierarchical model necessitated some restraints on competition amongst commercial publishers and therefore copyright law and the property paradigm, though not perfect, were a natural response.[55] Finally, the Internet has facilitated the unleashing of volunteer productive forces and the free independent sharing of information, such that an information commons has once again become an established social arrangement for organizing access to and use of informational objects. The fact that it has emerged spontaneously from the free interactions of people is proof in itself that it is to the common benefit and accord.

53 F. Hayek, *The Sensory Order* (Chicago: University of Chicago Press, 1952).

54 See D. Friedman, "A Positive Account of Property Rights", in Frankel Paul, *Property Rights*.

55 It is worth pointing out that Hayek rejected the idea that copyright and patents followed the evolutionary pattern: Hayek, *The Fatal Conceit: The Errors of Socialism*, p. 36.

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