The International Political Economy of Intellectual Property Rights

NEW HORIZONS IN INTELLECTUAL PROPERTY

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The International Political Economy of Intellectual Property Rights
Meir Perez Pugatch

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Abbreviations

ABPI	Association of the British Pharmaceutical Industry
CBI	Confederation of British Industry
CEFIC	European Chemical Industry Council
DTI	Department of Trade and Industry
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understandings
EFPIA	European Federation of Pharmaceutical Industries and Associations
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
LDCs	Least Developed Countries
MFN	Most Favoured Nation
MNCs	Multinational Companies
MSF	Médecins Sans Frontières
NCEs	New Chemical Entities
PhRMA	Pharmaceutical Researchers and Manufacturers Association of America
SPC	Supplementary Protection Certificate
TABD	Trans Atlantic Business Dialogue
TRIPs	Trade-related Aspects of Intellectual Property Rights
TT	Technology Transfer
UNCTAD	United Nations Conference on Trade and Development
UNICE	Union of Industrial and Employer's Confederations of Europe
US IPC	US Intellectual Property Committee
VFA	Verband Forschender Arzneimittelhersteller
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Preface

This book explores the manner in which the R&D-based pharmaceutical industry in Europe organized and operated between 1995 and 1999 in order to secure its interests with regard to the agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO).

The TRIPs agreement represents a major increase in the global protection of intellectual property rights (IPRs). In fact, the agreement contradicts the general direction of the WTO, that is trade liberalization, since it increases the monopolistic features of international trade in knowledge products.

The research was motivated by one basic and fundamental question: why and how is such a strong international intellectual property agenda in place?

A pure economic approach does not provide a sufficient and satisfactory explanation for the creation of IPRs. For example, economists cannot conclude whether patents confer a net benefit or entail a net loss to society. This is due mainly to the structural trade-off built into the patent system: that by aiming to increase the amount of available knowledge in the future, the system represses the free and widespread use of available knowledge in the present.

The international IP system, as exemplified by TRIPs, is even more difficult to explain in purely economic terms, particularly with respect to the uneven distribution of IPRs between 'northern' and 'southern' countries. The importance of IPRs to future economic growth, foreign direct investment and technology transfer is also in dispute.

As an alternative to an explanation based on global welfare, this book suggests that a dynamic approach, based on the international political economy of interest groups and systemic outcomes, provides a better starting point for explaining how the international intellectual property agenda (TRIPs) is determined.

This approach is tested here by focusing on the strategies, organization and actions of the R&D-based pharmaceutical industry in Europe and its IP allies, which aimed at preserving and exploiting the TRIPs agreement. Using their highly sophisticated and well-coordinated organizational build-up, the advanced pharmaceutical industry in Europe and its IP allies were able to mobilize regional authorities, such as the European Commission, in order to protect their current international IP achievements. This was despite opposition to the TRIPs agreement from developing and least developed countries, which became particularly fierce in 1999.

About the author

Dr. Meir Perez Pugatch specializes in the fields of intellectual property policy and the commercialization of knowledge assets. He is an independent consultant to the private and public sectors, including pharmaceutical, biotechnological and IT companies, healthcare organizations and hospitals, agricultural boards and the Israeli Government. He finished his B.A. studies in 1997 at the University of Tel-Aviv and received his MSc. degree from the London School of Economics in 1998. He was awarded his Ph.D. from the London School of Economics in July 2002. Dr. Pugatch lectures on the subjects of intellectual property and knowledge management at Haifa University and the Ben-Gurion University.

1. Introduction

This book investigates the realm of intellectual property rights (IPRs) within the context of the international political economy (IPE). In particular, it examines the extent to which powerful interest groups, such as pharmaceutical multinational companies (MNCs), influence and shape the political dynamism underlying the field of IPRs.

As a case study it takes the agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO) and relates it to the advanced (research-based) pharmaceutical industry in Europe. It explores the manner in which the latter organized and operated between 1995 and 1999 to secure its interests with regard to the international intellectual property (IP) agenda, as set by the TRIPs agreement.

1.1 THE AIMS AND PURPOSE OF THIS BOOK

The TRIPs agreement represents a major increase in the global protection of IPRs.[1] It aims to control the distribution and exploitation of different types of knowledge such as inventions, artistic creations, trade secrets and information for consumers on different products. In other words, the TRIPs accord extends the monopolistic position of IP owners. Thus, while the WTO aims at trade liberalization, it seems that the TRIPs agreement contradicts the general trend and increases the monopolistic features of international trade in knowledge products.

This book is therefore concerned with a basic and fundamental question: why and how is such a strong international IP agenda in place?

1.2 THE INADEQUATE ECONOMIC JUSTIFICATION FOR THE ESTABLISHMENT OF IPRS

Providing a pure economic explanation for the creation of IPRs is quite difficult, as explained in Chapter 2. Since they refer to different types of knowledge it is impossible to treat IPRs as one homogeneous group. Consider, for example, two forms of IPRs: patents and trademarks. Common to these two forms of

IPRs is the creation of market exclusivity (monopoly) in the use of existing knowledge-inventions for patents and consumer information for registered trademarks. However, the economic theory of patents is far more problematic, since currently it is not possible to conclude whether they confer a net benefit or entail a net loss to society.[2] The structural trade-off built into the patent system – that in order to increase the amount of available knowledge in the future the efficient use of existing and available knowledge is inhibited in the present – is probably its most problematic aspect.[3] As a result, there is no clear theoretical path one could follow in order to decide on the overall economic merits of patents.

The economics of registered trademarks, although more coherent than that of patents, implies that the social utility of such a system will ultimately depend on the way in which trademarks are used. A system of registered trademarks may be considered an efficient source of information as long as it enables consumers to obtain additional and accurate knowledge on different products.[4] If this is not the case (for instance when trademarks artificially differentiate between products that are for all purposes identical, such as in the case of generic pharmaceutical products, or when, due to extravagant advertising activities, the reputation of a given trademark exceeds the actual value of its product), trademarks can easily become a source of useless, inaccurate and even false information.

All of the above suggests that a pure economic approach cannot provide a sufficient and satisfactory explanation regarding the creation of IPRs. Furthermore, Chapter 3 concludes that the international IP agenda, as derived from the TRIPs agreement, is even more difficult to explain solely in economic terms. Issues concerning IPRs at the international level, such as the importance of IPRs to future economic growth, their relationship to foreign direct investment (FDI) and technology transfer, and their uneven distribution between 'northern' and 'southern' countries, are as economically, if not politically, disputable as IPRs themselves.[5]

1.3 AN INTERNATIONAL POLITICAL ECONOMY FRAMEWORK IS ESSENTIAL FOR INVESTIGATING THE LINKAGE BETWEEN INTEREST GROUPS AND THE INTERNATIONALIZATION OF IPRS

We submit that by focusing on the link between powerful and influential interest groups and international systemic outcomes, it would be possible to provide a good starting point for explaining how the current international IP agenda is determined.

An IPE interest-based approach builds upon previous studies which identified a close link between: (1) the conditions of the international economy; (2) interest group activities, and (3) economic policy-making, both at the national and the regional levels.[6]

According to Krasner, an IPE interest-based approach outlines two major lines of inquiry.[7] The first examines the implications of changes in the international economy on political structures and groups, mostly at the domestic level. For example, Frieden and Rogowski, using theories of international trade, adopt this approach when explaining the effects of international economic integration on domestic politics, policies and institutions.[8]

The second line of inquiry, which is more relevant, explains how political forces shape foreign economic policy, thereby influencing international systemic outcomes. In this case – a bottom-up approach – causation is reversed and political activities are treated as the explanatory variable. This approach is based on two underlying assumptions: (1) there is a close link between the conditions of the international economy and domestic political activities; (2) national economic policies are subject to different forces and pressures, and that 'knowing who the relevant domestic actors are and what their trade (or other economic) preferences are, is essential for understanding the influence of a sector's policy "structure" on policy outcomes'.[9]

Milner, researching the foreign economic policies of the United States and France, argued that in both countries multinational companies played a significant role in resisting projectionist policies in times of economic crisis.[10] She concludes that the preferences of these firms were one of the most important influences on trade policies in these countries.[11] Another study by Oatly and Nabors on the Basle Capital Adequacy Accord of December 1987 demonstrates the influence of domestic and cross-domestic factors on international financial agreements.[12] Oatly and Nabors argue that domestic politics create an incentive for redistributive (though not equally rewarding) international institutions.[13] Accordingly, they suggest that the focus on domestic rent-seeking forces provides a better explanation for the creation of the Basle Accord than theories of market failure and international cooperation.[14]

Other studies, focusing primarily on collective action, examined the complex interaction and linkage between interest group activities and policy-making at the regional level. Greenwood and Aspinwall found that the most effective European groups come from business sectors with a high degree of concentration, a limited number of members, most of which are multinational companies, and with a clear sectoral definition aimed at limiting the danger of diverging interests.[15] They mention the European Federation of Pharmaceutical Industries and Associations (EFPIA), the main body representing the European advanced pharmaceutical industry, as one of the most effective interest groups working at the European level.[16]

Many authors acknowledge that powerful business groups, particularly pharmaceutical MNCs, played a crucial role in 'pushing' the issue of IPRs to the international arena.[17] Nogués, for example, argues that the research-based pharmaceutical industry in the US, represented by the Pharmaceutical Manufacturers Association (PMA) (today called PhRMA), was the main driving force behind the 1998 intellectual property amendments to Section 301 of the Omnibus Trade and Competitiveness Act.[18] Explained in Chapter 3, Section 301 allows the US to impose unilateral sanctions against countries engaging in what the US considers to be 'unfair competition' in the field of IPRs. During the 1980s, Section 301 was used against developing countries such as South Korea and Brazil, in order to force these countries to grant stronger IP protection to pharmaceutical products, as well as to negotiate the creation of an agreement on IPRs under the auspices of the WTO.[19] Braithwaite and Drahos argue that the CEO of Pfizer, Mr. Edmund Pratt, was one of the most dominant figures advocating the inclusion of IPRs under the WTO framework (then GATT).[20] According to the authors, the Advisory Committee for Trade Negotiations (ACTN), which was chaired by Mr. Pratt during the 1980s, was pivotal to the IP-strategy of the US, that is linking IPRs to international trade by making them an integral part of the WTO.[21] Braithwaite and Drahos also refer to other key groups, such as the Intellectual Property Committee (IPC) and the Business Software Alliance (BSA), that have considerable influence on US international IP-policy.[22]

Nevertheless, this recognition of the power of IP-based groups is rather superficial, as it does not elaborate on the strategies, mechanisms and processes through which these groups secure their interests in the international trading system. Nor does it examine the extent to which particular IP interests are translated into what may be regarded an acceptable international IP reality. Instead, attention shifts almost exclusively to IPRs with regard to the 'north–south' dispute, that is the implications of the international IP system on the economic and social conditions of developed and developing countries. This is not to deny the importance of the north–south debate on IPRs, but simply to argue that it is as essential to focus on the process leading to creation of the international IP agenda as it is to study its effects.

Therefore, it is suggested that the focus on the process through which the internationalization of IPRs is taking place will make the discourse in the field more informed and might even change some of its themes. For example, the term 'intellectual property rights' is in itself politically constituted and not as value free as one might assume. It is the result of well balanced and strategically coordinated efforts during the 19th century which defused the negative implications of the previous term: 'intellectual monopoly privileges'.[23] This kind of political triumph enabled advocates of IPRs to emphasize their 'pure moral content' in terms of rights, and their economic desirability in terms of property.[24] It also leads to a false distinction between IPRs and other types

of undesirable monopolistic behaviour. *The Economist*, for example, when referring to anti-monopolistic policies, notes that 'intellectual property laws that award a kind of monopoly through patents are not easily reconciled with the whole notion of antitrust lawsuits'.[25]

Hence, there is a need to adopt a more dynamic approach, based on the political economy of interests and systemic outcomes that would underscore the process leading to the establishment, management and exploitation of the international IP system.

1.4 THE ADVANCED PHARMACEUTICAL INDUSTRY IN EUROPE AND THE TRIPS AGREEMENT

That case studies contribute to our knowledge and understanding of political and economic phenomena, and to so-called 'black-box' issues, has already been established in the academic literature.[26] Therefore, in light of the insufficient empirical data concerning the internationalization of IPRs and interest groups activities, it is necessary to focus on a specific case study that would provide a solid starting point for the political-economy study of IPRs. As previously noted, this book explores the manner in which the advanced pharmaceutical industry in Europe organized and operated between 1995 and 1999 in influencing EU policy-making with respect to the TRIPs agreement, thereby securing its interests and objectives. In this regard, the term 'advanced pharmaceutical industry' refers to research-based pharmaceutical companies able to create new products by undertaking extensive R&D projects, and to their organizational structure and capacity.

The methodological justification is based on four pillars: (1) the importance of IPRs to the advanced pharmaceutical industry; (2) the significant contribution of the advanced pharmaceutical industry in Europe to collective action in the field of IPRs; (3) the relevancy of the TRIPs agreement and the period of 1995 to 1999 to the international IP agenda, and (4) the manner in which the data-gathering supported the efficacy and accuracy of the case study. These methodological foundations are discussed below.

1.4.1 The Importance of IPRs to the Advanced Pharmaceutical Industry

Using 'Olsonian' terminology, IPRs provide a powerful incentive for collective action in the advanced pharmaceutical industry.[27] IPRs (patents, trademarks and trade secrets) are of crucial importance to the economic well-being of pharmaceutical MNCs, as demonstrated in Chapter 4. Moreover, IPRs provide a common ground upon which pharmaceutical MNCs cooperate, rather than

compete, with one another. Using game theory terminology, one can argue that, for pharmaceutical MNCs, the absolute gains generated by IPRs offset any temporary imbalances in the distribution of such gains (relative gains). Consider a case in which two research-based pharmaceutical MNCs compete for a patent on a new drug (it is assumed that both companies are equally capable of securing patent protection). Naturally, the winner has every reason to support patent protection, as this will enable it to reap all future profits from the prospective drug during the patent term, provided it is successful. Looking at the company that lost the race, it is still supportive of the patent system as a whole, mainly because it is capable of winning future patent races and thus will wish to secure patent (profit) protection on other prospective drugs.

1.4.2 The Advanced Pharmaceutical Industry in Europe as a Dominant Factor in the Field of IPRs

As discussed in Chapter 4, research-based pharmaceutical MNCs dominate the entire field of pharmaceuticals, both in terms of bringing new drugs to the markets and with respect to production and sales. Together with its US counterpart, the advanced pharmaceutical industry in Europe holds the lion's share of pharmaceutical activities world-wide. Indeed, Chapter 5 concludes that the advanced pharmaceutical industry in Europe uses highly sophisticated organizational build-up to secure its IP interest and objectives. The organizational structure includes intra-industry IP build-up across all levels (for example the corporate, national, regional and international levels), and inter-industry alliances with other powerful IP-based groups. The advanced pharmaceutical industry in Europe considers the regional European level as particularly important to its IP-related activities. Here it is important to note that previous studies have also found pharmaceutical collective action in Europe to be highly effective at that level.[28]

1.4.3 The TRIPs Agreement and its Effect on the International Agenda of IPRs during the Period 1995–1999

Starting from 1995, the international agenda of IPRs is defined and determined by the TRIPs agreement. Following the analysis in Chapter 6, the effect of the TRIPs agreement on the international IP agenda in general, and on pharmaceutical IPRs in particular, is threefold. First the TRIPs agreement revolutionized the international IP system by dramatically raising the global level of IP protection. Second, as part of the WTO institution, the TRIPs agreement embeds the field of IPRs into a much more committing and comprehensive multilateral framework. In this respect, the TRIPs agreement extends beyond any other institution, such as the World Intellectual Property Organization (WIPO), that deals with

IPRs internationally. Third, the field of pharmaceutical IPRs is probably the most sensitive issue in the TRIPs agreement, not least because of its obvious connection to our physical well-being.

The period between 1995 and 1999 is also crucial to our understanding of the international IP system (see Chapters 7 and 8). It was a defining period for the manner in which the TRIPs agreement was used as a tool for exploiting and preserving the international IP agenda. Also, the clashes of interest between the owners and consumers of IPRs, or between developed and developing countries, became more evident during this period. The advanced pharmaceutical industry in Europe, and as a result the EU, was particularly active in these years, making an important contribution to the exploitation and preservation of the international pharmaceutical IP agenda. It should also be noted that during the period preceding the establishment of the WTO, that is during the Uruguay Round negotiations, the US-based pharmaceutical industry played a much more prominent role. Therefore, it is more logical that the research would focus on the activities of the advanced pharmaceutical industry once the TRIPs agreement was signed in 1995.

1.4.4 The Role of the Data Gathering for this Book and its Contribution to the Efficacy and Accuracy of its Contents

In addition to relying on existing academic and professional literature, the contents of this work required substantial research, as well as gathering and generating new empirical data. For this purpose the research relied quite extensively on primary resources, including statistical data, annual reports, industry position papers, national and regional legislation and reports, proposals for the WTO by different member states, WTO reports and rulings, press releases and news clippings, and so on. Additional information was provided by corporate IP directors and IP policy makers.

A few examples may be given. For the economic analysis of IPRs, it was necessary to process and refine statistical data concerning the distribution of IPRs world-wide. Chapter 3 processes statistical data from the World Intellectual Property Organization (WIPO) concerning the share of foreign ownership of patents and trademarks in 1996 and 2000. In order to establish the dominance of the advanced pharmaceutical industry, particularly of that in Europe, Chapter 3 used data from professional publications, such as Scrip magazine and similar titles that rank leading companies in terms of sales, production, innovation and so on. An analysis of corporate annual reports made it possible to establish a solid link between the profit-making capacity of a given company and its in-patent drugs (usually via the so-called patented 'blockbusters'). In order to pin-point the specific IP interests and objectives of the advanced pharmaceutical industry in Europe and to map its intra-industry and inter-industry organizational

structure, the research relied on different position papers and industry reports. Open-ended interviews were particularly important to this aspect, providing as they did, invaluable insights into the research and substantiation of the submissions. They were also used in order to clarify to a greater extent the mechanisms and processes by which the advanced pharmaceutical industry interacts with policy makers at the national and regional levels. Finally, the author placed great emphasis on the use of WTO data, notably proposals of WTO members and reports issued by the Secretariat and the Dispute Settlement Body. The use of this data provided a golden opportunity accurately to describe the international pharmaceutical IP agenda and the processes leading to its materialization.

It must also be noted that in some cases, such as in the WTO disputes between the EU and India and between the EU and Canada, it was not possible to gain full access to the procedures and protocols that led the EU to initiate these disputes. Therefore, although the research provides convincing evidence that in these cases the EU not only represented the interests of the advanced pharmaceutical industry but also pursued them, it is still not possible to argue that a foolproof causality has been established.

1.5 THE STRUCTURE OF THIS BOOK

Chapter 2 considers the economic implications of IPRs on the allocation of resources for the creation of knowledge products, and on the allocation of knowledge as a resource. Focusing on patents and trademarks, the chapter concludes that, from the perspective of society as a whole, a purely economic approach cannot provide a sufficient and satisfactory explanation for the establishment of IPRs.

Chapter 3 assesses alternative explanations for countries' decisions to commit themselves to a stronger international IP system. In this respect, the chapter identifies the deep economic conflict between developed and less developed countries in the field of IPRs. Accordingly, it finds that political economy explanations focusing on trade retaliation and sanctions are superior to economic explanations that focus on international trade, technology transfer and foreign direct investment (FDI).

Chapter 4 surveys the world's pharmaceutical industry and focuses on the case of Europe. It shows that pharmaceutical MNCs based in a few developed countries are by far the most important actors in the industry. It then focuses on the crucial importance of IPRs (patents, trademarks and data exclusivity) to research-based pharmaceutical MNCs. Two major elements are emphasized: (1) the importance of patents and trade secrets (particularly data submitted to regulatory authorities) to pharmaceutical MNCs during the marketing and

pre-marketing stages of medicinal drugs; (2) the importance of trademarks to pharmaceutical MNCs as a complementary tool for market monopoly, particularly once patent-expiration has taken place.

Chapter 5 identifies the specific IP goals of the advanced pharmaceutical industry in Europe and maps its organizational structure with regard to IPRs. Specifically, it elaborates on the intra-industry (vertical) IP organizational structure at the national, regional and international levels (through bodies, such as EFPIA – the European Federation of Pharmaceutical Industries and Associations, IFPMA – International Federation of Pharmaceutical Manufacturers Associations, and INTERPAT – a formal body of IP directors in the leading pharmaceutical MNCs). The chapter also identifies the inter-industry (horizontal) IP build-up, through which European-based pharmaceutical MNCs coordinate their position with dominant actors from other industries. Emphasis is placed on inter-industry alliances with bodies such as the European Chemical Industry Council (CEFIC), the Union of Industrial and Employer's Confederations of Europe (UNICE), the Trans Atlantic Business Dialogue (TABD) and the US-based Intellectual Property Committee (IPC). *Inter alia*, the chapter concludes that, as regards IPRs, research-based pharmaceutical companies consider the regional European level to be highly important to its lobbying activities, perhaps even more than the national level.[29] Also, it is argued that pharmaceutical MNCs ensure that their influence and voice is maintained throughout the entire IP organizational structure of the advanced pharmaceutical industry in Europe.

Chapter 6 deals with the TRIPs agreement. It puts it in the context of the north–south dispute, mostly by providing an historical background to the negotiations on IPRs during the Uruguay Round. More importantly, the chapter examines the major elements of the TRIPs agreement (general provisions and basic principles, dispute settlements, enforcement of the agreement, TRIPs Council and the system of notifications). It also reports on TRIPs major flaws, focusing mostly on its lack of effectiveness in the elimination of anti-competitive practices and insufficient assistance to countries with low IP capabilities. Finally, focusing on TRIPs pharmaceutical IP agenda, the chapter assesses the extent to which the interests of the advanced pharmaceutical industry in Europe are reflected in the TRIPs agreement. It argues that overall, provisions of the TRIPs agreement are very beneficial to the industry.

Chapter 7 elaborates on the opposition to the TRIPs agreement from developing countries and LDCs, based on two periods:

1. 1996 to 1998 – during which opposition to TRIPs was rather lax, at least in terms of the position papers and communications submitted to the WTO ministerial meetings which took place in Singapore and Geneva.
2. 1999 (particularly towards the WTO ministerial meeting in Seattle, November 1999) – where opposition to TRIPs became highly intense, as well as goal-orientated.

The chapter analyses the key demands of developing countries concerning the TRIPs agreement structural framework and its pharmaceutical IP agenda in particular.

Chapter 8 focuses on the strategies and operations of the advanced pharmaceutical industry in Europe and its IP allies aimed at exploiting and preserving the benefits arising from the TRIPs agreement, and relates them to EU activities in that domain. Firstly, the chapter demonstrates that the IP views of the EU and its member states (specifically the UK and Germany) are highly similar to that of the industry and its IP allies. Secondly, the chapter focuses on the operational level, analysing the strategies and activities of the advanced pharmaceutical industry in Europe and of the EU concerning the TRIPs agreement. Again, two periods are identified:

1. 1995 to 1998 (first half) – during which the advanced pharmaceutical industry in Europe and its IP allies focused primarily on the exploitation of the TRIPs agreement, as well as interpreting the agreement in a manner that would make it more protective. Accordingly, EU operations during this period, as demonstrated by two major WTO disputes concerning pharmaceutical patents, reflected to a great extent the industry's goals and objectives, as well as its strategies.
2. Second half of 1998 to the Seattle ministerial conference – during this period, the advanced pharmaceutical industry in Europe and its IP allies were essentially concerned with the preservation of the TRIPs agreement, that is ensuring that the level of IP protection provided by the agreement was not downgraded.

The chapter also describes the two-layer strategy adopted by the advanced pharmaceutical industry in Europe:

1. Core strategy – emphasizing the non-downgrading of the TRIPs agreement as a pre-condition for negotiations on IPRs in Seattle.
2. Complementary strategy – presenting tough IP demands aimed at negating the request of developing countries and LDCs for modifying (downgrading) the agreement. As before, it finds that the IP position of the EU to the Millennium Round (Seattle) matched the core IP strategy pursued by the advanced pharmaceutical industry in Europe and its IP allies.

Chapter 9 summarizes the submissions. It suggests that an IPE approach, which focuses on the link between the advanced pharmaceutical industry in Europe and the current international IP agenda, as set by the TRIPs agreement, provides a sound basis for understanding how such an agenda is still in place. It

concludes that by being very active in the field of IP and by interpreting TRIPs provisions in a manner that aims to secure a stronger IP agenda in the future, the advanced pharmaceutical industry in Europe was able to preserve its current international IP achievements.

The chapter also provides an update on international IP developments which took place after the 1999 ministerial meeting in Seattle and assesses their relations with the key findings of this research. It focuses on three cases: (1) the patented AIDS medicines in South Africa; (2) the controversy surrounding 'Cipro', Bayer's patented drug against anthrax, following the attacks on the US (11 September), and (3) the negotiations and outcome of the WTO ministerial meeting in Doha.

Finally, the chapter considers the implications of this research on the study of IPRs in general and makes some suggestions for the international political economy study of IPRs in the future.

1.6 THE PLAUSIBILITY OF THE SUBMISSIONS AND RIVAL EXPLANATIONS

Academic research in the social sciences looks for plausible explanations and conclusions to existing political, economical and social phenomena. Here it is important to distinguish between the positive and negative aspects of plausibility in the social sciences.

Plausibility in the positive sense suggests that a satisfactory conclusion was reached by using both a merited and a methodologically coherent research. The former implies that the research focuses on a problem or a question that is important in the 'real world', at least in the sense that it significantly affects peoples' lives.[30] Moreover, according to King, Kehoane and Verba a merited research project, and subsequently its conclusions, should also contribute to an existing scholarly field by increasing one's ability to construct verified scientific explanations to the problem at hand.[31] A methodologically coherent research suggests that the research project was designed according to an acceptable scientific format, the components of which include: (1) posing the research question; (2) stating the research assumptions (hypotheses) and attempts to confirm or refute these hypothesis; (3) using the criteria of falsifiability (Popper's terminology) in order to allow for as many observations as possible; (4) collecting empirical data that optimize and increase our knowledge of the subject, and (5) drawing descriptive or even causal conclusions and inferences.[32]

In this respect, a case-study research can lead to a wide spectrum of plausible conclusions, starting from the descriptive level and leading up to full theory assertion.[33] Generally speaking, single-case studies may lead to descriptive conclusions and even to general propositions (although not to a universe of

populations), while the conclusions deriving from multiple-case studies may be used for the higher goal of theory-building.[34] According to Eckstein, a 'crucial case study' – defined as a single measure on any pertinent variable – can be used for explanatory purposes and provide a basis for establishing general propositions (hence theoretical development).[35] A crucial case study may also pass plausibility probes, provided that it is based on 'most-likely', or 'least-likely' observations.[36]

It is suggested that the study of the advanced pharmaceutical industry in Europe and the TRIPs agreement fits the model described by King, Keohane and Verba of a crucial case study with multiple observations (which the authors refer to as 'same measures, new units').[37] It is based on three primary observations (the dispute between the EU and Canada, the dispute between the EU and India, and the IP position of the EU at the Seattle ministerial meeting), coupled with existing data about the ability of pharmaceutical IP-based groups to mobilize national and regional authorities (Germany during 1880s, and the US and the EC during the 1980s). As described in the previous sections, the research aims to apply a methodologically coherent research design and may, therefore, lead to plausible conclusions of a descriptive type and even to general propositions (hypotheses) about the internationalization of IPRs.

However, plausibility in its negative sense indicates that conclusions in the social sciences must always be taken *cum grano salis*. Indeed, any type of project in the social sciences must leave room for scepticism and for uncertainty, especially as to the accuracy and comprehensiveness of one's conclusions, and the extent to which these conclusions provide a complete answer to the proposed investigation.

While it is suggested that an IPE interest-based approach provides a solid basis for answering the research question, it is always healthy to acknowledge the existence of additional, and sometimes rival, explanations relating to the internationalization of IPRs. Once again, the main difficulty here is that IPRs have not been thoroughly studied by political scientists and political economists.

Nevertheless, one may argue that institutions and ideas predominate in the creation and preservation of the international IP system. An institutional approach in its broadest sense may treat IP agencies as rule-based political frameworks that bring together a common set of interests, values and beliefs, thereby regulating and creating the day-to-day practices in the field of IPRs.[38] Institutional advocates may argue that existing international IP agencies, such as WIPO and the WTO, as well as domestic institutions such as national patent offices, dictate and determine the existing reality in the field of IPRs.

The difficulty of using an institutional approach for explaining as to why and how such a strong international IP agenda is in place is twofold. Theoretically speaking, as explained in Chapters 2 and 3, the logic of establishing IPRs is very

problematic, particularly in the international arena where the clash of interests between developed and developing countries is so apparent. In this respect, when using an institutional approach for explaining the internationalization of IPRs one would find it difficult to reconcile the deep conflict of interests and beliefs concerning the moral and practical efficacy of IPRs. An institutional IP theory must assume a priori that IPRs are a socially desirable phenomenon. Otherwise, there would be no point in establishing international IP institutions at all. Doern, providing an institutional examination of national and international IP agencies, concludes that in the trade-off between the protection and dissemination of IPRs, the former serve as the basis of every IP agency institution:

> Despite the exposed tension in the core IP trade-off, the main mandate and institutional culture of the IP agencies are still overwhelmingly centred on the protection role. The main IP agencies still essentially revolve around the core business or case application and operational cycles. This is the bread and butter of their existence and defines their organisational and regulatory cultures.[39]

In other words, before exploring the manner in which IP institutions affect the reality and practices of IPRs, it is vital to employ an interest-based approach that would investigate whose IP interests are being institutionalized and to what purpose.

An institutional IP approach also faces some fundamental empirical problems. Two extremes emphasize these points. First, the creation of the TRIPs agreement as part of the WTO is a vivid reminder as to the extent to which the international IP agenda is influenced by the interests of key industries in developed countries, most notably the US and the EC. As explained in Chapter 6, the growing dissatisfaction of these countries at the lack of WIPO's ability to enforce the IP obligations of its member states made them look into, and subsequently create, an alternative institution (WTO-TRIPs) with binding and punitive powers.[40] That developed countries were able to override such an impressive and vibrant institution (WIPO) suggests that, in the case of IPRs, interests matter more than institutions.

Secondly, looking at the regional level, it is difficult to place the IP-related activities of the EU in a specific institutional context. Chapter 5 describes the diverse and complex nature of international IP policy-making in the EU, which involves joint competence between the Commission and member states, qualified majority voting under the Article 133 Committee, and the inclusion of IPRs in the EU's Common Commercial Policy. It is because of this complex process that IP policy-making is not confined to a single institution but rather takes place in the corridors of the Commission (DG Trade, DG Internal Market) and government offices, such as the Department of Trade and Industry in the UK and the Federal Ministry of Justice in Germany. Moreover, it is also very

problematic to assume that the EU's international IP-related activities are based on an institutional consensus on the merits of IPRs. Indeed, that the EU, and particularly the Commission, express IP views that are very similar to those of the advanced pharmaceutical industry (discussed in Chapter 8), does not imply that other groups, such as the generic-based companies and consumer groups, do not express different views about IPRs. Consumer groups such as the Trans Atlantic Consumer Dialogue and the BEUC (the European Consumers' Organisation), that have developed fruitful working relationship with the Directorate General for Health and Consumer Protection of the European Commission, have consistently expressed their reservations about the TRIPs agreement and IPRs in general.[41] The fact that the international IP-related views and activities of the EU are closely linked to the interests of the advanced pharmaceutical industry simply suggests that the latter was able to pursue its interests in a more efficient and fruitful manner.

Therefore, it is argued that an interest-based approach provides a better starting point for revealing and mapping the major interests and driving forces underlining the international IP environment.

NOTES

1. Reichman (1998: 581–601); Cornish (1999: 19); Blakeney (1996: Chapter 1)
2. Machlup (1958: Chapter 4); Hindley (1971: 1–31), Primo-Braga (1990c: 17–32)
3. Robinson (1956: 87); Arrow (1962: 609–627); Hindley (1971: 12–13)
4. UNCTAD (1979: Chapter 2); Chamberlin (1947: 56–64, 249); Hindley (1971: 69–74)
5. Siebeck (1990); Penrose (1951); UNCTAD (1996); Chin and Grossman (1990: 90–197)
6. Milner (1988); Milner (1997); Keohane and Milner (1996); Rogowski (1989); Frieden and Rogowski (1996: 25–47)
7. Krasner (1996: 120–22)
8. Frieden and Rogowski (1996: 25–47); see also: Frieden (1991: 425–54)
9. Milner (1988: 14–15)
10. Milner (1988: Chapter 2)
11. Milner (1995: 371)
12. Oatly and Nabors (1998: 35–54)
13. Ibid., pp. 37–41
14. Ibid., p. 52
15. Greenwood and Aspinwall (1998: 20–22)
16. Ibid.; also see: Greenwood (1994c: 183–198); for an overview of European lobbying see: Greenwood, Grote and Ronit (1992); Mazey and Richardson (1996: 200–215)
17. Jackson (1997: 310–312); Doane (1994: 465–97); Oaxly (1990: 190–91); Nogués (1990b: 7–9)
18. Nogués (1990b: 7–8)
19. See Chapter 3, section 3.4.2
20. Braithwaite and Drahos (2000: Chapter 7, pp. 61–5)
21. Ibid., pp. 61–3
22. Ibid., p. 71
23. Penrose and Machlup (1950: 1–29)
24. For such references see: Phillips and Firth (1995: 8–9) Holyoak and Torremans (1995: 12–19)

25. *The Economist* (6–12 March 1999c: 212)
26. Greenwood (1994b); for a more general view see: King, Keohane and Verba (1994: 44–8)
27. Olson (1965: 23–41, 48–50); Olson (1982: 29–35)
28. Greenwood and Ronit (1992: 69–98)
29. The importance of the regional European level to pharmaceutical companies was already recognized by other scholars. See Greenwood and Ronit (1992: 69–99)
30. Shively (1997)
31. King, Keohane and Verba (1994: 17)
32. Ibid., Chapter 1; for the criteria of falsifiability and deductive research see: Popper (1968); for the process of scientific research design see: Nachmias and Nachmias (1992); Labovitz and Hagedorn (1971); Nagel (1961)
33. Greenwood (1994a: 11–15)
34. Ibid.; Bailey (1992: 47–54); Yin (1994)
35. Eckstein (1975); Also see: King, Keohane and Verba (1994: 209)
36. Greenwood (August 1994b: 10–15); King, Keohane and Verba (1994: 17, 209); according to Greenwood, 'in "most likely" observations conditions should be so favourable to the phenomenon under investigation that if it fails to occur then it is unlikely to exist at all' (p. 14)
37. King, Keohane and Verba (1994: 17, 209, 223–4); The authors argue that 'a single case often involves multiple measures of key variables… hence, by definition, it contains multiple observations'
38. This approach builds upon different studies in the field: March and Olsen (1989); Weaver and Rockman (1993: 1–40); North (1990); Milner (1997: 18–20)
39. Doern (1998: 108)
40. Braithwaite and Drahos (2000: 58–65); Ryan (1998: Chapter 5); Emmert (1990: 1317–99); Trebilcock and Howse (1995: Chapter 10)
41. For 'anti–TRIPs' views see: BEUC (2000); Trans Atlantic Consumer Dialogue (1999); for the lobbying activities of consumer groups and their relations with the European Commission see: Greenwood (1997: 193–204)

Semantic clarifications As described in Chapter 4, the word 'Europe', when used in conjunction with the term advanced pharmaceutical industry, refers to leading Western European countries, such as the UK, Germany, France, Switzerland and Italy. For internal consistency, this book uses primarily the term 'EU', rather than the term 'EC', although the latter appears in this book mainly with respect to the period preceding February 1992 (Maastricht Treaty). In this regard it is worth mentioning Tsoukalis who argued that 'a neat separation between the EC and the EU is practically impossible, especially when policies are discussed in a historical context' (1997: 1, footnote 1). Also, the term 'EC' seems to be more accurate with respect to the Community's international trade policy, including in the field of IPRs. Terms such as 'IP agenda', 'IP environment' and 'IP system' are all used in order to describe the new reality resulting from the establishment of an internationally binding, ruled–based system of IPRs.

2. The economic theory of IPRs (patents and trademarks)

2.1 INTRODUCTION

Economists explore ways of efficiently allocating scarce resources to unlimited wants and find that private property rights are a plausible way of dealing with scarcity in an efficient manner. Knowledge, however, is a unique resource given that it is not inherently scarce. Theoretically speaking, the potential use of existing knowledge is unlimited and may be diminished only when such knowledge becomes obsolete. Thus, the use of any invention by one individual does not reduce its accessibility to others but is more likely to increase it.

Patents, copyrights, trademarks and other forms of intellectual property rights (IPRs) create a temporary monopoly on varying types of knowledge, allowing their owners to restrict, and even prevent, others from using that knowledge. The result, as Hindley put it, is that 'the establishment of private property rights in these cases artificially creates the symptoms of scarcity; they do not derive from it'.[1]

Although treated as a group, IPRs are fundamentally different and refer to different types of knowledge resources. The following chapter will thus focus on patents and trademarks as they are more relevant to the R&D pharmaceutical industry, although more emphasis is placed on the former.

The chapter concludes that current economic knowledge does not provide a satisfactory basis for explaining the establishment of IPRs. It should also be noted that the international implications of IPRs, particularly with respect to the 'north–south' divide, are considered in Chapter 3.

2.2 THE ECONOMICS OF PATENTS

Economics, when exploring the issue of patents, focuses on the aggregate wealth of the community, calculating, for example, the net benefit or loss to society from the introduction of patents.[2] On the other hand, since patents refer to inventions deriving from individuals or firms from the private sector, there is no alternative but to take private interests into consideration.

According to the TRIPs Agreement, patents can be granted for any inventions, products or processes, provided that they are 'new, involve an inventive step and are capable of industrial application'.[3] Generally speaking, a patentee has the right to prevent others from making, using, selling, offering for sale or importing his invention without his permission. He also has the right to assign or to transfer the patent and to enter into licensing agreements.[4] Thus, a patent actually involves granting the inventor temporary ownership and, since the invention is unique, a temporary monopoly on his intellectual creation.

Attempting to reach a general conclusion about the social desirability of patents is far from simple. The issue encompasses theoretical complexities combining both individual and community perspectives. In order to obtain a more informed view on the subject, the discussion on patents will focus on three major elements. First, it will consider the production and distribution of inventions in the absence of a patent system, or any other institutional alternative. Second, it will consider an alternative system for patents, and, third, it will assess the patent system itself.

At the outset, there is a need to elaborate on the knowledge to which patents refer. This knowledge results from R&D activities and is aimed towards the production of inventions.

2.2.1 Research, Development and Inventions

The official definition of R&D is as follows: 'Research and experimental development (R&D) comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society and the use of this stock of knowledge to devise new applications.'[5]

Generally speaking, there are two types of research: basic research and applied research. Basic research is defined as 'experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena or observable facts, without any particular application or use in view'.[6]

Applied research is defined as an 'original investigation undertaken in order to acquire new knowledge…directed primarily towards a specific practical aim or objective'.[7] Thus, while basic research is considered to create knowledge that is in itself too broad or too general to be directly applied as a source of production for a specific purpose, applied research is considered to create knowledge that has a direct, specific and applicable use. Therefore, one might tentatively conclude that the relationship between basic and applied research has a clear direction in which knowledge produced by the former may be used by the latter to achieve instrumental and commercially orientated results.

It should be noted, however, that it is often very difficult to distinguish between basic and applied research on the basis of their results. Nelson argues that 'significant advances in scientific knowledge, the types of advances that are likely to result from successful basic research projects, very often have practical value in many fields'.[8] Machlup, supporting this view, notes that 'difficulties are especially great where "intentionally basic" research has resulted in new substances or devices and where "intentionally applied" research has resulted in a better understanding of physical or organic phenomena'.[9] Nevertheless, this chapter places more emphasis on applied research and assumes that this type of research produces commercially orientated results.

Development is defined as: 'systematic work, drawing on existing knowledge gained from research and practical experience that is directed to producing new materials, products or devices; to installing new processes, systems and services; or to improving substantially those already produced or installed'.[10] According to this definition there is a rather clear distinction between the research and the development stages. Yet, since development is also concerned with experiments, tests and, in some cases, further research, it is preferable to describe it as a process beginning from the point at which raw findings are obtained and ending once those findings are at the stage of production.

Additional distinction should be made between inventions and discoveries. Invention, as its Latin source suggests, is the act of making or coming upon something which did not previously exist. It may be regarded as the 'mental finding' of something existing only in one's mind.[11] Discovery, on the other hand, is the act of finding something unknown but which nonetheless exists.

Associating these concepts with the two types of research is often confusing. Some regard invention as directly related to applied research, insofar as it is concerned with matter and substance. On the other hand, discovery is regarded as basic research, as it is concerned with the abstract, such as the discovery of a certain law of physics. Others view discovery as applied research, as it is concerned with finding existing phenomena perceived by the senses (hence with applicable potential), and invention as basic research, as it involves creativity and ideas that do not necessarily have an application.[12] Furthermore, any attempt to define inventions or to measure inventive activities, such as differentiating between inventions and improvements to inventions, assessing their economic usefulness, and measuring their input or output in a given industry, is bound to face difficulties. Sanders, for instance, concludes that the 'contribution of social scientists to our understanding of inventiveness has so far added much to the heat of argumentation and very little to the light of understanding'.[13]

A technical invention is therefore defined for our purposes as the 'human activity directed towards the creation of new and improved practical products and processes'.[14] With regard to products and processes, the former is defined as 'a product whose intended use, performance characteristics, attributes,

design properties, added services or use of materials and components differ significantly from previously manufactured products'.[15] The latter, on the other hand, leads to the adoption of 'significantly improved production methods… intended to produce new or improved products, which cannot be produced using conventional plants or production methods or to increase the production efficiency of existing products'.[16]

Therefore, the discussion on the economic desirability of patents, despite difficulties of definition and measurement, will focus on inventions deriving from R&D of an applicable type. It will assume that these inventions have the potential for creating new and economically valuable processes or products.

2.2.2 The Production and Distribution of Inventions in the Absence of Patents

In the absence of patents or any other institutional provisions for inventions, society may face two major problems when allocating resources for the production and distribution of inventions: free-riding and secrecy.

First, the fact that knowledge has the characteristics of public goods (non-rival and non-excludable), any attempt to treat it as a commercial commodity, without adequate institutional provisions, is likely to face the problem of free-riding.[17] More specifically, in the absence of patents, free-riding occurs when the inventor cannot prevent others from exploiting his invention free of charge. Consider a case in which an inventor was able to develop a revolutionary product, such as a pharmaceutical compound for the cure of various types of cancer. If the inventor decides to sell his invention in the market he cannot expect that potential buyers would pay for the invention without first assessing its potential uses, effectiveness and value. Yet, doing so will effectively allow potential buyers to obtain information from the inventor free of charge.[18] Moreover, once a potential purchaser has gained sufficient information, and provided he has the capabilities, he is now in a position to copy the invention without paying for it at all.[19]

Consequently, the problem of free-riding creates a disincentive for private entrepreneurs from engaging in inventive activity, as they will not be able to receive commercial returns for their work. This problem has already been recognized and noted by Bentham who argued that 'without the assistance of the law, the inventor would almost always be driven out of the market by his rival, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his deserved advantages, by selling at a lower price'.[20] Bentham concludes that 'he who has no hope that he shall reap will not take the trouble to sow'.[21]

On the other hand, from the community's perspective, the rapid and free imitation of a given invention is ultimately a good thing, as it would allow society to increase its benefits from the use of that invention.[22] Consider a case in which an invention, for example a chemical process, can be used to create an improved product. If the invention is free for all without payment, then society is likely to benefit mainly for two reasons. First, with full competition the price of the improved product would probably be lower than that of a monopoly. Second, given that the use of the invention by anyone other than the inventor saves the costs invested in its production, consumers are likely to benefit by not paying any additional costs involved in developing the invention.[23]

Thus, free-riding presents the first and most fundamental problem in the production of inventions in the absence of patents. On the one hand, from the perspective of the community, widespread use of an invention is always preferable to its use by a single user. On the other hand, without receiving adequate returns for his invention, the inventor would be reluctant to invest time and resources in producing it in the first place.[24]

Regarding secrecy, the lack of institutional arrangements for inventions increases the tendency towards producing secret inventions. From the community's perspective it is preferable to have an invention that can be kept secret than not to have one at all, provided that the invention has social value. This is because the use of the invention releases resources for the production of other goods, thereby increasing the net social benefit.

However, the impetus towards secret inventions generates two sets of problems. First, there are opportunity costs, in terms of the potential to release additional resources. These costs derive from the use of the invention by a single manufacturer (an individual company for instance) instead of by the entire branch to which the invention could apply. In other words, the singular use of the invention, although increasing the community's net benefit, is always less than optimal.[25] The community might also bear additional opportunity costs caused by cases in which the original inventor does not use his invention in the most efficient way. If the original inventor could sell his invention to more efficient firms then the community would gain from the release of extra resources not only because the invention is used by more firms but also because it is used more efficiently.[26]

Second, if the original inventor is able to keep his invention secret for a long period, thereby maintaining his competitive advantage, others would be tempted to try to come up with the same invention by initiating their own R&D projects. Here, the resources used by other firms for the production of an identical invention may be regarded as misallocated.[27] Some would argue that firms that adopt different methods for the production of a certain invention generate new and valuable types of knowledge. Yet, this argument in itself does not justify the initial allocation of scarce resources, particularly when it

is unclear whether different types of research for the production of an existing invention will, in fact, yield satisfactory and desirable results in terms of valuable knowledge to society.

In the absence of institutional provisions for inventions, society would face the problems of free-riding and secrecy. The former creates a state of underproduction in inventive efforts, while the latter prevents the widespread use of inventions. Both generate losses of additional resources that might have been released and used more efficiently, if more inventions had been available and accessible to society. Furthermore, society may also face the risk of diverting additional resources in short supply for the production of inventions that already exist. Therefore, there is social merit in the creation of institutional provisions for inventions that will optimize both the allocation of resources towards inventive activities and the disclosure of inventions to society.

2.2.3 An Alternative Reward System for Patents

It was previously established that in the absence of institutional arrangements for inventions, firms would regard the allocation of resources to inventive activities as a risky investment. Central intervention of governments is thus required to reduce market risks and thereby securing the production and distribution of socially desirable inventions.

Theoretically speaking, a government can take upon itself the entire inventive enterprise. Alternatively, it can establish mechanisms aimed at rewarding the inventor. The latter alternative is more relevant to the following discussion as it involves inventions originating from the private sector.[28]

A centrally administered reward system for inventions

A system based on centrally administered rewards for inventions uses public funds to recompense inventors for their work. By attempting to break the link between inventions and market-oriented behaviour, it seeks to optimize both the level of inventive activities and the distribution of inventions to society. As Polanvyi put it: 'In order that inventions may be used freely by all, we must relieve inventors of the necessity of earning their rewards commercially and must grant them instead the right to be rewarded from the public purse.'[29]

Two aspects are particularly important in such a system. The first is concerned with government decisions regarding the value of the reward and the ways for granting it to the inventor. The second focuses on the need to finance the reward.

With respect to the former, a government can reward the inventor either before or after his invention is developed. In cases where it is able to predict future inventions and to assess their social value, a government can auction the right to invent. Using this method, and provided that a competitive industry exists,

the government could pay the inventor a sum that is equal to the anticipated and quantifiable social benefits. From the inventor's perspective, the bid would be equal to the quantified social benefit minus his predicted private costs for developing the invention.[30]

If, on the other hand, a government believes that it is preferable to focus on existing inventions, it can establish a mechanism for rewarding the inventor on the basis of his invention. Polanvyi suggests a sophisticated rewarding system in which both the government and the inventor agree on an annual reward based on their assessments of the economic value generated by the invention in the previous year.[31] Others have suggested that instead of paying the inventor an annual fee, the government should buy the invention from the inventor and make it available to all, free of royalty charges.[32]

However, since inventions are extremely heterogeneous and vary in their actual and potential use, even when classified into categories, it would be very difficult to come up with non-discretionary methods for rewarding inventors.[33] Furthermore, the expected efficiency of such a system greatly depends on whether the reward is socially adequate. If it is too high, society will use too many resources in inventing, while if the reward is too low, there will be under-production of inventions.

In this respect, patents may be regarded as an efficient solution since they reduce discretionary decisions and are supposed to provide identical treatment to all inventions. By choosing the method of patents, a government only has to decide whether to make a given invention the exclusive property of its inventor, thus effectively shifting the task of granting the reward to the patentee.

With regard to the second dimension – financing the reward – the government must collect additional tax in order to pay inventors from the public purse. It will thus have to consider which method of taxation is the least expensive in terms of welfare losses. It is quite clear that in this case the government must not introduce an excise tax on the invention as this will non-optimally reduce demand for the invention.[34] Still, even if the government is able come up with the optimal tax system for financing rewards, it will still have to face the political consequences of raising taxes.

By establishing a system of patents, the government can avoid the political 'headache' of collecting additional taxes from the public. On the other hand, choosing such a system, which due to its monopolistic features allows patentees to charge higher prices for their inventions, is similar to the adoption of a tax that is based on a single good – the inventions. Thus, a trade-off exists between the discretionary features of an administered reward system and the non-efficient nature of the patent system.

It would seem that by attempting to reward the inventor from the public purse, a centrally administered regime tends to reduce the link between inventions

and commercially oriented behaviour. It aims to optimize both the allocation of resources towards inventive activities and the distribution of inventions to society. The main flaw of such a system lies in its inability to escape problems of discretion particularly in decisions concerning the amount of the reward and the methods for granting it. In this respect a patent system is less discretionary since, in theory, it treats all inventions alike. Furthermore, since public rewards require financing, a government will have to consider both the economic and political consequences of raising taxes. Choosing patents will allow it to avoid such difficulties. However, since a patent system is basically an excise tax it entails greater social costs than any other tax form that might have been adopted by a centrally administered reward system. Given the trade-off between the discretionary manner of a centrally administered reward system on the one hand and the non-efficient nature of patents on the other, it is not currently possible to conclude which is superior with regard to rewarding inventors. Nevertheless, since patents are the main concern of this chapter it is now important to focus on some specific aspects of the patent system itself.

2.2.4 The Patent System

A patent system establishes property rights in inventions for a given period of time. On the one hand, it serves as an incentive for future inventive activities mainly due to the fact that a patentee has the legal right to prevent others from using his inventions without his permission. On the other hand, such a system could lead to the non-efficient allocation of new and valuable knowledge as it creates a temporary monopoly on the use of inventions. Therefore the structural conflict built into the patent system is such that, in order to increase the number of inventions, and thus knowledge, in the future, it restricts the use of existing inventions in the present. Robinson refers to this problem as the 'paradox of patents' arguing that the 'justification for a patent system is that by slowing down the diffusion of technical progress it insures that there will be more progress to diffuse'.[35]

The following discussion reviews some of the theoretical implications of patents on inventive efforts and on inventions, once they are developed. It seeks to emphasize the complexities and contradictions regarding patents and to argue that currently it is very difficult, if not impossible, to come up with theoretical conclusions about the social desirability of such a system. This section, therefore, considers and elaborates on some specific aspects concerning patents. First, it assesses the effects of patents on the allocation of resources to inventive activities, the allocation of resources within the sphere of inventive activities, and on the allocation of inventions as a factor of production.[36] Secondly, it examines the issue of the patent term of protection. Finally, it reviews some problematical aspects regarding the system itself, such as the difficulties of

setting criteria for patentability, and the extent to which patent concentration increases the misallocation of resources in the inventive sphere.

The allocation of resources to inventive activities

The extent to which patents optimize the allocation of resources to inventive activities is not currently clear.

Some antagonists may express the view that patents are both irrelevant and inadequate regarding their ability to serve as an incentive for future inventive activities. They may argue that inventors, like artists, experience the 'starving artist' phenomenon and as such have the intellectual and emotional need to invent regardless of any potential rewards.[37]

Other opponents may hold the view that since social progress is much more important for the creation of inventions than the individual inventor, any system of pecuniary rewards for inventors, such as patents, is completely inadequate. Indeed this argument has its roots in the big patent debate of the second half of the 19th century. J. L. Ricardo, an advocate of the social progress perspective, argued that since 'nearly all useful inventions depend less on any individual than on the progress of society' there is no need for it to 'reward him who might be lucky enough to be the first on the thing (invention) required'.[38] Thus, according to its opponents, a patent system is irrelevant and unnecessary mainly because the incentive to invent lies either within the inventor or within society, not in the system.[39]

The main problem with the 'starving inventor' and 'social progress' arguments is that they rely on the rather outdated assumption that the bulk of inventions are developed by, or attributed to, individuals. The fact is that any attempt to understand the effect of patents on modern inventive projects must take the profit-seeking firm as its basic unit of observation. Most R&D projects, originating in the private sector and aimed at producing new inventions, are too complex, costly and time consuming to be initiated by calculations other than profits.[40]

Therefore, it is quite likely that patents, by allowing firms to secure commercial returns for their inventions, are important for future inventive activities. In fact, some empirical data is available to support this view. A study by Mansfield shows that several industries attached great importance to the existence of patents when deciding on developing new inventions during the early 1980s.[41] He found that in the pharmaceutical industry, between 60 to 65 per cent of inventions would not have been introduced or developed in the absence of patents.[42] Levin reports similar results.[43]

On the other hand, if patents are likely to enhance the rate of inventive activities it is important to consider whether they do so in an efficient manner. Plant suggests that patent monopolies may lead to a state of over-investment in inventive activities.[44] He argues that any benefits generated by the allocation of

additional resources towards inventive output as a result of patent protection, do not necessarily outweigh the costs of not allocating the same resources towards the production of other output.[45] In other words, since scarcity implies that when more resources are diverted to inventive activities, fewer resources are allocated to other economic activities, particularly when patents are introduced. One cannot conclude that society would always benefit from higher levels of R&D expenditures.[46] Indeed, Dasgupta and Stiglitz, focusing on the optimal level of R&D activities, suggest that 'there may be excessive duplication of research effort in a market economy in the sense that industry-wide R&D expenditure exceeds the socially optimal level even though cost reduction is lower'.[47]

The increase in the level of inventive activities as a result of patent protection, may also lead to the problem of diminishing returns in inventive output.[48] Diminishing returns are particularly relevant in cases where additional inventive efforts result in similar or even identical inventions.[49] In this respect, patent advocates may argue that since inventions have the potential to shift the entire technological curve of a given industry they are too dynamic to be analysed by standard economic tools, such as diminishing returns. But the fact that some inventions in the future may revolutionize an entire technological sector does not mean that one should ignore the cost of allocating additional resources for inventive efforts in the present.[50]

Finally, the extent to which patents optimize the timing of inventive activities, in terms of the introduction of inventions, has also been questioned. Barzel concludes that the attempt to secure patent protection may drive firms to introduce inventions sooner than is optimally desirable.[51]

Although it is likely that patents increase the level of inventive activities, it is not clear whether they do so efficiently. Some scholars have suggested that patents create a tendency for over-inventing in the sense that the resources allocated to the production of inventions are in excess of the social need. As such, one cannot determine what is more costly to society: the misallocation of resources to inventive efforts when a patent does not exist, or the misallocation of resources when it does.

The allocation of resources within the scope of inventive activities

The question of whether patents have a positive or a negative effect on the allocation of resources within the scope of inventive activities is also problematic. In the absence of patents, there would be a market bias either towards the production of inventions in industries that are less prone to competition, such as monopolistic or oligopolistic ones, or towards the production of inventions that can be kept secret.[52]

A patent system may solve the first problem as it increases the incentive to invent in industries under competition. Since the output of a given industry is likely to be greater under competition than under monopoly it would be more

profitable for a given firm to sell its cost-reducing invention to a competitive industry than to a monopolized one.[53]

As for the second problem – the market bias towards the production of 'secret inventions' – the introduction of patents can only have a partial effect. The main question here is whether patents can be considered a sufficient incentive for the disclosure of secret inventions. Indeed, this problem has roots in the great patent debate of the 19th century. At the time its advocates argued that patents are the result of a 'social contract' between the inventor and society in which the former agrees to disclose his secret in exchange for receiving temporary protection from the latter.[54] As Penrose put it:

> This theory of purpose of the patent grant has frequently been put in the form of 'social contract' theory: Society makes a contract with the inventor by which it agrees to grant him the exclusive use of his invention for a period and in return he agrees to disclose his secret in order that it will later be available to society.[55]

Its antagonists, on the other hand, argued that if an inventor is able to keep his invention secret for a period longer than that granted by patent term, he would be reluctant to disclose his invention to society. Marshall, supporting this view, notes that despite the existence of patents a 'large manufacturer prefers to keep his improvement to himself and get what benefit he can by using it'.[56] A well-noted example is the case of Coca-Cola, which prefers to keep its formula secret rather than applying for patent protection.

Thus, it is more likely that an inventor will apply for a patent mainly when he believes that he would not be able to keep his invention secret for a period that is longer than, or at least equal to, that of the patent term. Resources are still likely to be invested in the creation of secret knowledge in spite of the existence of a patent system.

Finally, it is also important to consider the allocation of resources towards the production of existing inventions. Firms, in the absence of patents, may invest resources in order to reproduce existing inventions, provided that they are unable to copy them in the first place. This can lead to the misallocation of valuable resources since, from the community's perspective, it is preferable that these firms invest in other projects rather than that of duplicating inventions.[57]

Some may argue that the allocation of resources towards the production of similar or even existing inventions may be socially desired if, as a result, new knowledge is acquired. Even so, this does not mean that the benefits to society from such knowledge exceed the costs of allocating valuable resources towards the duplication of existing inventions. As Machlup notes: 'The production of knowledge in how to do in a somewhat different way what we have already learned to do in a satisfactory way would hardly be given highest priority in a rational allocation of resources.'[58]

In this respect a patent system can have both positive and negative effects on the allocation of resources towards the production of existing inventions.

Considering the positive potential of patents, firms will be reluctant to invest resources in the production of inventions that are identical to patented ones, as they would be unable to appropriate returns for these investments during the term of protection.

At the same time, however, patents can increase the phenomena of 'inventing around' and 'blocking'.[59] The former occurs when firms, interested in competing against a patent owner, try to come up with alternatives to the original patent, hence inventing around it. The latter occurs when a patentee, facing the danger of inventing around, attempts to block his rivals by patenting all available alternatives to its original invention, even inferior ones.[60] Gilbert and Newbery suggest that blocking can occur when firms engage in 'preemptive patenting' – securing patent protection for technologies that are neither used nor licensed to others ('sleeping' patents) – in order to raise entrance barriers.[61]

It is far from clear whether a patent system has a positive or a negative effect on the allocation of resources within the province of inventive activities. A patent system may increase the incentive to invent in industries that are more prone to competition, hence reducing the natural bias towards the production of inventions under a monopoly. An inventing firm would prefer to sell the rights for the use of its invention to an industry under competition rather than to one under a monopoly, particularly when that firm does not have the necessary capabilities to exploit it for production purposes.

Simultaneously, patents are much less likely to affect the disclosure of secret inventions. Large corporations that are able to keep their inventions secret for a long period of time, such as Coca-Cola's famous formula, would still prefer to continue doing so instead of relying on a limited protection period of patents.

Furthermore, patents may also enhance the misallocation of resources in cases where firms choose either to invent around existing patents, or to block others from doing so themselves by patenting all available alternatives to the original invention.

The allocation of inventions as factors of production

This section considers the ability of patents to optimize the allocation of new inventions as a factor of production. For the purpose of theoretical clarity it will be assumed that: patents may be the only form of monopolistic behaviour, that firms are operating in perfect competition, and that they are subject to diseconomies of scale. Furthermore, since the focus here is on inventions and not on inventive efforts one should ignore any positive or negative effects of the patent system on the latter.

The issue of secrecy, which was referred to in the previous section, is particularly important with regard to the allocation of inventions. Two aspects should

be explored. One is concerned with the inventor's ability to keep his invention secret, while the other focuses on his intentions – whether the inventor prefers to keep his invention secret or is interested in selling the rights for its use.

First, consider a case in which a firm was able to invent and to develop a cost-reducing invention, such as a process for the manufacturing of a specific product. If the transmission of the knowledge contained in the invention is both without cost and instantaneous, that is it cannot be kept a secret, and provided that a patent system does not exist, firms are likely to exploit that invention immediately for commercial purposes. If, however, a patent system does exist, then granting the invention a patent will inhibit its rapid dissemination to society and, as a result, will have a disturbing effect on its efficient use as a factor of production.

Thus, in terms of efficient allocation of existing inventions as a resource, it is preferable not to grant patent protection to inventions that can be copied easily and rapidly. Plant makes this point when rejecting claims that a patent system will have a positive effect on the allocation of inventions:

> In a perfect competition all production will take place at a lower cost per unit product. How can it be argued that any departure from such a condition, induced by the grant of monopoly power (patents) to raise prices and increase sectional income by restricting output will achieve greater general usefulness?[62]

This is not to say that society should not reward those firms focusing on the production of such inventions. In fact, many of the most sophisticated products and processes, such as pharmaceutical compounds and computer software, can be easily copied. Nevertheless, in terms of their ability to optimize the allocation of these products and processes, patents cannot be considered efficient.

Second, suppose now that the inventing firm is able to keep its cost-reducing process secret, yet despite its ability to do so, it is still interested in selling the rights for the use of the invention. It is quite clear that in the absence of patents the inventing firm will prefer to keep its invention secret since it will not expect to gain from an attempt to sell it to other interested parties. Given the primary assumption that there are no economies of scale, the price of the product will fall only slightly, as the inventing firm would expand its sales while those of its competitors would contract.[63]

If a patent system does exist, then the inventing firm could sell rights to the use of its invention (that is licensing) at a price per unit which is equal to the vertical shift in its marginal cost curve (from the use of a cost-reducing process).[64] Since the cost curves of other firms would not effectively shift, the cost reducing process would affect neither the price nor the quantity of the product in question .[65]

In this case, granting a patent to a cost-reducing invention does essentially optimize its allocation as a factor of production, as it is now utilised across the industry. It is, therefore, possible to argue that a patent system is likely to increase social gains in cases where firms are able to keep their inventions secret but nevertheless have an incentive to sell the rights for their use.

Finally, suppose that the inventing firm is both able and willing to keep its newly invented process secret. Here, the existence of a patent makes no difference to the allocation of that process, as the inventing firm knows that by applying for a patent protection it would limit its monopolistic position for a period close to that of the patent term.

Therefore, the introduction of a patent system will have a non-optimizing effect on the allocation of inventions that can be easily and rapidly copied. A patent system may thus improve the allocation of inventions, as factors of production, in cases where the inventor can keep his invention secret but nonetheless still be interested in selling the rights for its use to others. This conclusion is plausible as long as the invention is not subject to 'economies of scale' and when firms find it cheaper to buy the right to use the invention rather than to re-develop it themselves.

2.2.5 The Patent Term of Protection

The optimum patent term of protection has been the subject of much attention in the relevant literature. A longer patent term increases the incentive to invent in the future, but also prolongs inefficiencies associated with the monopolistic control on inventions.

Theoretically speaking, the optimum term of protection for a given invention is one in which the social cost of restricting the free use of that invention during the term of protection is balanced by the social benefit of greater inventive output in the future.[66] In practice, however, it is very difficult to come up with a positive term that may be considered optimal to society. Machlup illustrates some of the difficulties one faces when considering the merits for extending the patent term for a given invention.[67] Doing so will require three major factors to be taken into account:

1. One should calculate the nominal and real profits generated from the added term of protection. It should be noted that the percentage of increase in the term of protection does not equal the percentage of increase in financial rewards, as the present value of earnings from *s* years is greater than the present value of earnings from *s+t* years, given a positive increase in interest rates.[68] Moreover, profits are expected to decrease sharply if a superior invention is introduced to the market.

2. There is a need to consider the positive or negative effects concerned with investing the profits gained from the extra years of protection in the creation of new inventions. Calculations should include the amount of additional labour force hired and diverted towards inventive tasks and the increase in national productivity (in methods and in products) due to the use of new inventions.
3. One must assess the social costs, such as the loss of productivity, resulting from prolonging the restrictions on the free use of that invention due to its extended patent term.

Given these difficulties, it is unrealistic to decide a priori on a positive term that may be considered more optimal than other patent terms. Furthermore, not only is it difficult to assess the optimal patent term of protection but it is also plausible that such a term may differ from one invention to another. Using Nordhaus's model, which calculates the optimum patent term for inventions on the basis of their ability to reduce costs and which takes into account different values of demand elasticity and social discount rates, one can reach the following conclusions:[69]

1. The optimal patent life should be made shorter when demand elasticity to the invention is high, and when R&D expenditures are subject to considerable diminishing returns.[70]
2. For 'run-of-the-mill' inventions (inventions that 'reduce costs insufficiently to induce price reduction and output expansion'), the easier it is to achieve a cost-reducing invention in a given R&D investment the shorter the patent term must be.[71]
3. There is an inverse relationship between the optimal life and the social rate of discount.[72] Finally, 'drastic' inventions, that is those inventions that reduce costs considerably, should receive a longer patent term.[73]

Thus, since the model demonstrates that it is not possible to have one optimal patent term for all inventions, any decision on a given term of protection, such as the current period of 20 years as stated in the TRIPs Agreement, must be arbitrary. Nordhaus, for instance, expressed a rather cynical view on the way in which the US government has decided on its previous patent term of 17 years. Quoting Machlup's reference to the post-1624 English patent term of 14 years that was based 'on the idea that 2 sets of apprentices should, in seven years each, be trained in the new techniques', he concludes that in the US it was decided 'that 2.43 apprentices, or 17 years, would be the proper length'.[74]

It is also important to note that the effective term of protection is different from that stated in the patent law. It can be longer if firms are allowed to conduct clinical tests on the invention only after the patent has expired, or shorter if

there is a gap between the grant of the patent and the time it is approved for market use.[75]

Considering the above, it is quite plausible that some inventions, mainly those that require considerable resources, are worthy of a positive term of protection. Yet any decision on such a term is bound to be arbitrary, not only because it is difficult to assess the costs and benefits to society from various terms of protection, but also because different inventions should probably receive different patent terms. Thus, there is no reason to assume a priori that there is a patent term of s years of protection that is better than a term of $s+t$ years.

2.2.6 Problematic Aspects of the Patent System

This section focuses on two major aspects. First it assesses some of the difficulties concerned with setting criteria for patentability. Secondly, it considers to what extent the concentration of patents increases the misallocation of resources in the inventive field

The difficulties of setting criteria for patentability

Any patent system requires specific criteria in order to have a clear mechanism with regard to the decision on the patentability of inventions. However, setting criteria for patentability is far from trivial and can lead to increased inefficiencies in the inventive realm.

Suppose that patentability criteria are too loose to effectively allow the patenting to any slight improvement to or modification of an existing invention. Here, inefficiencies in the allocation of resources in the inventive sphere may occur mainly due to problems such as inventing around and blocking.[76] Moreover, loose criteria for the granting of patents also increase administrative costs resulting from the examination of patent applications, the registration of patents, the enforcement of patent rights, and so on.[77] Excess costs are particularly severe when patents are useless in terms of their ability to contribute to society, especially when similar or even identical patents already exist.[78]

If, however, the conditions and criteria for the grant of patents are too strict and patent rights are too broad, there is always a risk that future inventive activities will be discouraged.[79] When patent criteria are too strict, society may forego the opportunity to have new inventions, or improvements to inventions, that may be considered economically significant yet legally irrelevant. When criteria are too broad, a patentee would be uncertain of his ability to exploit his own patent as he may face accusations of infringement from other patentees.[80] Scherer argues that ‘inventors like Lee de Forest and Edwin Armstrong were forced to sell out their rights in key patents because, as Armstrong later lamented, he was in danger of being litigated to death’.[81]

Facing such difficulties, a government can adopt a system based on the granting of patents either upon registration or upon examination.[82] Neither is satisfactory. The administrative costs of a registration system, under which patent applications receive a rather superficial review, are cheaper than those of an examination system, which reviews patent applications much more carefully.[83] On the other hand, a registration system is likely to increase the number of patentable inventions which, upon examination, would not have been found to be 'patent-worthy'.[84] Indeed, the attempt to enforce patent rights could lead to a mass of lengthy and expensive litigation, the social costs of which negate, and may even surpass, the benefits of adopting a registration system.[85] In contrast, an examination system, though costlier, can reduce the likelihood of non-valid patents. According to Machlup, such a system would reduce the 'mass of worthless, conflicting, and probably invalid patents', as it is likely to prevent the 'fraudulent practice of registration and selling patents similar to the claims being patented by others'.[86] Thus, it is far from clear which system is superior in terms of its ability to administer and to enforce patent rights.

Establishing criteria for the granting of patents may be subject to serious economic, legislative and technical difficulties. The entire effectiveness of a given patent system may come into question if, as a result of these difficulties, the administration and enforcement of patent rights increases the misallocation of resources in the inventive sphere.

Patent concentration

It is unclear whether the tendency towards the concentration of patents increases or reduces patent inefficiencies. The phenomenon of patent concentration may occur in two instances. First, it can be the outcome of a natural and genuine attempt made by firms to test several inventions, while patenting them all, in order to achieve the most desirable and cost-effective result. Second, and as previously argued, it may be the result of a strategic decision of those firms wishing to preserve their market monopoly by patenting all substitutes for their original inventions.[87]

Whether it is a result of a natural process or of a well-planned corporate strategy, patent concentration is likely to increase both the monopolistic position of patentees and their ability to behave in an arbitrary manner.

Consider a case in which two firms were able to develop and to patent similar inventions, and that these inventions vary in their capability to reduce production costs. Theoretically speaking, the owner of the more cost-effective patent can charge a price that is equal to the price of the economically inferior process plus the added value of his superior invention.[88] His ability to set a price for his invention is much more limited compared to a situation in which he was the only patentee.

Moreover, firms are more likely to be able to exploit the monopoly embodied in their patents under a state of patent concentration.[89] Patent pooling agreements, which essentially allow firms to use each other's patents either through cross-licensing or by deciding upon royalties in advance, have been known to create patent cartels, such as that achieved and led by AT&T in the 1930s.[90]

However, it is also plausible that firms will have more incentive to invest in future inventive activities if they are able to control the majority of patents in a given class of inventions. Consider a case in which one firm owns an entire class of patents. Suppose now that a different firm was able to come up with a related invention, yet does not have the capabilities to exploit it commercially.[91] Since in this case the smaller firm will have little choice but to negotiate with the controlling firm, it will naturally be interested in any positive price for its invention.[92] If both parties are willing to negotiate, it is plausible that they will agree on a price (*P*) that ranges between the minimum price (*Pmin*) that the owner of the improved invention is willing to accept, and the maximum price (*Pmax*) that the controlling firm is willing to offer. However, if and when *P* is smaller than *Pmax* there is a disincentive, in terms of commercial returns, for the production of improved or related inventions by those other than the firm controlling them.[93] Thus, a patent system acts as a commercial incentive mostly to those who already own and control a large quantity of patents in a given industry.[94]

Finally, there may be cases in which firms will find it in their own interests to share, rather than control, different types of research findings that is to create conditions of non-patent concentration. Current R&D ventures are very risky in terms of their high expenditure costs and the uncertainty of their outcome. The average R&D costs for the production of new medicines are estimated at $500–$800 millions and the average period for turning a newly-synthesized active substance into a marketable product is about 10–12 years.[95] Furthermore, according to EFPIA, only one or two out of 10 000 synthesized substances will pass every test to become a marketable drug.[96]

As a result, some firms may find it more cost-effective to enter into joint R&D ventures, be it with other companies or with academia, hence giving up the opportunity to obtain commercially valuable patents. This may be particularly relevant in the realm of basic research in which R&D findings, although not commercially applicable in the present, may become extremely important to firms in the future.[97] For instance, according to the FT there is growing cooperation between pharmaceutical giants and academic institutions in the area of DNA mapping.[98] The data obtained from this type of research is designed to create a genetic 'road map' that, in addition to its availability to all researchers, would not encounter the moral dilemma of 'patenting life'.[99]

It is not clear whether the tendency towards patent concentration would reduce or increase inefficiencies in the patent system. The concentration of

patents in a given industry will increase the monopolistic powers of patentees and increase their non-competitive and discretionary behaviour. However, it will also increase their incentive to invest in future inventive activities. Furthermore, there may be cases in which firms would prefer to enter joint R&D ventures, given the high level of risk of such ventures, thereby creating conditions for non-patent concentration.

2.3 THE ECONOMICS OF REGISTERED TRADEMARKS

The economic theory of trademarks is based on the assumption that there is a social need for providing product information to consumers. Ideally, if consumers could obtain accurate and complete information on competing products they would be able to reduce their purchasing errors substantially, thereby increasing their real income. From a macro perspective, this behaviour will benefit society, as more resources would be transferred from inefficient to efficient firms.

However, when left to the market, the production of information to consumers is under-supplied mainly for two reasons. First, it is quite improbable that consumers would be able and willing to conduct a thorough investigation on each and every product they are interested in purchasing. Second, as with inventions, in cases where such information is produced for commercial purposes, it is likely to face the problem of free-riding. Suppose that a given company specializes in the production of consumer reports on various products. Once this firm attempts to sell its product in the market it would be unable to prevent others from obtaining this information free of charge.

This is not to say that product information to consumers does not exist in the market. Daily newspapers, magazines, television programmes and so on play an important role in the dissemination of information on available products. Consumers' tastes and past experiences are another way of transferring information among individuals. Nevertheless, these alternatives are not aimed at providing consumers with comprehensive information on the entire range of available products in the market.

Thus, there is a social interest in the creation of institutional arrangements for the supply of product information to consumers. The main problem is to find an adequate mechanism in which the social benefits of such information would, at least, be equal to the social costs deriving from its production.

The following discussion elaborates on the economic logic underlying the establishment of property rights in trademarks and assesses their ability to function as an efficient mechanism for providing relevant product information to consumers. It will focus on three major issues. First, it will assess the extent to which trademarks optimize the production and dissemination of product

information to consumers. Second, it will consider the link between trademarks and market power. Finally, it will elaborate on cases in which trademarks provide irrelevant and even confusing information to consumers, thereby becoming a social burden.

For purpose of clarity and simplicity, it should be noted that terms such as 'identifying marks', 'trade names', 'brand names' and so on are used as synonyms for the term 'trademark'.

2.3.1 Registered Trademarks as a Method for Optimizing the Production and Dissemination of Product Information to Consumers

A trademark is any sign or combination of signs (such as personal names, letters, numerals, figurative elements and combination of colours and so on) capable of distinguishing goods or services of one undertaking from other undertakings.[100]

Since trademarks, by definition, are considered a method for product differentiation, they are expected to meet two major criteria: the indication of origin and the indication of quality. More specifically, trademarks may be considered an efficient method of providing product information to consumers whereby they can improve their knowledge not only about the origins of various products but also regarding their quality. Considering the first criterion, trademarks are aimed at providing consumers with additional information on the origins of various products, hence acting as indicators of origin. Yet, in itself, the indication of origin is of no particular relevance to consumers if they do not have any prior information about the class of products to which the specific brand-named item belongs. In other words, the indication of origin can effectively achieve the goal of product differentiation only when consumers realize that a range of similar products (in terms of the function of these products) is available at their choice.[101] Once such information becomes available, then trademarks, as indicators of origin, may enable consumers to identify those goods that have proved satisfactory.[102] This is particularly true in the case of 'experience goods', that is goods that can be evaluated only after they have been purchased, mainly because their attributes and characteristics are not apparent upon inspection.[103]

Regarding the second criterion, the indication of quality, it is widely believed that trademarks, in their modern form, identify quality as well as ownership. In fact, it is often claimed that the indication of quality is by far more important and relevant than the indication of origin.[104] Schechter argues that 'marks designating ownership are not trade-marks at all but merely proprietary marks, which may or may not incidentally serve to designate the origin or the source of the goods to which they are affixed'.[105]

The indication of quality is ultimately related to the ability of firms to register their trademarks legally, that is to obtain market exclusivity for the use of such marks. In the absence of property rights in trademarks there would be an impetus towards free-riding, that is the 'borrowing' of successful marks by those other than the original firms.

Two problems may occur: first, from the consumers' perspective, the transfer of reliable marks to non-reliable products is likely to increase purchasing errors, hence reducing consumers' real income. Second, free-riding may reduce the overall quality of a given class of goods, as the manufacturers of high-quality products would be reluctant to continue investing resources in maintaining their quality.[106]

Exclusive rights in trademarks can solve both these problems. By prohibiting the unauthorized use of identifying marks, registered trademarks secure a direct and exclusive communication route between trademark owners and consumers. They will also increase the incentive of trademark owners to associate their products with high quality. By doing so, manufacturers will be able to secure their competitive position by achieving 'goodwill' for their products, which is defined as the 'attachment of buyers to, and their propensity to purchase, the product of a particular firm'.[107]

It should be noted that there may be cases in which counterfeiting in brand-name products can lead to quality upgrading. Grossman and Shapiro argue that when quality is under-supplied, due to lack of sufficient consumer information, the introduction of counterfeit goods through importation may force trademark owners to raise the quality of their products in their home country.[108] This, however, will happen only when there are a fixed number of home firms and when border policy inspections are not sufficiently tight to deter the importation of low quality products.[109]

More importantly, one should make a distinction between the reputation of a given brand-name product and its actual value. Although it is plausible that some trademarks may indeed provide reliable information about the quality of their associated products, this is not necessarily always the case.[110]

Trademark owners, besides having to manufacture products of good value, engage in advertising activities aimed at establishing a reputation for their products. In fact, brand names have become an inseparable part of any advertisement activities.[111] Thus, when a trademark owner chooses to focus more on building the reputation of his product rather than providing it, he reduces the effectiveness of his trademarks as an indicator of quality. Furthermore, in cases where the reputation of a given brand-name product does not match its actual quality, it may lead consumers to commit 'errors of commission', that is purchasing the product on the basis of its inflated, or excessively favourable, pre-purchase assessment.[112]

Modern trademarks are aimed at achieving product differentiation. Their primary function is the indication of origin, enabling consumers to identify the source of those goods that proved satisfactory in their previous purchase. An indication of origin would be an effective method of differentiation as long as consumers are familiar with other products that are similar in function to the brand-named product.

Trademarks may also function as indicators of quality provided that property rights are established and that the reputation for the marked product is compatible with its actual value as a product. When these criteria are not met, then trademarks may increase purchasing errors and cannot be considered an efficient way for providing product information for consumers.

2.3.2 Trademarks and Market Power

A registered trademark creates a monopoly in the use of a specific mark for a given product. However, this type of monopoly is somewhat different from the one created by patents. While the latter grants market exclusivity for the use of a tangible asset – the invention – the former grants it for the use of an intangible asset – the trademark. Therefore, the monopolistic nature of a given trademark is closely linked to the economics of product differentiation and monopolistic competition.

Product differentiation, as previously described, is aimed at securing brand loyalty (goodwill), that is customers' loyalty to specific brand names.[113] Once established, product differentiation makes firms behave as if they were monopolists, hence leading to monopolistic competition.[114]

The tendency towards monopolistic competition in brand names is particularly intensive in the pharmaceutical industry. A report by UNCTAD, using evidence from 1975, found that 'the predominance of product competition is indicated by the large numbers of trademarks registration and brand proliferation in the (pharmaceutical) industry'.[115] Citing evidence from SCRIP (1981), the report also notes that 40 per cent of the trademarks used throughout the world relate to pharmaceuticals and associated products.[116] The market power obtained by monopolistic competition may increase the reliability of trademarks as indicators of quality, particularly when firms attempt to standardize the quality of their products in order to secure brand loyalty.

However, this would be true only in cases where trademarks are considered valuable assets. When firms do not regard their trademarks as commercially significant they would have little or no incentive to preserve their value by providing good quality products.[117]

One must also note that there may be cases in which trademarks establish market power beyond that of monopolistic competition. Consider a case in which two similar products are identical in quality and price, yet only one

has a well-known and reputable trademark. If consumers consider themselves incapable of comparing the products, they are likely to purchase the one with the more reputable mark. In other words, in the absence of sufficient information, consumers are likely to 'stick' with known brand-names, hence increasing the market power of their owners.[118]

Lack of sufficient information may also allow the owner of a successful trademark to charge a premium for his product. Economically speaking, consumers will be willing to pay such a premium as long as it does not exceed the cost of obtaining additional information on rival products. Thus, when such a premium becomes too high, consumers are likely to include price calculations in their decisions.[119]

Yet, practically speaking, brand loyalty implies that consumers will continue to purchase their favourite products even when the premium on such products is greater than the cost of obtaining information on other products.[120] In such cases, the market power generated by trademarks is in excess of the social need as consumers are allocating fewer resources for obtaining information on other products that may be more valuable in terms of quality.

Furthermore, even when information is available, brand loyalty may be strong enough to make calculations of price and quality less relevant. Relying on various empirical findings, UNCTAD argues that doctors in the US are hardly influenced by price calculations when prescribing drugs, despite their being aware that there are alternative sources of similar quality.[121]

Successful trademarks can also raise entrance barriers for new competitors. Since the greater the reputation of existing trademarks in any given industry, the greater is the cost of establishing the reputation of a new product, firms may find it too expensive to enter markets in which such trademarks exist. In fact, it is possible that reputable trademarks create a type of monopoly that is closer to the pure model than that of the competitive one. Chamberlin argues that there is no real difference between the monopoly created by reputable trademarks and that created by patents:

> Are there any bases, after all, for distinguishing between patents and trademarks? It would be ordinarily supposed that the degree of monopoly was greater in the case of patents. Yet the huge prestige value of such names as 'Ivory', 'Kodak' 'Uneeda', 'Coca Cola'…to cite only a few, is sufficient to at least make one sceptical.[122]

A trademark, as a form of product differentiation, will allow its owner to behave as a competitive monopolist, provided that he was able to create goodwill for his product. A known trademark can increase its owner's market power beyond that of a competitive monopolist, particularly in cases where consumers do not have sufficient information on alternative products. Known and reputable

trademarks can also raise entry barriers when potential competitors believe that the cost of achieving a reputation for their products is too high.

2.3.3 Trademarks as a Social Burden

It was previously argued that trademarks could function as indicators of quality as well as of origin. With regard to the former, trademarks will be considered socially desirable as long as they provide consumers with valuable information about the differences in quality of various products. Thus, there is not much logic in keeping trademarks in their current form if, for a given class of goods, they do not fulfil the above criterion.[123]

Most notable are cases in which registered trademarks create an artificial differentiation between products that are for all purposes identical. When two identical products are subject to different trademarks, there is a risk of providing consumers with irrelevant and sometimes even confusing information about the features and qualities of these products. In economic terms, since additional product information should be provided only if its marginal social benefit exceeds or equals its marginal social cost, registered trademarks for identical products may entail social losses.

The relevance of trademarks has been questioned mostly with regard to generic products, such as pharmaceuticals and chemicals.[124] Generally speaking, consumers do not have complete information regarding the qualities and functions of these types of products. Therefore, they are likely to be more confused when confronted with different brand names for identical pharmaceutical compounds.[125]

For these products it is preferable to use generic names as their primary identifying marks, not only because it will avoid confusion, but also because, given a wider variety of choice, it is likely to increase competition and to reduce prices.[126] Aspirin is one case in which a US court of law decided to convert a known trademark to a generic name because of the need to prevent the public from being confused.[127]

On the other hand, if all identical products were to be amalgamated and sold under one generic name, there would be an impetus for manufacturers to reduce their production costs by investing fewer resources into maintaining the quality of their products. The risk of quality reduction would require additional resources for providing mechanisms of quality control, which may prove extremely costly.[128]

Thus, only when quality-control facilities, such as the Food and Drug Administration (FDA) in the US, are in place regardless of the existence or absence of brand-name products, will the added costs of maintaining the quality of amalgamated products be tolerable. When such facilities are absent, such as in less developed countries, it is not clear whether a policy of product

amalgamation generates benefits that are in excess of the costs of assuring the quality of generic products.[129]

Trademarks may become a social burden when they provide consumers with irrelevant and confusing information, particularly with regard to products that are identical in function and in quality. In the latter case, it would be more plausible to give these products a common generic name, provided that mechanisms for quality assurance are available.

2.4 CONCLUSION

The chapter suggests that a pure economic approach cannot provide a sufficient and satisfactory explanation for the establishment of IPRs. Since they refer to different types of knowledge, it is impossible to treat IPRs as one homogeneous group. Therefore, the chapter focused on the economic theory of patents and registered trademarks. Common to these two forms of IPRs is the creation of market exclusivity in the use of existing knowledge: inventions for patents and consumer information for registered trademarks. However, as summarized below, the economics of patents is far more complex and it is not currently possible to conclude whether they confer a net benefit or entail a net loss upon society.

2.4.1 Patents

The structural trade-off built into the patent system – that in order to increase the amount of available knowledge in the future the efficient use of existing and available knowledge is inhibited in the present – is its most problematical aspect.

In the absence of institutional provisions for inventions, society would face a state of under-production in inventive activities due to the problem of free-riding. Establishing property rights in inventions, that is patents, will allow inventors – both firms and individuals – to secure commercial returns for their work and as such will increase their incentive to invest in future inventive activities. On the other hand, a patent system inhibits the free and rapid dissemination of existing knowledge. Once it has been granted a patent, an inventing firm essentially becomes a monopoly since it has the exclusive right to control both the quantity and the price of its invention. Facing these conflicting aspects, economists have to consider which is more important to society: more available knowledge in the future or less accessible knowledge in the present. No conclusive answer is currently available.

Economists also disagree about the effects of patents on the allocation of resources to inventive activities, the allocation of resources within the sphere of

inventive activities and on the allocation to inventions as a factor of production. First, it is not clear whether the allocation of resources to inventive activities is better or worse when patents are introduced. Second, it is also difficult to assess the extent to which patents optimize the allocation of resources within the inventive sphere. Third, patents may also have an uneven effect on the allocation of inventions as factors of production. Since patents, by definition, limit the dissemination of existing knowledge in the present, they cannot be considered an efficient method for allocating those inventions that can be easily and rapidly copied, provided that such inventions cannot be kept secret.

The optimum patent term of protection is also highly disputable. A longer patent term increases the incentive to invent but also prolongs the restriction on the use of existing knowledge. Therefore, not only is it difficult to establish one patent term optimal to society, but it is also likely that different inventions require different terms of protection. Thus, since a decision on a specific patent term for all inventions is bound to be arbitrary, there may be a term that is more socially desirable than the current period of 20 years.

Problems may also occur with respect to the criteria for patentability. Inefficiencies may occur if patent criteria are too 'loose', such as allowing patent rights to any slight modification of existing inventions. Loose criteria can lead to the misallocation of resources to activities such as 'inventing around' and 'blocking'. On the other hand, when patent criteria are too strict, there would be a risk of under-investment in inventive activities, as potential inventors would be uncertain as to whether they could secure patent rights for their inventions.

Many scholars emphasize the natural tendency towards the concentration of patents. Patent concentration will increase the monopolistic position of those who control the bulk of inventions in a given industry and will allow them to behave in a more arbitrary and harmful manner. On the other hand, it is also likely that the incentive to invent, in terms of commercial returns, will be greater under patent concentration.

Lack of theoretical coherence and insufficient empirical data does not currently enable one to draw a conclusion on the overall economic merits of patents. Back in the 1950s Fritz Machlup argued that 'no economist on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss to society'.[130] Sadly enough this statement also seems to be true in our days.

2.4.2 Trademarks

The economic theory of registered trademarks is more coherent than that of the patent system. Generally speaking, there is a social need for the creation of product information for consumers. Such information will reduce the purchasing errors of consumers, increase their real income and may even

transfer social resources from inefficient to efficient firms. However, given that information for consumers has the characteristics of public goods (non-rival, non-excludable), it is likely to be under-supplied when left entirely to the market, again due to the problem of free-riding. Thus, as with patents, it is in the social interest to create institutional arrangements for the supply of product information to consumers.

Although trademarks cannot solve the problem of under-supply in information for consumers they are capable of improving the situation. Designed to operate as a method for product differentiation, trademarks are expected to carry out two major functions: the indication of origin and the indication of quality.

The indication of origin, which essentially differentiates between products on the basis of their origins, helps consumers to identify goods that have proved satisfactory, particularly those that can only be evaluated after their purchase ('experience goods'). The indication of quality, which is designed to provide consumers with additional information about the quality of products, can be achieved only after property rights in trademarks are established (for example registered trademarks). This is because consumers are likely to face problems of false information and quality reduction when firms are allowed to free-ride a particular trademark by 'borrowing' and using it for their own products. Since registered trademarks create a direct and exclusive channel of information between manufacturers and consumers, they are likely to increase the incentive of firms to maintain the quality of their products, as this secures brand loyalty.

A given trademark will function as an efficient indicator of quality as long as its reputation is balanced by its actual value. Trademarks cannot be considered efficient indicators of quality when the allocation of resources towards 'reputation', such as excessive advertising, is at the expense of good value.

Trademarks are also linked to market power. As a method for product differentiation, trademarks may lead manufacturers to behave as competitive monopolists. This would be particularly relevant for firms who regard their trademarks as profit-generating assets, as they are likely to dedicate sufficient resources for the creation of good value in order to secure brand loyalty.

In some cases, known and reputable trademarks can secure a type of monopoly that is closer to that created by patents. When consumers do not have sufficient information on a given class of products they are likely to purchase known brand names in order to avoid purchasing errors. As a result, the owners of reputable trademarks can charge a premium for their products that may be even higher than the additional cost of obtaining information on other competing products. Successful trademarks can also raise entrance barriers against potential competitors, who, facing the high costs of establishing the reputation for their own products, choose not to enter markets in which such trademarks exist.

Finally, if, for a given class of products, trademarks provide information that is in excess of the social need, there is no logic in keeping them in their current form. In the case of generic pharmaceutical products, trademarks create an artificial product differentiation that is likely to cause consumers to be more confused rather than better informed. It would be better to give these products a common and primary generic name.

All the above suggests that the social usefulness of registered trademarks ultimately depends upon the way in which they are used. Trademarks may be considered an efficient source of information as long as they enable consumers to obtain additional and accurate knowledge about different products. When this is not the case, trademarks can easily become a source of useless, inaccurate and even false information.

It follows that a pure economic approach does not provide an adequate theoretical and empirical basis for the establishment of IPRs. Therefore, it is necessary to consider to what extent the internationalization of IPRs is economically justified, or whether it may be explained by a different approach, which is primarily politically orientated.

NOTES

1. Hindley (1971: 1)
2. Distributional aspects are discussed in Chapter 3
3. The TRIPs Agreement, Article 27.1
4. Ibid., Article 28
5. OECD (1993: 29)
6. Ibid., p. 68
7. Ibid., p. 69
8. Nelson (1959: 302)
9. Machlup (1962a: 147)
10. OECD (1993: 70)
11. Machlup (1962a: 162)
12. Kuznets (1962: 20)
13. Sanders (1962: 77)
14. Nelson (1959: 299)
15. OECD (1993: 75)
16. Ibid.
17. Arrow (1962: 614–16); Stiglitz (1999: 308–25)
18. Arrow (1962:615)
19. As long as the resources invested in copying are cheaper than those required for purchasing the invention or from conducting a separate R&D to produce it
20. Bentham (1843: 71)
21. Ibid.
22. Polanvyi (1944: 65)
23. Machlup (1958: 58–61)
24. Arrow (1962: 616–17)
25. Ibid., p. 618
26. Hindley (1971: 6)
27. Beck (1981: 91–110)

28. This does not, by any means, imply that there is no logic in having an invention system based upon centralized initiatives. Under centralized initiatives, the payoff structure for inventions is calculated differently as governments, despite being subject to political pressures as well as economic constraints, may still be able to consider calculations of profits in a more balanced manner. In theory, this can reduce the problems of free-riding and secrecy as governments, considering the net benefit for society, will be interested in spreading new inventions as widely and as quickly as possible.
29. Polanvyi (1944: 65)
30. Hindley (1971: 10); For a similar view see also Beck (1981: 103–6); Kitti (1985: 89–90)
31. Polanvyi (1944: 66–9)
32. Machlup (1958: 15)
33. Polanvyi also acknowledges the problem of discretion when arguing that any decision regarding the grant of the reward would be prone to 'corruption and arbitrary oppression which is never removed from the grant of public subsidies' (p. 68). Nevertheless, he still holds the view that a centralized reward system, despite its flaws, would not be less fair, to say the least, than the patent system
34. Hindley (1971: 10)
35. Robinson (1956: 87). The term 'paradox of patents' is mentioned in her table of contents.
36. Hindley (1971: 12–21); See also Machlup (1958); For a more contemporary literature review see: Primo-Braga (1990c: 17-32)
37. Plant refers to the need to invent for the sake of inventing: (1934: 33–4)
38. *The Economist* (26 July 1851: 812); also see: Penrose and Machlup (1950: 18)
39. Machlup (1958: 24)
40. For a vivid description concerning the transformation of the 'inventive industry' in the corporate era see Kahn (1940 :475–91, p. 481 in particular)
41. Mansfield (1986: 173–81) ; See also: Nogués (September 1990 11–14)
42. See in Nogués (1990b: Table 2)
43. Levin, Klevorick, Nelson and Winter (1987: 783–820); See also Nogués (1990b: Table 3)
44. Plant (1934: 40–42)
45. Ibid., p. 40
46. Ibid.
47. Dasgupta and Stiglitz (1980: 289)
48. Machlup (1962b: 159–69)
49. Ibid., pp. 159–60
50. Ibid., p. 163
51. Barzel (1968: 348–55)
52. Hindley (1971: 8–9)
53. Arrow (1962: 619–22)
54. Penrose and Machlup (1950: 25–8)
55. Penrose (1951: 32)
56. Marshall (1946: 234, footnote 1); also see: Machlup (1958: 32)
57. For the waste of R&D efforts resulting in similar inventions see Beck (1981: 97–103)
58. Machlup (1958: 51)
59. Ibid., pp. 50–52
60. Marshall (1946: 234, footnote 1)
61. Gilbert and Newbery (1982: 514–26)
62. Plant (1934: 43)
63. Hindley (1971: 18)
64. Ibid.
65. The cost curve of other firms, although slightly lower than before, now also includes the amount paid for purchasing the right to use the cost reducing process
66. Nordhaus (1969: 76)
67. Machlup (1958: 66–73)
68. Hindley (1971: 20–21)
69. Nordhaus (1969: Chapter 5); for geometrical interpretations see Scherer (1972: 422–7); also see: Nogués (1990a: 6–9)

70. Nordhaus (1969: 79); Nogués (1990a: 6)
71. Scherer (1972: 423); Nordhaus (1969: 79), Nogués (1990a: 7)
72. Nogués (1990a: 7); Nordhaus (1969: 80–81)
73. Nogués (1990a: 7)
74. Nordhaus (1969: 52, footnote 18)
75. These issues are discussed in length in Chapter 4
76. Discussed earlier in the chapter
77. Primo-Braga (1990a: 73–4) Nogués (1990a: 12–13)
78. Machlup (1958: 8); Nogués (1990a: 13)
79. Hindley (1971: 24)
80. Polanvyi (1944: 70); Engel (1985: 95–101); Kahn (1940: 484–6)
81. Scherer (1970: 391); also quoted in Nogués (1990a: 13)
82. Primo-Braga (1990a: 74)
83. Sherwood (1990a: 182); Primo-Braga (1990a: 74)
84. Machlup (1958: 8)
85. Nogués (1990a: 12)
86. Machlup (1958: 8)
87. Gilbert and Newbery (1982: 514–16); Beck (1981: 97); Primo-Braga (1990c: 21–23); Machlup (1958: 50–52)
88. Hindley (1971: 27)
89. Edwards (1949: 224)
90. Kahn (1940: 486–7)
91. The inability to exploit the invention does not necessarily have to be the result of lack of production capabilities, such as economies of scale. The larger firm, attempting to 'fence out' competitors, can raise legal difficulties for the smaller one by forcing it to enter into expensive and time-consuming litigation that will prevent it from using the invention. See: Machlup (1958: 11); Polanvyi (1944: 70)
92. Polanvyi (1944: 70)
93. Hindley (1971: 27)
94. Gilbert and Newbery (1982: 526)
95. For estimates of pharmaceutical figures see: PhRMA (2003: 1–7); EFPIA (1998b: 10); ABPI (1996); Luscombe, Walker, Griffiths and MacFarlane (1997: 193–9); Burns and Pilling (1999: 6)
96. EFPIA (1998b:10)
97. Nelson (1959: 303–4)
98. Pilling (1999b); For the preference of pharmaceutical firms to cooperate with academia also see: *The Economist* Survey of Innovation in Industry (1999a: 11)
99. Pilling (1999b)
100. TRIPs Agreement, Article. 15.1
101. Hindley (1971: 70)
102. UNCTAD (1979: 1–3); Edwards (1949: 3)
103. UNCTAD (1979: 7); In contrast, 'search goods' are products, such as fruits and vegetables, that can be inspected and compared before the purchase, thus reducing the need for identifying marks. For the role of trademarks with regard to 'experience goods' see also: Economic Council of Canada (1971: 191)
104. UNCTAD (1979: 1)
105. Schechter (1925: 20)
106. Chamberlin (1947: 249)
107. Edwards (1962: 26); Today it is more common to use the term 'brand loyalty' instead of 'good will'
108. Grossman and Shapiro (1988: 59–75)
109. Ibid., p. 73
110. Economic Council of Canada (1971: 193)
111. UNCTAD (1979: 9)
112. UNCTAD (1979: 7)
113. Chamberlin (1947: 56)

114. Krugman and Obstfeld (1997: 127–8)
115. UNCTAD (1981: 3)
116. Ibid.
117. Economic Council of Canada (1971: 195)
118. Hindley (1971: 71)
119. Ibid.
120. UNCTAD (1979: 32)
121. UNCTAD (1981: 5)
122. Chamberlin (1947: 62)
123. Hindley (1971: 72)
124. According to UNCTAD, 'a generic name for a drug applies to all those brands of that drug…which contain the same active ingredient, have the same action and can generally be used as substitutes for each other, provided that their qualities have been assured'. UNCTAD (1981: 8)
125. UNCTAD (1979: 38–40)
126. UNCTAD (1981: 8–14)
127. Lunsford (1974: 83)
128. Hindley (1971: 73)
129. UNCTAD (1981: 12)
130. Machlup (1958: 79)

3. Economic and political explanations for the emergence of a stronger international IP system

3.1 INTRODUCTION

To understand the emergence of a stronger international IP system one must shift one's attention from the perspective of the community as a whole to that of the individual country. The ability to create new types of IP-related products varies between countries. Also different are the costs and benefits that these countries face when deciding whether to support, or to oppose, a stronger international IP agenda.

This chapter reviews and assesses some explanations concerning countries' decisions to commit themselves to a stronger international IP system. For clarity, it makes a distinction between 'north' (developed) and 'south' (developing) that is between capable and less-capable countries in the field of IP, in order to study the effects of a stronger international IP system. The distinction, as will later be shown, is both theoretically and empirically valid.

The chapter assumes the existence of two major elements in the international IP system. The first and most fundamental element is the principle of 'national treatment', requiring member countries to treat the nationals of other countries no less favourably than their own. National treatment will thus enable foreigners to exploit their IPRs in countries other than their own. Yet, since countries may still have considerable gaps in the scope of their IP legislation, the principle of national treatment in itself is insufficient. For example, under the International Convention for the Protection of Industrial Property in 1883, in which the principle of national treatment was first adopted with regard to IPRs, both Switzerland and the Netherlands were able to adhere to that principle without having any kind of patent legislation whatsoever.[1]

The second requirement of an international IP system is standardization, implying that member countries joining an international IP system agree to enact and to implement the same domestic IP legislation. It is well acknowledged that in reality full standardization does not exist and that IP domestic legislation still varies between countries. Even the TRIPs agreement falls short of securing a completely harmonized system of IPRs between WTO member states.

Nevertheless, despite its simplicity, the assumption of standardization emphasizes the main problem concerning the issue at hand – the inherent tension between the attitudes of northern and southern countries with regard to the international IP system. To a large extent this problem also relates to the differences in legislation between countries with a strong and a weak commitment to IPRs.

In order to assess possible economic and political explanations for a stronger international IP system, this chapter focuses on three major issues. First, it assesses the theoretical and empirical implications of an international IP system on trade in IP-related products (those products that are entitled to various types of IP protection such as patents, copyrights, trademarks and so on) and on royalty payments. Second, it focuses on the extent to which an international IP system affects the rate of technology transfer from developed to developing countries. Again, more emphasis is placed on the international patent system although trademarks and copyrights will also be discussed. Third, it considers the link between the political decision of developed countries to retaliate against countries with weak IP protection and the commitment of the latter to a stronger international IP agenda.

The main conclusion is that, among the three issues mentioned above, trade retaliation seems to provide the most plausible explanation as to why countries with weak IP capabilities, and legislation, commit themselves to a stronger international IP system.

3.2 THE EFFECTS OF AN INTERNATIONAL IP SYSTEM ON TRADE IN IP-RELATED PRODUCTS

3.2.1 Theoretical Implications

An international IP system has two features that are particularly relevant to the ability of member countries to trade in IP-related products.

First, it creates a monopolized trading environment in the sense that it allows IP owners, regardless of their nationality, to be the sole exporters of their products to other member countries. For example, once a firm is able to obtain a patent for a given invention, such as, a new pharmaceutical drug, in a foreign member country it becomes the sole exporter of this drug to the country granting the patent. In other words, it would be illegal for domestic firms to manufacture or even sell the patented drug without the permission of the foreign patenting firm. Second, since IPRs create a temporary monopoly in knowledge products, they effectively allow IP owners to charge prices that are in excess of what they would otherwise have charged in the absence of such protection.[2]

Referring to the first feature, the argument is that the more capable a country is in the realm of IP – that is, that its domestic firms and entrepreneurs are able to develop new types of IP products and to exploit them internationally – the more likely it is to increase its net benefit by entering such a system. This conclusion is fairly straightforward and easy to explain. A country with strong IP capabilities will benefit from entering an international IP system as it essentially becomes an exporter of IP products. This in turn will improve its terms of trade and will increase its national income.[3] As Penrose argues: 'If the patented exports are at all important, the increased proceeds permit the exporting countries to import more goods in exchange for their exports…and the improvement in their terms of trade thus results in an increase in the real income of the country'.[4]

The second feature presumes that a country with strong IP capabilities will also increase its national income due to the ability of its nationals to charge higher prices for their exported products. Conversely, if a given country has little or no IP capabilities, it would be better off not joining the international IP system at all.[5] Upon deciding not to join an international IP system, a country with weak IP capabilities enables its domestic firms to exploit different IP products freely, once they have been purchased, and thus to import fewer of these products in the future. Theoretically speaking, by exporting those products that its firms can imitate and exploit, a county with low IP capabilities can increase its prospects of becoming a potential competitor in the international IP marketplace.

In this respect, a formal model developed by Chin and Grossman compares the welfare economics (focusing on consumer and producer surpluses) of northern and southern countries, when patents originating from the former are either protected or infringed by the latter.[6] The model assumes that IP capabilities are found only in the north. The south, though, is capable of successfully imitating the newly developed products. The authors conclude that it is generally in the interest of southern countries not to provide patent protection to northern firms, particularly in the absence of licensing agreements, that is when there is no voluntary diffusion of technology from northern to southern firms.[7] They argue that even with licensing agreements, a southern country should grant patent protection for northern firms only if its own firms have superior bargaining power when negotiating such agreements and when its share of world consumption of the patented technology is sufficiently high.[8]

By not entering an international IP system, the country in question could also increase its national income by a sum that is equal to the excess in prices its residents would have paid foreign firms for their knowledge products if their IPRs were recognized.[9]

It should thus be noted that the ability to reduce the level of imports and the excess of monopolistic prices in IP-related products also depends on the way in which both domestic and international IP legislation is set. If an international patent system prohibits the re-exportation of patented products by those other

then the patentee then foreign firms may find it in their interest to reduce the prices of their patented goods in the non-patenting country to marginal cost.[10] In this case, and assuming that domestic and foreign products are equal in price and quality, the attraction of purchasing foreign patented goods is still high and the level of imports is determined by non-price calculations.

Alternatively, if the country in question does not adopt the principle of national treatment and grants patent protection only to its residents, then domestic firms, exploiting patented products from abroad, can apply for patent protection in that country and become the new patent owners of these products. Such firms would now be able to charge prices for their products that are equal to or even higher than those charged by the original foreign patentees, hence making other residents worse off than before. In this case, the country in question will face the paradox of increasing its national income while worsening its overall social welfare.

Naturally, the decision of a country with low IP capabilities not to grant IPRs to foreigners depends on its access to foreign markets, that is, its domestic firms are able to purchase alternative IP products in the first place. Indeed, such a country may be forced to strengthen its IP commitments when facing the threat of trade retaliation by countries with strong IP capabilities. However, since the issue of trade retaliation is determined by political calculations as much as by economic ones it merits a separate discussion later on in this chapter.

Some would also argue that in order for a country with weak IP capabilities to become less dependent on the importation of IP-related products it must also obtain know-how capabilities essential for the commercial exploitation of such products. This argument is discussed in depth in the following section. Yet it is still generally agreed, and frequently argued by developed countries, that in most cases it is fairly easy and inexpensive to imitate cutting-edge IP products, such as pharmaceutical drugs and computer software.

Finally, it should also be noted that when a country decides not to join an international IP system, it might face the problem of 'talent migration'. Since the decision not to join is likely to prevent the more creative and innovative domestic firms from receiving monopoly privileges abroad, they may decide to base their activities elsewhere.[11] In this case, that country will have to consider the extra IP products it would have to import.

All things considered, it is theoretically clear that, with regard to trade in IP-related products, the incentive of countries with low IP capabilities to protect the IPRs of foreign firms is much weaker than that of countries with considerable capabilities in this field. This is why Vernon, as early as the 1950s, argued that an 'under-industrialised nation would be derelict of its own interests if it failed to consider the possibility that unlimited patent protection to foreigners might worsen its terms of trade'.[12] Thus, he concludes, 'such nations might reasonably

look upon the grant of patent monopolies to foreigners rather differently from an industrialised nation'.[13]

3.2.2 Empirical Implications

With the theoretical framework of the effects of an international IP system on trade in IP-related products having been set out, it is important to examine some of the empirical data available for this area. In this respect, the extent to which IPRs are distributed between member countries is critical to the economic assessment of trade in IP-related products.

Here, the evidence is quite striking and shows the dominance in IP of developed countries. UNCTAD, in one of the most comprehensive studies of the international patent system, found that in the years 1964 and 1972 nationals of developed countries owned 97 per cent and 95.6 per cent respectively of all patents granted to foreigners.[14] In contrast, the foreign ownership of patents by nationals of developing countries in these years amounted to less than 1 per cent.[15] UNCTAD also emphasizes the fact that in both 1964 and 1972, five developed countries owned approximately 80 per cent of patents granted to foreigners, with the US holding around 40 per cent of these patents. The other 40 per cent were distributed between Germany (then the Federal Republic of Germany), Switzerland, the United Kingdom and France.[16] Data gathered in 1996 and 2000 (based on WIPO's statistics) suggests that developed countries are able to maintain their dominance in the foreign ownership of patents with a total of 95 per cent and 93 per cent respectively.[17] As in previous periods, the five leading countries owned around 76 per cent of these patents, with the US holding a total of 26 per cent.[18]

With regard to the national share in the grants of patents in a given country, it seems that nationals of developing countries were able to increase their share from 12 per cent in 1964 to 16 per cent in 1972.[19] On the other hand, the share of nationals in patents granted by developed countries seemed to decrease considerably, from 43 per cent in 1964 to 36 per cent in 1972.[20] However, data from 2000 suggests that the national ownership of patents decreased both in developed and developing countries to a level of 19 per cent and 12 per cent respectively.[21]

As for trademarks, a different study by UNCTAD in1974 found that 98 per cent of registered trademarks granted to foreigners originated in developed countries while only 2.2 per cent originated in developing countries.[22] The distribution of registered trademarks granted by developing countries in 1964 and 1974 is broadly similar to that of patents, with the US holding around 34 per cent of these trademarks and Japan, the United Kingdom, Germany and France holding another 43 per cent between them.[23] Interestingly, it was also found that 72 per cent of trademarks registered abroad by nationals of developing

Table 3.1 Share of developed countries in patents granted to foreigners in 2000

Country	Total	Share in %
United States	98682	25.70
Japan	74033	19.30
Germany	59784	15.59
France	25408	6.63
United Kingdom	20206	5.27
Total		**72.52**
Switzerland	13903	3.63
Italy	11393	2.97
Netherlands	11060	2.88
Others	9991	2.61
Sweden	8826	2.30
Canada	7473	1.95
Belgium	3989	1.04
Denmark	3606	0.94
Austria	3296	0.86
Australia	3101	0.81
Norway	2001	0.52
Luxembourg	606	0.16
New Zealand	544	0.14
Total		**93.32**

Source: WIPO, *Industrial Property Statistics – Patents granted to non-residents in 2000*, Publication B (Geneva: 2002), Ref: IP/STAT/2000/B

countries in 1974 were registered in other developing countries.[24] As UNCTAD put it: 'when the nationals of developing countries register trademarks abroad, they tend to choose other developing countries for such registration'.[25] The distribution between the share of nationals and foreigners in the registration of trademarks is again skewed in favour of developed countries, even more than patents. UNCTAD, looking at data from 1964 and 1974, found that while the foreign share of registered trademarks in developed countries has decreased from 20 to18 per cent, it has increased in developing countries from 27.5 to 50 per cent.[26]

Also available are empirical findings concerning income from trade in IP-related products, though mainly for developed countries. Using statistical data from OECD countries we can learn that the seven major developed countries have

Table 3.2 National and foreign share of patents granted in 2000

Developing countries	Residents	Non-residents	Total	% National share	% Foreign share
Argentina	145	1 442	1 587	9.14	90.86
Botswana		43	43	0.00	100.00
Brazil (1999)	424	2 795	3 219	13.17	86.83
Chile	24	160	184	13.04	86.96
China	6 475	6 881	13 356	48.48	51.52
Colombia	21	574	595	3.53	96.47
Croatia	114	265	379	30.08	69.92
Egypt	53	400	453	11.70	88.30
Gambia		51	51	0.00	100.00
Ghana		64	64	0.00	100.00
Guatemala	2	21	23	8.70	91.30
Honduras	2	61	63	3.17	96.83
Hong Kong	41	2 696	2 737	1.50	98.50
India (1999)	633	1 527	2 160	29.31	70.69
Israel	455	1 578	2 033	22.38	77.62
Kenya	2	115	117	1.71	98.29
Madagascar(1999)	6	29	35	17.14	82.86
Malawi	1	109	110	0.91	99.09
Malta	21	68	89	23.60	76.40
Pakistan	20	361	381	5.25	94.75
Philippines	8	558	566	1.41	98.59
Republic of S. Korea	22 943	12 013	34 956	65.63	34.37
Singapore	110	4 980	5 090	2.16	97.84
Sudan		59	59	0.00	100.00
Swaziland		85	85	0.00	100.00
Thailand	153	388	541	28.28	71.72
Uganda		112	112	0.00	100.00
Uruguay	6	134	140	4.29	95.71
Venezuela	14	742	756	1.85	98.15
Zambia		46	46	0.00	100.00
			Average	**11.55**	**88.45**

Table 3.2 continued

Developed countries	Residents	Non-residents	Total	% National share	% Foreign share
Australia	1 301	12 615	13 916	9.35	90.65
Austria	1 122	10 144	11 266	9.96	90.04
Belgium	750	11 372	12 122	6.19	93.81
Canada	1 117	11 108	12 225	9.14	90.86
Denmark	313	8 171	8 484	3.69	96.31
Finland	25	2 532	2 557	0.98	99.02
France	10 303	26 101	36 404	28.30	71.70
Germany	16 901	24 684	41 585	40.64	59.36
Ireland	35	5 882	5 917	0.59	99.41
Italy	4 726	20 211	24 937	18.95	81.05
Japan	112 269	13 611	125 880	89.19	10.81
Luxembourg	63	5 838	5 901	1.07	98.93
Netherlands	2 280	14 232	16 512	13.81	86.19
Norway	395	2 017	2 412	16.38	83.62
Spain	1 730	14 079	15 809	10.94	89.06
Sweden	2 082	11 730	13 812	15.07	84.93
Switzerland	1 345	10 913	12 258	10.97	89.03
United Kingdom	4 170	29 586	33 756	12.35	87.65
United States	85 071	72 425	157 496	54.01	45.99
			Average	**18.50**	**81.50**

Source: WIPO, *Industrial Property Statistics – Patent applications filed and patents granted during 2000*, Publication B (Geneva: 2002), Ref: IP/STAT/2000/B

increased their income from $1.9 billion in 1970 to $65 billion in 2001 and their profit from $0.3 billion to $20 billion respectively.[27] The US, the UK and France are the major net exporters of IP-related products. Not surprisingly, the US is the main beneficiary from trade in IP-related products, increasing its net income from $1.1 billion in 1970 to $14.3 billion in 2001.[28] According to the IMF, trade flows of IP products as a percentage of total trade in services also grew in these countries from an average of 4.4 per cent in 1971 to 5.8 per cent in 1991.[29]

Finally, several studies focusing on developing countries found that the grant of patents would result in considerable welfare losses and in price increases. For example, Subramanian, using 1988 data, calculated the potential welfare losses from the grant of patents to pharmaceutical drugs. Considering cases in which a foreign patent monopoly emerges either from a perfectly competitive

Table 3.3 Intellectual property transactions – royalties and licence fees ($US Million)

		1970	1980	1991	1995	1999	2000	2001
Canada	Net	–162	–559	–1605	–1509	–1763	–2042	–1977
	Credits	5	37	183	374	1569	1564	1497
	Debit	167	596	1788	1883	3332	3606	3474
Germany	Net	–218	–838	–2338	–2805	–2018	–2694	–2090
	Credits	128	606	1885	3132	3121	2898	3145
	Debit	346	1444	4223	5937	5139	5592	5235
France	Net	–132	–531	–355	–465	–300	266	716
	Credits	69	496	1430	1856	1982	2313	2604
	Debit	201	1027	1785	2321	2282	2047	1888
Italy	Net		–341	–1234	–732	–819	–636	–863
	Credits		677	467	876	556	555	443
	Debit		1018	1701	1608	1375	1191	1306
Japan	Net	–358	–974	–3174	–3416	–1671	–778	–659
	Credits	55	354	2865	6026	8173	10230	10441
	Debit	413	1328	6039	9442	9844	11008	11100
UK	Net	58	209	242	1839	1543	1855	2253
	Credits	341	1135	2792	4692	8083	7980	8157
	Debit	283	926	2550	2853	6540	6125	5904
US	Net	1100	4324	13784	23370	24293	23492	22309
	Credits	1324	4998	17819	30289	36902	39607	38668
	Debit	224	674	4035	6919	12609	16115	16359
Total net (billions US$)		**0.29**	**1.29**	**5.32**	**16.28**	**19.27**	**19.46**	**19.69**
Total credit		**1.92**	**8.30**	**27.44**	**47.25**	**60.39**	**65.15**	**64.96**
Total debit		**1.63**	**7.01**	**22.12**	**30.96**	**41.12**	**45.68**	**45.27**

Source: *Services Statistics on International Trade in Services*, Royalties and Licence Fees, 1990–2001, (OECD, 2003)

industry or from a domestic symmetric duopoly, he found that annual welfare losses would range between $100 million to $410 million in Argentina, and from $341million to $1.26 billion in India, depending on price elasticities of demand.[30] Vaitsos, focusing on over-pricing, found that in 1968, pharmaceutical companies in Colombia charged prices that were 155 per cent in excess of the world average.[31] Similar results were also reported by Katz who estimated the weighted overpricing of patented pharmaceutical products in Argentina in 1968 at around 150 per cent.[32]

On the other hand, Maskus and Konan, using 1988 data, suggest that the price increases for pharmaceutical products in five developing countries are much more moderate.[33] Their most realistic model (model C) examined a case in which a foreign inventing firm has to face competition both from pirate-fringe firms and from firms selling substitute generic products. Assuming that the introduction of patent protection will eliminate the pirate-fringe competition but not the generic one, they predicted that prices will increase more moderately: between 10 to 27 per cent in India, 8 to 23 per cent in Argentina and from 2 to 4 per cent in Brazil.[34] The authors argue that while 'price rises are far from trivial, their considerably lower magnitudes suggest that strong claims about anticipated monopoly price gouging [sic] may be exaggerated'.[35]

Lately, the issue of overpricing in patented products has received renewed attention with regard to the availability of pharmaceutical drugs, particularly HIV medicines, in developing countries. In an article in *The Economist*, Sachs argues that patented drugs originating from Western MNCs prove to be too expensive for poor countries, such as South Africa.[36] He argues that the latter is on the verge of authorizing its domestic firms to produce AIDS medicines despite patents held by American and European firms. Sachs justifies this course of action and argues that 'in a world in which science is a rich-country prerogative while the poor continue to die, the niceties of intellectual property rights are likely to prove less compelling than social realities'.[37]

The empirical data, therefore, validates the previous theoretical claim that countries with strong IP capabilities are likely to benefit most from the extension of IPRs internationally. These countries will increase their national income not only because they become exporters of IP-related products but also because, given the monopolistic features of IPRs, they will be able to set higher premiums for their products. Conversely, countries with weak IP capabilities have less incentive, at least from a trade perspective, to enter into such agreements.

Generally speaking, a developing country choosing not to recognize the rights of foreign IP owners would be able to freely exploit imported IP products in its own domestic economy, hence becoming less dependent on the future importation of these products. Alternatively it could import these products from another non-patent country at lower prices than if it maintained a patent system. Using the words of Chin and Grossman, it seems that the conflict of interests between developed and less developed countries regarding the international IP trading system is the 'rule rather than the exception'.[38]

3.3 AN INTERNATIONAL IP SYSTEM AND TECHNOLOGY TRANSFER

It is frequently argued that, by joining an international system of IPRs, countries with low IP capabilities will be able to increase their attractiveness to technology

transfer (henceforth TT).[39] Yet a closer theoretical and empirical observation suggests that, as far as developing countries are concerned, the link between an international IP system and TT is far less clear.

Since TT is a broad concept, there is a need to be more precise about its relation to IPRs. Of particular importance is the distinction between the direct and indirect effects of IPRs on TT. The former refers mainly to the argument that foreign IP owners, in exchange for obtaining protection in developing countries, are required to make the technology embodied in their products (or processes) available and accessible in these countries. The latter reflects the view that stronger IP protection creates a more secure and attractive environment in which various forms of TT (licensing agreements, joint ventures, foreign direct investment and so on) can take place.[40] The main difficulty with these two aspects – the direct and indirect effects of IPRs on TT – is that they are not mutually compatible and may even be contradictory. Therefore, it is important to discuss them separately.

3.3.1 Direct Effects on Technology Transfer – the Extent to which the Granting of IP Protection to Foreigners Forces them to make their Technologies more Accessible and Available in Developing Countries

As an example, consider the direct effects of patents on technological access and availability. Regarding accessibility, patent laws require every patentee to disclose all the information concerning his or her inventions to the patent office of the granting country. It is often argued that by granting such rights to foreigners, a developing country will enable its domestic firms to gain direct access to new technologies. These firms in turn would be able to use the newly disclosed information either as a basis for further inventive activities or in order to imitate the original invention, once its patent term has expired.[41]

This argument (that is more accessible technology in exchange for patents) is both logically and empirically flawed. It is quite likely that a foreign firm seeking to extend its patent rights in other countries has already disclosed the details of its invention to the patent office in its own home country. This means that firms of other countries, including firms from developing countries, can behave as free-riders and obtain the disclosed information from the patent office of the home country.

Thus, theoretically speaking, a developing country cannot expect to benefit much, in terms of additional access to information, from granting patent rights to foreign technology owners since its domestic firms can obtain the same information elsewhere.[42] Indeed, the entire basis for IP protection rests on the assumption that once new information is available to the market it will be transmitted in a rapid and cost-free manner.

Furthermore, large quantities of counterfeit goods suggest that many developing countries, particularly those with reverse-engineering capabilities, are able to copy IP-related products without relying on any disclosed data.[43] A few examples may be given. Data from 1985 suggests that the sales of pirated goods in six developing countries (Brazil, India, Mexico, South Korea, Singapore and Taiwan) are extremely common.[44] The sales of counterfeit pharmaceutical products in these countries amounted to a total of $1.6 billion, of which $920 million was generated in India.[45] A notable and often quoted survey conducted by the US International Trade Commission (ITC) found that the losses of 193 US-based firms from various pirated activities, including trademark counterfeiting and patent infringements, amounted to $23.8 billion in 1986.[46] It should be noted however that a more accurate study, using the same ITC data but constructing a model in which there is competition between the dominant and the infringing firms, found that losses for US companies amounted only to $2.3 billion while gains to consumers (US and foreign) reached $3 billion.[47] The European Commission issued a Green Paper in 1998 on combating counterfeiting within the single market.[48] Citing various sources, the Commission has estimated that counterfeiting accounts for 5 to 7 per cent of world trade and leads to 100 000 job losses per year in the EC alone.[49] It argues that since the 1980s 'counterfeiting and piracy have grown considerably to a point where they have now become a widespread phenomenon with a global impact'.[50] This evidence suggests that the ability of developing countries to counterfeit IP-related products in such magnitude, regardless of its illegal nature, is in itself a strong alternative to TT. As Subramanian explains:

> There is an important ethical/legal distinction between counterfeiting and piracy on the one hand and IP protection in the technology areas on the other, but in terms of the economics there is very little difference. Counterfeiting and piracy are potentially more likely areas of conflict as they better fulfil the copyability criterion…Copyability can almost tautologically be defined as the lack of the need for technology transfer.[51]

Hence, developing countries may find that the access to the information disclosed by foreign technology owners in exchange for granting them IPRs is not only insufficient but in many cases irrelevant.

The extent to which the information disclosed by the patentee contains all the particulars of his or her invention is also questionable. In fact, many authors note that the data provided to the patent office is often incomplete in the sense that it is not possible for others to re-develop the invention using this data alone.[52] Additional information, which is usually described as 'know-how', is often required in order to commercially exploit those products and processes that cannot be easily copied.

Regarding availability, one must not forget that the establishment of property rights in intellectual creations, such as inventions, artistic works and

so on, restricts the use of newly created knowledge and inhibits its rate of dissemination. There may also be cases in which IP owners make their products even scarcer than intended by the legislator. 'Sleeping' or 'non-working' patents is one example for which patentees not only prevent others from using their inventions but also do not use them themselves.

The percentage of non-utilized patents (that is patents that are not used for production purposes) is high both in developed and in developing countries, although greater in the latter. From 1950 to 1970 approximately 90 to 95 per cent of foreign owned patents were not utilized in nine developing countries.[53] In comparison, around 50 to 60 per cent of patents in the US were commercially utilized in the years 1932 to 1953.[54] According to the Economic Council of Canada, only 15 per cent of the patents granted to foreigners from 1957 to 1963 have been 'worked' in that country.[55] To what extent the magnitude of unused patents may be attributed to technology obsolescence or to monopolistic behaviour, such as 'pre-emptive patenting', is unclear.[56] UNCTAD, making a distinction between developed and developing countries, expresses a rather harsh view on the matter. It argues that in developed countries a large extent of non-use of patents derives from the fact that they are no longer of commercial interest, while in developing countries it must be connected to 'business interests and commercial strategies of maximising the profits of the foreign patent owners'.[57] However, lack of sufficient data does not currently permit one to conclude that the non-use of patents in developing countries is strategically different from that of developed countries.

Regardless of its purpose, the most common tool for solving the problem of non-use is through compulsory licensing which forces the patentee to license his or her invention to other potential users while enabling him or her to receive some form of financial compensation in exchange. The economic desirability of compulsory licensing is in itself a highly debatable issue. Suffice it to say that it contains all the disputable and contradictory elements embedded in the patent mechanism, such as balancing between private and public interests, the incentive to invent in the future vis-à-vis the restrictive use of patented inventions in the present, the extent to which monopoly power is exploited and so on.[58]

Yet empirical evidence shows that the actual use of compulsory licensing against non-working patents is negligible. Both in developed and in developing countries the number of applications for compulsory licenses is surprisingly small and the granting of such licences is even smaller. UNCTAD, citing evidence from various countries (developed and developing), found that in the period 1958–1963 there were very few instances of implementation of compulsory licence provisions.[59] The number of compulsory licences granted in Canada between 1935 and 1970 amounted to an annual average of 0.01 per cent of patents granted.[60]

This section has focused on the direct effects of IPRs on TT and assessed the extent to which the granting of IPRs to foreigners requires them to make their technology accessible and available in developing countries. It concludes that a developing country may find this aspect inadequate and unsatisfactory mainly due to three reasons.

First, any information disclosed by a foreign IP owner in exchange for extending his or her rights in a developing country, such as that given to the patent office, does probably already exist in his or her home country. Therefore, a developing country can behave as a free-rider, that is, it can obtain the same information from the original home country without the cost of granting IP protection to that foreigner. Furthermore, the problem of piracy suggests that numbers of IP products, many of which are extremely costly in terms of R&D expenditures, can be easily copied. In these cases developing countries, particularly those with copying capabilities, would find it unnecessary to obtain any disclosed information at all.

Second, for those products that do require technological disclosure it is often the case that any information submitted by foreign IP owners, such as the particulars of an invention, is insufficient in the sense that additional know-how is required in order to exploit these technologies in full.

Finally, the problem of non-working patents suggests that many foreign IP owners decide not to utilize their inventions in the granting country. Whether this decision can be attributed to simple monopolistic calculations or to technological obsolescence is unclear. What is clear is that the use of compulsory licences in order to tackle this problem is negligible.

Having considered the direct implication of IPRs on TT there is a need to examine the more indirect and dynamic aspect of that link.

3.3.2 Indirect Effects of IPRs on Technology Transfer – the Extent to which a Stronger IP Environment Influences Technology Transfer Calculations

It is logical to assume that foreign firms, especially those that are technology-intensive, would be more willing to invest and to utilize their technologies in countries that provide them with strong IP protection. Indeed, this is probably the most common argument used by IP proponents. Sherwood argues that 'Once a country gains a reputation for non-protection among potential technology suppliers they will tend to respond negatively to all requests for technology transfers, whether the requested technology is at their leading edge or further behind the curve'.[61]

Before discussing the empirical data regarding the link between stronger IP environment and greater TT, there is first a need to mention briefly three of the common forms of technology diffusion mentioned in the relevant literature: licensing agreements, joint ventures and foreign direct investment (FDI).

Licensing agreements are probably the best known example for TT under IP protection. A licence, in itself, does not involve any type of technological disclosure; it only grants the licensee legal permission to use the technology owned by the licensor. Yet, once granted, a licence is usually accompanied by the disclosure of additional and complementary know-how, which in many cases is essential for the successful utilization of the acquired technology. For this reason technology licences are considered a strong tool for TT.[62]

It should be noted however that licensing agreements, by nature, are usually restrictive and impose considerable limitations on the competitive ability of the licensee. Most common are restrictions on the degree, extent, quantity, duration and territorial (export limitations) uses of newly acquired technologies.[63] For trademarks, it is often required that the licensee will also invest in advertising activities in order to maintain the product's reputation in the market.[64] This may pose additional costs since, in the long run, 'the licensee's efforts will result in greater prestige for the licensor and not for the licensee', particularly when the former has the option to terminate the contract of the latter.[65]

Nevertheless, it is quite likely that the overall benefits of licensing agreements as a vehicle for TT are in excess of the costs they impose. As Vernon argues: 'For an under-developed country this added cost might clearly be outweighed by the gains, for we must not underestimate the stimulating impact in such a country which may be generated by the introduction of new information, new attitudes and new methods'.[66]

Joint ventures, which can generally be described as different types of local and foreign partnerships, are also said to be influenced by the IP environment of a given country. According to Mansfield some IP advocates argue that in countries with weak IP protection, technologies would tend to be transferred almost exclusively through wholly-owned subsidiaries and much less through joint ventures.[67] Since joint ventures are extremely heterogeneous they cannot easily be treated as a single entity. A useful distinction is offered by Vernon who differentiates between joint ventures on the basis of their contribution, in terms of TT, to the local partner.[68] At the one end of the spectrum there are those ventures in which 'the local partner is no more than a figurehead', while at the other end there are partnerships in which 'the local partner aggressively attempts to master the technology being provided from the foreign source'.[69] The latter is more important to the local partner as it provides them with opportunities not only to adapt new products and processes to local conditions, but also to raise its technological capabilities through 'learning by doing', that is by acquiring learning skills and experience regarding the utilized technologies.

Foreign direct investment (FDI) is the vaguest among these issues mainly because the concept is not treated very clearly in the relevant literature. Some authors dealing with IPRs and FDI prefer to have little or no discussion on its contents while others choose to focus on one particular aspect, such as on

manufacturing, investment capital, licensing, and so on.[70] The result is, as will be demonstrated shortly, that opinions about the relationship between IPRs and different types of FDI vary considerably.

Having mentioned some of the more relevant types of TT with regard to IP protection, it is now possible to review the available empirical data. Two major problems are common to the attempts to present empirical assertions on the link between a stronger IP environment in developing countries and a greater attractiveness to TT. First, there is difficulty in capturing and assessing the dynamic aspect of the IP–TT link. More specifically, it is often argued that any attempt to quantify the IP–TT link empirically is bound to underestimate the more long-term and wider effects of a stronger IP environment on the rate and magnitude of TT. Secondly, since IPRs are only one of many factors accounting for MNCs decisions to invest in developing countries, it is very difficult to isolate the quality, not to mention the quantity, of TT that is affected only by the IP variable.

A few examples may be given. Frischtak's study on the link between IPRs and technological development in Brazil during the 1980s emphasizes the gaps between the dynamic and static effects of IPRs.[71] With regard to the former, he concludes that there is insufficient data to suggest that the Brazilian IP regime affects either the volume and composition of FDI or the rate of foreign technology flows through licences.[72] He notes that MNCs consider other factors, such as the size and growth-dynamics of Brazil's domestic market, its factor supply and costs, and the overall stability of its macroeconomic environment, as more important to FDI.[73] This is also the case in licensing agreements where factors such as the limits on royalty payments, confidentiality clauses void upon expiration, and labour skills are considered the major obstacles for the transfer of 'technology packages'.[74] However, when addressing the dynamic aspect of the IP–TT equation, Frischtak strongly believes that a stronger IP regime is important to Brazil's ability to attract greater magnitudes of FDI and technology flows.[75]

Sherwood, studying IPRs in Brazil and Mexico, stresses the need to divert more attention to the dynamic and unquantifiable importance of a country's IP environment to foreign technology owners.[76] He uses the term 'invisible statistic' to describe the numerous decisions of Brazilian firms not to approach foreign technology owners simply because they know from past experience that their requests will be refused because of weak IP protection.[77]

Regarding the problem of isolating TT as a function of IPRs and the attempt to identify an association, an OECD 1987 survey, based on the responses of executives from manufacturing MNCs (using multiple answers) found that lack of industrial property protection was considered as one of the major obstacles for international technology licensing in developing countries.[78]

Mansfield, in one of the most comprehensive and best-known survey studies on the subject, examined the importance of IPRs to FDI and TT by sampling 100 US firms. He differentiates between five types of FDI: sales and distribution outlets, rudimentary production and assembly facilities, facilities to manufacture components, facilities to manufacture complete products, and R&D facilities.[79] His conclusion is that 'the percentage of firms indicating that intellectual property protection has a major effect on their foreign direct investment decisions depends greatly on the type of investments in question'.[80] His finding suggests that as the level of technological investment rises so does the importance of IPRs. Only 20 per cent of the firms reported that IPRs are important to them for investments in sales and distribution outlets, while around 80 per cent regarded them as important for investment in R&D facilities.[81] Mansfield also shows that different sectors, such as the chemical and the transportation equipment industries, attach varying importance to the effect of IPRs on their decision to invest in a given country.[82] Vernon, referring to some older surveys from the 1950s, expresses a more negative view and argues that US companies did not even once mention patents as a potential obstacle in their investments abroad.[83]

Other studies focusing on static data tend to argue that there is no clear link between IPRs and TT. A 1993 UN report is one example of this type of conclusion:

> For some, a strong system of IPRs is an essential component of a climate conducive to FDI, technology transfer, and R&D by transitional corporations. For others, including many governments and experts in developing countries, a high degree of protection does not necessarily mean a higher or a better composition of FDI flows.[84]

According to this report, in many countries with weak IP protection, such as Argentina, Brazil and Turkey, the rate of FDI is still high, while in other countries such as Nigeria the granting of patents is not sufficient for FDI to take place.[85]

Schumann, examining IPRs in South East Asia, found that during the 1980s the granting of foreign licences in South Korea was extremely intensive, despite the fact that, at the time, it was part of the US intellectual property Watch List and subject to an investigation under US 'Special 301'.[86] He concludes that although the Asian NICs may find it in their own interest to grant stronger IP protection as they move up the technological ladder, become more export oriented, and attract greater FDI, there is still no causal link between these economic factors and IPRs.[87]

Maskus and Konan, using 1982 data obtained from the Department of Commerce, examined the effect of IP protection on decisions concerning either the physical presence or investment of US firms in seven broad manufacturing sectors in 44 countries.[88] They conclude that there is 'little basis to claim that the structure of IPR protection affects foreign investment'.[89]

IP advocates thus claim that foreign firms are more willing to invest and utilize their technologies in countries that provide them with stronger IP protection. Although this argument is quite plausible, it is still difficult at this point to assess the extent to which a stronger IP environment increases the magnitude and composition of TT. A major difficulty is the problem of reconciling the dynamic and static aspects of the subject. A static analysis suggests that different types of IPRs vary in their effect on the decision of firms in different industrial sectors to invest and to transfer new technologies. Furthermore, even in sectors where IPRs are considered essential, such as the R&D in the pharmaceutical industry, it is still not possible to arrive at a method for assessing the quantity, in money terms, and quality, in innovative terms, of TT decisions affected only by the level of IP protection.

Nevertheless, a dynamic approach will tend to focus on the importance of IPRs not only as to the attractiveness of countries for future technological investments but also for their ability to climb up the technological ladder and to become more innovative. Such benefits cannot be easily quantified and may be either greater or smaller than any static estimate. What is clear is that IP advocates will argue that any attempt to focus only on the static aspect of the IPR–TT link is bound to degrade its importance.

Thus, the attempt to justify the decisions of developing counties to join an international IP system on the basis of TT is both difficult and problematic. The previous section has already demonstrated that the argument in favour of IPRs as a direct vehicle for TT is both logically and empirically flawed. This section suggests that although no clear-cut conclusion is currently available, it is still plausible that a stronger IPR environment may indeed have a positive effect on the overall decision of foreign firms to invest and to utilize their technologies in developing countries. Currently no method is available for concluding which of these aspects is more dominant in its effects on TT.

It is now important to depart from the economic sphere and to examine an alternative explanation rooted in the political-economy domain. The following and final section considers the argument that trade retaliation, a politically constituted behaviour, can provide a better explanation for the emergence of an international IP system that is closer to the model of developed countries.

3.4 THE POLITICAL USE OF TRADE RETALIATION AS A TOOL FOR ACHIEVING STRONGER INTERNATIONAL IP PROTECTION

Since the attempt to provide pure economic explanations for the establishment of a stronger international IP system is as problematic as the attempt to do so for IPRs themselves, it is now important to consider an alternative approach.

The final section of this chapter uses an international political economy oriented explanation and suggests that trade retaliation may be considered an important factor in the decisions of countries (mostly, but not only, those countries with weak IP capabilities) to support a stronger IP agenda. It is based on the assumption that the threat of trade retaliation may significantly affect the way in which countries, particularly those that are linked to the economies of countries with strong IP legislation, assess the costs and benefits of joining an international IP system.

Most important is the potential loss of trade revenues that a country may face due to trade retaliation.[90] Nogués, focusing on pharmaceutical products, argues that, when facing the threat of retaliation, a country must consider whether the social cost deriving from retaliation is higher than the net social benefit of having weak patent protection (provided that there is any patent protection at all). He notes that 'when this cost is higher than the net social benefits, then from an economic point of view, patents should be introduced'.[91] Hindley suggests that large industrial countries with strong IP capabilities are interested in preventing defection from the international IP system and therefore may retaliate against those countries wishing to do so.[92]

Two examples may be given to emphasize the effectiveness of trade retaliation as a tool for forcing countries to support a stronger IP agenda. The first concerns Switzerland's decision to adopt a patent system in 1887.[93] The second focuses on the actions taken by the US (and the EC, although to a much lesser extent) during the Uruguay Round negotiations, particularly in the second half of the 1980s.

3.4.1 External Pressures on Switzerland to Adopt a Patent System (1888 to 1907)

Although very active in the inventive realm, Switzerland was deeply divided in its perspective on the merits of patents. Despite joining the International Union for the Protection of Industrial Property in 1878, in which the principle of national treatment was paramount, Switzerland did not have a patent system at the time. Its nationals were able to receive patent protection abroad while not being able to secure the same protection in their own country. According to Penrose, Switzerland's decision finally to adopt a patent system was mainly due to pressure from other countries, particularly Germany. She argues that since Switzerland was 'spurred by economic pressures from outside industrialised powers' it had no choice but to enact patent legislation.[94] External pressures from various interest groups, such as the German chemical industry, strengthened the political leverage of patent proponents within Switzerland and enabled them to secure patent legislation in 1888.[95]

Nevertheless, Switzerland's patent system in its initial version excluded the protection of processes. This was considered very harmful to the German chemical industry which exerted heavy pressure on both the German and Swiss governments. In 1904, during tariff negotiations between the two countries, it was agreed that Germany would raise duties on the import of Swiss coal-tar dyestuffs if the latter did not change its patent law to include processes by the end of 1907.[96] As a result, Switzerland amended its law in June 1907.

3.4.2 The Use of Trade Retaliation by the US and the EC during the Uruguay Round

Pressures were directed mainly towards specific developing countries, such as Argentina, Brazil, India, South Korea and India, aimed at forcing them to change their domestic IP legislation and to agree to an IP framework under the auspices of GATT.[97]

Between the two industrialised blocs, the US was more active during that time and was able to achieve considerable results. This was mainly due to its ability to use two policy tools. The first was the threat of denying developing countries the benefits of the General System of Preferences (GSP) under which selected countries are entitled to special preferential treatment from the US.[98] The second concerns the use of section 337 of the US Tariff Act of 1930 and section 301 of the Trade Act of 1974. Both enable the US to make credible threats, and in some cases to execute them, against countries which, according to its view, provided inadequate IP protection.[99] Section 337 is more domestically orientated and allows for punitive action to be taken against imported products of which IP rights were violated.[100]

Section 301, particularly after its amendment by the Omnibus Trade and Competitiveness Act of 1988, is much more internationally orientated and allows the US to impose unilateral sanctions against countries engaging in 'unfair competition', which includes the field of IP.[101] The US Trade Representative (USTR) uses section 301 (known as Special or Super 301 after 1988) to identify Priority Foreign Countries which, according to US criteria, provide inadequate protection for IPRs thereby causing the greatest adverse impact on US right holders or products.[102] The USTR, before retaliating against such a foreign country, is required to launch an investigation within 30 days in order to study the case or cases leading to that identification.[103] The USTR has also established a Priority Watch List and a Watch List for countries whose actions meet some, but not all, of the criteria for identifying priority foreign countries.[104]

According to Nogués, the R&D-based pharmaceutical industry in the US was the main driving force behind the creation of Special 301.[105] Pressuring the US government towards taking a much more hawkish position against IP violations,

the R&D pharmaceutical industry sought to amend the original section 301 in order to make it much more operational.[106]

The use of section 301, and later Special 301, was particularly intensive during the second half of the 1980s. The cases of Korea and Brazil are two known examples of the use of trade pressures regarding patent protection for pharmaceutical products. In the case of the former, considerable reforms were made in Korea's IP legislation mainly because of US pressures and in spite of fierce domestic opposition.[107] Initially, Korea did not grant patent protection for chemical and pharmaceutical products but only to processes. At that time extensive violations of copyrights were also taking place in South Korea. Bilateral negotiations between the two governments during the period of 1983 to 1985 did not produce a satisfactory outcome as far as the US was concerned. As a result, in 1985 the Reagan administration used section 301 to launch an investigation concerning Korea's IP legislation.[108] In its announcement the White House argued that South Korea's IP legislation 'appears to deny effective protection for US intellectual property' and that among other things the protection for 'chemicals and pharmaceuticals is limited to process patents'.[109]

Korea's decision to amend its IP laws in 1986, including the granting of patents to pharmaceutical and chemical products, was a result of a settlement between the US and Korean governments.[110] These changes were introduced despite fierce domestic opposition particularly from the Korean Pharmaceutical Association and the Korean Publishers' Association.[111] Gadbaw and Richards argue that the 'process of reform of Korea's intellectual property regime was achieved almost exclusively because of US trade leverage'.[112] They note that South Korea is a country 'in which the government was able to achieve broad intellectual property rights reform where domestic opposition far outweighed internal support'.[113] Gadbaw and Richards also conclude that a strong association exists between countries' dependence on exports to the US and their willingness to strengthen their domestic IP legislation because of US pressures.[114]

While the threat of trade retaliation was sufficient to change South Korea's domestic IP legislation, in the case of Brazil the US had actually retaliated before achieving concessions from the Brazilian government. The dispute between the US and Brazil started when the research-based pharmaceutical industry in the US, represented by the Pharmaceutical Manufacturers of America (PMA), filed a petition complaining that Brazil's patent law did not provide protection for pharmaceutical products and processes.[115] In July 1988 the USTR launched an investigation against Brazil. However, consultations between the two governments did not produce any favourable outcome for the US. As a result, the US decided in October 1988 to use Special 301 to impose a 100 per cent *ad valorem* tariff increase on selected Brazilian goods including some pharmaceutical products. Brazil, as a counter-measure, used the GATT dispute settlement process to lodge a complaint against the US

arguing that the US decision to impose sanctions contradicted US obligations to non-discriminatory practices.[116] Brazil claimed that the lack of protection for pharmaceutical products and processes in its patent law was in accordance with its international legal obligations. Yet despite overwhelming support for the Brazilian side from the GATT panel, the US did not suspend its decision. The dispute came to an end in June 1990 when the Brazilian government declared that it would seek legislation to provide patent protection for pharmaceutical products and processes.[117] The USTR in turn agreed to terminate its retaliation measures arguing that 'Brazil was taking satisfactory measures to eliminate the practices that were determined by the president to be unreasonable and a burden or restriction on US commerce'.[118]

The use of trade retaliation as a tool for forcing countries to strengthen their IP legislation and to enter into multilateral IP agreements did not come to an end with the conclusion of the TRIPs agreement. Many interest groups argued, and continue to do so, that the US must enforce IPRs globally. For example, the Intellectual Property Committee (IPC), a group consisting of some leading US companies, issued a position paper in 1994, immediately after the final version of the TRIPs agreement was concluded, in which it urged the US to continue to use the bilateral dimension in order to secure a stronger IP environment:

> The United States cannot be complacent. The US private sector needs a strategy to deal with what we believe to be a unique situation facing TRIPs – the long transition period when our 'multilateral' hands are tied – and the continued assaults on our intellectual property – the very lifeblood of US creativity and competitiveness...The IPC urges the administration to continue the current Special 301 program in support of strong intellectual property protection abroad.[119]

The EC has also taken measures for retaliating against IP-violating countries. Commencing in 1986, the EC has adopted legislation enabling it to protect its external frontiers by preventing the free circulation of counterfeited goods originating from non-member countries.[120] The so-called New Trade Policy Instruments of 1984, and particularly the Trade Barriers Regulation, allows the EC to 'engage in trade retaliation against illicit commercial practices of non-union countries', though this tool has not been used as frequently and as aggressively as its US parallel.[121]

One exception is the case of Korea's IP legislation in 1987. Korea's patent law, as agreed upon in the US–Korean settlement, was amended in a way that provided patent protection only to US pharmaceutical firms. Naturally, the EC has regarded the amendments as discriminatory and retaliated in 1987 by excluding Korea from its GSP.[122] As a result, Korea has agreed to amend its patent law to also protect pharmaceutical firms based in Europe.

Hence, the use of trade retaliation by developed countries, notably the US and the EC, has been, in many cases, a successful tool for securing greater

commitment to a stronger domestic and international IP system. The decision of many developing countries to change their domestic IP legislation and to agree to a multilateral IP agreement under a GATT framework (TRIPs) did not derive from the conclusion that there are clear economic benefits to the introduction of IPRs. In some countries, such as Korea and Brazil, there was fierce domestic opposition to the introduction of stronger IP legislation. These countries decided to commit themselves to a stronger IP agenda mainly because of fears of retaliation from the US and the EC.

Even today, despite the existence of the TRIPs agreement and its built-in dispute settlement mechanism, the US and the EU still maintain the right to retaliate against countries with weak IP protection. The reason for this probably lies in the knowledge that convincing developing countries, particularly those with weak IP capabilities, that it is in their own economic interest to strengthen their domestic IP legislation may prove a difficult task. For this purpose the use of trade retaliation, a politically constituted tool, seems to be much more effective.

3.5 CONCLUSION

This chapter reviewed and assessed the reasons behind the decisions of countries to commit themselves to a stronger IP agenda. Doing so required it to shift its focus from the perspective of the community as whole to that of the individual country. The chapter used the familiar distinction between developed and developing countries (or between countries with strong IP capabilities and countries with weak IP capabilities) in order to review the problems of establishing a stronger international IP system. It also assumed that at the core of such a system lies the principle of national treatment, and that all its members are required to standardize their domestic IP legislation.

Different countries may find it in their interests either to support or to reject a stronger international IP system for various reasons. Most noteworthy are calculations concerning: (1) the effects of a stronger international system of IPRs on trade in IP-related products; (2) its impact on the rate and magnitude of technology transfer and (3) the extra costs – due to trade retaliation – which a country may face when choosing not to enter such a system.

Regarding trade in IP-related products, there is strong tension between the interests of developed and developing countries. By definition, an international system of IPRs creates a monopolized trading environment in IP-related products as it enables the owners of these products to become the sole exporters to all member countries in such a system. Under an international system of IPRs a country with strong IP capabilities will not only improve its terms of trade by becoming an exporter of IP-related products but will also benefit from additional

income which represents the excess in prices that IP owners are able to charge because of their monopolistic position. On the other hand, countries with weak IP capabilities are likely to benefit most from trade in IP-related products when choosing not to join the international IP system. Doing so will enable them to freely exploit and imitate IP-related products in their own domestic economies. Where they are successful, these countries may even be able to compete with the original IP owners thus becoming exporters of such products themselves.

Empirical data confirms the above theoretical statements. The global ownership and commercial exploitation of IPRs is completely dominated by a group of developed countries. Data from the 1970s shows that developed countries owned more than 95 per cent of patents and trademarks granted to foreigners. Additional calculations based on 1996 and 2000 figures suggest that the dominance of developed countries in the area of IPRs remains unchanged.

The second part of this chapter examined the argument that a stronger commitment to IP protection will enable developing countries to secure a greater rate of technological transfer. It made a distinction between the direct and indirect effects of IPRs on technology transfer (TT) in order to assess their relationship more accurately.

When examining the direct effects of IPRs on TT it is quite plausible that countries with weak IP capabilities are better off not extending IP protection to foreigners. A notable example is the disclosure of information concerning the particulars of an invention by a foreign IP owner in exchange for obtaining patent protection in a developing country. Here it makes no sense for that country to grant patent protection to the foreign inventor as it can behave as a free-rider and obtain the same information from the patent office in the inventor's original home country.

Empirical evidence suggests that many developing countries, particularly those with reverse-engineering capabilities, are able to copy IP-related products without relying on any disclosed data. When IP-related products cannot easily be copied it is often due to the fact that information disclosed by patentees is incomplete in the sense that additional 'know-how' is required for the successful exploitation of these products and processes. Empirical findings indicate that more than 90 per cent of patents granted in developing countries are not utilized at all. The same phenomenon exists in developed countries although on a smaller scale. To what extent the non-use of patents in developing countries can be attributed to the fact that the patented technologies are obsolete or to the fact that commercial interests aimed at preventing others from using these technologies, is not currently clear. What is clear, however, is that the use of compulsory licences as a tool for making patents 'work' is statistically irrelevant both in developed and developing countries.

With respect to the indirect effects of IPRs on TT, it is plausible that stronger IP legislation is positively correlated to TT. Many IP advocates argue that a stronger IP commitment would not only make developing countries more attractive to future technological investments but would also enhance their ability to climb up the technological ladder and to become more innovative.

However, a survey of existing data leads to the conclusion that it is not currently possible to identify a causal relationship between a stronger IP environment and greater TT. Some studies argue that IPRs are extremely important to foreign technology licensing while others conclude that the granting of such licences may take place despite weak IP protection. Views about the importance of IPRs to joint ventures and FDI also vary considerably. Furthermore, even in sectors where IPRs are considered essential, such as in the R&D pharmaceutical industry, it is still not possible to arrive at a method for assessing the quantity, in money terms, and quality, in innovative terms, of TT decisions affected only by the level of IP protection. Therefore, using the argument that IPRs promote technology transfer to justify developing countries' decisions to adhere to stronger IP protection is very problematic.

The third and final part of this chapter digressed from pure economic observations towards a more political-economy orientated explanation. It sought to assess which retaliatory measures taken by countries with strong IP capabilities are effective tools for forcing developing countries to support a stronger IP agenda. Although it is aimed at achieving economic goals, the decision to use trade retaliation is ultimately politically motivated. A notable example is the decision of the US in 1988 to amend section 301 (Special 301) of the Trade Act of 1974 in order to allow the USTR to have more leverage in influencing US trading partners to accept its views on various issues including IPRs.

The basic assumption underlying the use of trade retaliation is that it may impose additional costs, such as the loss of export revenues due to the increased tariffs, on those countries tolerating weak IP protection. These countries will have to reconsider whether the predicted benefits of not protecting IPRs are still higher than the costs of retaliation. In cases where they are not, there is a strong incentive for a country with weak IP protection to strengthen its domestic IP legislation.

Historical evidence suggests that the use of trade retaliation as a tool for securing stronger international IP protection has proved successful on numerous occasions. One example is the case of Switzerland, which agreed to adopt a patent system in 1888. Domestically, Switzerland was deeply divided in its views regarding the merits of patents. However, strong external pressures, particularly the threat from Germany to raise tariffs on selected Swiss products, played an important factor in its decision to provide patent protection not only to products but also to processes.

The use of trade retaliation by the US, and to some extent the EC, during the Uruguay Round was particularly extensive. The US, using Special 301 on the one hand and by threatening to exclude various countries from its GSP on the other, was able to secure some considerable concessions in the sphere of IPRs and eventually to include an IP framework under the GATT.

For example, the US was able to force the Korean Government to change its IP legislation in 1986 to include, *inter alia*, patent protection to pharmaceutical products and processes. Facing an investigation under Special 301, the Korean government agreed to amend its IP legislation despite fierce domestic opposition. In the case of Brazil, the US actually imposed a 100 per cent *ad valorem* tax increase on selected Brazilian goods forcing it to amend its patent laws in 1990, again to protect pharmaceutical products. The EC, although less active, was also able to force the Korean government in 1987 to protect pharmaceutical products and processes originating from European-based companies after threatening to exclude it from its GSP.

Despite the existence of the TRIPs agreement and its built-in dispute settlement mechanism, even today, aware of its effectiveness, the US and the EC still reserve the right to use the tool of trade retaliation against countries with weak IP protection.

Therefore, attempting to economically justify countries' decisions to create and to join a strong international system of IPRs is problematic, as there is a real conflict of interest between developed and developing countries regarding IPRs. However, a focus on a more politically-orientated explanation, that is trade retaliation, suggests that the international IP agenda mainly represents the interests of developed countries. The following chapters provide a more accurate and in-depth analysis of the way in which the international IP agenda (the TRIPs agreement) is linked to the interests of powerful sectors in developed countries, notably the advanced pharmaceutical industry in Europe.

NOTES

1. For an in-depth historical review of the Paris Convention see: Penrose (1951: Chapters 3, 4) ; Ladas (1975: Chapter 4)
2. Vernon (1957: 13); Diwan and Rodrik (1989: 6)
3. Vernon (1957: 12)
4. Penrose (1951: 95)
5. Again, this conclusion derives from the two features mentioned above and refers to trade in IP-related products under an international IP system.
6. Chin and Grossman (1990: 90–107)
7. Ibid., pp. 92–8
8. Ibid., pp. 99–105
9. Penrose (1951: 95–6)
10. Hindley (1971: 58)
11. Ibid., p. 55

12. Vernon (1957: 13)
13. Ibid., p. 13
14. UNCTAD (1975a: 38)
15. Ibid.
16. Ibid., p. 39
17. See Table 3.1; data from 1996 suggests that developed countries owned 95.5 per cent of patents granted to foreigners in that year
18. Ibid.
19. UNCTAD (1975a: 36–7)
20. Ibid.
21. See Table 3.2; Data from 1996 suggests that the share of nationals of developed and developing countries in patents granted was 14 per cent and 16 per cent respectively
22. UNCTAD (1979: 15–16)
23. Ibid.
24. Ibid., pp. 16–17
25. Ibid., p. 17
26. Ibid., pp. 14–15
27. See Table 3.3
28. Ibid.
29. IMF (1994: Table 10, p. 12)
30. Subramanian (1995: 252–3); For an overview on this study and on additional studies see: UNCTAD (1996: Annex 1)
31. Vaitsos (1971: 56–7); also see: Vaitsos (1972: 71–98, p. 86 in particular)
32. Katz (1973: 33–5); also cited in UNCTAD (1975a: 58)
33. Maskus and Konan (1994: 441–6)
34. Ibid., 416–26
35. Ibid. p. 425
36. Sachs (1999: 17–20)
37. Ibid., p. 19
38. Chin and Grossman (1990: 97)
39. Primo-Braga (1990a: 69–88)
40. Sherwood (1990a: Chapters 5 and 6); OECD (1989: 11)
41. For a discussion on this argument see: Grundman (1970; 193–207); Yankey (1987: 15–19); Maskus and Konan (1994: 441–6)
42. Grundman (1970: 196); Maskus and Konan (1994: 415)
43. Evenson (1990: 325–56)
44. Gadbaw and Richards (1988).
45. Ibid., Table 1.2, p. 12
46. US International Trade Commission (1998); see also: Abbott (1989: 697–702)
47. Feinberg and Rousslang (1990: 79–90); see also: Maskus and Konan (1994: 416–17)
48. Commission of the European Communities (1998)
49. Ibid., p. 4; trade estimates were taken from: International Chamber of Commerce, Counterfeiting Intelligence Bureau (1997)
50. Ibid.
51. Subramanian (1990: 517)
52. Penrose (1973: 771); Gilifillan (1964: 60); Edwards (1949: 222–3)
53. UNCTAD (1975a: 40)
54. Ibid.
55. Economic Council of Canada (1971: 62); the term 'worked' is defined as 'the manufacture of the major part of a patented product'
56. Preemptive patenting, as one form of monopolistic strategy, is discussed in Chapter 2
57. UNCTAD (1975a: 41)
58. For a discussion on the economics of compulsory licence with regard to patents see: Penrose (1951: Chapters 7–9)
59. UNCTAD (1975a: 50)
60. Ibid.; see also: Economic Council of Canada (1971: 67–8)

61. Sherwood (1990a: 145)
62. Penrose (1973: 771); Vernon (1957: 17–18); For licensing agreements in trademarks see: UNCTAD (1979: 22–7)
63. UNCTAD (1975a: Chapter 3); Yankey (1987: 24–38); Vaitsos (1972: 83–5)
64. UNCTAD (1979: Chapter 4)
65. Ibid., p. 22
66. Vernon (1957: 18–19)
67. Mansfield (1994: 1)
68. Vernon (1990: 255–70)
69. Ibid., p. 260
70. For the issue of FDI and IPRs see: OECD (1987); Frischtak (1990: 61–98); Maskus and Konan (1994: 401–54); Mansfield and Lee (1996: 181–6); United Nations Department of Economic and Social Development (1993)
71. Frischtak (1990: 61–98)
72. Ibid., pp. 8–80
73. Ibid., p. 78
74. Ibid., p. 80
75. Ibid., pp. 80–4
76. Sherwood (1990a: Chapters 5 and 6)
77. Ibid., pp. 125–6
78. OECD (1987: Table 40)
79. Mansfield (1994: 1–3)
80. Ibid., p. 1
81. Ibid., pp. 1–2
82. Ibid., Tables 2–4, pp. 5, 19
83. Vernon (1957: 15–17)
84. United Nations Department of Economic and Social Development (1993: 1)
85. Ibid., pp. 3–5
86. Schumann (1990: 157–202)
87. Ibid., pp. 194–195
88. Maskus and Konan (1994: 438–9). According to the authors, US foreign presence is measured by the following: US direct investment abroad, net property, plant and equipment of US affiliates abroad, employment of US affiliates abroad, net direct investment flows in 1982, and net royalties and licence fees associated with direct investment in 1982.
89. Ibid., p. 195
90. For a similar view see: Primo-Braga (1990a: 83–4); Primo-Braga (1989: 262)
91. Nogués (1990a: 25)
92. Hindley (1971: 61)
93. For an historical overview on Switzerland's patent system see: Penrose (1951: 120–25)
94. Ibid., p. 123
95. Ibid., pp. 123–4
96. Ibid., 1951, p. 16
97. Gadbaw and Richards (1988: 21–31); Abbott (1989: 689–744); for the desire to include IPRs in a GATT framework see: Emmert (1990: 1317–1399)
98. Gadbaw and Richards (1988: 21–6)
99. For a general overview on the use of Sections 337 and 301 see: Trebilcock and Howse (1995: Chapter 10); Abbott (1989: 689–743); Mody (1990: 203–39)
100. Trebilcock and Howse (1995: 259–60)
101. Ibid., pp. 260–61; Mody (1990: 218–21)
102. For the procedures of identifying a priority country see: US Information Agency (1995)
103. Ibid.
104. Ibid.
105. Nogués (1990b: 7–8)
106. Ibid., pp. 7–8
107. Gadbaw and Richards (1988: 272–310)
108. USTR (1998a)

109. The White House, Office of the Press Secretary, 'Fact Sheet' (16 October 1985: p. 2) as cited in: Gadbaw and Richards (1988: 273–4)
110. USTR – *Section 301 Table of Cases – Korea Intellectual Property Rights* (1998a)
111. Gadbaw and Richards (1988: 277–85)
112. Ibid., p. 276
113. Ibid.
114. Ibid., pp. 20–24
115. USTR – *Section 301 Table of Cases – Brazil Pharmaceuticals* (1998b); Nogués, (1990b: 7–8)
116. Abbott (1989: 710)
117. USTR – *Section 301 Table of Cases – Brazil Pharmaceuticals* (1998b)
118. Ibid.
119. Intellectual Property Committee (1994b: 4)
120. Council of the European Union, Council Regulation (EEC) No. 3842/86, OJL 357, 18, (18 December, 1986: 1); new provisions were adopted in 1994 and implemented in 1995: Regulations (EC) No. 1367/95, OJL 133, (17 June, 1996: 2)
121. Trebilcock and Howse (1995: 261–2); Council of the European Union, *Council Regulation (EEC) 3286/94*, *Trade Barriers Regulation* (22 December 1994);
122. Brueckmann (1990: 291–310); Nogués (1990b: 8); Trebilcock and Howse (1995: 261–2); Mody (1990: 225–6)

4. The advanced pharmaceutical industry in Europe and IPRs

4.1 INTRODUCTION

In previous chapters we established that the internationalization of IPRs cannot be explained by a pure economic approach. It is linked, rather, to the political activities of developed countries seeking to secure the interests of key IP-based groups.

The advanced pharmaceutical industry is one of the important players, perhaps the most important one, in the field of IPRs. By focusing on its interests, organizational structure and activities, this book provides a solid basis for understanding the determination of the international IP agenda.

Linking the advanced pharmaceutical industry in Europe with the TRIPs agreement is a multiphased task. Initially, it is necessary to make an analysis of the advanced pharmaceutical industry in Europe and, most importantly, to understand why IPRs are so crucial to its well-being.

That is the purpose of the current chapter, which focuses on three major elements. First, it provides a general overview of the world pharmaceutical industry while elaborating on the attributes and characteristics of the advanced pharmaceutical industry. Secondly, the chapter focuses on Europe, identifying the sources of strength and weakness of the European pharmaceutical sector. Finally, the chapter places particular emphasis on the importance of IPRs to the advanced pharmaceutical industry. In other words it explains why IPRs provide such a powerful incentive for collective action to the advanced pharmaceutical industry in Europe.

The term 'advanced pharmaceutical industry' refers to pharmaceutical companies who are able to create new products by undertaking extensive R&D projects. Terms such as research-based pharmaceutical MNCs, pharmaceutical MNCs, or research-based companies should be treated as synonymous.

4.2 AN OVERVIEW OF THE WORLD'S PHARMACEUTICAL INDUSTRY

For over a century, the pharmaceutical industry has been one of the world's largest and most solidly established manufacturing industries. Its modern roots can be

traced to the invention and development of milestone medicines, such as aspirin in 1897, by Hoffman (which made Bayer the first known pharmaceutical MNC), and penicillin in 1948, by Florey and Chain.[1] The industry has consistently demonstrated incredible manufacturing capabilities, sales growth, innovative potential and capacity to generate profits. World production in pharmaceuticals grew from $70 billion in 1975 to $150 billion in 1990 and to more than $300 billion in 2000.[2] Sales of prescription pharmaceutical drugs world-wide grew from $40 billion in 1972 to about $420 billion in 2002.[3] Pharmaceutical R&D expenditures in the largest industrialized blocs, the US the EU and Japan, almost tripled between 1990 (€18 billion) and 2001 (€52.6 billion).[4]

Table 4.1 Pharmaceutical R&D expenditure in Europe, US and Japan (euro Million)

	1990	1995	1997	2000	2001
Europe	7871	10787	13441	17202	18869
USA	5342	9078	13683	23121	26230
Japan	2810	5221	4963	7499	7460
Total	18013	27081	34084	49822	54560

Sources: EFPIA, (1999a; 2003)

4.2.1 The Dominance of Research-based Pharmaceutical MNCs

Research-based pharmaceutical MNCs, such as Merck, GlaxoSmithKline, Pfizer and Novartis, are by far the most dominant and influential players in the industry. The economic might of such MNCs, or 'Alchemists', as referred to by *The Economist*, is most impressive, both within the industry and outside it.[5] Total 2001 sales of prescription drugs, that is drugs that can be purchased only by prescription, by the 20 leading pharmaceutical MNCs amounted to $234 billion, an average of 12 per cent increase over the previous year.[6] In addition, the average profit margin of the ten most profitable companies in 2001 was 34 per cent.[7] All leading pharmaceutical MNCs are based in developed countries, mostly the US and the EU. With regard to cross-industry significance, a 2003 *BusinessWeek* survey found that five pharmaceutical MNCs were ranked among the leading top 20 companies world-wide in terms of market value.[8] Similarly, a *Financial Times* (FT) April 2000 survey found that five pharmaceutical MNCs were ranked among the leading top 20 companies in Europe in terms of market value.[9]

Table 4.2 Leading companies in sales of prescription pharmaceuticals – 2001 ($US million)

Ranking	Company	Country of origin	Phar. Sales ($US Million)	% increase
1	Pfizer	US	25 518	13.1
2	GlaxoSmithKline	UK	24 791	6.2
3	Merck & Co	US	19 732	6.2
4	AstraZeneca	SWE/UK	16 183	6.3
5	Bristol-Myers Squibb	US	15 300	6.3
6	Aventis	FRA/GER	14 879	7.9
7	Johnson & Johnson	US	14 851	17.3
8	Pharmacia	SWE/US	11 970	10.6
9	Novartis	SWI	11 963	11.6
10	Wyeth	US	11 717	8.8
11	Eli Lilly	US	10 856	6.5
12	Hoffmann-La Roche	SWI	10 114	6.6
13	Schering-Plough	US	8 369	0.3
14	Abott Laboratories	US	8 177	38.9
15	Takeda	JAP	6 741	
16	Sanofi Synthelabo	FRA	5 675	12.2
17	Bayer	GER	5 129	–6.7
18	Boehringer Ingelheim	GER	4 717	54.8
19	Schering AG	GER	4 190	4.9
20	Shionogi	JAP	2 948	1.3
	Total		**233 820**	
	Average		**11 691**	**11.2**

Source: Scrip (2003b: 40)

Over the years pharmaceutical MNCs based in the US, the EU and, to some extent, Japan have been able to expand their global presence and to 'tighten their grip' over markets world-wide. Empirical evidence suggests that, since the 1970s, a relatively small number of about 50 companies account for more than two thirds of world production and export.[10] A 1982 survey of the pharmaceutical industry in the EC enumerated more than 1480 pharmaceutical companies, of which only 33 were identified as research-based MNCs.[11]

Two significant processes enabled pharmaceutical MNCs to establish this oligopolistic pattern. The first is the series of mergers and acquisitions (M&As) between leading EU and US-based pharmaceutical MNCs, particularly since the end of the 1980s, aimed at consolidating their global market position.[12]

It is estimated that between 1988 and 1992, there have been 760 M&As in the pharmaceutical and biotech industries world-wide, the total value of which exceeded $47 billion.[13] Notable mergers of European based MNCs in the last decade include: SmithKline and Beecham (1989), Hoffman La Roche and Syntex (1994), Glaxo and Wellcome (1995), Sandoz and CibaGeigy (1996 – known today as Novartis), Hoechst AG and Rhone Poulenc (1998), Astra and Zeneca (1999), and GlaxoWelcome and SmithKline Beecham (2000).[14] According to Scrip, M&As in the pharmaceutical industry reached an all-time high of $133 billion in 1999.[15]

Table 4.3 Leading companies by profit margin – 2001

Ranking	Company	Origin	Profit ($US million)	Sales ($US million)	% Profit margin
1	Merck & CO	US	12 200	19 732	61.8
2	Pfizer	US	10 936	26 949	40.6
3	Johnson & Johnson	US	4 928	14 851	33.2
4	Eli Lilly	US	3 552	10 856	32.7
5	Takeda	JAP	2 176	60 741	32.3
6	Schering-Plough	US	2 523	8 369	30.1
7	Wyeth	US	3 504	11 717	29.9
8	Abott Laboratories	US	2 358	8 177	28.8
9	Novartis	SWI	3 365	11 963	28.1
10	GlaxoSmithKline	UK	6 203	24 791	25
	Total		**51 745**	**198 146**	
	Average				**34.3**

Source: Scrip (2003b: 41)

Secondly, pharmaceutical MNCs have also expanded their R&D and knowledge-based alliances with other firms and research bodies, particularly in the field of cell and gene therapy.[16] According to PhRMA, the number of strategic alliances grew from 121 in 1986 to 627 in 1998.[17] Overall, M&As and strategic alliances over the last decade have enabled pharmaceutical MNCs to maintain and even strengthen their global market position.[18]

In terms of marketable products, research-based pharmaceutical MNCs are the only ones capable of introducing new and innovative drugs to the market. This should not come as a surprise given the protracted period and vast financial resources required for the development of a new pharmaceutical drug (as discussed in Chapter 2, it takes more than 10 years on average to develop a

new pharmaceutical drug and the average development costs are estimated at about $500 to $800 million).

As regards existing out-of-patent products, pharmaceutical MNCs face serious competition from generic-based companies. As their name implies, generic-based companies focus mainly on the production of existing generic compounds, in respect of which patent protection has expired, rather than focusing on the development of new drugs. Generic-based companies are much smaller than pharmaceutical MNCs in terms of scope of operations, capital base, product diversification, and so on. Annual sales of such companies in the 1990s were relatively 'modest', and varied between $25 million and $200 million. Such sums cannot possibly finance massive R&D projects of the kind that are currently undertaken by MNCs.[19]

This does not necessarily mean that generic-based companies lack innovative potential or capabilities. Many of these companies are indeed able to secure patent protection for new pharmaceutical substances or processes. However, in the absence of sufficient R&D resources and lack of 'economies of scale' capabilities, generic-based companies prefer to exploit their patents by licensing them to MNCs rather than using them for the purpose of developing marketable drugs. Despite their smaller size, generic-based companies are not at all excluded from the international markets. Some generic-based companies are large enough to own foreign subsidiaries and to have their own export and distribution channels, while others prefer to exploit their products overseas by entering into joint ventures or by using international trading houses.[20] One example is the Israeli-based company, Teva Pharmaceuticals, currently regarded as one of the world's leading generic companies. Demonstrating impressive sales ($1.3 billion in 1999) and profit-generating capability ($118 million in 1999), Teva seized a considerable share of the US market for generic products by entering into strategic alliances with major league companies, such as with Merck in 1993, and by establishing its own subsidiaries.[21] Moreover, the relatively small size of generic companies allows them to be more flexible and, at the same time, more functional. Companies can focus on the production of new pharmaceutical substances from existing generic compounds, specialize in specific market areas, such as gene therapy, or cooperate with larger companies during the various R&D stages of a given project, such as safety testing.[22] Overall, the generic market is becoming increasingly important in the global pharmaceutical scene, with an average growth rate of 15 per cent between 1996 and 2001, and a market share of 11 per cent of the total prescriptions market ($42 billion in 2001).[23]

Facing rising competition from generic-based companies, pharmaceutical MNCs employ various strategies aimed at securing their position in the market for generics. Three methods may be mentioned. First, pharmaceutical MNCs establish their own generic-based units.[24] Some companies such as Merck,

Zeneca, and CibaGeigy (now part of Novartis) compete against their own original brand-name products via newly established generic subsidiaries.[25] By these means, companies aim to seize control of both the generic and brand-based markets in a given product. Secondly, pharmaceutical MNCs such as SmithKline Beecham (today GlaxoSmithKline) and Zeneca (now AstraZeneca) can forge strategic alliances with generic-based companies.[26] This strategy can save substantial costs for pharmaceutical MNCs while serving as a tool for regulating competition between generic and research-based companies.[27] Finally, pharmaceutical MNCs, such as Hoechst and Marion Merrell Dow, can take over existing generic companies.[28] Such a strategy can be particularly useful when domestic companies ('national champions') have better access to regulatory authorities and political institutions.[29]

4.2.2 The Global Distribution of Pharmaceutical Capabilities

R&D in the pharmaceutical industry refers to both finished products (end-use) and to new processes and techniques, such as in the field of biotechnology, that may be used as inputs for future medicines. It is easier to focus on the statistics of end-use products, however, not least because many companies prefer to keep the existence of substances, techniques and processes secret for as long as IP protection has not been granted.

Under the heading of 'end use' products, one can distinguish between products that are based on the discovery and development of new chemical entities (NCEs) and those products based on existing, out of patent, generic compounds. Given their innovative character and their profit-making capacity, NCE-based drugs are much more important than generic-based drugs. A 1985 report by the OECD concluded that 'products of this type (NCEs) are responsible for the spectacular growth of the pharmaceutical industry since the 1930s, and are the ultimate source of prosperity not merely for the innovative company, but for the generic sector as well'.[30]

Generally speaking, NCE-based products, such as Lipitor, Prozac and Augmentin, have four main common characteristics: (1) they are new to the market; (2) they are developed almost exclusively by pharmaceutical MNCs; (3) they are patentable; (4) they can be purchased only by prescription. In other words, the four characteristics of NCE-based drugs allow their owners to secure commercial returns substantially higher than those obtained by generic products. With regard to generic-based drugs, suffice to say that such products are sold either by prescription or as over-the-counter (OTC) drugs. As previously mentioned, competition in the generic market is fierce.

Referring to data concerning the global distribution of pharmaceutical output in end-use products one can conclude that the oligopolistic pattern of

the industry is clearly located in developed countries. A few elements should be emphasized. First, pharmaceutical industries in developed countries are the only ones capable of introducing NCE-based drugs to the market. It is estimated that more than 90 per cent of new drugs produced and marketed world-wide since the 1960s originated in the ten leading countries (Belgium, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the UK and the US).[31] Although some developing countries such as India, China and South Korea have some innovative potential, the current innovative sector of the industry lies almost exclusively in developed countries.[32] It is estimated that the leading industrialized blocs: the US, EU and Japan, account for more than 90 per cent of global R&D expenditures.[33] Second, developed countries have maintained and even increased their complete dominance of the global production of pharmaceuticals. In 1975 developed countries accounted for 67 per cent of world pharmaceutical production and in 1990 they accounted for 73 per cent.[34] The ten leading countries were able to increase their share from 60 per cent in 1975 to 69 per cent in 1990.[35]

Third, developed countries are the largest beneficiaries of international trade in pharmaceutical products. In 1975 and 1988 developed countries accounted for around 81 and 88 per cent of world exports respectively.[36] Developing countries accounted for about 7 per cent in those years.[37] Consumption and sales of pharmaceutical products in developed countries are greater by far than those in developing and least developed countries (with a few exceptions such as Brazil and Argentina).[38] Consumption per capita in developed countries increased from an average of $61 in 1975 to $131 in 1990, while in developing and least developed countries it increased from about $6 to $7 in these years.[39] In 1975 and 1990, more than 65 per cent and 70 per cent respectively of all marketable drugs were sold in developed countries.[40] Figures issued on 2000 and 2002 suggest that more than 80 per cent of marketable drugs are consumed by the residents of developed countries.[41] The obvious gap between the purchasing ability of consumers from developed and those from developing countries is emphasized even more when one considers the fact that the latter accounted for more than 75 per cent of the world population.[42]

The pharmaceutical industry is thus characterized by two main features. First, the industry is dominated by a small number of pharmaceutical MNCs based in a few developed countries. These firms are the only ones capable of introducing new drugs to the market and they also control the market for existing generic products. Second, developed countries dominate the production, trade and consumption of new and existing pharmaceutical products. Though impressive growth has taken place in a few developing countries, such as Argentina, Brazil, China and India (mainly in the production of generics) developed countries are still the major source of the industry's output.

4.3 THE ADVANCED PHARMACEUTICAL INDUSTRY IN EUROPE

The pharmaceutical industry in Europe is not homogeneous. Pharmaceutical industries in European countries, the most sophisticated and innovative of which are based in the EU and in the European Free Trade Association, have different capabilities for innovation, production and trade. Furthermore, from a demand-side perspective, the vision of a Single European Pharmaceutical Market is still far from a reality. It faces some serious obstacles such as variations in drug prices, inequality in the levels of consumption, and diverse national policies.

This section surveys some key features of the advanced pharmaceutical industry in Europe. It makes generalizations on its overall performance and, at the same time, focuses on some of the differences between various European countries. Particular emphasis is placed on the capabilities of the advanced pharmaceutical industry in leading European countries.

4.3.1 Production and Trade

By any yardstick, the overall performance of the pharmaceutical industry in Europe is impressive. Two elements, however, need to be emphasized.

First, the industry in Europe is one of the world's biggest producers of pharmaceutical products, second only to the US. Between 1970 and 2000 the industry in Europe accounted for more than 30 per cent of world production in pharmaceuticals.[43] Between 1986 and 1990 the major European countries in pharmaceuticals (Germany, UK, France, Switzerland and Italy) demonstrated the most dramatic production growth rates (total increase of 45 per cent), ahead of the US (19 per cent) and Japan (31 per cent).[44] During the late 1990s Europe lost its lead as the world's largest producer of pharmaceuticals to the US. With an output of €121.3 billion in 2000, the United States has taken over the top position, followed by Europe (€112 billion) and Japan (€62 billion).[45] Data from 2001 indicates that France is the largest producer of pharmaceuticals in Europe (with approximately 19 per cent of the European pharmaceutical output), followed by the UK (15 per cent) Germany and Switzerland (approximately 14 per cent each).[46]

Second, leading European countries, together with the US and Japan, are the world's largest traders in pharmaceuticals. On average, pharmaceutical exports originating from the four leading European countries (Germany, UK, France and Switzerland) grew from $448 million in 1960 to $55 billion in 2000, while those from the US increased from $275 million to $13.3 billion respectively.[47] Data from the 1990s and 2000 indicates that European-based companies maintained their top trading position.[48] According to the German Association of Research-Based Pharmaceutical Companies (VFA), in 2000

Germany and Switzerland were the worlds largest exporters of pharmaceuticals ($17 billion and $13.9 billion), followed by the US ($13.3 billion), the UK ($13 billion) and France ($11.4 billion).[49] Moreover, during the 1980s and 1990s, intra-European imports of pharmaceuticals accounted for more than two-thirds of total imports by European-based countries, most of which took place in the leading countries.[50]

4.3.2 Capacity for Innovation

Together with its US counterpart (and also, to a lesser extent, Japan) the industry in Europe dominates the innovative spectrum of the pharmaceutical industry. A few indicators may be given.

First, the European pharmaceutical industry has been the main source of NCEs over the past 50 years. Out of 2230 NCEs discovered from 1950 to 2002 more than half originated in Europe.[51] Second, the European industry is a major source of new commercially successful drugs. It is estimated that out of 152 major drugs introduced to the market between 1975 and 1994, the US accounted for about 45 per cent and Europe for about 40 per cent (UK: 14 per cent, Switzerland: 9 per cent and Germany: 7 per cent).[52] Third, the industry in Europe is the biggest investor, after the US, in projects aimed at developing new pharmaceutical products. European R&D expenditures for the development of new pharmaceutical products increased from €4.3 billion in 1985 to €14.5 billion in 1998.[53] Again, the UK, Germany, France and Switzerland are the primary investors. In 1996 they accounted for more than 70 per cent of total European R&D expenditure (ECU 11.4 billion).[54] Finally, pharmaceutical MNCs are the main innovative force in Europe. Data compiled from 1982 suggests that out of 1450 pharmaceutical companies listed in the EC, only 33 were capable of introducing new drugs to the market.[55]

However, compared with the US, the innovative strength of the pharmaceutical industry in Europe has declined over the years. The share of European countries in the development of NCEs declined from about 65 per cent during the 1960s to about 40 per cent in 2000.[56] One possible explanation for this decline is the fact that since the late 1990s the pharmaceutical industry in Europe allocates fewer financial resources to R&D projects relative to the US. The average R&D expenditures by the US pharmaceutical industry in 2000 and 2001 (€23 billion and 26 billion) exceeded that of Europe's (€17 and 19 billion) and Japan's (€7.5 billion).[57] R&D expenditure as a percentage of sales is also higher in the US. In the 1990s it was estimated at about 15 per cent in the US and 11 per cent in Europe.[58] Yet looking at individual countries, in 1990 the US ratio of R&D expenditure to sales was lower than that of the UK (16 per cent) and equal to that of Germany.[59]

Table 4.4 Number of NCEs developed between 1950 and 2002

Period of 1950–1989

Origin	NCEs	% of total
USA	788	35.34
Japan	236	10.58
Germany	232	10.40
France	227	10.18
Switzerland	227	10.18
UK	153	6.86
Italy	121	5.43
Belgium	114	5.11
Sweden	59	2.65
Holland	32	1.43
Denmark	31	1.39
Austria	9	0.40
Ireland	1	0.04
Total	**2230**	**100.00**
Total Europe	**1206**	**54.08**

Period of 1988–2002

Origin	NCEs	% of total
Europe	255	41.26
USA	195	31.55
Japan	153	24.76
Others	15	2.43
Total	**618**	

Sources: Economic and Social Commission for Western Asia (ESCWA) (1998: 42–3); EFPIA (2003)

The pharmaceutical industry in Europe is, therefore, one of the strongest of its kind. It is particularly prosperous in Germany, the UK, Switzerland and France. Together with the US, the advanced pharmaceutical industry in Europe is the largest producer and net trader of pharmaceuticals, and dominates the innovative spectrum of the pharmaceutical industry world-wide.

4.4 THE IMPORTANCE OF IPRS TO THE ADVANCED PHARMACEUTICAL INDUSTRY

This section focuses on two major elements. First it elaborates on the importance of patents and trade secrets (particularly data submitted to regulatory authorities) to pharmaceutical MNCs during the pre-marketing and marketing stages of medicinal drugs. Second, it emphasizes the importance of trademarks to pharmaceutical MNCs, particularly with regard to brand loyalty during the post-patent life of original drugs.

4.4.1 The Importance of Patents to Research-based Pharmaceutical MNCs during the Marketing Stage of Innovative Drugs

Patents are the most important forms of IPRs to the advanced pharmaceutical industry. They allow research-based pharmaceutical MNCs, as well as other innovative companies, to secure a market monopoly, though for a limited period, on innovative products and processes. Their role is crucial during both the marketing and pre-marketing stages of such products and processes.

The simplest and most straightforward explanation of the importance of patents to research-based companies, is that they allow pharmaceutical MNCs to reap exceptional profits, due to patent monopoly, from their marketing of innovative drugs. This is also the reason (at least from a business perspective) for pharmaceutical MNCs to allocate huge financial resources to the development of new drugs. Naturally not every new drug proves to be a commercial success. Yet when a patentable drug does prove to be a profit-generating asset, commercial returns are vast. A few examples may be given. In 2002 the sales of the 10 leading patentable pharmaceutical drugs exceeded $40 billion and enjoyed an average growth rate of more than 10 per cent.[60] Total 2002 sales of Lipitor, Pfizer's anti-cholesterol drug, were estimated at about $8 billion (an increase of 24 per cent from the previous year) which amounted to 25 per cent of the company's global revenues in that year ($32 billion).[61] GlaxoSmithKline's respiratory drug Seretide/Advair enjoyed a spectacular growth of 96 per cent, from $1.3 billion in 2001 to $2.4 billion in 2002.[62] Sales of Zocor, Merck's cholesterol-reducing drug, reached $5.6 billion in 2002, with a 12 per cent growth from the previous year.[63] Launched in April 1998, Pfizer's Viagra, possibly the best-known drug at present, broke all sales records for a new pharmaceutical product ($788 million in that year) and enjoys an annual average growth rate of 13 per cent ($1.7 billion in 2002).[64]

In light of the huge profit-generating potential of patented drugs (commonly referred to as pharmaceutical 'blockbusters') it is easy to understand why pharmaceutical MNCs invest between 10 to 20 per cent of their global annual sales in future R&D projects.[65] For instance, R&D expenditures by GlaxoSmithKline and Lilly in 1997 were estimated at about $1.4 billion (per company) accounting for 11 and 16 per cent of total sales respectively.[66] In 1998 Roche spent more than 19 per cent of its sales on R&D projects ($1.9 billion).[67]

The importance of patent protection to profit flows has increased since the 1980s when fierce competition emerged in the generic drugs market. The ability to copy cutting-edge pharmaceutical products cheaply and rapidly implies that, once a patent has expired, other companies can produce 'instant' generic substitutes.[68] It also means that post-patent prices of generic drugs are expected to be substantially lower than prices of original in-patent drugs. According

to Nogués, there was a reduction of up to 90 per cent in prices of various pharmaceutical drugs once patents had expired.[69]

Table 4.5 Global pharmaceutical sales and patent protection periods of leading products in 2002

Audited product	Date of market approval	Minimum patent expiration date in the US	Sales ($US billion)	% Global sales	% Growth (year over year)
Lipitor	1996	2009	8.6	2	+20
Zocor	1991	2006	6.2	2	+13
Losec/Prilosec	1989	2002	5.2	1	–19
Zyprexa	2000	2011	4	1	+21
Novarsc	1992	2006	4	1	+6
Erypo/Eprex	1999		3.8	1	+18
Ogastro/ Prevacid	1995	2009	3.6	1	+3
Seroxat/Paxil	1997	2006	3.3	1	+13
Celebrex	1998	2013	3.1	1	–1
Zoloft	1991	2005	2.9	1	+12
Total			**44.7**	**12**	**+11**

Note: The minimum patent expiration date refers to the first patent expiry of the drug (bearing in mind that there are usually numerous consecutive patents for a given drug).

Source: IMS Health (2003b); US FDA (2003)

The profitability of pharmaceutical MNCs depends, among other things, on their patented products. GlaxoSmithKline argued that patent expiry for its two major products, Zantac and Zovirax, was the major reason for the dramatic fall in sales from £8341 million in 1996 to £7980 million in 1997.[70] Once patents for these products had expired, GlaxoSmithKline experienced a reduction in global sales of more than 21 per cent, generating an overall loss of more than £580 million.[71] Another notable case is the patent expiry of Losec, AstraZeneca's best-selling drug, leading to 18 per cent decline in sales, from $5.6 billion in 2001 to $4.6 billion in 2002.[72]

Referring to patent expiries the FT commented that 'one of the pitfalls of relying on blockbusters…is that when one product loses its patent, group earnings can plummet overnight'.[73] Patent expiries may therefore have a negative effect on the share prices of pharmaceutical MNCs. More specifically, when pharmaceutical giants are facing closer deadlines of patent expiries,

without having new patentable products in the pipeline, the price of their stock is adversely affected. According to the FT, the fall in the price of Merck's stocks, from $159 in November 1998 to $137 in January 1999, can be explained by the company's failure to introduce a new anti-depressant drug and also to expected patent expiries on its two main products, Pepcid and Prilosec, in 2000.[74] The FT also reports that other companies, such as Eli-Lilly and AstraZeneca, face similar problems.[75] The latter was reported to have suffered a 10 per cent drop in its share price (24 February 2000) due to increasing worries over the expected patent expiry (2001 in the US) of its best and biggest selling drug, Losec.[76] Despite record sales of Losec in 1999 of about $6 billion, which accounted for some 40 per cent of AstraZeneca's global sales, investors were worried about its post-patent performance. In light of the above, the FT concludes that patent expiries 'are one reason why the defensive quality of the sector suddenly seems less attractive'.[77]

Pharmaceutical MNCs also take patent expiries into account in their merger strategies. Patent expiries as a partial determinant of the 'urge to merge' probably derives from a strategy aimed to minimize the effect of post-patent losses on companies' portfolios. SCRIP reports that 'according to the AstraZeneca management, one of the factors behind the two companies joining forces was that as a combined group there would be a better opportunity to minimise the impact of patent expiry'.[78]

4.4.2 The Role of Patents and Data Exclusivity during the Pre-marketing Stage of Pharmaceutical Drugs – an 'Insurance' Tool

During the pre-marketing stage of 'pipeline drugs' (drugs that are still in various development stages) patents reduce the level of risk involved in time-consuming, risky and expensive R&D projects. Pipeline products are very important to innovative pharmaceutical companies, particularly because they are considered the basis upon which future profits will be generated. This is the reason pharmaceutical MNCs include an inventory of pipeline drugs at various stages of development in their annual reports.

In order to emphasize the relevance of patents to pipeline products, it is necessary to describe, in brief, the current structure of R&D projects designed to introduce new drugs to the market. Despite tremendous scientific and technological progress, current pharmaceutical R&D projects are still considerably protracted. While the 'R' component of a given R&D venture is becoming shorter, due to implementation of advanced screening and synthesizing techniques, development stages require even stricter and lengthier testing procedures.[79]

A typical pharmaceutical R&D project consists of one pre-clinical stage and four clinical stages (clinical stages are also referred to as phases).[80] At

the pre-clinical stage scientists attempt to isolate new chemical or biological entities by using advanced screening and synthesizing techniques. This stage also involves initial safety tests on animals and various assessment studies, such as toxicology. Clinical phases involve safety trials on volunteers (phase I), small patient groups (phase II), large patient groups (phase III), and regulatory and post-marketing studies (phase IV). Overall, current pharmaceutical R&D projects take about ten to twelve years, of which four years are spent on the pre-clinical stage and about eight years on clinical phases.[81] Statistically, only one or two out of 10 000 molecules screened at the pre-clinical stage will reach the end of the development pipeline and become a marketable product.[82] It was noted previously that the current average development costs for successful drugs, that is drugs that have been approved for market use, are estimated at about $500 million to $800 million.[83] It should also be noted that not all finished products are commercially successful. Citing data from Grabowski and Vernon, PhRMA argues that only three out of ten marketed drugs produce revenues that match or exceed average R&D costs.[84]

In view of the above statistics, and because of fierce competition between MNCs on the introduction of innovative products, it is common practice for companies to seek protection of their investments via patents. Chapter 2 has already cited evidence indicating that the pharmaceutical industry is one of the most patent-dependent industries (it is argued that 60 to 65 per cent of drugs would not have been developed or produced in the absence of patent protection).[85] When asked about the importance of IPRs to the pharmaceutical industry, a corporate IP manager of a leading pharmaceutical MNC went as far as to argue that patents are so important to the industry that without them the industry would not exist.[86] It is shown in Chapter 5 that such statements are quite common among corporate IP executives and reflect, to some extent, the importance of IPRs to pharmaceutical MNCs. Scrip also acknowledges the importance of patents to the industry. It argues that pharmaceutical MNCs 'will have to consider patenting as part of their product development strategy' and that IPRs 'will become central to a company's ability to innovate and no longer simply a support for business planning'.[87]

Moreover, in order to protect their pipeline investments, pharmaceutical MNCs apply for patent protection as early as the pre-clinical stage, that is when a leading compound is isolated.[88] This in turn means that for most of its life a patent is used as an insurance, aimed at preventing competitors from developing identical pharmaceutical products, rather than a direct tool for profit-making.[89]

The exposure to the shrinking period of effective patent monopoly motivates research-based pharmaceutical companies to explore other ways of extending their market exclusivity. One way that pharmaceutical MNCs seek to maintain market position is through the granting of data exclusivity, that is by securing a period of 'non-disclosure/non-reliance' (between five to ten years) with

regard to information submitted by these companies to regulatory authorities for the purpose of obtaining marketing approval for new drugs.[90] Research-based companies argue that since such information falls within the category of 'trade secrets' it must be used exclusively by its originators and not by the generic competitors or even the government (indirect reliance may take place when comparing a generic version with the original drug). In other words, data exclusivity enables research-based companies to prolong their market exclusivity vis-à-vis generic-based companies. Denying generic companies the free use of data submitted for regulatory approval forces them either to produce such data themselves, which is usually a costly and time-consuming process, or to wait until the term of exclusivity expires. In both cases research-based companies are the main beneficiaries. It is shown later (Chapters 5, 6 and 8) that research-based companies, aware of the benefits of data exclusivity, would like to interpret Article 39.3 of TRIPs in a manner that secures stronger protection of data exclusivity.

Patents and data exclusivity are thus crucially important to research-based pharmaceutical MNCs, particularly with respect to the marketing and pre-marketing stages of pharmaceutical products. During the marketing stage of a pharmaceutical product, the monopoly embodied in patent protection enables pharmaceutical MNCs to generate exceptional revenues and profits from the sales of their innovative drugs. Once a patent on a leading product expires, the sales of that product are likely to be reduced dramatically, not least because of fierce competition from generic-based companies. It is also logically and empirically plausible that patent expiration has a negative effect on the equity value of research-based pharmaceutical MNCs, particularly when companies fail to introduce successful pipeline alternatives. Pharmaceutical MNCs also consider patent protection and patent expiry in their merger strategies.

During the pre-marketing stage of pharmaceutical drugs, patents are used as an insurance tool protecting potentially successful pipeline drugs. Current R&D projects aimed at introducing innovative drugs are extremely expensive and risky. Because of this, pharmaceutical MNCs seek the protection of patents as soon as they are able to synthesize and isolate a new leading compound. This, in turn, implies that a patent for a pharmaceutical drug also functions as a tool for preventing free-riding. Research-based pharmaceutical companies also attach great importance to the protection of any data submitted for the purpose of regulatory approval. Data exclusivity grants pharmaceutical MNCs an additional period of market exclusivity vis-a-vis generic-based competitors.

4.4.3 The Importance of Trademarks to Pharmaceutical MNCs

It was previously submitted that there is a considerable difference between patent and trademark monopolies. The former secures a monopoly on an invention,

be it a product or a process, while the latter secures a monopoly on the use of an identifying mark. Hence, the market power derived by patents is closer to a model of 'pure monopoly', while that generated by the 'product-differentiation' function of trademarks is closer to a model of monopolistic competition.[91]

Nevertheless, pharmaceutical companies attach great importance to trademarks and consider them an important tool for securing the market power of their products. In fact, it has been estimated that the pharmaceutical industry as a whole is one of the most sophisticated and active users of trademarks. Evidence from 1974 and 1981 suggests that pharmaceutical and other related products had an overwhelming share (approximately 40 per cent) of the world-wide use of trademarks.[92] The advanced pharmaceutical industry is also one of the most intense users of brand advertising aimed at creating goodwill for brand-based drugs. It is estimated that pharmaceutical MNCs spend as much as 35 per cent of annual sales on promotion of brand-based drugs worldwide.[93] In the US alone, the pharmaceutical industry spent more than $5.8 billion on product promotion in 1998, a 19 per cent increase from the previous year.[94]

The ability of trademarks to prevent the rapid decline in the market share of out-of-patent drugs vis-à-vis generic-based substitutes makes them an important tool for research-based pharmaceutical MNCs. Consider, as an example, prescription drugs. By definition, prescription drugs can only be purchased with a doctor's approval. Given that prescription drugs are extremely important in terms of their life-saving ability and profit-generating capacity, information on these products is provided primarily to doctors and pharmacists. During the patent term of protection, research-based MNCs have an exclusive period in which they can influence doctors' decisions by creating brand loyalty. Promotional activities in this sphere are quite notorious and involve gifts, banquets, seminar trips, bonus deals, one-to-one meetings (usually referred to as 'detailing'), presentation gimmicks, and so on.[95]

Empirical evidence suggests that expenditures aimed at creating the brand loyalty of doctors soared during the last decades. Expenditure on advertising directed to physicians in the US reached $4.6 billion in 1998, an 18 per cent increase from 1997 levels (approximately $4 billion).[96] With regard to one-to-one detailing, it was estimated that in the five leading European markets (Germany, France, UK, Italy and Spain) in 1993 there were about 62 000 medical representatives for approximately 350 000 GPs, that is about one representative for every five physicians.[97]

Once achieved, brand loyalty becomes an important factor in the ability of pharmaceutical MNCs to preserve the market position of their out-of-patent prescription drugs. Several studies have indicated that doctors' preferences for well-known brands (as opposed to generic substitutes) derive not from calculations of price or quality, but rather because pharmaceutical MNCs are able to secure brand loyalty during the market exclusivity of their original products.[98]

Furthermore, not only does brand loyalty enable original brands to continue to lead the market, but it also allows pharmaceutical MNCs to charge prices that are still considerably higher than existing generic alternatives. For instance, using data from frequently prescribed generic drugs in 1975, UNCTAD found significant price differences reaching to hundreds and even thousands of per cent, both in developed and developing countries, between generic substitutes and leading original brands.[99] Thus, despite the reduction in prices due to patent expiry, brand loyalty to original out-of-patent prescription drugs allows pharmaceutical MNCs to continue to charge a premium for their products.

Pharmaceutical MNCs also invest in other promotional strategies aimed at creating brand loyalty in prescription drugs. One of the most dominant forms of brand marketing since the 1990s is 'direct to consumer' (DTC) advertising of prescription drugs. As its name implies, DTC advertising is directed primarily at consumers. Apart from its 'informational' value, DTC advertising in prescription drugs enables pharmaceutical MNCs to increase consumer demand for brand-based products.

Several studies have shown that pharmaceutical MNCs regard DTC advertising in prescription drugs as an extremely effective tool in their battle against generic-based substitutes.[100] In the US, where DTC advertising has been legal since 1983, promotional expenditures 'exploded' from about $13.1 million in 1989 to $2.7 billion in 2001.[101] Not surprisingly, pharmaceutical MNCs, such as GlaxoSmithKline, Pfizer, AstraZeneca, Merck and AHP, invested most of their prescription drugs advertising in DTC promotions.[102] The phenomenal success of DTC advertising in the US spurs the demand of pharmaceutical MNCs that such advertising should also be legalized in Europe. For this purpose, research-based pharmaceutical companies, as well as their related associations, labour to promote the idea that DTC advertising is beneficial to consumers.[103] For instance, in 1999 the Association of the British Pharmaceutical Industry (ABPI) established a task force known as the Informed Patient Initiative aimed at presenting pharmaceutical MNCs as responsible and reliable information agents.[104]

Finally, the ability to create product differentiation through trademarks also implies that pharmaceutical MNCs have an overwhelming advantage in the market of OTCs. Since OTCs can be purchased directly by consumers, pharmaceutical companies can secure brand loyalty through aggressive advertising campaigns. Superior financial resources allow pharmaceutical MNCs to invest more in promotional campaigns and, as a result, to secure the market position of their products.[105] This conclusion is emphasized by the European Commission:

> Once again, therefore, price is less important than other considerations. Moreover, in this field as elsewhere, the large company is better placed than the small one. Whereas

with research-based drugs, it is the cost of innovation that is the barrier to entry or survival, here it is the cost of marketing.[106]

Pharmaceutical MNCs have also been known to seek regulatory approval for the re-classification of prescription drugs to OTCs as their patent expiry date approaches.[107] Such a strategy enables pharmaceutical MNCs to use the period of market exclusivity granted by the patent term of protection in order to create brand loyalty for their products. Thus, pharmaceutical MNCs may engage in 'preemptive advertising' in order to beat generic-based competitors in the race for brand loyalty in OTCs.

Pharmaceutical MNCs consider trademarks as important intangible assets. Varying methods of brand advertising can secure the loyalty of both doctors and patients. In the case of doctors, extensive brand promotion breaks the linkage between drug prescription and calculations of price and quality. Therefore, trademarks are used as a complementary tool for extending the market position of original out-of-patent prescription drugs vis-à-vis generic alternatives. They allow pharmaceutical MNCs to charge a high premium on their products, though to a much lesser extent than that charged during the patent term, despite the existence of cheaper generic and quality assured alternatives. In the case of the general public, trademarks allow pharmaceutical MNCs to use their superior financial capabilities to invest in aggressive advertising campaigns that will secure their domination in the market for OTCs. In the US, pharmaceutical MNCs also invest heavily in DTC advertising of prescription drugs, creating an additional route of brand loyalty for such products.

4.5 CONCLUSION

The main purpose of this chapter is to emphasize the crucial importance of IPRs to the advanced pharmaceutical industry in Europe.

Initially the chapter provided an analysis of the world's pharmaceutical industry, identifying two main characteristics. First, the industry is dominated by an increasingly small number of research-based MNCs. Empirical data suggests that about 30 to 50 pharmaceutical MNCs account for approximately two-thirds of world output in pharmaceuticals. The ongoing trend, particularly since the 1980s, of mergers and acquisitions and strategic alliances, makes the industry increasingly oligopolistic. Moreover, not only are research-based MNCs the only ones capable of introducing new drugs to the market, they also have a particular interest in the segment of generic-based products. Rising competition from generic-based companies drives pharmaceutical MNCs to employ various strategies aimed at dominating the market for generics. These may include

the creation of new generic units, entering into alliances with generic-based companies, or taking over existing generic operations.

Second, the world-wide distribution of pharmaceutical capabilities is deeply biased towards developed countries. The bulk of pharmaceutical activities takes place in the three industrialized blocs: US, Europe (particularly the UK, Germany, France, Switzerland, Italy, Belgium, Sweden and Denmark) and Japan. Over the past four decades more than 90 per cent of NCEs originated from these countries. The three industrialized blocs also account for more than 90 per cent of R&D expenditure and for more than two-thirds of world production in pharmaceuticals. Developed countries are also the biggest exporters (approximately 80 per cent) and net traders of pharmaceuticals. Also, consumption of pharmaceutical products in developed countries is far greater than in less developed regions.

The chapter then focuses on the advanced pharmaceutical industry in Europe. Bearing in mind that the industry in Europe is far from homogeneous, the chapter mapped its main sources of strength, as well as its weaknesses. Particular emphasis was placed on the advanced pharmaceutical industry in the leading European countries, notably the UK, Germany, France and Switzerland. As a bloc, the European pharmaceutical industry is the largest producer of pharmaceuticals, accounting for more than 30 per cent of world production. It had impressive production growth rates of more than 40 per cent during the second half of the 1990s. Germany, France and the UK are the biggest producers of pharmaceuticals. The leading European countries are also ranked among the top exporters and traders of pharmaceuticals. Intra-European trade in pharmaceuticals during the 1980s and 1990s accounted for more than two-thirds of overall total European trade, most of which took place in the leading countries.

The advanced pharmaceutical industry in Europe, together with its US counterpart, is a leader of innovation in the field of pharmaceuticals. European-based companies discovered more than half of new chemical entities (NCEs) between 1950 and 2000, and developed approximately 40 per cent of the leading pharmaceutical drugs between 1975 and 1995. It is also the biggest investor in R&D projects after the United States. One should note, however, that compared with the US, the relative innovative force of European-based companies has declined since the 1990s. With the exception of Germany and the UK, European-based companies allocate fewer resources to R&D projects, both in absolute and in relative terms (ratio of sales).

The link between IPRs and research-based pharmaceutical MNCs was explored in the third and final section of the chapter. Two major elements were emphasized: (1) the importance of patents and trade secrets (particularly data submitted to regulatory authorities) to pharmaceutical MNCs during the pre-marketing and marketing stages of medicinal drugs; (2) the importance

of trademarks to pharmaceutical MNCs as a complementary tool for patent monopolies in out-of-patent products.

Patents are the dominant forms of IPRs to pharmaceutical MNCs. Their importance is emphasized by two major factors. First, patent protection is one of the most important profit-making tools during the marketing stage of pharmaceutical drugs. Successful in-patent drugs, such as Viagra and Prozac, enable pharmaceutical MNCs to reap exceptional profits, covering massive R&D costs and fuelling further innovative projects. Successful in-patent products (referred to as 'blockbusters') are the biggest commercial assets of pharmaceutical MNCs, and account for the bulk of these companies' sales. Once a patent on a given product has expired the mother company is forced to compete with much cheaper generic substitutes. As a result, the company may experience a serious drop in sales (for instance, the 1997 patent expiration of Zantac, GlaxoSmithKline's 'flagship' drug). Recent evidence suggests that a combination of expected patent expiries and a lack of new promising pipeline products can adversely affect companies' equity prices. Patent protection and patent expiries also play a role in intra-industry merger considerations.

Second, patents function as an 'insurance tool' during the pre-marketing stage of 'pipeline' drugs (drugs that are still in various development stages). The development of innovative pharmaceutical products is a time-consuming, expensive and risky business. Estimates suggest that it takes more than ten years to introduce a new drug to the market, for which R&D costs are between $300 to $800 million per drug. Moreover, only two out of 10 000 NCEs screened and synthesized at the initial stage of given R&D projects (pre-clinical phase) would survive the rigorous clinical trials (comprising the four phases of the clinical stage) to become marketable drugs. Even then, it is not certain that the new drug will be commercially viable. That, combined with fierce competition surrounding the introduction of new drugs, drive pharmaceutical MNCs to seek patent protection, as a means of protecting their massive R&D investment, as soon as they are able to isolate a new leading compound.

The granting of patents to potential 'would-be' products ten years before their actual marketing shortens the effective market exclusivity to much less than the nominal 20 years. As a result, research-based pharmaceutical companies seek to expand their market exclusivity via other means of IP protection. One of these ways is to secure IP protection on data submitted to regulatory authorities for the purpose of marketing approval. Data exclusivity, defined as a trade secret, forces generic-based companies to generate their own information when launching substitutes to out-of-patent drugs. The resources and time needed for this information allow research-based companies to extend their market monopoly, hence to continue to charge premium prices for their products.

Trademarks are also considered an extremely effective tool by pharmaceutical MNCs (which are considered the most active users of brand-proliferation

techniques based on trademarks). Most notably, trademarks allow pharmaceutical MNCs to prevent, or at least restrain, their sales from declining rapidly once their leading products are facing patent expiries.

With respect to prescription drugs (medicines authorized for use only by doctors' prescription) pharmaceutical MNCs invest heavily in activities aimed at securing the brand loyalty of doctors. In parallel to the exclusive period of patent protection, doctors are subject to massive, and sometimes notorious, promotional activities by pharmaceutical MNCs. Empirical evidence suggests that brand loyalty, the result of promotional activities to physicians, enables pharmaceutical MNCs to continue to charge higher prices for their products even when post-patent generic substitutes are available on the market. Since the 1980s, pharmaceutical MNCs in the US approach consumers directly, via advertising, providing them with information on their branded prescription drugs. Their aim is to make consumers more aware of available drugs and to ensure that patients demand specific branded products from their physicians, hence creating an additional layer of brand loyalty. Expenditure on direct to consumer (DTC) advertising in prescription drugs has soared to billions of dollars in the 1990s. Currently there are growing pressures to legalize DTC in the EU.

As for over-the-counter drugs (OTCs), advertising is a key tool for achieving strong market share primarily because it exposes consumers to these products. The superior financial base of pharmaceutical MNCs enables them to invest more resources on OTC brand advertising, hence capturing greater market share for a given product. As part of their efforts to dominate the market for OTCs, pharmaceutical MNCs may attempt to re-classify prescription drugs that face patent expiries as OTCs. In this case the patenting company adopts a strategy of 'preemptive advertising', achieving brand loyalty for OTCs during the remaining period of patent exclusivity.

As we have seen, the advanced pharmaceutical industry in Europe is a key player in the pharmaceutical industry as a whole. The importance of IPRs to its economic well-being is phenomenal. The next chapter isolates the major IPR interests of the advanced pharmaceutical industry in Europe and maps the organizational structure through which it strives to secure these interests.

NOTES

1. The original discovery of penicillin was made by Fleming in 1929. For an overview of pharmaceutical development see: Davies (1967:Chapter 1); *The Economist* (1998: 3); Scrip (2000a: 37–40)
2. Ballance et al. (1992: 22–23, 29). Production estimates for the year 2000 refer to developed countries and are based on: VFA (2002: 9-11); According to the VFA, total pharmaceutical output in the US, the EU and Japan was €305 billion in 2000

3. For 1972 data see: Reekie and Weber (1979: 20); for 2002 data see: Scrip Magazine (February 2003a: 34–36)
4. Calculation based on data from: EFPIA (1999a: 14), and EFPIA (2003: 4) ; see Table 4.1
5. *The Economist* (1998: 3–4); see also: Cookson (1998: pp. 4–5)
6. See Table 4.2
7. See Table 4.3
8. BusinessWeek (2003: 45–55). Leading pharmaceutical MNCs are: Pfizer, Johnson & Johnson, Merck, GlaxoSmithKline and Novartis. Market value is defined as 'share price on May 30, 2003 multiplied by latest available number of shares outstanding, translated into US dollars at May month-end exchange rates'
9. Financial Times Survey (2000: 14). The five companies were: Glaxo-Wellcome Novartis, AstraZeneca, Roche and SmithKline Beecham
10. Ballance et al. (1992: 4); Commission of the European Communities (1985: Chapter 5)
11. Commission of the European Communities, Economic Advisory Group (1985: 50–59); UNCTAD (1997: 168)
12. Mossialos et al. (1994: 40–45)
13. Ibid., p. 41
14. For M&As see: PhRMA (1999: Chapter 5); Pilling (1998: 1)
15. Scrip Magazine (2000d: 47–9)
16. Scrip Magazine (1994: 36–7)
17. PhRMA (1999: 60)
18. Mossialos et al. (1994: 50, Tables 4.7, 4.8)
19. Ballance et al. (1992: 5)
20. Ibid.
21. Scrip Magazine (1993: 40–41); Aizenberg (2000)
22. Commission of the European Communities, Economic Advisory Group (1985: 55–9)
23. Peny (2003: 13–17)
24. Faigen (April 1993: 13–14)
25. Ibid.
26. Ibid.; also see: Macarthur (1994: pp. 43–5)
27. Macarthur (1994: 43)
28. Ibid.
29. Mossialos et al. (1994: 41–2)
30. OECD (1985: 12)
31. Ballance et al. (1992: 10); EFPIA (2003:16)
32. Ibid. Table 1.1, pp. 9–10
33. Mossialos et al. (1994: 53-60 and Table 5.1 in particular); Kermani (2002: 56)
34. Ballance et al. (1992: Table 2.1). For the dominance of developed countries see also: UNCTAD (1975a: Table 1)
35. Ballance et al. (1992: 11)
36. Ibid., pp. 63–7
37. Ibid.
38. Ibid., Table 3.3
39. Ibid., Table 2.3
40. Ibid., pp. 29-32
41. PhRMA (2003: 81, Table 9); EFPIA (2003: 8)
42. Ballance et al. (1992: Table 2.3)
43. Mossialos et al. (1994: 21–22 and Table 3.3); EFPIA (1998b: 17); Commission of the European Communities, Economic Advisory Group (1985: 22–25)
44. Mossialos et al. (1994: 21–2)
45. VFA (2002: 10)
46. Calculations based on: EFPIA (2003: 6)
47. Calculations based on: OECD (1985: Tables A3 and A4) and VFA (2002: 16)
48. Mossialos et al. (1994: 25–7); Ballance et al. (1992: pp. 61–8); US International Trade Commission (1999: 18–20)
49. VFA (2002: 10)

50. Mossialos et al. (1994: 26); Commission of the European Communities (1985: 25)
51. See Table 4.4
52. PhRMA (1999: 75, Figure 7–3)
53. EFPIA (1999a: 3)
54. EFPIA (1998b: 20)
55. Commission of the European Communities, Economic Advisory Group (1985: 50–57)
56. Calculation based on: EFPIA (2003: 16)
57. Ibid.
58. Mossialos et al. (1994: 53–58 and Table 5.1 in particular)
59. Ibid.
60. See Table 4.5
61. Pfizer (2003, 31)
62. GlaxoSmithKline (2003 2, 67); average exchange rate is set at $1.5=£1
63. Merck (2003: 5)
64. Pfizer (1999; 2003); Scrip Magazine (1999: 54–6)
65. PhRMA (1999: 17, Figure 2–3)
66. SmithKline Beecham (1998: 5)
67. Scrip Magazine (2000c: 45)
68. Nogués (1990b: 26–8)
69. Ibid., pp. 26–8
70. Glaxo Wellcome (1998a: 14)
71. Ibid.
72. AstraZeneca (2003: 14)
73. Pilling (1999a: 21)
74. Corrigan (1999: 24)
75. Ibid.; for the case of AstraZeneca see: Urry (2000: 21)
76. Ibid.
77. Corrigan (1999: 24)
78. Baynon (2000: 32)
79. ESCWA (1998: 3–4); Ballance et al. (1992: 157–8); Grabowski and Vernon (1990); Glaxo Wellcome (1998b); PhRMA (1999: Chapter 2)
80. For an overview of different pharmaceutical R&D phases see: Gambardella (1995: Chapter 2); Ballance et al. (1992: Chapter 4); *The Economist* (1998: 4); ABPI (1996: 8–10); IFPMA (1998: Chapter 3); PhRMA (1999: Chapter 3)
81. *The Economist* (1998: 4); PhRMA (1999: Figure 3–1)
82. EFPIA (1998b: 10); *the Economist*, (1998: 4)
83. EFPIA (1998b: 21); PhRMA (1999: 84); PhRMA (2003: 1–7)
84. PhRMA (1998: Chapter 2, Figure 2–8); Grabowski and Vernon (1994)
85. Mansfield (1986: 173–81)
86. Interview with the Director of European Patent Operations, Lilly, 28 October 1998
87. Scrip Magazine (2000a: 33)
88. IFPMA (1998: 17); ABPI (1996: 9); Commission of the European Commission, Economic Advisory Group (1985: 67)
89. Nogués (1990b: 22); For shrinking exclusivity periods of 'breakthrough' drugs see: PhRMA (1999: 59–60)
90. Data exclusivity in the US is granted for a period of up to 5 years. Data exclusivity in the EU is granted for a period of up to 10 years, see: US Federal Food, Drug, and Cosmetic Act (US FDA: 1997), Chapter 5, Section 505 (355) (D); European Parliament (2001a)
91. See Chapter 2, section 2.3.2
92. UNCTAD (1981: 3); UNCTAD (1979: 26)
93. UNCTAD (1981: 3); Silverman and Lee (1974: 55); Delvin and Helmsley (June: 183)
94. IMS Health (1999a)
95. UNCTAD (1975b: 37–8); Mansfield (1997) Branthwaite and Downing (1995: 32–5); Zuger (1999)
96. IMS Health (1999a)
97. Frankel (1993: 26–9).

98. UNCTAD (1981: 3–6); Nogués (1990: 27–8); Commission of the European Communities, Economic Advisory Group (1985: 72–3); Bond and Lean (1977); Ballance et al. (1992: 60–161)
99. For empirical evidence see: UNCTAD (1981: 2–6); UNCTAD (1979: 26); UNCTAD (1975b: 27)
100. Holmer (1997: 380–82); Hollon (1999: 382–4); Freudenheim (1998)
101. IMS Health (1999a; 1999b; 1999c; 2003); Hollon (1999, p. 383)
102. IMS Health (1999a; 1999c)
103. Law (1999: 6–7); Scrip Magazine (1999: 6)
104. Law (1999: 6)
105. Ballance et al. (1992: 159–63)
106. Commission of the European Communities, Economic Advisory Group (1985: 74)
107. Nogués (1990b: 31); see also: Michaels (2000); in the UK, Glaxo-Wellcome (today GlaxoSmithKline) reformulated one of its most successful products, Zovirax, in a manner that allowed it to be purchased as an OTC starting from September 1993. The new product appeared close enough to its patent expiry date (1997)

5. Core IP interests and the organizational structure of the advanced pharmaceutical industry in Europe

5.1 INTRODUCTION

The fact that IPRs provide a powerful incentive for collective action in the advanced pharmaceutical industry in Europe was established in the previous chapter.

This chapter identifies the specific IP objectives of the advanced pharmaceutical industry in Europe, and, more importantly, describes the organizational structure through which the industry pursues its IP interests.[1] It demonstrates the high levels of uniformity and cooperation among pharmaceutical MNCs regarding IPRs. First, the chapter identifies the primary IP interests of the advanced pharmaceutical industry in Europe. The focus here is on interests per se and not on the strategies and activities taken by the industry in order to secure these interests (elaborated in Chapter 8). Second, it maps the intra-industry (vertical) IP organizational structure of the advanced pharmaceutical industry in Europe, at the national, regional and international levels. Third, it identifies the inter-industry (horizontal) IP build-up, through which European-based pharmaceutical MNCs coordinate their position with dominant 'players' from other industries, such as chemical and software companies.

Particular emphasis is placed on the ability of pharmaceutical MNCs to preserve their position and dominance throughout the different levels of intra-industry and inter-industry IP organizational structure. It should be noted, however, that although the author aims to provide detailed and precise information regarding the specific structures dealing with IPRs (of industry and government) during the period 1995 to 2000, some of these structures might have changed their names or their functions.

5.2 PRIMARY IP INTERESTS: SECURING AND MAINTAINING A STRONG INTERNATIONAL SYSTEM OF IPRS

The advanced pharmaceutical industry in Europe is interested in a strong international IP trading system, such as that created by TRIPs, under which

relevant IP components (patents, trade secrets and trademarks) are highly protected. Industry arguments in favour of such a system tend to link the future of pharmaceutical innovation, as well as its survival, with the existence of IPRs. A few examples may be given. EFPIA consistently argues that 'development of the pharmaceutical industry crucially relies on intellectual property rights', adding that 'any small change, positive or negative, in the IPR rules could dramatically…make our pharmaceutical companies more or less advantageous in developing new, risky and costly technologies'.[2] GlaxoWellcome's Chairman and CEO, Sir Richard Sykes, expressed a similar, though more melodramatic, view on the matter: 'The research-based pharmaceutical industry tends to be firm in its defence of intellectual property rights because they are the lifeblood of our industry – we literally could not exist without them.'[3] Merck's chairman, Raymond V. Gilmartin, argues that a strong system of IPRs is one of the most essential conditions determining the ability of US and European pharmaceutical industries to continue to introduce new cutting-edge medicines.[4] When referring to biotechnological inventions the German association of pharmaceutical research-based companies, the VFA, argued that the 'future of the research based pharmaceutical industry in Europe hinges on the establishment of legal certainty (IPRs) in this technology of the future'.[5]

Focusing on specific IP components (patents, trade secrets and trademarks), the demand of the advanced pharmaceutical industry for a strong international IP system becomes even clearer. Together, these forms of IPRs create a strong monopolistic trading environment in which pharmaceutical MNCs are able both to protect their knowledge assets and to exploit them commercially. The IP interests relevant to the advanced pharmaceutical industry in Europe are discussed below.

5.2.1 Strong Patent Protection

The advanced pharmaceutical industry repeatedly expresses its need for strong patent protection, both in terms of scope and duration. Interestingly, the rhetoric used by the industry has two distinctive features.

First, it is quite melodramatic with respect to the ability of patents to stimulate future inventive activities. A typical example is a position paper by IFPMA noting that 'without patent protection, the world would have been deprived of the innovative medicines which have saved countless lives…because the industry as we know it today would not exist'.[6]

Second, the language used by the advanced pharmaceutical industry is quite vague when dealing with patent monopolies. The industry either disregards the monopolistic effect of patents or, alternatively, argues that patents actually stimulate competition rather than stifle it. As EFPIA put it: 'Pharmaceutical patents do not provide a monopoly for treating a disease. They only confer an

exclusive right, for a prescribed time – i.e. 20 years from the date of filling the patent application – to prevent others from manufacturing and selling the patented medicine without the permission of the patent holder.'[7] Given the negative connotation of the term 'monopoly' in general, and under a neo-liberal orientated institution such as the WTO in particular, this may not come as a surprise.

5.2.2 Protection of Trade Secrets via Data Exclusivity

The advanced pharmaceutical industry in Europe is interested in internationalizing the use of IPRs as a means of protecting data submitted to regulatory authorities for the purpose of obtaining product marketing approval (data exclusivity). As argued by the IFMPA: 'Data submitted to meet government registration requirements for a pharmaceutical product should be treated as confidential and not be made available directly, indirectly, or by reference for the benefit of any other commercially interested party.'[8]

As discussed in Chapter 4, data exclusivity would allow pharmaceutical MNCs to preserve their effective market position (in addition to that provided by patents) vis-à-vis generic competitors. Similar to its patent rhetoric, the advanced pharmaceutical industry uses a defensive tone arguing that to allow generic companies to rely on such data is economically harmful, legally unjust, and may even put patients' health in danger.[9]

5.2.3 Protection of Trademarks as a way of Securing Brand Loyalty

Pharmaceutical MNCs also aim to maintain a strong international trademark system, one that would allow them to secure the brand loyalty of doctors and consumers. In other words, the advanced pharmaceutical industry in Europe opposes policies aiming to restrict the market power which derives from brand-based strategies, such as the Single Community Trademark policy in Europe (Directive 2309/93 EEC, July 1993).

Again, the industry justifies its need for a strong trademark system by linking it to public safety and, at the same time, by blurring its monopolistic implications. EFPIA argues that a strong trademark system, in addition to protecting brand owners, reduces the risk to consumers from counterfeit or non quality-assured products that may frequently appear under more 'lax' systems of product differentiation.[10] EFPIA adds that 'trade mark rights for medicines are vital for protecting patients and should be strengthened rather than threatened'.[11]

Thus, the advanced pharmaceutical industry in Europe is in favour of continuing to secure a strong system of IPRs. Specifically, such a system should include the following: (1) long term and wide scope of patent protection; (2) exclusivity period for trade-secrets, particularly for information submitted to regulatory

authorities for the purpose of product market authorization (data exclusivity); (3) high level of brand proliferation via extensive trademark rights.

5.3 THE INTRA-INDUSTRY IP ORGANIZATIONAL STRUCTURE OF THE ADVANCED PHARMACEUTICAL INDUSTRY IN EUROPE

5.3.1 The Company Level

One of the most striking elements characterizing the IP organizational structure of the advanced pharmaceutical industry in Europe is the high level of dominance of research-based companies. Pharmaceutical MNCs have both influence and voice that are preserved throughout the different levels of industrial organization.

Placing pharmaceutical MNCs within a broader theoretical context can provide a more informed perspective of the overall contribution of MNCs to collective action/rent-seeking activities in the field of IPE. Such a context is provided by Sally's work focusing on MNCs as dominant politico-economic players.[12] Stressing their importance to the structure of international production and to the institutional arrangements of nation states, as well as to subnational and supernational regions, Sally argues that MNCs (which he calls multinational enterprises – MNEs) are an essential component of IPE scholarship.[13]

Sally notes that the traditional preference of IPE scholarship to more aggregate units of analysis, notably trade unions and industry associations, can lead to an incomplete and, in some cases, incoherent theoretical picture. What he offers is a more interdisciplinary approach, based on institutional political economy and international business, which considers the MNC as a player in its own right in the politico-economic domain.[14] Though Sally's research ultimately deals with domestic institutional political economy, its overall tone is also suitable for corporate collective action and rent-seeking activities at the international level.[15] As he puts it:

> MNE [MNC] political action at regional [sub and supranational] level is a promising avenue of research. Certainly much more work needs to be undertaken to examine the growing activities of MNEs at the supranational level in the integrating EC, involving interaction with the Commission, other supranational authorities, industry associations and national governments in emergent policy networks and communities.[16]

Translating the above to a more specific path, MNCs must be placed at the core of the interaction between the international IP system and the advanced European pharmaceutical industry. In many senses, pharmaceutical MNCs are the building blocks of the entire European pharmaceutical IP array. Practically

speaking, the ability of pharmaceutical MNCs to form a basis upon which IP collective action takes place, derives from a remarkable similarity in their internal IP structure and functions. In terms of bureaucratic and structural functions, each company has its own corporate IP division responsible for the management of day-to-day IP-related activities. Corporate IP activities have two major goals: (1) securing IPRs at the contract level, including the identification of patent opportunities, patent applications, trademarks registration, protection of test data and so on; (2) enforcing IPRs and exploiting their commercial benefits. Activities at this level include licensing agreements, material transfer agreements (MTAs), royalties, franchising, litigation, and so on.

Moreover, IP personnel (particularly in senior positions) have a common professional and academic background. Many are patent attorneys with academic and/or professional experience in life sciences (Biology or Chemistry).[17] A pronounced similarity in the corporate IPR array (structures, functions, practices and culture) of pharmaceutical MNCs leads to a strong sense of 'epistemic community'. Haas defines epistemic community as a professional knowledge-based group that believes in the same cause and effect relationship and shares a common understanding of a problem and its solution.[18] That is also the case in IPRs. Having in common the same professional language, set of beliefs and day-to-day practices, corporate IP directors are able to form a strong cooperative basis. That, in turn, enables them to maintain a strong level of solidarity and a considerable amount of influence when participating in different national, regional and international IP forums.

5.3.2 The National Level

National pharmaceutical associations are one of the most prominent channels through which pharmaceutical MNCs engage in IP collective action and rent-seeking activities. Representing the interests of research-based companies, including IPRs, national associations such as ABPI (UK), VFA (Germany) and SNIP (France), enable pharmaceutical MNCs to speak in one voice and to act in a unitary manner. Two examples may be given: ABPI and VFA.

The Association of the British Pharmaceutical Industry (ABPI)

ABPI is the main body bringing together prescription-based (branded and generic) pharmaceutical companies in the UK (more than 100 companies in 2000). Aiming to influence and shape policies affecting the pharmaceutical industry, ABPI operates via a network of vertical and horizontal relations, both at the national and international levels. The ABPI works closely with the Department of Health (DoH) and the Department of Trade and Industry (DTI) on

a wide range of pharmaceutical issues concerning the industry, the government and the National Health Service.[19]

Between 1978 and 2000 the ABPI was involved in issues such as the Pharmaceutical Price Regulation Scheme (PPRS), the DoH 1999 initiative concerning the establishment of a National Institute for Clinical Excellence (NICE), strategies aimed at improving industry competitiveness and so on.[20] In April 2000 the ABPI, together with CEOs of pharmaceutical MNCs, became a member of the Pharmaceutical Industry Competitiveness Task Force, established by the DoH. Using four primary work groups, the task force focused on the industry's relationship with the British market, IPRs, bio-pharmaceuticals and R&D and medicines licensing in Europe.[21] ABPI's industry-related activities also involve maintaining close and regular contacts with consumer groups, healthcare professionals, research councils, patients' advocacy groups and MPs.[22] It is also a member of the Confederation of British Industry (CBI), hence interacting with other industry associations on a wide range of issues including IPRs.

ABPI incorporates the area of IPRs, in both its strategic and operational levels. Strategy no. 3 of ABPI of 1998 – ensuring a fair commercial return for the pharmaceutical industry operating in the UK – explicitly refers to IPRs: 'GATT TRIPs Agreement has the capacity to protect Intellectual Property Rights internationally so as to provide the industry with a more confident base for its investment.'[23]

At the operational level, ABPI has ten permanent committees dealing with a range of aspects relevant to the industry, one of which is the Intellectual Property Committee (IPC).[24] Generally speaking, members of the ABPI-IPC are directors of corporate IP divisions of pharmaceutical companies. The IPC is chaired by one of its members. For example, between 1998 and 2000 the IPC was chaired by the Director of Corporate Intellectual Property of Glaxo Wellcome (today GlaxoSmithKline).[25] Official IPC meetings take place five times a year, at which various IP issues (legislation, industry position, present and future IP activities) are discussed.[26]

The ABPI interacts primarily with the DTI and the Patents Office – the main national bodies responsible for the formulation of the UK's global IP position.[27] Mechanisms through which the advanced pharmaceutical industry in the UK fed input to national agencies between 1997 and 2000 include:

1. Official meetings which took place twice a year between the ABPI, British Pharma Group, officers of the DTI's Trade Policy Section, the Patent Office (Intellectual Property Policy Directorate) and the DoH.
2. Periodical meetings between officers of the DTI, Patent Office, DoH and company representatives.

3. Correspondence, position papers, and personal meetings between ABPI staff and relevant government officials.

In 1998 ABPI targeted a core group of about 250 MPs by sending them explanatory materials, conducted personal meetings and invited MPs to attend professional conferences.[28] One corporate IP director argued that the ABPI, as well as individual companies, dedicate special attention to 'problematic' MPs who do not see eye-to-eye with the industry.[29]

Influenced mostly by research-based companies, ABPI's international IP objectives are typical of the interests of the advanced pharmaceutical industry in Europe. For example, ABPI 1998 IP objectives focused on three issues:[30]

1. Fighting attempts to shorten the effective life of patent protection. In particular, ABPI opposed the principle of international exhaustion of IPRs. According to this principle, once an IP owner has sold his product in one country he has exhausted his right to prevent the resale of that product to other countries. In other words, international exhaustion is equal to parallel trade in IP-related products.[31] ABPI also sought to prevent generic companies from conducting clinical tests on patented pharmaceutical products (so called Bolar exemptions).[32]
2. Setting a 10-year period of data exclusivity to the international IP system (the TRIPs agreement).
3. Preventing the use of generic names as a substitute for trademarks.[33] As discussed later, ABPI objectives reflect, and derive from, the regional IP position of the advanced pharmaceutical industry in Europe.

Verband Forschender Arzneimittelhersteller (VFA)

Established in 1994 the VFA represents 37 research-based pharmaceutical MNCs in Germany (1999).[34] Among its members are companies such as Merck, Bayer, GlaxoSmithKline and so on. Historically, the introduction of the German cost containment legislation (Gesundheitsstrukturgesetz – GSG) in January 1993 was one of the primary reasons for establishing the VFA by research-based companies. At the time, the seven major German-based pharmaceutical companies were dissatisfied with the performance of the Bundesverband der Pharmazeutischen Industrie (BPI), the veteran German pharmaceutical association.[35] The research-based companies felt that a conflict of interests existed between themselves and other BPI members, particularly medium and small-sized companies.

Similarly to the ABPI, the VFA operates through various departments and committees which deal with a wide range of issues related to the industry. At present, (1998–2000) the Department of Legal Affairs (specifically, the Division of Pharmaceutical Law, Patents and Trademarks) is the main unit

responsible for VFA's IP activities.[36] The department is guided by the decisions of two sub-committees for IPRs, one on patents and one on trademarks, both of which are hierarchically located under the Committee for Legal Affairs (Rights).[37] As with the ABPI's Intellectual Property Committee, members of the VFA's patent and trademark committees are usually directors of corporate IP divisions in pharmaceutical MNCs. For instance, during the period 1999 to 2000, the corporate directors of patents and trademarks divisions in Boehringer Ingellheim and Bayer AG chaired the sub-committees for patents and trademarks respectively.[38] Members of the patent and trademarks committees meet at least three times a year.[39]

The VFA's IP objectives for the years 1999–2000 were as follows: (1) implementation of EU Directive 98/44 on patents for biotechnological inventions; (2) fighting the international exhaustion of patent rights; (3) strengthening data exclusivity, that is placing a 10-year period of exclusivity; (4) protecting IPRs in the context of EU enlargement, and (5) Safeguarding trademarks (branded products) vis-à-vis generic names.[40]

In carrying out its informational and lobbying activities, VFA maintains close contact with the Federal Ministries of Justice, Health, Economics and Technology, Economic Cooperation and Development and with the Ministry of Education and Research. With respect to IP-related matters, the Ministry of Justice is the primary contact (specifically, the Divisions of Commercial and Economic Law, International Law and Legal Development and the German Patent and Trademark Office). The Ministry of Justice coordinates and facilitates Germany's position on IPRs and TRIPs, as well as representing Germany on the TRIPs Council. On issues concerning WTO the VFA also maintains contact with the Directorate-General of External Economic Policy and European Integration Policy (DG V) of the Ministry of Economics and Technology.

VFA's activities include correspondence and regular meetings with officials from the above ministries. However, industry and government meetings do not take place on a formal basis. Rather they occur when there is a need to discuss some specific issue, such as the industry position on gene patenting (TRIPs Article 27.3.b).[41] One government official noted that the research-based pharmaceutical industry is one of the best informed industries on patent issues. In some cases, he noted, the industry provided government officials with information of which they are not aware or to which they do not have access.[42] Finally, the VFA and its committee members also maintain close contacts with German and European MPs and MEPs.

Thus, while representing the interests of pharmaceutical MNCs, national pharmaceutical associations are guided by the same international IP inputs and formulate almost identical IP objectives. As a result, their IP structures, functions and operations are similar, regardless of the national environment in which they operate.

5.3.3 The Regional Level – the European Federation of Pharmaceutical Industries and Associations (EFPIA)

The regional level is the hub through which IP collective action by the advanced pharmaceutical industry in Europe takes place. Specifically, EFPIA is the centre and focal point of pharmaceutical collective action/rent-seeking activities in Europe. Established in 1978, EFPIA is one of the most prominent representatives of the European-based advanced pharmaceutical industry. Its IP input flows both horizontally, to European-based institutions, and vertically, to the national and international levels.

Operating both as a lobbying and informational body, EFPIA covers a wide spectrum of activities.[43] As a lobbying group, EFPIA targets three major audiences: (1) EU policy-making institutions such as the European Commission, Council of the European Union, European Parliament and the Economic and Social Committee; (2) EU regulatory authorities, such as the European Medicine Evaluation Agency (EMEA), and (3) health-care professionals and consumer associations.[44]

As an information provider, EFPIA organizes conferences, info-days, visits to pharmaceutical companies, exhibitions and so on. EFPIA also produces and distributes economic surveys and position papers on a wide range of issues, including IPRs. All these activities, as EFPIA outlines, aim to keep 'its target audiences informed of the contribution of the pharmaceutical industry to society, its needs and recent developments'.[45]

As of 1998 and to date EFPIA's members are both national associations and individual companies.[46] This structure seems to fit the model of inter-group relations in which European-based organizations comprise both federations and direct company membership.[47] The decision to allow direct company membership reflected the desire of research-based companies to become directly involved in policy-making at the European level.[48] The refined structure enables executives of pharmaceutical MNCs to maintain their voice and dominance at the European level while avoiding any bureaucratic 'complications' deriving from indirect representation by national associations. In 1998 EFPIA had 19 members from national associations, including non-EU members such as Switzerland, and about 40 company members.[49] EFPIA's executive board comprises representatives of 11 member associations and 11 member companies (1998).[50] The board executes the tasks and decisions determined by the General Assembly, which meets annually.[51]

To carry out its policy objectives, EFPIA has three major policy committees: (1) Economic and Social Policy Committee – ESPC; (2) Scientific, Technical and Regulatory Policy Committee – STRPC; (3) Intellectual Property Policy Committee – IPPC.[52] Each committee is assisted by an appropriate department in EFPIA. The Department of Legal Affairs works closely with the IPPC on various

IPR-related activities. EFPIA also has ad hoc Priority Action Teams (PATs) dealing with burning issues to the industry.[53] Relevant examples to IPRs are the 1999 PATs responsible for the issues of data exclusivity and to the preparations for the Millennium Round.[54] EFPIA's Committees and PATs are chaired by Directors of research-based companies.[55] When necessary, EFPIA Committees and PATs also designate ad hoc working groups on specific issues concerning their area of responsibilities, such as trademarks and data exclusivity.

EFPIA has a dominant role in formulating and representing the IP objectives of the industry in Europe. Two factors should be emphasized. First, the combination of joint membership between national associations and research-based companies makes EFPIA, and in particular the IPPC, the focal point of IP inputs and outputs for the advanced pharmaceutical industry in Europe. As we shall see in Chapter 8, the international IP objectives of the advanced European pharmaceutical industry during the period 1995–2000 originated mostly from EFPIA. Decisions by the IPPC, relevant PATs and their working groups are carried out both by EFPIA itself, at the regional level, and by associations working at the national level. That IPPC members are also members of IP committees of national associations, is an important factor contributing to the smooth transfer of inputs from regional to national levels and vice versa.[56] In fact, it is plausible that, on matters concerning IPRs, relationships between EFPIA and national associations may be characterized more as top-down rather than bottom-up. When interviewed, corporate IP directors asserted that the interaction between the regional (EFPIA) and national levels (national associations) is guided more by the former than the latter.[57]

EFPIA also has a key role in pharmaceutical IP lobbying, and in particular regional IP lobbying, due to the institutional process through which European IP-related policies are formulated. In 1994, following a request by the European Commission, the European Court of Justice (ECJ) was asked to submit an opinion on the competence of the European Community and its member states to conclude the WTO TRIPs Agreement.[58] The landmark ruling, based mainly on the interpretation of Articles 100a and 228(6) of the EC treaty, established that the European Community, represented by the Commission and its member states were jointly competent to conclude TRIPs.[59] The ECJ also referred to the enforcement of IPRs (TRIPs Part III, Section 4) arguing that 'since measures of this type can be adopted autonomously by the Community institutions on the Basis of Article 113 of the EC treaty, it is for the Community alone to conclude international agreements on such matters'.[60]

Joint regional and national competence on multilateral IPR-related negotiations created a strong need for collaboration between the Commission and member states. The ECJ itself noted that 'the duty to cooperate is all the more imperative in the case of agreements such as those annexed to the WTO Agreement (TRIPs), which are inextricably interlinked, and in view of the cross

retaliation measures established by the Dispute Settlement Understanding'.[61] The primary mechanism through which such collaboration takes place is the 133 Committee, established under Article 133 (previously Article 113) of the EC Treaty dealing with Europe's Common Commercial Policy.[62] Article 133 established that 'the Commission shall conduct these negotiations in consultation with a special committee appointed by the Council to assist the Commission in this task and within the framework of such directives as the Council may issue it'.[63] According to Paragraph 4, Community members shall decide upon agreements concerning trade in goods on the basis of qualified majority voting. On the other hand, agreements concerning trade in IPRs and services require a unanimous vote.[64] However, paragraph 5 also enables the Council to extend the qualified majority voting system to IPRs and to services.[65] Recently, such an initiative was launched at the European Inter-Governmental Summit in Nice (December, 2000).[66]

Members of the 133 Committee (that is representatives from member states and the Commission) meet once a week in Brussels and deal with different trade-related issues, including IPRs.[67] The Advisory Committee established by the Council of the European Union in 1994 (Council regulation No. 2641/94) functions as an additional mechanism for coordinating members' positions on WTO agreements.[68] This committee, which consists of representatives of member states and the Commission, tackles all aspects concerning WTO negotiations (including IPRs).[69] Consultations are not formalized but rather take place at the request of member states or on the initiative of the Commission itself.[70] The latter is responsible for providing information gathered by the Advisory Committee to the 133 Committee.[71]

Finally, the Internal Market Working Party on IPRs, consisting of representatives of the Commission (Directorate General for Internal Market-DG XV) and member states, is one of numerous committees and working parties reporting to the Council of the European Union.[72] The Working Party on IPRs covers trademarks, utility models (technical inventions), design patents and copyrights.[73] Its role is to examine and recommend on intra-European IPR policies, such as the single community trademark, exhaustion of trademarks and parallel imports.[74]

This rather complex mechanism of IP policy-making in the EU has two important implications. First, that the European Commission, and particularly DG Trade, plays an important role in devising the EU's trade-related IPR policies. As discussed in Chapter 8, aside from its legal status in being jointly responsible together with the member states for the EU's international IP trade policy, the Commission also functions as a pivotal information provider and facilitator. De facto, this combination gives the Commission dominance in setting the pace and tone for the EU's international IP policy-making.[75] Second, and even more interesting, because of its complexity the EU's international IP policy-making

is not currently associated with a single and transparent institution. Although the 133 Committee is responsible for setting the agenda for international IP negotiations, it hardly functions as 'The Institution' for IPRs. This in turn implies that lobbying activities aimed at influencing the EU's international IP objectives and activities are not concentrated and directed towards a single institution.

Nevertheless, aware of the prominent role of regional institutions, particularly the Commission, in devising trade-related IPR policies, EFPIA maintains close contacts with two Directorates General: Trade (DG I) and Internal Market (DG XV). Both Directorates General deal with IPRs: DG I via its division for 'New Technologies, Intellectual Property and Public Procurement', and DG XV via its division of 'Free Movement of Information, Intellectual Property, Media, Data Protection and Industrial Property'.[76] Periodic meetings, regular correspondence, position papers, conferences and exhibitions are only part of EFPIA's lobbying agenda.[77]

A few examples may be given in the IPR sphere. During the 1980s and early 1990s EFPIA lobbied for the extension of patent protection on pharmaceutical products. According to Greenwood and Ronit, intensive lobbying by EFPIA forced the issue of patent extension onto the political agenda, despite initial objections from the Commission.[78] The result was the introduction of a Supplementary Protection Certificate (SPC) in 1992, following the decision of the Council in June 1992 (EC Regulation No. 1768/92).[79] When granted an SPC, a pharmaceutical company extends its patent monopoly by an additional period of up to five years, as long as the effective patent life does not exceed 15 years from the date of marketing authorization.[80] In the case of SPCs, Greenwood concludes that 'the transnational interest association (EFPIA) had achieved as a collective federation more for its industry than had once been possible by a single national association'.[81]

In September 1997 EFPIA held an exhibition entitled 'Biotechnology applications in healthcare' at the European Parliament, aiming to get MEPs to support the legal protection (patents) of biotechnological inventions.[82] That was the climax of intense industry lobbying at the national and regional levels, which proved successful in May 1998 when the European Parliament approved Directive 98/44/EC on the legal protection of biotechnological inventions.[83]

Regarding trademarks, in February 1997 EFPIA sponsored a joint workshop with the European Commission on the Single Community Trademark (one trademark for a pharmaceutical product in every member country).[84] At the workshop, seven major companies expressed strong objections to the Single Community Trademark policy and explained the reasons for their objections.[85] Yet thus far the advanced pharmaceutical industry in Europe has had very limited success in reversing this policy, although it did manage to secure the use of a second trademark once the first was cancelled.[86]

Part of EFPIA's lobbying activities also includes contacting high-ranking officials. For instance, in June 2000, during its annual meeting, EFPIA hosted the President of the European Commission, Romano Prodi, as its guest of honour.[87] The link between IPRs and access to medicines in developing countries was one of the issues discussed at that meeting. Expressing the industry's position on that matter, EFPIA's president, Gallardo, argued that 'it is important to understand that reducing IPRs is not a solution to the issue but exacerbates the problem and potentially encourages the dangerous use of counterfeit medicines'.[88]

Finally, European lobbying by EFPIA also proved highly effective in other areas such as price regulations, control over the supply of information to physicians and consumers, and the granting of marketing approval to new drugs.[89]

EFPIA is thus one of the most important and effective IP representatives of the advanced pharmaceutical industry in Europe. It incorporates national associations and pharmaceutical MNCs as members, allowing the latter to maintain a high level of dominance, influence and voice. EFPIA also has a key role in devising the industry's IP objectives and strategies. Moreover, to date (2000) decisions concerning European IP-related policies and objectives (both internal and international) are subject to a complex process in which authority is shared both by the European Community and by its member states. In practice, bodies such as the Commission and the Council of the European Union play a decisive role in the European IP decision-making process. That in turn requires EFPIA to operate directly at the regional level in order to secure a more favourable environment for research-based companies. As previously shown, and as will be discussed later, EFPIA was able to carry out its IP duties in a highly organized, efficient and effective manner, especially during the 1995–2000 period.

5.3.4 The International Level

Research-based pharmaceutical companies, world-wide, recognize the benefits of a united global front and operate at the international level aiming to coordinate their views, positions and operations. It is worth elaborating on two forums of particular importance to the global coordination of pharmaceutical MNCs in the area of IPRs: IFPMA and INTERPAT.

The International Federation of Pharmaceutical Manufacturers Associations (IFPMA)

Founded in 1968, the IFPMA represents the world-wide research-based pharmaceutical industry and manufacturers of prescription medicines in general. Its activities include promoting the exchange of information between members

of IFPMA, developing position papers on various policy issues (including IPRs) and representing its members vis-à-vis major international non-state actors.

To date, the IFPMA enjoys official consultative status with the following agencies: World Intellectual Property Organization (WIPO); World Trade Organization (WTO); United Nations Industrial Development Organization (UNIDO); United Nations Conference of Trade and Development (UNCTAD); United Nations Economic and Social Council (UNESCO) United Nations Children's Fund (UNICEF); World Health Organization (WHO); and the Council of Europe.[90]

National and regional associations are members of IFPMA, which represents research-based pharmaceutical MNCs and other manufacturers of prescription medicines from developed and developing countries. In 2000, IFPMA had 53 national and regional member associations.[91] The IFPMA assembly is responsible for the admission of new members, the creation of IFPMA codes of practice, and for the formulation of its policies.[92] Members of the IFPMA Council are directors of national associations and CEOs of research-based companies.[93]. The US, the UK, Germany, France, Italy and Switzerland are permanent members of the Council.[94]

IFPMA activities are guided by its various advisory committees such as those dealing with patent protection (Intellectual Property Protection Coordination Committee), international economics (Advisory Committee on Trade and Economics) and biotechnological products (Biotechnology Committee).[95] Ad hoc groups are also convened when necessary to undertake specific tasks such as preparations for multilateral trade negotiations (Seattle WTO ministerial meeting, December 1999).[96] IFPMA has four main areas of activity: (1) public/private partnerships; (2) IP protection; (3) research, development and innovation, and (4) information and marketing.[97] Not dissimilar from its sister organizations at the national and regional levels, the IFPMA attaches great importance to the protection of IPRs:

> A viable research-based pharmaceutical industry operating in an open market – with adequate and effective protection of intellectual property in line with other industries and with regulatory policies designed to ensure the rapid introduction of new chemical and biological products – is essential to patients' well-being and to the economic development of all countries around the world.[98]

The IFPMA focuses on three IP elements in particular: the protection of patents, IP protection under the WTO TRIPs Agreement, and the prevention of counterfeiting.[99] The IFPMA has, by virtue of its official NGO advisory status, an important role in transmitting the IP requirements of research-based pharmaceutical MNCs to decision makers and key bureaucrats. It is also a vibrant and effective producer of position papers, reports, booklets and newsletters focusing on the need for strong IP protection. For example, between 1995 and

2000, IFPMA published titles such as 'GATT TRIPs and the Pharmaceutical Industry' (1995), 'The Questions of Patents – The Key to Medical Progress and Industrial Development' (1998) and 'Parallel-Trade: A Recipe for Reducing Patients' Access to Innovative and Good Quality Medicines' (2000).

INTERPAT

Unlike the IFPMA, which operates as an official representative of the industry on a wide range of issues, INTERPAT is a much more specialized forum representing only members of research-based pharmaceutical companies and focusing solely on IPRs.[100] Its main objective is to

> provide an international forum for fostering improvement in the field of international intellectual property law with respect to pharmaceuticals by advocating government actions to improve, strengthen and harmonise intellectual property regimes throughout the world and supporting the mutual exchange of information among its members regarding technical developments and legal practice in said field.[101]

INTERPAT's organizational structure consists of six major units (1998): the General Assembly, Country Groups, the Liaison Group, INTERPAT President, IPR Work Groups and the Treasurer.[102] The General Assembly is in charge of admitting/dismissing member companies, forming working and country groups, electing INTERPAT's president, and so on. [103] INTERPAT's Liaison Group functions as its managing board, coordinating and facilitating its activities.[104] Most important are INTERPAT's working groups, dealing with specific IPR topics relevant to research-based pharmaceutical MNCs.[105] Designated tasks include issues such as biotechnology, the protection of IPRs in different countries and regions (Canada, India, China, Mediterranean), international exhaustion, effective patent life, registration know-how (data exclusivity), trademarks and so on.[106]

Operating as a specialized forum for IPRs, INTERPAT enables pharmaceutical MNCs from different home-based countries to communicate directly with each other and, as a result, to feed inputs to their representatives from the national, regional and international levels. Furthermore, not only does INTERPAT deal with issues under consensus, it also strives to resolve tensions arising from different national laws. A notable example is the difference between the US, Europe and Japan (as well as other countries) regarding priority conflicts in patent grants. The US uses a system known as 'first to invent', tracing priority on the basis of inventive activities, while Europe and Japan use a system known as 'first to file', based on the date of the patent application. Non US-based companies, including pharmaceutical ones, argue that the first to invent system is discriminatory, as it does not rely on activities which took place outside US borders when tracking priority invention dates (Section 104 of the US Patent Statute). [107] Despite the political reality that does not currently allow change

in the US patent statute, INTERPAT did express its support for the European mode of patent application. Following INTERPAT's meeting in October 1991, one of its senior members commented that the US first to invent system is out of line with the first to file system used in the rest of the world, and leads to discriminatory treatment against non-US inventors.[108]

By using forums such as the IFPMA and INTERPAT, pharmaceutical MNCs are able to expand their IP organizational structure internationally. Much broader in scope, the IFPMA uses its special consultative position with international institutions such as the World Bank, WTO and WIPO in order to promote awareness of the IP demands of pharmaceutical MNCs. In addition to its lobbying activities, the IFMPA is one of the most dominant information providers with regard to IPRs. INTERPAT is a much more consolidated forum focusing specifically on IPRs. Given that INTERPAT's membership is restricted only to pharmaceutical MNCs, its role as an international intra-industry forum for IP consultation is pivotal. It allows companies to submit much more coherent input to their representatives at the various levels of lobbying activities and to resolve tensions arising from different legislative environments.

5.4 THE INTER-INDUSTRY (HORIZONTAL) IP ORGANIZATIONAL STRUCTURE OF THE ADVANCED PHARMACEUTICAL INDUSTRY IN EUROPE

The European-based advanced pharmaceutical industry recognizes the crucial importance of inter-industry cooperation on matters concerning IPRs. Being able to present a unified cross-industry position increases the ability of IP-intensive groups, such as the pharmaceutical and chemical industries, to secure desirable results when dealing with multi-dimensional and multilateral IP issues. For this purpose, the advanced pharmaceutical industry in Europe links up with, and interacts with, other industries via different forums and organizations, both at the regional and international levels.

5.4.1 The Regional Level – the European Chemical Industry Council (CEFIC) and the Union of Industrial and Employer's Confederations of Europe (UNICE)

At the regional level, CEFIC and UNICE are particularly important to European-based pharmaceutical MNCs.

CEFIC is the primary representative of the European Chemical Industry. Like EFPIA its members are national associations and leading MNCs, some of which are also key players in the pharmaceutical sector (Novartis, Bayer). CEFIC deals

with IPRs mainly via its High Level Steering Group (HLSG) for Intellectual Property, hierarchically located under the Executive Committee.[109] CEFIC's IPR objectives are very similar to those of the advanced pharmaceutical industry in Europe, as one can learn from CEFIC's 1998 position paper concerning TRIPs: 'The chemical industry is based upon commitment to research and development, improving environmental performance, enhancing the quality of life and sustaining a competitive edge. This is only possible if effective patent legislation is in place.'[110] CEFIC also expresses a similar position to that of EFPIA in its opposition to the international exhaustion of IPRs.[111]

UNICE is the umbrella organization for industry associations and federations in Europe. Created in 1958, UNICE represents about 35 business federations from 27 countries (2000).[112] Pharmaceutical companies are represented via their national industry confederations, such as the Confederation of British Industry (CBI) and Bundesverband der Deutschen (BDI).

UNICE devises its policy objectives via five committees: Economic and Financial Affairs, External Relations, Social Affairs, Industrial Affairs and Company Affairs.[113] Policy Committees delegate their tasks to different working groups consisting of experts (usually from companies) that are nominated by the national federations.[114]. IPRs receive special attention under the Committee for Company Affairs.[115] Currently, there are eight working groups dealing with various IPR policies: intellectual property, patents, biotechnology, licences, trademarks and designs, copyrights, TRIPs and data protection.[116]

One of UNICE's priorities is to strengthen and secure the international protection of IPRs. Its rhetoric is quite similar to that of EFPIA and CEFIC. For example, according to UNICE, 'without the essential combination of R&D and intellectual property, many European businesses will fail in the face of low-cost foreign competitors, with serious consequences for employment and economies generally in the European Union'.[117] Regarding the TRIPs agreement, UNICE considered it to be 'one of the most fundamental and important consequences of the Uruguay Round and therefore places great importance on correct and timely implementation, notably for patents, by all WTO members'.[118]

EFPIA, CEFIC and UNICE work closely together, aiming to harmonize their objectives and approach to IPRs. As shown later in Chapter 8, such cooperation took place during preparations to the Seattle ministerial meeting (November 1999). That some corporate IP executives are members of IP committees in EFPIA, CEFIC and UNICE simultaneously is also an important factor in the successful exchange of views between these three forums.[119]

5.4.2 The International Level – the Trans Atlantic Business Dialogue (TABD) and the US Intellectual Property Committee (IPC)

Aside from working closely with regional confederations, the advanced pharmaceutical industry in Europe also takes part in, and cooperates with, international

interest-group forums. With respect to IPRs, two forums are relevant to the advanced pharmaceutical industry in Europe: TABD and US IPC.

Established in 1995 and representing more than 100 MNCs (2000), TABD aims to influence and shape the international trading and investment system by promoting close and effective interaction between the international business community and the US/EU governments.[120] TABD defines itself as a 'process that brings leaders from across the European Union and the United States together with a common goal: to help create a transatlantic marketplace without barriers to trade and investment and to support the multilateral trading system'.[121]

To date, TABD has five primary work groups: standards and regulatory policy, business facilitation, global issues, small and medium sized enterprises and e-commerce.[122] Each group is jointly chaired by CEOs of companies from the EU and the US.[123] Overall, TABD has more than 40 working sub-groups (issue groups) covering both sectoral issues, such as pharmaceuticals, telecommunications and electronics, and horizontal topics such as customs, intellectual property and climate change.[124]

The IPR issue group is hierarchically located under the Global Issues work group.[125] Between 1998 and 2000, corporate IP executives from GlaxoWellcome (today GlaxoSmithKline), Pfizer and Time Warner chaired the IPR issue group.[126] To a large extent TABD's international IPR objectives reflect the interests of the advanced pharmaceutical industry, as well as of other industries such as the film and music industries. For instance, TABD is in favour of strong patent protection (both in scope and duration) and data exclusivity, and opposes international exhaustion and the single community trademark.[127] Like INTERPAT, TABD aspires to resolve tensions between EU and US partners. In 1997 it called for the harmonization of EU–US protection periods of data exclusivity in pharmaceuticals to a minimum period of 10 years, and for the adaptation of their patent systems to bring them closer to the first to file model, thus adopting existing European policies.[128]

Finally, the advanced pharmaceutical industry in Europe also cooperates with the US Intellectual Property Committee, though mainly via UNICE, representing the IP interests of dominant MNCs from the pharmaceutical, computer, electronics and film industries.[129] Among IPC members are companies such as General Electric, IBM, Johnson and Johnson, Merck, Monsanto, Pfizer, Procter and Gamble, Time Warner, and Texas Instruments.[130] Cooperation between the IPC and UNICE includes the creation of position papers, joint statements and direct lobbying.

A few examples may be given. In 1988 the IPC, UNICE and the Japanese Federation of Economic Organizations (Keidanren) presented a joint paper reflecting their views on IPRs and GATT.[131] The paper called for the introduction of a rule-based agreement with binding provisions that would significantly increase the global protection of IPRs. The three parties stated that they would

continue to cooperate and to coordinate their activities, both internally and externally, in order to monitor and secure negotiations on a comprehensive GATT IP agreement (that is TRIPs).[132] In 1998 a joint IPC–UNICE delegation undertook a series of meetings with officials from the WTO, WIPO and the European Commission. Their aim was to present the industry view regarding possible negotiations on TRIPs to the WTO Seattle ministerial meeting (November 1999) and to argue for the rapid and full implementation of TRIPs by member countries.[133]

In seeking to secure and to promote its international IP interests, the advanced pharmaceutical industry in Europe has expanded its organizational IP build-up beyond the intra-industry spectrum. Direct and indirect cooperation with other IP-based industries, such as the chemical and computer software industries, takes place through various organizations and forums. At the regional level, CEFIC as the primary representative of the chemical industry and UNICE as the umbrella organization of industry federations and associations are the natural partners of the European-based advanced pharmaceutical industry. Not only do EFPIA, CEFIC and UNICE share the same IP interests, but cooperation and coordination between these organization is a necessity given that pharmaceutical MNCs are members of all three organizations (directly in the case of EFPIA and CEFIC and indirectly in the case of UNICE).

At the international level, European-based pharmaceutical MNCs are either part of, or partners with, forums such as TABD and the US IPC (representing the IP interests of well-established and dominant MNCs from several industries). Active and influential membership in the TABD IPRs Issue Group allows European-based pharmaceutical companies to reach a wider audience from US and European governments and institutions. It also allows pharmaceutical MNCs to cooperate with companies from other industries, such as the movie and telecommunication industries. Cooperation with the US IPC, mainly via UNICE, allows the advanced pharmaceutical industry in Europe to present an additional IP unified front, either via position papers (sometimes jointly with Japan), or through direct lobbying.

5.5 CONCLUSION

The impressive intra-industry, as well as inter-industry, IP organizational structure through which European-based pharmaceutical MNCs strive to secure their IP interests leads to the conclusion that, as far as IPRs are concerned, the term advanced pharmaceutical industry in Europe is a reality.

IPRs provide pharmaceutical MNCs with a powerful incentive for collective action, both due to their crucial economic importance and given their ability to provide a platform for cooperation between such companies. In general, the

advanced pharmaceutical industry in Europe would like to secure and increase the international protection of IPRs. Specifically, the industry desires strong and extended protection (in scope and term) for patents, data exclusivity and trademarks.

Guided by Sally's work, which advocated the study of MNCs as a basic unit of analysis in politico-economy scholarship, the chapter mapped the intra-industry (vertical) and inter-industry (horizontal) IP organizational structure of the advanced pharmaceutical industry in Europe.

With regard to vertical relations (corporate, national regional and international), pharmaceutical MNCs should be placed at the core of the industry's IP organizational structure. At the corporate level, each company has its own department responsible for securing, exploiting and enforcing IPRs (contracts, patent and trademark applications, litigation, royalties, and so on). Similar professional backgrounds and common day-to-day practices create a strong sense of epistemic community among corporate IP directors of pharmaceutical MNCs. The existence of an epistemic community within the IPR pharmaceutical sector allows corporate IP directors to share similar views and objectives, as well as to secure considerable amounts of influence when participating in different national regional and international IP forums.

National pharmaceutical associations, such as ABPI and VFA, are a primary channel through which European-based pharmaceutical MNCs engage in IP collective action at the national level. Though operating in different national environments, the ABPI and VFA are guided by the same international IP input and follow similar IP objectives. Both have specific committees dealing with IPRs: the Intellectual Property Committee in the case of ABPI, and the sub-committees for patents and trademarks, hierarchically located under the Committee of Legal Affairs, in the case of VFA. Members of IP committees in ABPI and VFA are corporate IP directors in pharmaceutical MNCs. Operating as lobbying groups, ABPI and VFA target relevant government departments, such as DTI and DoH in the UK, and the Federal Ministries of Justice, Economics and Technology in Germany. ABPI and VFA also regularly approach MPs, as well as other key groups, such as physicians, consumers' associations and patients' advocates. Contacts take place via personal meetings, correspondence, conferences, position papers and so on.

The regional level is the focal point of pharmaceutical IP input and output in Europe. Most important is EFPIA, the primary representative of pharmaceutical MNCs. Having both national associations and pharmaceutical MNCs as members (allowing the latter to maintain a high level of dominance, influence and voice via direct membership), EFPIA plays a major role in initiating and facilitating the industry's IP objectives and strategies. To date, EFPIA's Intellectual Property Policy Committee (IPPC), consisting of IP corporate directors, its IP Priority

Action Teams (PATs), chaired by CEOs of pharmaceutical MNCs, and ad hoc work groups are responsible for the dominant portion of pharmaceutical IP objectives in Europe.

Moreover, EFPIA's importance as a key IP lobbying group also derives from the complex structure of European IP decision-making processes. Following the conclusion of TRIPs in 1994, the ECJ ruled that the European Community and its member states share joint competence with regard to multilateral IP trade-related negotiations and agreements. The manner in which international IP policy-making is taking place in the EU (formally via the 133 Committee) suggests that there is no single and transparent institution that functions as a focal point for IP inputs and policies. Instead, there are different national and regional channels that formally and practically affect the international IP objectives and strategies of the EU, the most important of which is probably the European Commission (DG Trade).

Given that bodies such as the Commission and the Council of the European Union are crucial to the European IPR decision-making process, both formally and practically, EFPIA is required to operate directly at the regional level in order to secure a more favourable environment for research-based companies. Focusing on its target audience from the Commission (DG Trade and DG Internal Market), Council of the European Union, MEPs, regulatory authorities (EMEA), physicians, consumer groups and so on, EFPIA's IP lobbying activities are extensive, covering a wide range of issues including TRIPs, patents, data exclusivity and trademarks. Such activities, as was discussed in this chapter and will be elaborated on in Chapter 8, have proved highly effective over the past decade.

Internationally, the advanced pharmaceutical industry in Europe takes part in two important forums: IFPMA and INTERPAT. Representing the world-wide research-based pharmaceutical industry and manufacturers of prescription medicines in general (more than 50 national associations in 2000), IFPMA is much broader in scope, dealing with a wide range of issues, including IPRs. Specifically, the IFPMA, guided by the Intellectual Property Protection Coordination Committee, uses its special consultative position with institutions such as the World Bank, WTO and WIPO in order to promote awareness of the IP demands of pharmaceutical MNCs. It is also one of the industry's most dominant information providers regarding IPRs.

Incorporating only pharmaceutical MNCs as members, INTERPAT is a much more specialized forum focusing solely on IPRs. Its role as an international intra-industry forum for IP consultation and collective action is pivotal, as it allows companies to feed homogeneous input to their representatives at the various levels. INTERPAT also strives to resolve internal IP tensions arising from different legislative environments, such as the 'first to invent' vs. 'first to

file' dispute between the US and other developed economies (notably Europe and Japan).

Looking at inter-industry IP relations, pharmaceutical MNCs attach great importance to their ability to join other key industries in the 'battle' for increased global IP protection. At the regional level, the advanced pharmaceutical industry in Europe has two natural partners: CEFIC and UNICE. The former is the key representative of the European chemical industry. CEFIC's IP objectives, as set by its High Level Steering Group (HLSG) for Intellectual Property, are similar, if not identical, to those of the advanced pharmaceutical industry. Like EFPIA it allows for direct company membership. In fact, some companies (Novartis, Bayer) are members of both EFPIA and CEFIC, which makes cooperation between the two bodies even more important.

UNICE is the umbrella organization of industry associations and federations in Europe. It receives input from the research-based pharmaceutical and chemical industries and attaches great importance to IPRs. UNICE uses its various IP working groups (intellectual property policy, patents, biotechnology, licences, trademarks and designs, copyrights, TRIPs and data protection), and advocates the creation of a strong IP environment, such as that provided by the TRIPs agreement.

In the international arena, European-based pharmaceutical MNCs cooperate with companies from other industries (for example: telecommunications and film industries) via forums such as TABD and the US Intellectual Property Committee (IPC). Operating as a transatlantic business lobbying group, TABD reflects, to a large extent, the IP interests of the advanced pharmaceutical industry. TABD IP objectives, as formulated by its IPRs Issues Workgroup, include support for strong patent protection, 10-year period of data exclusivity and opposition to the international exhaustion of IPRs, as well as to the single community trademark.

European-based pharmaceutical MNCs, mostly via UNICE, also cooperate with the US IPC, an organization representing the IP demands of dominant companies across the board (IBM, Pfizer, Texas Instruments and so on). Joint position papers (also with Keidanren, Japan), and direct lobbying vis-à-vis institutions such as WIPO, WTO and the Commission, allow European-based pharmaceutical companies to take part in an additional, and sometimes expanded, global IPR front. This is presented as a graphical outline in Figures 5.1 and 5.2.

Overall, the vertical and horizontal IP organizational structure used by the advanced pharmaceutical industry in Europe enables it to operate in a highly efficient and effective manner. This lobbying IP build-up is a key factor in the ability of European-based pharmaceutical MNCs to preserve, and even strengthen, the IP results that have emerged from the TRIPs agreement.

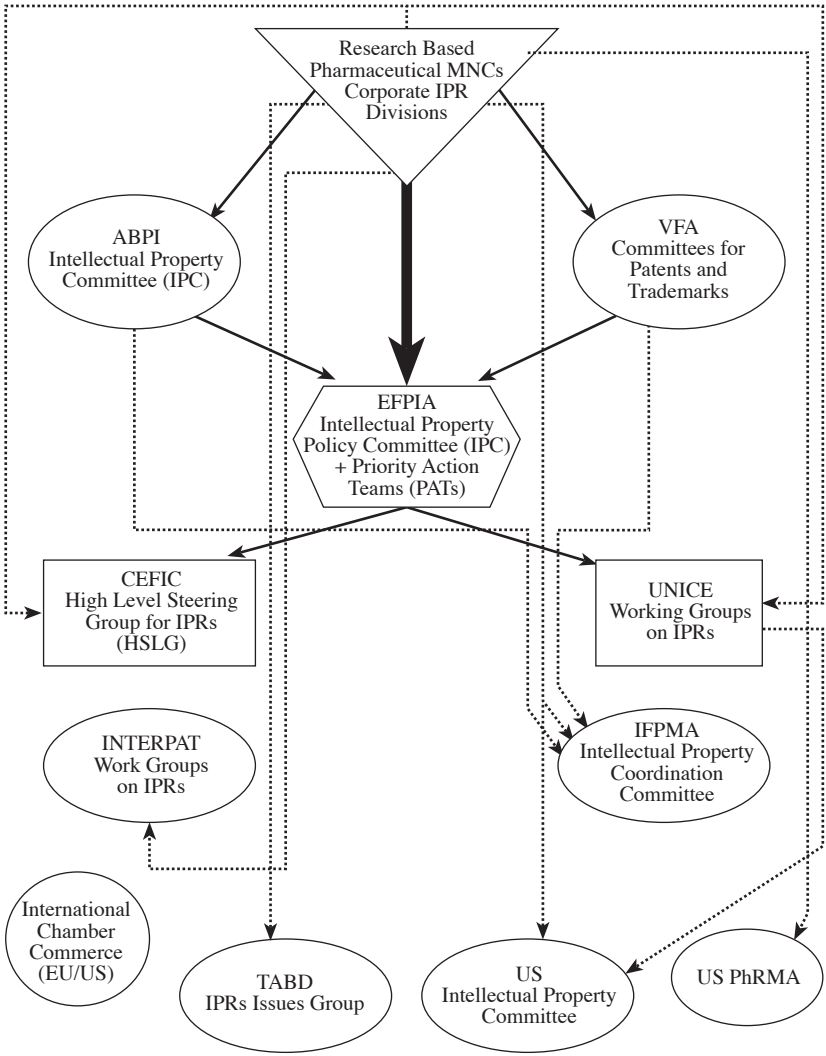

Figure 5.1 *The IP organizational structure of the advanced pharmaceutical industry in Europe*

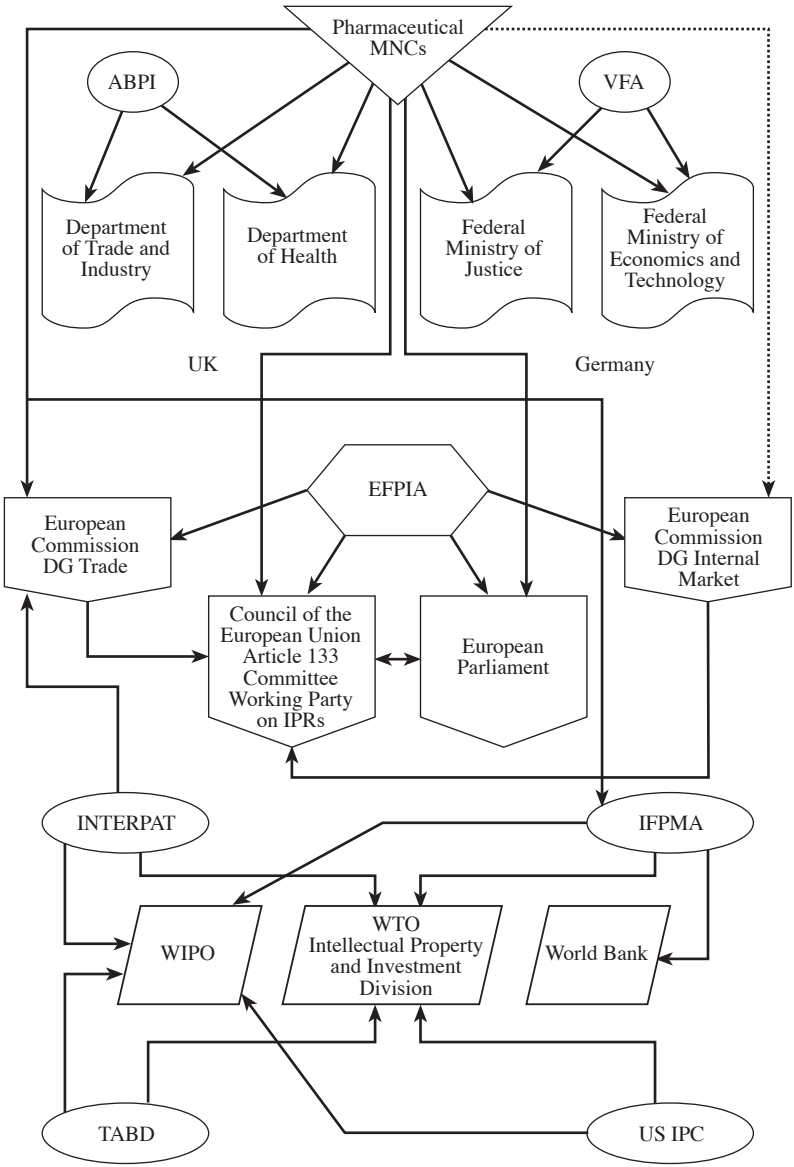

Figure 5.2 Industry–government IP interaction scheme

NOTES

1. For simplicity's sake, the term 'industry' is sometimes used here instead of the term 'advanced pharmaceutical industry in Europe'. It may also refer to the 'advanced pharmaceutical industry' as a whole, particularly in section 5.2
2. EFPIA (1999d: 3–4)
3. GlaxoWellcome's Chairman, Sir Richard Sykes (2000: 4); see also: Burns and Pilling (1999: 6)
4. Chairman and Chief Executive Officer of Merck & Co Inc., Raymond V. Gilmartin (1998)
5. VFA (1997: 17–18)
6. IFPMA (1997: 1)
7. EFPIA (1999b), see EFPIA website: http://www.efpia.org; Richardson (1999)
8. IFPMA (1989: 8)
9. EFPIA (June 2000b); EFPIA (1999d; 1999h); Leschly (1997: 51). These views were also expressed in the course of interviews with the corporate IP directors of SmithKline Beecham (16 November 1998), Lilly (28 October 1998) and Glaxo Wellcome (25 November 1998)
10. EFPIA (1999f)
11. Ibid., p. 6
12. Sally (1994: 161–92); Sally (1995: Chapter 4)
13. Sally (1994: 162–6)
14. Ibid., pp. 181–4
15. According to Sally, institutional domestic political economy 'highlights the structural linkages between the domains of "government", "finance", "industry" and "labour" in national political economies' (1994: 164)
16. Ibid., p. 184
17. Most of the corporate IP directors interviewed for this study have such a background
18. Haas (1990: 52–60)
19. ABPI (1998: 1); see ABPI (2000a: 1–11)
20. For PPRS see: ABPI Press Release (2000c); ABPI Press Release (1999b); Greenwood and Ronit (1992: 74). For NICE see: ABPI Statement (1999a). For Industry Competitiveness see: ABPI Press Release (2000b); ABPI Press Release, 2000c)
21. ABPI Press Release (2000b)
22. ABPI (1998: 11)
23. Ibid., p. 7
24. Ibid., pp. 21–36; ABPI (2000a: 34–5);
25. ABPI, 2000a, p. 34
26. Interviews with the Director of Law and Intellectual Property, ABPI (26 October 1998) and with the Director of European Patent Operations, Lilly, (28 October 1998)
27. Department of Trade and Industry, UK (1999)
28. ABPI (1998: 11)
29. Interview with the Manager of Global Intellectual Property, GlaxoWellcome (31 August 1999)
30. ABPI (1998: 29)
31. Parallel imports or parallel trade of patented pharmaceuticals is the importation of patented drugs from low price countries to high price countries without using the services of local patentees or licensees
32. Bolar exemption is discussed in depth in Chapter 8
33. ABPI (1998: 29)
34. VFA (2000b)
35. Interview with the Director of Pharmaceutical Law, Patent and Trademarks, VFA (31 May 2000); see also: Greenwood (1994c: 195–6); Koehler (1997); BPI (1998).
36. VFA (2000b: 35–43)
37. Ibid.; information was also provided by the Director of Pharmaceutical Law, Patents and Trademarks, VFA (31 May 2000); Manager of European Affairs, VFA (13 June 2000), and the Director of Patents Division, Boheringer-Ingelheim (13 June 2000)

38. Ibid.
39. Ibid.
40. Information provided by the Director of Pharmaceutical Law, Patents and Trademarks, VFA; see also: VFA (1999b)
41. Interview with an official from the Federal Ministry of Justice (9 August 2000)
42. Ibid.
43. For a background on EFPIA as an effective lobbying group see: Greenwood and Ronit (1992: 75–83)
44. EFPIA (1999b); also see EFPIA 1997a and 1998a Annual Reports
45. EFPIA (1999b)
46. EFPIA 1997 Annual Report (1998: 11); Scrip (1997: 2)
47. Greenwood (1997; 71–4)
48. Scrip (1997: 2)
49. EFPIA 1998 Annual Report (1999: 12–13)
50. EFPIA (1999c)
51. EFPIA (1999c)
52. EFPIA, 1997a and 1998a Annual Reports. Information was also provided by the Manager of International Intellectual Property & Environment Division, EFPIA (6 January 1999) and the Head of Corporate Intellectual Property, Novartis, (18 November 1999)
53. Ibid.
54. EFPIA (1999c); EFPIA PAT for Data Protection presented its work at EFPIA's 'Annual Meeting 2000', which took place in Venice, 21–23 June 2000
55. EFPIA (1999c)
56. For instance, between 1995 and 2000 directors of patent and trademark committees in ABPI and VFA were also members of EFPIA and the IPPC
57. Interviews with Corporate IP directors of Lilly, SmithKline Beecham, Glaxo Welcome, Pfizer, and Novartis
58. European Court of Justice (1994)
59. Ibid., pp. 103–23; for a discussion on the case see: Bossche (1997: 23–53)
60. Ibid., p. 113
61. Ibid., 123
62. Consolidated Version of the Treaty Establishing the European Community (1997); for an overview of EU trade policy and the '133' mechanism see: Woolcock (2000: 401–27)
63. Treaty Establishing the European Community (1997: 100); The term 'Council' stands for the 'Council of the European Union'
64. Article 133, paragraph 5; Article 300, paragraph 2
65. Ibid.
66. Commission of the European Communities (December 2000)
67. Department of Trade and Industry, UK (1999: 3–4)
68. Council of the European Union (1994a)
69. Ibid., Article 7
70. Ibid.
71. Ibid.
72. Council of the European Union (2000c).
73. Ibid.
74. Council of the European Union (2000a and 2000c)
75. See Chapter 8, section 8.3; the patent disputes between the EU and India and the EU and Canada are good examples of the manner in which the Commission is playing a pivotal role in the international IP-policy making of the EU
76. Official information on the internal structure of DG Trade and DG Internal Market can be obtained from at the European Commission website: www./europa.eu.int/comm/
77. EFPIA 1997a and 1998a Annual Reports; information was also provided by officials from EFPIA (6 January 1999); Novartis (18 November 1999); The European Commission, DG Internal Market, Directorate E (Free Movement of Information, Intellectual Property, The Media and Data Protection) (6 January 1999); The European Commission, DG Trade, Directorate M (Intellectual Property) (30 and 31 August 2000)

78. Greeenwood and Ronit (1992: 78–9)
79. Council of the European Communities, Regulation (EEC) No. 1768/92 (1992)
80. Ibid., Articles 13 and 14
81. Greenwood (1994c: 188)
82. EFPIA, 1997 Annual Report (1998:25)
83. European Parliament and the Council of the European Union, Directive 98/44/EC (1998); for the lobbying for biotechnological patents see: Schechter (1998: Chapter 4)
84. EFPIA 1997 Annual Report (1998: 23); for the decision on a Single Community Trademark see: Council of the European Union Regulation (EC) No. 40/94 (1994b)
85. EFPIA, 1997 Annual Report (1998: 23)
86. EFPIA 1998 Annual Report (1989: 39)
87. EFPIA (2000c)
88. EFPIA (2000e: 2)
89. Greenwood and Ronit (1992: 76–83)
90. IFPMA (2000a)
91. IFPMA, IFPMA Member Associations (2000b); see: www.ifpma.org/ifpma3.htm
92. IFPMA Administration and Objectives (2000a)
93. Ibid.
94. Ibid.
95. Ibid.
96. IFPMA (1999)
97. IFPMA, Main Areas of Activities (2000d)
98. IFPMA, Mission Statement (2000c)
99. IFPMA, Main Areas of Activities (2000d)
100. INTERPAT 'Statutes: As Accepted by the General Assembly' (1998a); in author's records
101. Ibid., Article 2
102. Ibid., Article 5
103. Ibid., Article 6
104. Ibid., Article 8
105. Ibid., Article 10; INTERPAT - General Assembly, 'INTERPAT Guidelines' (1998b); in author's records
106. INTERPAT Paris Conference, 'INTERPAT Work Groups' (1999); in author's records
107. Armitage (1992: 10–13)
108. Yorke and Jucker (1992)
109. European Chemical Industry Council (CEFIC) (2000b); (2000a: 8–12)
110. European Chemical Industry Council (CEFIC) (1998: 2)
111. CEFIC, Annual Report 1999 (2000a: 20
112. For Background on UNICE see: Collie (1993: 213–26); Cowles (1998: 108–25); Greenwood (1997: Chapter 5); see also UNICE web site: www.unice.org
113. Collie (1993: 21–26)
114. Ibid.
115. UNICE Company Affairs (2000b)
116. UNICE, Working Groups (2000c); see also UNICE website
117. Compendium of UNICE Position Papers (2000d: iii)
118. UNICE (1997)
119. For instance, between 1998 to 2000 a senior corporate IP director from Novartis was the chairman of EFPIA's IPPC, CEFIC's Industrial Property Working Party, and UNICE Working Group for Biotechnology.
120. Cowles (1998: 108 and 122); see also TABD website: www.tabd.org
121. TABD 'Charlotte Statement of Conclusions' (1998b: 1)
122. TABD, 'Working Group Structure' (2000), electronically available in TABD website
123. Ibid.
124. Ibid.; see aslo: TABD, 'Issue Briefings for the Rome Conference' (1997)
125. Ibid.
126. TABD, 2000 Issue Contacts (2000b); interview with the Manager of Global Intellectual Property, GlaxoWellcome (31 August 1999)

127. TABD (1998c; 1998a; 1997)
128. TABD (1998b: 3–4); TABD (1998a: 2)
129. See: Keidanren, IPCI and UNICE (1988); Gorlin and Levy (1994)
130. Keidanren, IPCI and UNICE (1998: 5)
131. Ibid.
132. Ibid., p. 4
133. US Intellectual Property Committee–UNICE, (1998); Beton (1998), in author's records

6. TRIPs and pharmaceuticals

6.1 INTRODUCTION

The interaction process through which the advanced pharmaceutical industry in Europe, as well as in the US, strives to secure its interests as regards to the international IP system is ultimately linked to the WTO agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs).[1]

Signed in Marrakesh (15 April 1994) as Annex 1C to the Final Act establishing the WTO, the TRIPs agreement came into effect in January 1995. It was one of the most innovative and important subjects to be included in the multilateral negotiations of the Uruguay Round. With respect to IPRs specifically, the TRIPs agreement represents a significant increase in the global level of IP protection. Some scholars, such as Reichman, consider TRIPs to be a 'revolution in international intellectual property law'.[2]

The primary task of this chapter is to analyse the TRIPs agreement as a whole and to assess its specific impact on the international pharmaceutical IP agenda. This analysis and assessment are necessary steps to understanding the interaction between the advanced pharmaceutical industry in Europe and the international pharmaceutical IP agenda. First, the chapter provides an overview of the history of TRIPs negotiations. Second, it analyses major elements of TRIPs (general provisions and basic principles, dispute settlements, enforcement, TRIPs Council and the system of notifications). Third, the chapter reports on TRIPs major flaws, focusing mainly on its lack of effectiveness in the elimination of anti-competitive practices and insufficient assistance to countries with low IP capabilities. Finally, the chapter examines and elaborates on TRIPs pharmaceutical IP agenda.

Putting the TRIPs agreement in the north–south context, the chapter concludes that the newly established international pharmaceutical IP agenda, as well as the IP system generally, is highly correlated with the position and interests of the advanced pharmaceutical industry based in developed countries.

6.2 A BRIEF HISTORY OF THE TRIPS AGREEMENT

The negotiating process leading to the establishment of the TRIPs agreement proved to be one of the most controversial and complicated tasks in the Uruguay

Round.[3] The inclusion of IPRs in the negotiating agenda in the first place, as indeed presented by the ministerial declaration of 20 September 1986, was primarily initiated by the US, backed by the EC, Switzerland and Japan.[4] These countries, particularly the US and the EC, exerted heavy pressure, including threats of unilateral trade retaliation, on some key developing countries such as India, Korea and Brazil, forcing them to agree to negotiate on a comprehensive IP agreement under GATT auspices. Naturally, there were also disagreements within the north–north agenda, such as between the US and the EC concerning the 'first to invent' vs. the 'first to file' patent system.[5] Yet, while such disagreements focused on the more subtle issues of the agreement, negotiations as a whole on the essence of TRIPs and on its practical outcome were ultimately linked to, and dictated by, the north–south divide.[6]

Chronologically, the decision to accept the joint Swiss-Colombian proposal, which also pushed for the inclusion of IPRs, as the primary platform for the Uruguay Round negotiations posed a serious problem for the developing countries.[7] As a result, negotiations on the TRIPs agreement during the early stages (1986–1988) were in complete deadlock and the gap between developed (US, EC, Switzerland and Japan) and developing countries (notably Brazil and India) seemed unbridgeable.[8] Whereas the developed countries presented a highly ambitious agenda, aimed at a rigorous rule-based IP system, the developing countries fiercely questioned the logic of 'inserting' IPRs into the GATT framework.[9] India, in particular, opposed the granting of patents in numerous technological fields, such as pharmaceutical and chemical products and micro-organisms (biotechnology).[10]

Following extensive bilateral pressures, mostly from the US but also from the EC, developing countries, at the Uruguay Round mid-term review of April 1989, agreed to negotiate on a wide rule-based framework for GATT IPRs.[11] The Draft contained most of the relevant elements of TRIPs: institutional arrangements, including the principles of national treatment and most-favoured-nation (MFN) treatment, dispute settlement, substantive standards of protection for different forms of IPRs, enforcement and the relationship between the GATT IPR agreement and WIPO.[12] In many respects the 1989 draft framework marked the shift from negotiations according to north–south lines to IP negotiations on north–north issues.[13]

During 1990, comprehensive negotiations between members of the TRIPs Working Group took place, resulting in five draft texts (from the US, the EC, Japan, Switzerland and a group of 14 developing countries).[14] Towards the end of 1990 (22 November), the GATT IPRs Working Group presented the first draft agreement of TRIPs.[15] Many issues still remained unresolved, including patent protection on pharmaceutical products, compulsory licences, trade secrets, copyrights and transitional arrangements.[16] The difficulty of settling pharmaceutical patent differences between developed and developing countries

is emphasized by the Director of WTO Division for Investment and Intellectual Property, Adrian Otten:

> The question of protection of pharmaceutical patents was one of the key issues in the negotiations as a whole and perhaps the key issue in the North–South axis of the negotiations…At the time, it was clear that there would be no TRIPs Agreement without commitment to make available patent protection for twenty years in virtually all areas of technologies, including pharmaceuticals, and that without a TRIPs Agreement it was doubtful that the Uruguay Round could be concluded.[17]

Throughout 1990 and 1991, negotiations continued with no significant progress, as indeed noted in the TRIPs Progress Report issued by GATT Director General, Arthur Dunkel (November 1991).[18] Aiming to cut the IP 'Gordian knot', and taking matters into his own hands, Dunkel decided to incorporate a compromise IPRs text agreement in his proposed Final Draft Act dated 20 December 1991 (Dunkel Draft).[19] In retrospect, the Dunkel Draft went a long way towards the IP interests of developed countries. On this point it is worth citing Reichman:

> The momentum of the multilateral negotiations during the Uruguay Round carried the developed countries well beyond their initial goal, which was to limit the capacity of free-riding copies of high-tech goods produced at great cost. Instead, by the time the Dunkel Draft appeared in 1991, the developed countries' strategic goal was to impose a comprehensive set of intellectual property standards on the rest of the world.[20]

However, despite their ability to secure a landmark agreement on IPRs (TRIPs) the IP-based industries, particularly the pharmaceutical and film industries, did not approve of the Dunkel Draft.[21] Among the objections expressed by the advanced pharmaceutical industry, both in the US and in Europe one could find the following: (1) objection to the extension periods granted to developing and least developed countries for the implementation of TRIPs; (2) strong opposition to TRIPs provisions relating to the international exhaustion of IPRs (parallel imports), and (3) dissatisfaction with TRIPs provisions relating to the transitional arrangements required from developing countries and LDCs, particularly with respect to the protection of existing subject matter ('pipeline protection').[22]

Nevertheless, following an agreement between the US and the EC on agricultural policies that enabled Uruguay Round discussions to resume as a whole in 1992, negotiations on the TRIPs agreement proceeded according to the lines of the Dunkel Draft. Eventually, the agreement reached in Marrakesh in April 1994 was almost identical to the Dunkel Draft.

That the TRIPs agreement represents the interests of IP-based industries in developed countries is discussed in depth in the following sections. Paradoxically both the mandate text provided by the Uruguay Round ministerial declaration

in 1986, which was evidently put forward by the developed countries, and the opening statement of TRIPs are highly similar.[23]

6.3 MAJOR ELEMENTS OF TRIPS

6.3.1 General Provisions and Basic Principles: Significant Increase in the Global Commitment to the Protection of IPRs

The TRIPs agreement, which aimed to increase and to harmonize the global protection of IPRs (nationally, regionally and internationally), is the most comprehensive and ambitious agreement ever to be reached in the IP domain. Three aspects should be emphasized.

First, as part of the WTO agreements, the TRIPs agreement incorporates the principles of national treatment and most-favoured-nation (MFN) treatment.[24] The former (TRIPs Art. 3) requires all members to treat nationals of other members no less favourably than their own nationals, on all issues concerning IPRs, subject to the exemptions laid down in previous IPR conventions and treaties.[25] The MFN principle (Art. 4) requires that any advantage, favour, privilege or immunity granted by a member to the nationals of any other member must be extended unconditionally to the nationals of all other members.

Second, the TRIPs agreement specifies the minimum protection standards that member countries must adopt under their domestic IP legislation: 'Members shall give effect to the provisions of this agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement'. (Art. 1.1) In this context, the TRIPs agreement incorporates four major international treaties: the 1883 Paris Convention for the protection of industrial property, as revised by the Stockholm Act of this convention (14 July 1967), the 1886 Berne Convention for the protection of literary and artistic works, as revised in the Paris Act of this convention (24 July 1971), the Rome Convention for the protection of performers, producers of phonograms and broadcasting organizations (26 October 1961) and the Treaty on intellectual property in respect of integrated circuits (IPIC) of 26 May 1989.[26] More importantly, the TRIPs agreement provides a detailed 'technical guide' for member countries with regard to the protection of IPRs. TRIPs articles refer specifically to Copyright and related rights (Art.9–14), Trademarks (Art.15–21), Geographical Indications (Art. 22–24), Industrial Designs (Art. 25–27), Patents (Art. 27–34), Layout Designs of Integrated Circuits (Art. 35–38) and the protection of Undisclosed Information (Art. 39).

Finally, implementation dates of the TRIPs agreement are subject to the 'developmental' status of WTO members (Transitional Arrangements, Art. 65), excluding the principles of National Treatment and MFN Treatment that had to be implemented by January 1996. Developed countries were required to implement TRIPs provisions within one year of its date of coming into force, that is January 1996 (Art. 65.1). Developing countries and countries in transition (mainly centrally-planned countries moving towards market orientated economies) were entitled to an additional period of four years (January 2000) (Art. 65.2–65.3). Least-developed countries (LDCs) are required to implement TRIPs over a period of 10 years from its date of coming into force (2006).

6.3.2 Dispute Settlement and Enforcement – an Agreement with 'Teeth'

TRIPs provisions concerning dispute settlement and enforcement make it particularly effective with respect to the global protection of IPRs. These two features are discussed below.

Dispute settlement

Subject to Art. 64, member countries can use the new and improved Dispute Settlement Understanding (DSU), as specified in Annex II to the WTO Agreement, in order to resolve IP-related disputes.[27] Building upon its GATT predecessor (GATT Art. XII and XIII) the DSU is designed to have more 'teeth', particularly with regard to structural, procedural, and ruling mechanisms.[28] To quote the former director of the WTO, Renato Ruggiero:

> No review of the WTO would be complete without mentioning the Dispute Settlement Body, in many ways the central pillar of the multilateral trading system and the WTO's most individual contribution to the stability of the global economy. The new WTO system (because of the DSU) is at once stronger, more automatic and more credible than its GATT predecessor.[29]

Structurally, the Dispute Settlement Body (DSB) is the main body responsible for settling disputes between member countries (DSU, Art.1).[30] The DSB has the sole authority to establish panels of experts for each and every dispute, to accept or reject panel findings and decisions and to monitor member states' compliance with the WTO dispute rulings. If and when a member country chooses not to comply with a given WTO dispute ruling, the DSB has the power to authorize trade-retaliation measures against that member (DSU, Art. 22).

In terms of process, a typical dispute comprises three major stages. First, members involved in a trading dispute are required to enter into consultation with each other (DSU, Art. 4). Second, should the consulting parties fail to resolve the dispute within a period of 60 days, and subject to the request of the

complaining member, the DSB would establish, within a period of 45 days, a dispute panel consisting of three (sometimes five) experts on the subject (DSU, Art. 6–8). The panel must conclude its report and submit it to the DSB, and to the parties concerned, no later than six months from the day the panel was established (DSU, Art. 12.8). Lastly, the DSB must decide whether to adopt or to reject the panel's report within 60 days from the day of its submission (DSU, Art. 16.4), unless an appeal is launched.[31] Unlike GATT, in which ruling on disputes could only be adopted by consensus, the WTO DSB automatically adopts a panel's report and may only reject it by consensus (DSU, Art.16).[32] Altogether, it should take the DSB between 12 to 15 months (with an appeal) to decide upon a given dispute (DSU, Art.20).[33]

Empirical evidence suggests that the WTO DSU is used quite extensively. According to WTO data, out of 188 complaints submitted between January 1995 and February 2000 (on 147 distinct matters) 31 panel reports have been adopted and an additional 31 cases have been settled or pronounced 'inactive'.[34] Over the period 1995 to 1998, developed countries used the DSU much more frequently (105 complaints on distinct matters and 135 requests for consultations) than developing and least-developed countries (complaints on 32 distinct matters and 46 requests for consultations).[35] During these years IP-related disputes accounted for about 10 per cent of total WTO disputes (14 IP complaints out of a total of 139 complaints).[36] The EU and the US were the primary users of the DSU with respect to IP-related disputes.[37] As discussed in Chapter 8, the US and EU used the DSU several times in order to force other members to raise the level of IP-protection provided for pharmaceutical products. Though most disputes were launched against developing countries, such as India and Pakistan, the US and the EU also targeted developed countries, such as Canada.[38]

TRIPs enforcement provisions

The TRIPs agreement specifies the minimum measures necessary for the adequate enforcement of its provisions (Art. 41 to 61).[39] Each WTO member must provide civil and judicial procedures in order to prevent, or at least inhibit, the infringement of IPRs (Art. 41). Members' remedies must include injunctions – 'to prevent the entry into channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right' (Art. 44), damages for injuries (Art. 45) and the destruction of infringed goods without compensation of any sort (Art. 46). Member countries are also required to adopt adequate border measures aimed at preventing the importation and circulation of counterfeit and pirated IP-related goods (Art. 51–60). Finally, in order to combat the illegal trade in pirated products involving copyright or trademark rights infringements, WTO members are required to adopt criminal procedures, and to allow for penalties to be applied, under their domestic IP legislation (Art. 61).

6.3.3 The Council for TRIPs: the System of Notifications and the Built-in Agenda

The Council for TRIPs is the primary body responsible for TRIPs' administration, operation and timely implementation (Art. 68). The TRIPs Council functions as a major forum for information and consultation on IP-related issues.[40] Two elements are particularly important to its work:

1. Notifications – aimed at helping the Council to monitor members' compliance with TRIPs obligations.
2. TRIPs built-in agenda – negotiations and discussions between WTO members on specific provisions that require further development starting from the year 2000, to which the TRIPs Council acts as the focal point.

WTO members are required to notify the Council of any changes made to their domestic laws aimed at aligning these laws with TRIPs obligations (Art. 63.2). To date (2000) the system of notification is based on three main features: first, in order to avoid duplication, the Council for TRIPs and WIPO share information concerning the implementation of the TRIPs agreement, allowing members to notify only one of these institutions.[41] Second, the Council made a distinction between legislation concerning IPRs directly and legislation of a more general nature, that is not dedicated to IPRs in particular, such as criminal procedures and anti-competitive practices. In the former case, WTO members are required to submit their notifications, including legislation itself, using one of the official languages of the WTO (English, French or Spanish). In the latter case members can provide notifications in the original language, together with a list of amended laws and regulations, and description of their relevance to the TRIPs agreement.[42] Third, in order to make the review mechanism clearer and more transparent, the TRIPs Council uses a method called 'peer-group examination', allowing each WTO member to submit further inquiries to other members concerning their notifications .[43] The review process itself is divided into four subject areas: (1) copyrights and related rights; (2) trademarks, geographical indications and industrial designs; (3) patents, trade secrets, integrated circuits and anti-competitive practices; (4) enforcement. Evidence suggests that between 1996 and 1997, when WTO members reviewed the IP legislative changes undertaken by developed countries, the peer-group mechanism proved quite successful. For instance, in the four subject areas mentioned above, about 30 countries submitted more than 4100 questions regarding developed countries' notifications.[44]

The TRIPs Council is also responsible for coordinating and facilitating discussions on the agreement as a whole and, particularly, on items covered by the built-in agenda.

First, starting from the year 2000, when developing countries were expected to implement the agreement, the Council for TRIPs needs to review the agreement in order to decide which IP areas require renewed assessment or modification (Art. 71.1).

Second, the Council for TRIPs has to examine the issue of 'non-violation' disputes – disputes over alleged IP violations that, in themselves, did not conflict with TRIPs obligations. Art. 64.2 provided for a five-year moratorium, ending in January 2000, on the use of the DSU mechanism for resolving non-violation disputes, including cases in which WTO members felt that their benefits from the TRIPs agreement were nullified or impaired due to such violations.[45] Subject to Art. 64.3, the Council for TRIPs should consider the scope and modalities for complaints of this kind (which are issued under subparagraphs 1(b) and 1(c) of Art. XXIII of GATT 1994) and submit its recommendations within the given five-year period.[46] To date (2000), the TRIPs Council has not been able to agree on a unified proposal. Countries such as Latvia, Colombia and Venezuela, feeling that not enough attention was given to this issue, proposed to extend the five-year moratorium period in order to allow the TRIPs Council more time to submit its recommendations.[47]

Third, WTO members are required to negotiate on the establishment of a registration system aimed at protecting the IPRs of geographical indications of wine (Art. 23.4). In addition, members need to consider whether to grant IP protection to geographical indications of products other than wines and spirits (Art. 24.1 and 24.2).[48] In 1999, a few WTO members (Turkey, CEFTA countries), proposed the extension of the scope of protection of geographical indications to products such as rice, tea, beer and so on.[49] As before, WTO members could not agree on the expansion of geographical indications at the end of the Seattle ministerial conference in November 1999.

Fourth, and of greatest importance to the pharmaceutical industry, TRIPs Council should review the current WTO state of play by the end of 1999, as provided by Art.27.3b, which allows members to exclude from patentability certain types of biotechnological inventions based on gene manipulation (also referred to as 'life-patenting').[50] Given its relevance to the advanced pharmaceutical industry in Europe, the issue of life-patenting is discussed in depth later.

Finally, in 1998 the Council for TRIPs was given the task of exploring the domain of IPRs in electronic commerce, including the protection of copyrights, trademarks and new internet-based technologies in general.[51] Examining IPRs and electronic commerce was part of a comprehensive work programme launched at the end of the WTO ministerial conference in May 1998.

To date, the international IP system established under the TRIPs agreement is more protective and more binding than any other available international

IP institutions, such as WIPO. Established on the basic WTO principles of national treatment and most-favoured-nation treatment, the TRIPs agreement specifies the minimum standards of IP protection required by member states. It incorporates previous IP treaties and, using its own provisions, provides a detailed technical guide for IP protection. It also set clear implementation dates for developed (1996) developing (2000) and least-developed countries (2006). TRIPs' mechanisms for dispute settlement and enforcement greatly enhance its operational capacity. The former allows WTO members to use the DSU process: indeed, the US and the EU have actively used the DSU in order to resolve TRIPs-related disputes. The latter requires WTO members to adopt civil, judicial and criminal procedures, including tools such as specific injunctions, damages for injuries, destruction of infringed goods and border control measures, which allow for the effective enforcement of IPRs.

The Council for TRIPs is the main body responsible for the administration, operation and timely implementation of the TRIPs agreement. In order to monitor members' compliance with TRIPs obligations, the Council uses a special system of notification, which requires members to notify it of the legislative changes undertaken in order to align members' domestic IP laws with the TRIPs agreement. The Council is also responsible for facilitating discussions and negotiations occurring under TRIPs built-in agenda. Members are required to consider the extent to which the TRIPs agreement needs to be modified as a whole, and to evaluate specific provisions concerning the five-year moratorium on non-violation disputes, the IP protection on geographical indications, and the granting of patent protection to technologies and techniques based on gene manipulation (biotechnological inventions).

6.4 TRIPS BUILT-IN FLAWS

Though in essence TRIPs' major objective is to increase the global level of protection granted to IP owners, TRIPs provisions also aim to protect the public in general, and countries with low IP capabilities in particular, from the negative consequences of an international regime of IPRs. These provisions are flawed. Two areas are particularly striking: (1) lack of efficacy in the elimination of anti-competitive practices by IP owners, and (2) insufficient assistance to countries with low IP capabilities, particularly in the rapid transfer of technologies to developing countries and LDCs in exchange for their commitments to a stronger IP environment. These are discussed below

6.4.1 Lack of Efficacy in the Elimination of Anti-competitive Practices

A regime of IPRs may trigger anti-competitive and even abusive behaviour.[52] Practices may include exploiting IPRs in order to create a cartel (pooling or

cross-licensing agreements), the creation of an advantage outside the market where the innovation took place (tying arrangements and exclusive dealings), the purchase and selling of technologies for reduced or excess prices, restrictions on the use of licensed technologies, and so on.[53] IP holders can also adopt strategies aimed at expanding the scope and duration of their market monopolies. According to Machlup, patentees may choose to engage in the 'successive patenting of strategic improvements (either by timing or delaying their R&D efforts) which make the unimproved inventions commercially unusable after the expiration of the original patent'.[54] Moreover, as mentioned in Chapter 3, patent owners tend to disclose partial and incomplete information to the patent office thereby forcing competitors to invest additional resources in order to obtain essential know-how capabilities.

Despite the above, it is very difficult, if not impossible, to make a distinction between abusive practices embedded in the international IP system, particularly due to its monopolistic and restrictive features, and abusive practices occurring beyond the system. Penrose had already made this point with regard to patents back in the 1950s: 'The term "abuse of the monopoly" is extraordinarily misleading. For the most part the so-called "abuses' are merely some of the costs that are inherent in the patent system and are only rarely connected with any malpractices on the part of the patentees.'[55] Furthermore, some practices, such as corporate mergers, which are not directly related to the field of IPRs, may have a profound effect on the state of competition in a given IP area. For instance, the Ciba-Geigy/Sandos merger (now Novartis) raised serious questions about the overall competitive and innovative structure of the market for gene therapy in Europe.[56] The merger was approved only after both companies, which at the time were the dominant IP players in that field, agreed to certain compulsory licence conditions.[57]

Facing the risk of abusive behaviour on the one hand, and the difficulty of identifying such phenomena on the other, the TRIPs agreement lacks the practical ability to prevent anti-competitive practices. Art. 8.2 provides a general, albeit vague, statement on this issue: 'Appropriate measures, provided that they are consistent with the provisions of this agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect international transfer of technology.' What makes Art. 8.2 ineffective is the absence of specific provisions that describe, in greater detail, various practices that may be considered abusive under a regime of IPRs. One exception is TRIPs' reference to anti-competitive practices in contractual licensing. TRIPs states that some licensing practices or conditions pertaining to IPRs 'may have adverse effect on trade and may impede the transfer and the dissemination of technology' (Art. 40). Though not elaborating which contractual practices may be considered abusive, Art. 40.2 does allow for WTO members to make such

specifications under their own domestic laws. The article also provides a few examples of abusive contractual practices: (1) exclusive grantback conditions – when a licensor forces a licensee to grant him or her the exclusive use of any improvement to the licensed technology; (2) conditions which prevent the licensee from challenging the validity of a patent, and (3) coercive package licensing which forces a licensee to acquire from the licensor technologies in excess of those required by the former.[58]

6.4.2 Insufficient Assistance to Countries with Low IP Capabilities

WTO members with low IP capabilities, mostly LDCs but also developing countries, are bound to face considerable obstacles in the process of TRIPs implementation. Many of these countries have incompatible, and in some cases non-existent, IP mechanisms both at the legislative and operational levels.[59] For LDCs in particular, the combination of low-technological basis, non-industrialized economy, and insufficient public IP awareness, would make it very difficult to establish an IP environment suitable for the TRIPs agreement.[60] In these countries, the costs expected from the increase in IP protection also include administrative costs. In Bangladesh, where partial IP mechanisms existed prior to TRIPs, the expected costs of judicial work concerning the agreement were estimated at more than $1 million annually over the 10-year implementation period, plus $US 250 000 one-time costs for legislative drafting.[61] Estimates did not include recruitment and training of new staff and the establishment of adequate institutions for the enforcement of IPRs in that country.

Hence, there is strong linkage between the level of assistance provided to countries with low IP capabilities and their ability to implement the TRIPs agreement. In fact, three different articles in TRIPs require that developed countries provide technological, technical and financial assistance to countries with low IP capabilities, particularly to LDCs. Referring to technology transfer in general, Art.7 states that

> the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social economic welfare and to a balance of rights and obligations.

More specifically, Art. 66.2 requires that developed countries provide incentives to enterprises and institutions in their territories in order to promote technology transfer to LDCs. According to Art. 67, developed countries should provide technical and financial assistance to developing countries and LDCs.

Despite such requirements, the current state of play (2000) suggests that IP-intensive countries (that is developed countries) do not provide adequate

assistance to countries with low IP capabilities. Maskus argues that lack of active technology-transfer initiatives from developed countries generates 'concerns that technology exporters do not intend to employ TRIPs in a manner that would be seen as internationally equitable by technology importers'.[62]

Moreover, lack of clear mechanisms and specifications regarding the transfer of technologies, and assistance in general, to countries with low IP capabilities makes this aspect of TRIPs even more problematic and incomplete. UNCTAD, in its *Least Developed Countries 1998 Report*, noted that although 'the promotion of technological innovation of transfer of technology is one of the objectives of the TRIPs Agreement, there are hardly any operational provisions to put it into effect'.[63] A number of LDCs, such as Haiti, asked the Council for TRIPs to put the issue of technological assistance (Article 66.2) on top of its agenda, as they were uncertain about the ways in which developed countries carried out their obligations.[64]

During preparations for the Seattle Ministerial Conference in 1999, several LDCs and developing countries emphasized the weakness of the TRIPs agreement with regard to technological and technical assistance. Colombia, for instance, proposed to amend Art. 7 – the transfer and dissemination of technologies – in order to give it 'teeth'. It argued that 'so far no specific mechanisms have been implemented to attain this objective'.[65] The 'African Group', represented by Kenya, proposed to improve Art. 66.2 – incentives to LDCs – in order to make it much more effective and operational.[66]

It should be noted, however, that some progress has been made in the area of technical assistance, particularly by inter-governmental agencies. International organizations and institutions, such as WIPO, the World Bank, and the WTO itself, provide technical, educational, and to some extent technological, assistance to LDCs in order to promote TRIPs benefits in these countries.[67] In this regard, Primo-Braga and Fink identified four main areas of assistance to developing and least developed countries:[68]

1. Supporting the IP reform process – whereby inter-governmental organizations could serve as 'honest brokers' in raising awareness to the pros and cons of IPRs.[69]
2. Implementing reforms and building IP institutions – using bilateral and multilateral assistance (training patent examiners, promoting the use of modern information and communication technologies in the area of patents and trademarks, and so on) that could lead to cost-effective IP administration and also promote international cooperation.
3. Enhancing the environment under which IPRs operate – developed countries and non-governmental agencies should assist countries with low IP capabilities to develop 'benign' IP policies, such as those focusing on competition rules, access to biological materials and the protection of

traditional knowledge. Assistance should also focus on technical elements, such as licensing and material transfer agreements.

4. The final aspect focuses on improving and increasing the understanding of the social and economic effects of IP protection. Here, Primo-Braga and Fink argue that international organizations and agencies could sponsor more research focusing on the role of IPRs in the economic development process, using country-specific and sector-specific data.[70]

Thus, while the TRIPs agreement is a priori biased in favour of the interests of IP intensive countries, it also presumes to restrict potential abusive acts undertaken by IP owners, as well as creating a system of incentives for countries with low IP capabilities. The TRIPs agreement is ineffective in both aspects. In the case of the former, and in spite of a wide range of non-competitive and abusive practices that are linked to IPRs, it is very difficult to make a distinction between practices embedded in the international IP system and practices undertaken beyond it. That, combined with the fact that Art. 8.2 in TRIPs is too general, reduces the ability of the TRIPs agreement to establish adequate mechanisms that would limit the potential and actual IP anti-competitive and abusive practices.

The TRIPs agreement is also highly problematic with respect to the technological, technical and financial assistance provided to countries with low IP capabilities, particularly LDCs. TRIPs provisions offer little information about the ways, methods, timetables and the level of assistance that should flow from developed countries to developing countries and LDCs. Inadequate assistance to these countries is particularly acute in light of the considerable short-term and medium-term costs that countries with low IP capabilities should expect from implementing a strong IP regime such as TRIPs.

6.5 TRIPS PHARMACEUTICAL IP AGENDA

The TRIPs agreement may be regarded both as an agenda-setting tool and as a binding legal contract. As an agenda-setting tool it established a highly favourable environment for pharmaceutical IP owners. This is also the case with TRIPs as a contract. Yet, like any other legal agreement, TRIPs provisions are also open to interpretation, and therefore to dispute, the results of which are not always compatible with the interests of the advanced pharmaceutical industry. Naturally, the two dimensions are linked, not least because the agenda-setting dimension defines the range of IP issues that are subject to interpretation (agenda-determined issues).

This book is ultimately concerned with the IPE nature of IPRs. The following section focuses primarily on the agenda-setting perspective of TRIPs as regards

to pharmaceuticals. It does so by reviewing specific TRIPs provisions relevant to the pharmaceutical field. Agenda-determined issues pivotal to the advanced pharmaceutical industry are also mentioned in the section, yet mostly as a preparation for a more detailed discussion in Chapter 8.

6.5.1 TRIPs Patents – an Enhanced International Patent Regime

The most significant achievement for the advanced pharmaceutical industry concerning the TRIPs agreement is the granting of patent protection for pharmaceutical products and processes. One should bear in mind that, prior to TRIPs, more than 50 countries did not grant patent protection to pharmaceutical products and processes at all but granted patentability only to pharmaceutical processes.[71] The following elements are particularly important to the TRIPs 'patent-regime'.

Patentable subject matter

According to Art. 27.1, patents shall be available for any invention, whether products or processes, in all fields of technology (that is including the pharmaceutical sector), provided that they are new, involve an inventive process and are capable of industrial application.[72] No less important, the TRIPs agreement explicitly applies the principle of non-discrimination when stating that 'patents shall be available and patent-rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'(Art. 27.1).

The TRIPs agreement also lays down the circumstance under which members can choose to exclude inventions from patent protection. First, members can deny patentability of inventions in order to protect *ordre public*, morality (including human, animal and plant life or health in general) and the environment, provided that the exclusion was not adopted strictly because their domestic laws prohibit the commercial exploitation of these inventions (Art. 27.2). Secondly, according to Art. 27.3a, members may exclude from patentability diagnostics, therapeutic and surgical methods for the treatment of humans or animals. Finally, Art. 27.3b allows members to prohibit the patenting of plants and animals, excluding micro-organisms, and essentially biological processes for the production of plants and animals, excluding non-biological and microbiological processes.[73] However, members are required to protect the IPRs of plant breeders either by patents or by any other effective *sui generis* system based on plant breeders' rights (PBRs). The provisions laid down in Art. 27.3 should have been subject to revision by the Council for TRIPs as of 1999. To date (2000), no decision has been made. This may not come as a surprise given that Art. 27.3b is closely linked to the wider issue of gene patenting, also known as 'patenting life'. As discussed in Chapters 7 and 8, the interpretation of Art. 27.3b became a

source of conflict between developed and developing countries during the 1999 ministerial meeting.

Exclusive rights and exemptions deriving from TRIPs patents

Exclusive patent rights for products and processes are described in Art 28. Generally speaking, the patentee has the exclusive right to prevent others from making, using, offering for sale, selling or importing (excluding parallel imports) the patented product or process without his consent.

Subject to their transitional arrangements (1996: developed countries, 2000: developing countries, 2005: LDCs) WTO members are also obliged to provide full protection to existing patents, that is patents granted to products and processes prior to the TRIPs agreement (Art. 70.2).[74]

WTO members can adopt limited exceptions to the rights conferred by a patent, provided that such exceptions 'do not unreasonably conflict with a normal exploitation of a patent, and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties' (Art. 30).

In its current state, Art. 30 is too general and vague, paving the way for 'interpretational battles' between advocates of stronger patent protection, such as the advanced pharmaceutical industry in Europe, and advocates of weaker patent protection. Two interpretational approaches should be cited. According to Blakeney, exemptions to exclusive patent rights include the following: (1) compulsory licensing in the public interest; (2) manufacture or use of the patented product for the sole purpose of scientific research and experimentation, and; (3) cases where third parties had, in good faith, manufactured or used the patented product prior to the patent application (simultaneous inventions for example).[75] A similar view is expressed by UNCTAD, which emphasized the use of patented products and processes for scientific and experimental purposes.[76] Pro-industry views, on the other hand, tend to minimize the extent to which Art. 30 may be used. Such is the approach of the International Chamber of Commerce arguing that 'it is impossible to foresee if and to what extent member countries may, in fact, abuse this provision (Art. 31)'.[77] As elaborated upon in Chapter 8, the interpretation of Art. 30 played a crucial role in the dispute between the EU and Canada regarding commercial experimentation in patented pharmaceutical products (so-called 'Bolar' exemptions).

Increased term of patent protection

Art. 33 established that the patent term of protection shall be no less than a period of 20 years from the filing date. Following this Article, both the term itself and its starting point are a major achievement for patent owners. Pre-TRIPs legislation in many countries, mostly developing but also developed, provided shorter patent term of protection. This varied between 5 to 15 years

for the group of developing countries and between 16 to 20 years for the group of developed countries.[78]

There were also discrepancies concerning the starting point of the patent term. In some countries, such as Argentina, Portugal, Spain and the US, the patent term began from the date it was granted, while in other countries, such as the UK, Germany and France the patent term was calculated from the date of filing.[79] For example, the US allowed for a patent term of 17 years from the date of the grant.[80] Hence, setting a minimum period of 20 years is a considerable increase in the global term of protection provided to patents. Moreover, by harmonizing the term of protection according to the filing date, the TRIPs agreement prevents third parties from using the information embodied in the patent filing applications without the applicant's consent.[81]

Compulsory licensing – putting binding conditionality on the mandatory use of patents

The TRIPs agreement also addresses the issue of compulsory licensing of patents, that is the use of a patent by the government, or third parties authorized by the government, without the patentee's consent (Art. 31).

Two elements in the TRIPs agreement make the issue of compulsory licensing in pharmaceuticals particularly beneficial to the advanced pharmaceutical industry. First, the granting of compulsory licences must not discriminate between different fields of technology. That is a result of Art. 27.1 – non-discrimination – and Art 31.i, stating that 'the authorisation of such use shall be considered on individual merits'. Prior to TRIPs, several member countries, such as India and Canada, explicitly allowed the use of compulsory licensing in patented pharmaceuticals products.[82] Second, under TRIPs, compulsory licensing cannot be easily granted on the basis of insufficient working of the patented invention. Originally, the non-working of a patent (patents that are not utilized for production purposes in the granting country) was a primary justification for the granting of compulsory licences, as indeed mentioned in Art. 5A(2) of the Paris Convention.[83] By omitting any reference to the non-working issue in Art. 31, and by implying that sufficient working can also be based on the importation of patented products (Art. 27.1), TRIPs greatly reduced the validity of compulsory licences on such grounds.[84]

Members can use compulsory licences only if they were unable to obtain voluntary authorization from the right-holder 'on reasonable commercial terms and conditions and within a reasonable period of time' (Art. 31b). Once authorization for compulsory licensing is granted, member countries are required to pay adequate remuneration to the patentee according to the circumstances of each case, taking into account the economic value of the licence (Art. 31h). The TRIPs agreement also put conditionality on the compulsory licensing of dependent patents – cases in which the granting of a compulsory licence on a

given patent infringes the rights of another patent. Dependent patents are mostly improvements to inventions that have already received patent protection. Here, the licence may be granted only if the dependent patent involves 'an important technical advance of considerable economic significance in relation to the invention claimed in the first patent' (Art. 31li*)*. The patentee of the original invention shall also be entitled to remuneration in the form of a cross-license (Art. 31lii).[85]

Finally, compulsory licence may be used in cases of national emergencies, such as health hazards. Art. 8.1 allows members to adopt measures necessary 'to protect public health and nutrition, and to promote the public interest in sectors of vital importance'.[86] Until 2000, the interpretation of this provision was highly disputable. Referring to Art. 8.1, the WHO argues that 'if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy, such as a vaccine against Aids or malaria, it should be possible to grant an ex officio (compulsory) license'.[87] The advanced pharmaceutical industry, on the other hand, strongly objected to this line of interpretation and argued that the use of compulsory licence should be subject to strict criteria concerning the nature of the disease and the scope of the crisis in any given country.[88] However, the recent WTO Ministerial declaration on TRIPs and Public Health (held in Doha, November 2001) reasserted the mandate of WTO members to use compulsory licences under conditions of national emergency. As noted in article 5c of the declaration:

> 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.[89]

The events and circumstances leading to the adoption of the Doha declaration on TRIPs and Public Health are discussed in greater detail in Chapter 9.

Special provisions relating to pharmaceutical and agrochemical patents

Developing and least-developed countries that did not grant patent protection to pharmaceutical and agrochemical products prior to the agreement are required to take specific patent 'protection building measures' during their transition periods (2000 and 2004 respectively).[90] In essence, the TRIPs' goal is to reduce any further delays in the patentability of these products, given that there is a considerable time-gap between a patent application and a patent grant in the pharmaceutical and agrochemical fields (more than 10 years).[91]

First, subject to the conditions laid down in Art. 70.8, developing and least-developed countries must provide adequate facilities for pharmaceutical and agrochemical patent applications (so called 'mailbox applications').[92] Second, such applications must be judged according to the patent criteria of the TRIPs

agreement (Art. 70.8b). Third, once their implementation period has expired, WTO members must protect any approved patent for the remainder of its term, commencing from its filing date (Art. 70.8c). Finally, in the unlikely event that a product is approved for market use before a decision to grant it patentability is made, developing countries and LDCs are obliged to grant it exclusive marketing rights (EMRs).[93] Market exclusivity will be granted for a period of up to five years, or until the patent is rejected or expires, whichever period is the shorter (Art 70.9). EMRs shall be granted only when the following conditions exist: the product concerned is a genuine invention, a patent application was filed, and another member granted patentability to that product and approved it for market use.[94]

However, in cases were there are no patent applications pending, the TRIPs agreement does not require that market exclusivity should also be granted to pharmaceutical products that enjoyed patent protection in the source countries.[95] This kind of retroactive protection (usually referred to as 'pipeline protection') was highly desired by the advanced pharmaceutical industry.[96] For instance, the IFPMA argued that the lack of pipeline protection in Art. 70.9 'delayed substantially any practical benefits from this provision'.[97]

The TRIPs agreement, therefore, secures a considerable increase in the global protection of patents. Most importantly, patents shall be granted, on a non-discriminatory basis, to all fields of technology, including pharmaceuticals, regardless of the issue of 'non-working'. The extensive patent rights guaranteed by TRIPs enable patentees to have much greater control, or even a monopoly, on the use of their inventions, both by themselves and by others. Patents also enjoy a longer term of protection: a minimum period of 20 years from the date of filing. The exclusion from patentability can be based on issues concerning public order and morality, the environment, health emergencies and life-patenting. It cannot be based on economic calculations concerning the commercial exploitation of a patent. Patent rights may be violated mainly for non-commercial purposes, such as academic research, yet without prejudice to the interests of the patentee. Compulsory licences, though authorized, are subject to restrictive and binding conditions including the principle of non-discrimination, avoiding the granting of a licence on the basis of non-working, and compensating the patentee in exchange for that licence. Finally, developing countries and LDCs are also required to establish adequate facilities (mailbox procedures) for pharmaceutical and agrochemical patent applications during their transition periods.

6.5.2 TRIPs Trademarks – Securing a Global System of Brand Proliferation

One of the most important elements of TRIPs provisions concerning trademarks is to secure a global system of branded services and goods, including

pharmaceutical products. These provisions are closely linked to the Paris Convention, as revised in 1967 in Stockholm.[98]

A few elements should be mentioned. First, Art. 15.1 establishes that a trademark may be given to any sign or combinations of signs (words, letters, numerals, figurative elements, colour combinations) capable of distinguishing the goods and services of one undertaking from other undertakings. Moreover, WTO members are obliged to protect well-known trademarks, subject to the conditions laid down in Article 6*bis* of the Paris Convention, that is not to allow domestic companies to use well-known foreign marks.[99] When refusing to register a trademark, WTO members are to rely on the conditions laid down in the Paris Convention (Art. 15.2). For instance, members may refuse to register trademarks that contradict 'morality and public order' or which 'deceive the public'.[100]

Second, non-discriminatory treatment is established by Article 15.4, according to which 'the nature of goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark'.[101]

Third, exclusive trademark rights include the right to prevent third parties, not having the owner's consent, from using identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered (Art. 16.1). As a specific example, generic-based drugs cannot have trademarks that are similar or identical to the original pharmaceutical product.[102] In other words, under the TRIPs agreement it is very difficult, if not impossible, to carry out policies which aim at the product amalgamation of identical drugs. IP owners also enjoy the exclusive right to set conditions for the licensing of their trademarks (Art. 21). The compulsory licensing of trademarks is prohibited (Art. 21).

Fourth, the trademark term of protection is indefinite, provided that it is constantly renewed after a period of no less than seven years (Art. 18).

Finally, and particularly relevant to branded pharmaceutical products, the TRIPs agreement requires that the use of a trademark shall not be unjustifiably encumbered by special requirements, such as use with another trademark or the use of the trademark in a special form or manner (Art. 20).[103] According to Gorlin, pre-TRIPs legislation in several developing countries, such as Brazil, concerning the labelling of branded pharmaceutical products required that the size of the trademark would be smaller than the name of the generic substance.[104] Alternatively, countries required that the packaging of such products would be of a certain colour, effectively making the trademark much less recognizable.[105] Henceforth, activities aiming to reduce the distinctiveness of branded products, as opposed to generic ones, are prohibited by the TRIPs agreement. However, in cases where foreign branded products are produced locally, Art.20 does allow WTO members to demand that the trademarks of such products be accompanied by the names of local producing companies.[106]

Thus the TRIPs agreement allows pharmaceutical IP owners to use the international trademark system as an effective tool for differentiating their products from generic substitutes, which may, to all purposes, be identical to the source products.

6.5.3 TRIPs and Undisclosed Information – Protecting Trade Secrets Globally

One of the most innovative elements of the TRIPs agreement is the obligation to protect trade secrets. In fact, TRIPs is the first international agreement ever to require such a protection.[107] The effect of TRIPs on trade secrets is twofold: reclassifying trade-secrets as IPRs, and expanding their scope to include pharmaceutical and agrochemical data submitted to regulatory authorities for the purpose of obtaining market approval. The latter was particularly revolutionary, as prior to TRIPs many countries (including India, Argentina, Chile, New Zealand and Canada) provided little or no IP protection, to pharmaceutical and agrochemical registration data.[108] Not surprisingly, Switzerland, the EC and the US were the strongest advocates of IP protection for trade secrets and registration data during the Uruguay Round negotiations.[109]

With regard to the categorization of trade secrets, Art 39.1 established that in order to prevent unfair competition, as defined in Art.10*bis* of the Paris Convention, members shall protect undisclosed information and data submitted to governments and governmental agencies.[110] Pursuant to Art. 39.2, WTO members shall allow natural or legal persons to prevent information lawfully within their control from being disclosed, obtained, or used without their consent in a manner contrary to honest commercial practices.[111] In order to be protected, undisclosed information must fulfil three criteria: (1) it must be secret in the sense that it is not generally known or accessible to persons who normally deal with this kind of information (Art. 39.2a); (2) it must have commercial value because it is secret (Art. 39.2b), and (3) reasonable steps were taken by the owner of that information to keep it secret (Art. 39.2c).[112]

As to registration data, Art. 39.3 requires WTO members to protect pharmaceutical and agrochemical information submitted to regulatory authorities, such as the results of clinical trials, for the purpose of obtaining product-marketing authorization. WTO members are obliged to protect such data both against unfair commercial use, that is by rival companies, and against disclosure, except when it is necessary to protect public health.[113] This new form of IP protection is usually referred to in the professional literature as 'data exclusivity'. Clearly, data exclusivity is one of the most prominent elements of TRIPs concerning pharmaceutical products. However, Art. 39.3 leaves two major issues unresolved. First, it does not specify the minimum or maximum period of data exclusivity required by WTO members (the term of data exclusivity

in Europe and in the US is 10 and 5 years respectively). Secondly, Art. 39.3 is not clear-cut when referring to the use of such information by the authorities, particularly in cases of indirect reliance, when a member country may choose to rely on the proprietary information of the original product in order to compare it to the chemical and toxic levels of a potential generic substitute (via bio-equivalency tests).

6.5.4 The International Exhaustion of IPRs – Adopting a Global Policy of Parallel Imports

That the pharmaceutical agenda established by the TRIPs agreement is highly beneficial to IP owners is in sharp contrast to TRIPs provisions concerning the global parallel imports of IP-based pharmaceutical products. Activity of such a kind relates mostly to the importation of patented pharmaceutical products from low-price countries into high-price countries, through channels other than those authorized by the local patentee or licensee. In order to make the global parallel import of patented pharmaceuticals or any other patented products legal, countries must adopt the principle of international exhaustion. Specifically, they must enter into an agreement stating that, once a patentee has sold his product in one country, he/she has exhausted his/her right to prevent the resale of that product to other countries.[114]

Though not explicitly recognizing the principle of international exhaustion, the TRIPs agreement essentially allows for parallel imports to take place under its newly-established IP regime. It does so by denying members the possibility of bringing cases concerning international exhaustion to the DSB. As stated in Art. 6: 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 (National Treatment and MFN), nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.' In order to avoid confusion, TRIPs also links Art. 6 to Art. 28 (exclusive patent rights) via a footnote to the latter, stating that 'this right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods is subject to the provisions of Article 6' (footnote 6 to Art. 28).

IP sceptics consider the establishment of a global parallel import regime under TRIPs as a blessed anomaly. For instance, protecting the notion of parallel imports, Abbott argues that 'rules prohibiting parallel importation are non-tariff barriers to trade that are inconsistent with the general terms, structure and spirit of the WTO'.[115] Referring to pharmaceuticals specifically, the WHO stressed that the combination of Art. 6 and the footnote to Art. 28 'is very important in so far as it allows the supply of the product to be increased and prices to

be moderated through competition, in other words, improving accessibility through importation'.[116]

The advanced pharmaceutical industry in Europe, on the other hand, considers the above combination to be one of TRIPs most harmful elements. As dramatically put by the EFPIA:

> International exhaustion should be explicitly prohibited and the enforcement of such prohibition should be effective. This issue is pivotal for the pharmaceutical industry, as the spread of international exhaustion would negatively affect Europe's capacity to innovate, would create health risks and would be detrimental to the poorer countries. If this issue is not resolved the advances brought by TRIPs would be largely illusory.[117]

Fighting global parallel imports is an ongoing quest for the advanced pharmaceutical industry. It used, and is still using, sophisticated arguments against this phenomenon, such as that parallel imports reduce incentives for future pharmaceutical R&D; that they increase health risks due to reduced level of quality assurance and greater exposure to counterfeited drugs; and that they unjustifiably weaken the IP protection granted to pharmaceutical companies.[118] As discussed in Chapter 8, the industry also raised this point with respect to possible negotiations on IPRs during the WTO 1999 Ministerial Conference in Seattle.

6.6 CONCLUSION

An analysis of the TRIPs agreement leads to one major conclusion: since 1995 the newly-established international IP system is designed primarily to serve the interests of IP owners, including those in the pharmaceutical domain, based in developed (IP-intensive) countries.

The emergence of the TRIPs agreement at the end of the Uruguay Round negotiations is, without a doubt, a result of heavy pressures exerted by the developed countries, notably the US, the EC, Switzerland and Japan. Motivated by powerful and influential interest groups, such as the pharmaceutical and film industries, these countries sought to include in the GATT framework an agreement that would secure and enforce their IP rights globally.

The structural elements of TRIPs make it the most robust and comprehensive international agreement to be reached on IPRs to date. Being part of the WTO agreements, the TRIPs agreement endorses the basic principles of national treatment and most-favoured-nation treatment. It also incorporates the major international IP treaties: the Paris Convention (1967), the Berne Convention (1971), the Rome Convention (1961) and the IPIC Treaty (1989). Moreover, the TRIPs agreement specifies the minimum standards of IP protection required by

member states in the areas of copyrights, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and the protection of undisclosed information. The implementation dates of TRIPs are also well defined: developed countries – January 1996, developing countries – January 2000, LDCs – January 2006 (Art. 65).

TRIPs operational capacity is guaranteed by three pivotal mechanisms. The first concerns IP-related disputes: subject to the provisions of Art. 63, WTO members can use the dispute settlement process in order to resolve IP-related disputes. Indeed, empirical evidence suggests that between 1995 and 1998 IP-related disputes accounted for about 10 per cent of total WTO disputes, and that the US and the EU were the most prominent users of the dispute settlement mechanism with respect to IPRs (many of which concerned pharmaceuticals). Second, in order to enforce the rights of IP owners and to prevent the infringement of IPRs, WTO members must adopt civil, judicial and criminal procedures in accordance with TRIPs requirements (Art. 41–62). The third component relates to the Council for TRIPs – the main body responsible for monitoring and facilitating members' compliance with the agreement (Art 68). In its administrative role the Council for TRIPs uses a special system of notifications, aimed at providing accurate information about the IP legislative changes undertaken by WTO members as part of their TRIPs commitments. In its consultative role, the Council operates as a focal point for negotiations on IPRs within the TRIPs framework in general, and on TRIPs' built-in agenda in particular.

Despite the above elements, and possibly because of them, the TRIPs agreement is ineffective in dealing with the possible negative implications of an international regime of IPRs, particularly in countries with low IP capabilities. TRIPs has two major built-in flaws. First, TRIPs (Art. 8.2) is quite vague and too general in dealing with potentially abusive practices undertaken by IP owners. Not only does TRIPs not specify which practices may be considered abusive under a regime of IPRs, it also fails to provide the necessary guidelines for dealing with such practices once they have occurred. Second, the TRIPs agreement lacks the effectiveness to oblige developed countries to provide financial, technical and technological assistance to developing countries and LDCs. The agreement has numerous provisions that aim to increase the flow of assistance from countries with strong IP capabilities to countries with weak IP capabilities (Art. 7, Art. 66.2, Art. 67) yet, thus far, it seems that the latter, particularly LDCs, have received neither the assistance required for the successful implementation of TRIPs nor the compensation needed for committing themselves to a much more rigorous IP agenda. In fact, it is inter-governmental agencies, such as the WTO, the World Bank and WIPO, that provide most of the assistance to LDCs, usually in the form of training.

The pharmaceutical IP agenda established by the WTO TRIPs framework is very impressive. Patent rights are probably the most essential component of the TRIPs pharmaceutical IP agenda (Art. 27–34).

The TRIPs agreement secures and increases the global protection of patented pharmaceuticals by focusing on several key aspects. First, it states that patents shall be granted, on a non-discriminatory basis, in all fields of technology, including pharmaceuticals. Second, under the TRIPs agreement patent owners have a considerable amount of monopolistic control on the uses of their inventions. They have the exclusive right to prevent others from making, using, offering for sale, selling or importing (except in cases of parallel imports) the patented product or process. Third, the term of patent protection granted to pharmaceutical products and processes must be at least 20 years from the date of filing. Given that during the pre-TRIPs era many countries, mostly developing and least-developed countries, granted much shorter terms of protection to pharmaceutical patents, the 20-year-period may be truly considered revolutionary. Fourth, the TRIPs agreement put restrictive and binding conditions on the use of compulsory licensing. When granting compulsory licences, WTO members must not discriminate between different fields of technology (as many countries did in the case of pharmaceuticals prior to TRIPs). Finally, the TRIPs agreement explicitly recognizes the need to make patent rights available in the pharmaceutical and agrochemical fields in developing countries and LDCs (Art. 70.8). These countries were required to establish administrative facilities for the processing of pharmaceutical and agrochemical patent applications (mailbox procedures) as soon as the agreement came into effect in 1996.

The trademark system established by the TRIPs agreement greatly enhances the ability of pharmaceutical IP owners to exploit their branded products internationally (Art. 15–21). As in the case of patents, pharmaceutical IP owners can register and obtain trademark protection without being discriminated against. Pharmaceutical trademark owners have the exclusive right to prevent others from using identical or similar signs for goods which are identical to their own trademarked pharmaceutical products. The TRIPs agreement does not put a time limit on the term of trademark protection, provided it is periodically registered.

Most important, the TRIPs agreement prohibits WTO members from placing special requirements on the use of trademarks for pharmaceuticals, such as the obligation to use a second mark that would make the exterior of brand-based drugs less distinctive. Hence, the TRIPs agreement allows pharmaceutical IP owners to use the international trademark system as an effective tool for distinguishing their branded drugs from the generic substitutes of other companies, even if these products are identical in purpose and quality.

Data exclusivity is one of the most innovative elements of TRIPs concerning the IP pharmaceutical agenda (Art. 39). Not only is TRIPs the first agreement

to treat trade secrets as IPRs, it also explicitly notes that pharmaceutical and agrochemical data submitted to regulatory authorities for the purpose of obtaining market approval (registration data) falls under this category. Practically, WTO members must grant IP owners the right to prevent information, lawfully within their control, from being disclosed, obtained, or used without their consent in a manner contrary to honest commercial practices. WTO members also need to protect the registration-data of pharmaceutical IP owners, both against unfair commercial use, that is by rival companies, and against the involuntary disclosure of such data, except when it is necessary to protect public health.

The parallel importation of patented pharmaceutical products is one element in the TRIPs pharmaceutical agenda that is strikingly inconsistent with the level of IP protection described thus far. The TRIPs agreement prevents WTO members from using the dispute settlement mechanism in cases concerning the international exhaustion of IPRs, thereby allowing for the parallel trade of patented products to take place under its international IP regime (Art. 6 and the footnote to Art. 28).

Overall, TRIPs provisions concerning the pharmaceutical IP domain are highly beneficial to the advanced pharmaceutical industry. They allow pharmaceutical IP owners to increase both the scope and the level of their control, or monopoly, in the international pharmaceutical trading and investment systems. In other words, under the TRIPs agreement, pharmaceutical IP owners are better equipped to secure their knowledge assets against potential competitors, say local companies in developing countries, and to exploit them commercially.

TRIPs provisions are thus open to interpretation and as such may lead to an increase or to a decrease in the level of IP protection provided to pharmaceutical products and processes. Indeed, since the TRIPs agreement came into effect in 1995, issues such as the 'patenting of life' experimentation in patented products and the effective patent term of protection, have become subject to a fierce debate between IP supporters and opponents. In order to preserve its achievements, the advanced pharmaceutical industry in Europe employed highly sophisticated tactics aimed at securing the current level of protection provided by TRIPs, as well as interpreting the agreement in a manner that would strengthen the level of protection provided by its provisions. These are discussed in the following chapters.

NOTES

1. In this text, the TRIPs agreement is also referred to as 'TRIPs' or as 'the agreement'
2. Reichman (1998: 585)
3. For the history of TRIPs see: Abbott (1989: 689–743); Stewart (1993a: 2245–333); Blakeney (1996: 1–9); Doane (1994: 465–97); Emmert (1990: 1317–99); for a pharmaceutical industry view of the negotiations see: Gorlin (1999: 1–8)

4. Abbott (1989: 712–14); Stewart (1993a: 2260–65); for pressures leading to the Uruguay Round mandate on IPRs see: Ryan (1998: 104–18)
5. Rice (1990)
6. Abbott (1989: 712–20); Emmert (1990: 1350–59); Beier and Schricker (1989); Maskus (1990: 165)
7. Stewart (1993a: 2262–4)
8. Montagon and Dulforce (1998); Abbott (1989: 712–20); Blakeney (1996: 2–7)
9. For the proposals of developed countries see: United States proposal to GATT (20 October 1987), document number: MTN.GNG/NG11/W/14; United States International Trade Representative (BNA, 1987: 1371); European Community proposal to GATT (7 July 1988), document number: MTN.GNG/NG11/W/26; Dulforce (1988); For the position of the IP-based industries see: Keidanren, UNICE and IPCI (1988); For the position of developing countries see Abbot (1989: 713–14)
10. Abbott (1989: 713–14); Montagon (1989a).
11. United States International Trade Representative (BNA, 1989: 469); Blakeney (1996: 6); Abbott (1989: 719)
12. Subramanian and Hartridge (1989: 893–910); Blakeney (1996: 6)
13. Abbott (1989: 719); Maskus (1994: 115); Winters (December 1990: 1288–303))
14. Gorlin (1999: 2–4); the list of developing countries included: Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe, document number: MTN.TNC/W/35/Rev.1
15. 'Draft Text on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeited Good 22 November 1990', document number: MTN.TNC/W/35/Rev.1 (3 December 1990)
16. Gorlin (1999: 2)
17. Otten (1997: 13); Montagnon (1989b)
18. Blakeney (1996: 6–7); GATT (1991), document number: MTN.TNC/W/89/Add.1; Stewart (1993a, 2276–80)
19. The formal name of the Dunkel Draft is: 'Draft Final Act Embodying the Results of the Uruguay Round of the Multilateral Trade Negotiations'
20. Reichman (1998: 585–6)
21. Blakeney (1996: 6–7); Intellectual Property Committee (US) (1991); *The Economist* (1992)
22. INTERPAT (1992); a letter addressed to the UK Department of Trade and Industry from Dai George, ABPI Director of Science and Intellectual Property, concerning ABPI comments on the TRIPs Agreement (7 January 1992), in author's records; UNICE (1991); UNICE (1990), in author's records; Intellectual Property Committee (US) (1994a); letter by PMA Senior Vice President, Dr. Harvey Bale, addressed to principal members of the International Section Administration Committee and Intellectual Property Task Force (EFPIA, PMA, ABPI) concerning a preliminary analysis of the GATT TRIPs text, 23 December 1991; pipeline protection is discussed later in the chapter
23. Uruguay Round Ministerial Declaration (20 September 1986); the TRIPs Agreement opening statement is as follows: 'Desiring to reduce distortions and impediments to trade, and taking into account the need to promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade'
24. Blakeney (1996: 40–42)
25. In this text the term 'Art.' stands for the term 'Article'
26. See: TRIPs agreement, Art. 2 and footnote 2; *Text of the Agreement between WIPO and WTO*, Geneva (22 December 1995); Blakeney (1996: 20–24)
27. WTO Annex 2, *Understanding on Rules and Procedures Governing the Settlement of Disputes*
28. For an overview of WTO dispute mechanisms see: WTO (1998: 38–42); Jackson (2000: Chapter 7)
29. WTO (1998: 38)
30. In fact, when reviewing disputes the General Council functions as the DSB
31. WTO (1998: 39–41)

32. Ibid.
33. Ibid., p. 39
34. WTO Secretariat (2000).
35. Ibid.
36. Otten (1998: 527–9)
37. Ibid., p. 528
38. For the case of India see: WTO DSB (5 September 1997c), document number: WT/DSB50/R; for the case of Pakistan see: WTO DSB (1997a), document number: WT/DS364/4; for the case of Canada see: WTO DSB (2000a), document number WT/DS114/R; Otten (1998: 528)
39. Blakeney (1996: 123–39); International Chamber of Commerce – ICC (1996: Chapter 12)
40. Geuze (September 1999); Otten (1998: 524–7); WTO – Council for TRIPs, 1996/7/8 Annual Reports (IP/C/8, IP/C/12 and IP/C/15 respectively)
41. Geuze (September 1999: 3)
42. Ibid., p. 4
43. Otten (1998: 524–7); Geuze (September 1999: 4–5)
44. Ibid.
45. This is a suspension of subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, as embodied in the WTO DSU mechanism
46. WTO – Council for TRIPs (1998a)
47. Communication from the CEFTA and Latvia (Geneva: 27 July 1999), document number: WT/GC/W/275; Also see: Communication from Columbia (14 September 1999), document number: WT/GC/W/316; WTO, Communication from Venezuela, (6 August 1999), document number: WT/GC/W/282
48. Otten (1998: 531–2); Geuze (1999: 13–14)
49. Communication from Turkey (13 July 1999), document number: WT/GC/W/249; Geuze (1999: 14)
50. WTO – Council for TRIPs (1998a)
51. TRIPs Council, 1999, p. 4
52. For an overview on IPRs and non-competitive behaviour see: OECD (1998); European Communities and the Member States (1998)
53. OECD (1998: 7–12); European Communities and the Member States (15 September 1998: 8–10); see also UNCTAD (1975a: Chapter 3); UNCTAD (1996: Chapter 8); Yankey (1987: 24–38); Vaitsos (1972: 83–5)
54. Machlup (1958: 10)
55. Penrose (1951: 153); in this statement Penrose rejects claims against the 'abusive' behaviour of foreign patentees with regard to domestic firms. She argues that it is not the foreign patentees that are abusive but rather the system itself.
56. OECD (1998: 10)
57. Ibid.
58. Blakeney (1996: 113–18)
59. UNCTAD (1996: 19–26); ESCWA (1999: 15–20)
60. Primo-Braga and Fink (1998: 537–54 and Table 1)
61. UNCTAD (1996: 25)
62. Maskus (1999: 22)
63. UNCTAD, *Least Developed Countries 1998 Report* (1999: 162)
64. WTO – Council for TRIPs, Annual Report (1998a: 4)
65. Communication from Colombia, (14 September 1999), document number: WT/GC/W/316
66. Communication from Kenya on Behalf of the African Group (6 August 1999) document number: WT/GC/W/302
67. WTO – Council for TRIPs (Annual Report 1998a: 5); Abbott (1998a: 519–20)
68. Primo-Braga and Fink (1998: 553–4)
69. Ibid., 1998, p. 553
70. Ibid., pp. 553–4
71. UNCTAD (1996: 30); ESCWA (1998: 16); Nogués (1990b: 4)
72. For an overview of TRIPs patent provisions see: WHO (1997: 13–20); Blakeney (1996: 81–5)

73. For a discussion on IPRs and genetic materials see: Correa (2000: Chapter 6)
74. WHO (1997: 24–5)
75. Blakeney (1996: 87)
76. UNCTAD (1996: 33–4)
77. ICC (1996: 50)
78. UNCTAD (1975a: 54); US President's Commission on Industrial Competitiveness (1985: 15–19)
79. Ibid.
80. Gorlin (1999: 41)
81. Blakeney (1996: 88)
82. ESCWA (1998: 53)
83. Blakeney (1996: 88–9); UNCTAD (1975a: 43–4)
84. Blakeney (1996: 90–91); WHO (1997: 27–30); ESCWA (1999: 54); Otten (1997: 13–14)
85. Blakeney (1996: 93)
86. Ibid, p. 90; Maskus (2000: 21)
87. WHO (1997: 29)
88. PhRMA (1997: 12)
89. WTO, *Ministerial Declaration on the TRIPs Agreement and Public Health* (14 November 2001b)
90. WHO (1997: 22–4); ESCWA (1998: 56–7); Blakeney (1996: 94–5); Otten (1997: 15–16)
91. See the discussion in Chapter 4, section 4.4.2
92. WHO (1997: 22–5)
93. Ibid.; ESCWA (1998: 56–7)
94. Otten (1997: 16)
95. Ibid.
96. Doane (1994: 478–9)
97. IFPMA (1995a and b: 4)
98. Blakeney (1996: 53–67); ICC (1996: Chapter 5)
99. Blakeney (1996: 60–65)
100. Ibid., p. 55
101. Ibid., p. 53
102. For a discussion of trademark product amalgamation see Chapter 2, section 2.3.3
103. Blakeney (1996: 59); UNCTAD (1996: 42), ICC (1997: 31–2)
104. Gorlin (1999: 19–20); for additional pre-TRIPs requirements on the use of trademarks see: Maskus (2000: 20)
105. Gorlin (1999: 19)
106. ICC (1996: 20–21)
107. UNCTAD (1996: 46); Blakeney (1996: 102)
108. Abbott (1989: 743–4); Gorlin (1999: 46–7)
109. GATT Secretariat (1990: 17), document number: MTN/GNG/NG11/17; Stewart (1993a: 2307)
110. Blakeney (1996: 102–3); UNCTAD (1996: 46–8)
111. According to TRIPs, footnote 10 to Art. 39.2: 'A manner contrary to honest commercial practices shall mean practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failure to know, that such practices were involved in the acquisition'
112. Blakeney (1996: 103–4)
113. Ibid., p. 107; ICC (1996: 60–61)
114. Abbott (1998: 607–36)
115. Ibid., p. 635
116. WHO (1997: 17)
117. EFPIA (1999h: 2)
118. IFPMA (2000); IFPMA (1998: 50–54); Bale (1998: 637–53)

7. Opposition of developing countries and LDCs to the TRIPs pharmaceutical IP agenda

7.1 INTRODUCTION

Prior to discussing the strategies and activities of the advanced pharmaceutical industry in Europe (which aimed at exploiting and preserving the international pharmaceutical IP agenda established by the TRIPs agreement), it is important to investigate the controversy surrounding the agreement between 1995 and 1999. This places the activities of the advanced pharmaceutical industry in Europe in a broader and more accurate context.

The deep divide between north and south did not vanish with the coming into effect of the TRIPs agreement in 1995. On the contrary, the resentment of developing countries and LDCs increased as the revolution caused by TRIPs in terms of the global level of IP protection became more and more evident.

This chapter provides a brief overview of the opposition of developing countries and LDCs to TRIPs in general, and to its pharmaceutical IP agenda in particular, between 1996 and 1999. Opposition to TRIPs is divided into two periods:

- 1996 to 1998 – during which time criticism against TRIPs by developing countries and LDCs was rather mute.
- 1999 and onwards (particularly towards the WTO ministerial meeting in Seattle, November 1999) – when opposition to TRIPs became highly vocal and goal-orientated.

We demonstrate the above by examining the official statements and demands of WTO members during the ministerial meetings of 1996, 1998 and 1999.

7.2 REACTIONS TO TRIPS DURING THE WTO MINISTERIAL MEETINGS OF 1996 AND 1998

During the 1996 ministerial meeting, held in Singapore between the 9 and 13 December 1996, the TRIPs agreement was not considered a major issue for developing countries and LDCs.[1]

On balance, the agreement was greeted with mixed reactions, while criticism was usually made in a non-explicit manner. For instance, Colombia, in referring to the Uruguay Round consequences, argued that

> it is clear that while developed countries have expanded market access for their goods and services, adapted multilateral subsidy policies to their own needs and substantially increased the protection of their intellectual property rights, the developing countries still face serious restrictions in their access to external markets for products in respect of which they are naturally competitive.[2]

Botswana, stressing the importance of technical assistance to LDCs, made the following statement:

> Slow progress in providing technical assistance is an issue of serious concern to Botswana. Many of us are struggling to meet compliance and notification requirements of the WTO Agreements. There is a clear need to build and develop institutional structures in developing countries to enable them to cope with the requirements of the WTO…We are thinking for example of such technical areas as developing legislation and safeguard for intellectual property rights. Thus far, we have experienced a plethora of offers of assistance from various agencies that to us do not appear well coordinated to be of practical assistance.[3]

Paraguay, on the other hand, was more positive about the TRIPs agreement, noting that it had placed before parliament new legislation concerning IPRs in line with the commitments it undertook under the agreement.[4]

During the Geneva ministerial meeting (18–20 May 1998) developing countries and LDCs adopted a more negative and sceptical approach towards the TRIPs agreement. Bangladesh, for instance, questioned the extent to which the agreement would benefit countries with weak technological capabilities, particularly in the areas of pharmaceuticals and agriculture: 'Owing to a general lack of technological attainments in these countries, their prospects of contribution in this area in the foreseeable future are dim. Hence the prospects of detrimental applications of patent rights relating particularly to seeds, plant varieties, pharmaceuticals, biotechnology, etc. raise important questions for LDCs.'[5]

Kenya endorsed this view even more explicitly, highlighting the expected costs it was likely to incur from implementing the TRIPs agreement:

> Kenya lacks technological infrastructure and other appropriate resources that would enable her to gain significantly from the Trade-Related Aspects of Intellectual Property Agreement. This means that we are likely to incur higher costs in terms of royalties when the transition period for implementing the Agreement expires in the year 2000. The cost will no doubt be transferred to the consumers resulting in social welfare and economic loss.[6]

Botswana reiterated its sceptical 1996 position on the ability of developing countries and LDCs to implement the agreement without adequate assistance.[7] A similar statement was made by the Dominican Republic: 'Even more difficult than all the foregoing will be attaining the development objectives built into the Marrakech Agreement and the Agreement on Trade-Related Aspects of Intellectual Property Rights, at the end of the transition period accorded to developing countries.'[8]

It is thus quite evident from the various statements provided by developing countries and LDCs during the ministerial meetings of 1996 and 1998, that the TRIPs agreement was not considered a serious obstacle to the economic and social well-being of these countries. Although criticism of TRIPs increased in 1998, particularly with regard to the implementation of the agreement in developing countries and LDCs, this criticism still lacked a sense of purpose and practicality.

7.3 THE IP DEMANDS OF DEVELOPING COUNTRIES AND LDCS DURING THE 1999 WTO MINISTERIAL MEETING IN SEATTLE – TRIPS UNDER FIRE

1999 brought a significant shift in the attitude of developing countries and LDCs towards the TRIPs agreement. Criticism against TRIPs was both harsh and practical in terms of the set of demands laid down by these countries. The adverse reaction to TRIPs by developing countries and LDCs grew substantially.

The IP demands of developed countries are discussed below. These refer both to the structure of the agreement in general and to its specific IP components, mainly in the areas of pharmaceuticals, traditional knowledge and geographical indications.

7.3.1 Demands Concerning TRIPs Structure – Technology Transfer, Non-violation Disputes and Transitional Periods

Both before and during the Seattle ministerial meeting, developing countries and LDCs argued that the TRIPs provisions dealing with the supply of technical, financial and technological assistance to these countries are ineffective.

Kenya, on behalf of the African Group, fiercely questioned the efficacy and practicality of Art. 66.2 – transfer of technologies from developed countries to LDCs:

> The provisions of the Article (66.2) are couched in 'best endeavour' terms. Best endeavour provisions are fundamentally flawed in that they are neither enforceable nor do they constitute a real benefit for developing countries and least-developed

countries. Consequently many developed countries have as yet not demonstrated how they are fulfilling the provisions of this Article.[9]

As a solution, Kenya proposed monitoring the implementation of Art. 66.2 by developed countries, using a full and a regular WTO review.[10]

Venezuela requested that Art. 66.2 be extended to developing countries in addition to LDCs.[11] It also requested a review of TRIPs objectives and principles, as laid out in Art. 7 and 8, in order to make them more operational.[12] Moreover, Venezuela proposed that WTO members establish e-commerce mechanisms that would strengthen and induce technological transfer to developing countries and LDCs.[13] Similar views were also presented by Colombia.[14]

India submitted the most detailed proposal concerning the establishment of an operational WTO technology transfer mechanism, which included the field of IPRs.[15] Noting that TRIPs has a central role in the transfer of technologies to developing countries, India argued that 'the need of the hour is therefore to strengthen the language in existing agreements to make the provisions legally binding commitments'[16]. India's proposal was to establish a working group on the transfer of technology that would aim to:

1. Identify the technology-transfer constraints faced by developing countries.
2. Look at existing WTO agreements for the purpose of making the necessary adjustments for technology transfer to developing countries at advantageous terms.
3. Consider the reasons that existing technologies were not transferred to developing countries.
4. Factor technology transfer issues critical to developing countries into all future negotiations.
5. Investigate the possibility of establishing an institutional body within the WTO Secretariat dealing with technology transfer.
6. Offer specific support measures to ensure technology transfer from developed countries to developing ones.
7. Focus on the incentives that developed countries grant to enterprises and institutions in their own countries in order to disseminate and transfer technologies to developing countries.[17]

Developing countries and LDCs also sought to modify the issue of non-violation disputes (Art. 64.2 and 64.3). As we saw in Chapter 6, the Council for TRIPs had to convene and reconsider the scope and modalities of non-violation complaints in order to submit its recommendation to WTO members by the end of 1999. Many developing countries and LDCs held the view that, due to the lack of attention given to this topic, there is a need to extend the five-year

moratorium periods on such disputes in order to allow the council to have more time to consider its recommendations. As described by Latvia:

> In light of the lack of clarity regarding even the relevant basic notions with respect to the complaints of the type under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to the TRIPs Agreement, the genuine complexity of the issues involved and the divergence of views as to their applicability, the CEFTA countries and Latvia believe that further analysis is needed.[18]

On that basis, Latvia proposed preserving the moratorium on non-violation disputes, as set by Art. 64.2, as long as the recommendations submitted by the TRIPs Council were not approved by the ministerial meeting.[19] Identical requests came from other WTO members, such as the African Group, Colombia, Venezuela and Canada[20]. The latter, which traditionally held less protective IP views than those of the US and the EU, justified its opposition to the inclusion of non-violation disputes on social grounds:

> The non-violation remedy was developed in a context wholly different from TRIPs as a means of ensuring market access. In Canada's view transplanting this remedy into the TRIPs environment is not suitable in the context of IP and will introduce uncertainty into the Agreement, constraining Members' abilities to introduce new and perhaps vital measures such as those related to social, economic development, health and environmental objectives.[21]

Finally, and most importantly, developing countries and LDCs, such as Pakistan, Bangladesh, Cameroon, Senegal and Morocco, proposed extending the transitional periods (2000 and 2005 respectively) at the end of which they were required to fully implement TRIPs.[22] Deferring TRIPs implementation was based on the argument that, over the years, it had become evident that TRIPs did not benefit countries with weak IP capabilities. As put forward by Pakistan:

> The costs of the TRIPs Agreement are becoming especially evident. The balance between producers of intellectual property, mainly the industrialised countries, and the developing country users has been heavily tilted in favour of the former – through higher levels of protection, longer periods of monopoly rights and more stringent requirements to enforce these rights. One immediate fallout has been the increase in prices of pharmaceuticals and chemicals due to higher levels of patent protection.[23]

Senegal went even further arguing that the TRIPs agreement was actually a barrier to its future growth:

> The provisions of certain Agreements, instead of fostering development have become constraints to growth. The benefits arising out of compliance with the TRIPs Agreement, for example, must be measured against the substantial cost of such compliance and the increased price of products with significant intellectual property components. This could really retard technological development essential for the future economic development of the developing countries.[24]

7.3.2 Demands Concerning TRIPs Pharmaceutical and Biotechnological IP Agenda

Developing countries and LDCs were also 'demanders' with regard to the TRIPs provisions dealing with the pharmaceutical and biotechnological fields. Proposals for modifying and/or redefining TRIPs pharmaceutical provisions focused on three major issues: traditional-knowledge (TK), patenting of plants and animals (the so-called 'patenting of life') and the patentability of essential drugs.

Establishing IP protection in traditional knowledge

In Seattle, developing countries and LDCs called for the establishment of IPRs in the field of traditional knowledge. According to WIPO, traditional knowledge refers to different types of knowledge, such as creations, innovations and cultural expressions that have been: transmitted from generation to generation; regarded as pertaining to a particular people or its territory; developed in a non-systematic way and which are constantly evolving in response to a changing environment.[25] Other terms relating to the same subject matter include 'expressions of folklore', 'indigenous knowledge', 'indigenous heritage' and 'customary heritage rights'.[26] Thus, the field of traditional knowledge is far from being well-defined.

Historically, the WIPO/UNESCO Model Provisions for National Laws for the Protection of Folklore Against Illicit Exploitation and Other Prejudicial Actions of 1985 set the basis from which discussions on the nature and scope of traditional knowledge emerged.[27] The model sought to provide an IP framework for protecting different forms of folklore, mainly via copyrights (section III, sub-paragraphs 1 to 14).[28] In the model, the term 'expression of folklore' referred primarily to artistic expressions, such as language, literature, music, arts, architecture, customs, rituals and handicrafts (Part II).[29] During the 1990s several indigenous communities, mainly from Africa and Australia, expressed growing dissatisfaction with the term 'folklore', arguing that it was too narrowly defined.[30] As a result it became evident that 'folklore' was no longer an appropriate term for describing the various types of traditionally owned knowledge and the term 'traditional knowledge' was coined.[31]

Broadening the scope, traditional knowledge also encompasses plants and animals in medicinal treatment, as well as biodiversity issues.[32] Summarized below are the arguments for protecting traditional knowledge via IPRs, as presented by developing countries and LDCs, such as Bolivia, Colombia, Ecuador, Nicaragua, Peru, Cuba, Venezuela and Honduras.[33]

First, these countries highlighted the contrast between the well-protected IP needs of developed countries and the non-existing IP protection of knowledge assets of indigenous people.[34] As described in a joint communication by Bolivia, Colombia, Ecuador, Nicaragua and Peru: 'The entire modern evolution of intellectual property has been framed by principles and systems which have

tended to leave aside a large sector of human creativity, namely the traditional knowledge possessed by local and indigenous communities.'[35]

Second, developing countries and LDCs emphasized the issue of traditional medicinal knowledge, particularly with respect to the application of genetic, biological and natural resources and the management of such resources.[36] Specifically, the patentability of pharmaceutical products based on substances and methods used by indigenous peoples posed a serious problem for developing countries and LDCs. In its statement to the Seattle ministerial meeting, Pakistan argued that developed countries have appropriated, without permission or compensation, traditionally owned medicines such as Neem and Haldee, as well as agricultural products, most notably Basmati rice.[37]

At WIPO's Round Table on IPRs and Indigenous Peoples of 1998, the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA) presented various cases in which, according to its view, the medicinal know-how of indigenous people was appropriated and patented by Western pharmaceutical bodies.[38] COICA argued that in 1996 a US-based organization, namely the International Plant Medicine Corporation, patented a variation of the medicinal plant Ayahusaca (known as 'Yage').[39] COICA explained that the plant Yage has been used and domesticated for centuries by the indigenous peoples of Amazonia and concluded that the patent was a 'glaring case of biopiracy'.[40] COICA also referred to a case in which a medicinal plant for the treatment of the tropical disease Leishmaniasis was patented by the French Institute of Scientific Research and Development Cooperation (ORSTOM).[41]

Third, and in view of the above, developing countries called for the establishment of an international legal framework, using either TRIPs or a *sui generis* system, that would allow legitimate holders of traditional knowledge to exercise effective control over the access, use, reproduction, imitation, exploitation and transmission of such knowledge for commercial purposes.[42]

Developing countries and LDCs outlined a two-stage programme for achieving the goal of establishing IPRs in traditional knowledge: (1) carry out studies in order to recommend the most appropriate means to protect traditional knowledge, including medicinal practices and expressions of folklore, and (2) on the basis of these studies, WTO members should negotiate the establishment of a multilateral system for the protection of traditional knowledge via IPRs.[43] Separate communications from Honduras, Venezuela and India also laid down the demand for IP protection of indigenous and traditional knowledge.[44]

Prohibiting patents based on plants and animals ('life-patenting') and excluding the WHO list of essential drugs from patentability

Developing countries and LDCs had serious reservations about the patentability of pharmaceutical and biotechnological inventions based on plants and animals. In sharp contrast to the position of the R&D-based pharmaceutical

and biotechnological industries (see Chapter 8), developing countries sought to amend Art. 27.3b in order to prohibit the patentability of such inventions. As noted in the previous chapter, WTO members had to review Art. 27.3b – exclusion of plants and animals from patentability and the protection of plant varieties – by the end of 1999. Regarding the exclusion from patentability of plants and animals, developing countries and LDCs raised two major objections.

The first focused on the way in which the Art. 27.3b is formulated, that is, that according to this article the exclusion from patentability of plants and animals is optional rather than obligatory.[45]

The second objection concerned the distinction made in Art. 27.3b between plants and animals and 'essentially biological processes' that can be excluded from patentability, and micro-organisms and microbiological processes for which a patent is compulsory. Developing countries and LDCs argued that such a distinction compromised a fundamental rule of the modern patent system: that patents may be granted only to inventions and not to existing substances and processes (such as micro-organisms and microbiological processes) that are considered for all purposes a discovery.[46] As argued by Kenya on behalf of the African Group:

> By stipulating the compulsory patenting of microorganisms (which are natural living things) and microbiological processes (which are natural processes), the provisions of Article 27.3b contravene the basic tenets on which patent laws are based: that substances and processes that exist in nature are a discovery and not an invention and thus are not patentable.[47]

This argument was also supported by *TIME* magazine, which, using a rather controversial cover-page titled 'Who Owns Nature?' (30 November 1998) concluded that 'companies often end up trying to pass off as invention what are, in fact, discoveries – glimpses, really – into the magical processes rolling into nature's crucible.[48]

Moreover, linked to the mapping of the human genome (Genomics), the issue of 'life-patenting' became subject to an intense global public debate. Commencing in 1999, the race to publish the first blueprint of the human genome between the publicly-funded Human Genome Project and private biotechnological companies such as Celera, came close to the finishing line.[49] So intense was the question of gene-patenting that in March 2000 US President Bill Clinton and British Prime Minister Tony Blair issued a joint statement calling for the free use of human raw data: 'To realise the full promise of this research, raw fundamental data on the human genome, including the human DNA sequencing and its variations, should be made freely available to scientists everywhere.'[50] However, in their statement, the leaders made a distinction between raw fundamental data that should be made freely available to all and gene-based inventions

that should be entitled to IP protection, thus protecting the position of the pharmaceutical and biotechnological industries on that issue.[51]

With regard to the protection of plant varieties, Art. 27.3b requires that plant varieties be protected either by patents or by an effective *sui generis* system or by a combination of both. Given their reservations about life-patenting, developing countries proposed that plant varieties would be protected by a *sui generis* system that is based on the principles of the UN Convention on Biological Diversity (CBD), particularly Art. 15, and the International Undertaking on Plant Genetic Resources.[52] Both conventions aim to protect the right of local farming communities and to publicly conserve biological resources as well as to promote biological diversity.[53]

Finally, several developing countries and LDCs also asked that Art. 27.3b – exceptions from patentability – should be expanded to included the WHO's list of essential drugs.[54] The WHO model of essential drugs list (EDL), first published in 1977, identified individual drugs which together could provide safe and effective treatment for the majority of communicable and non-communicable diseases.[55] The WHO's EDL programme seeks to increase the access and affordability of essential drugs for low-income populations, particularly in developing countries and in LDCs.[56] In 1997, the WHO published its 10th model list of essential drugs, containing a list of 306 pharmaceutical drugs.[57] Practically, the extent to which incorporating a list of 'patent-free' drugs in the TRIPs agreement would damage the economic performance of pharmaceutical companies was not clear. However, the precedent of removing drugs from patentability was obviously controversial, as it negated the principle of non-discrimination in patented fields of technology.

In conclusion, as the Seattle ministerial meeting approached, developing countries and LDCs became highly resentful of the TRIPs agreement. Criticism of TRIPs became much more practical, seeking to modify the agreement in order to accommodate the needs of developing countries and LDCs. Demands by developing countries and LDCs concerning the structural capacity of TRIPs focused on three elements: (1) obliging developed countries to provide technical, technological and financial assistance to developing countries and LDCs in order to reduce the substantial costs, at least during the short term, that these countries may incur by implementing the TRIPs agreement; (2) extending the moratorium on the so-called non-violation disputes, and (3) granting longer periods to developing countries and LDCs for implementing the agreement.

Developing countries and LDCs also sought to limit the scope of protection granted by TRIPs in the field of pharmaceuticals. Here, demands focused on the grant of IP protection to traditional knowledge, particularly in practices involving the use of traditional medicine or those that are based on indigenous biological materials. Developing countries and LDCs also fiercely argued against life-patenting – the patenting of inventions that are based on plants

and animals. Indeed, from 1999 (when the Human Genome project was at a crucial phase) this issue became the subject of a world-wide debate. Finally, demands were also submitted with respect to the non-patenting of drugs that are included in the WHO list of essential drugs.

7.4 CONCLUSION

During the period immediately following the coming into effect of the TRIPs agreement, developing countries and LDCs expressed little criticism of the agreement, a surprising reaction given the intense opposition to the agreement by these countries during the Uruguay Round negotiations. Although a certain amount of criticism against TRIPs was raised during the 1998 WTO ministerial meeting, developing countries and LDCs did not set specific goals for changing the new reality resulting from the agreement. As a result, such criticism expressed, at best, the growing discomfort of developing countries and LDCs caused by TRIPs, rather than paving a path for re-negotiating the agreement.

Towards the 1999 ministerial meeting, developing countries and LDCs became much more active regarding TRIPs. Operating both as individuals and groups, developing countries and LDCs expressed harsh criticism of the agreement and, at the same time, put forward very clear demands. With respect to the TRIPs structure, developing countries asked that the provisions dealing with technological, technical and financial assistance become much more operational and obligatory. They also proposed that WTO members agree to extend the moratorium on IP disputes that are categorized as non-violation disputes. Most notably, developing countries and LDCs argued that, in the light of TRIPs negative implications on their economies, they should be granted a longer transitional period for implementing the agreement.

Concerning TRIPs pharmaceutical IP agenda, developing countries and LDCs called for the establishment of a new category in TRIPs that would protect their traditional-knowledge assets. Developing countries and LDCs also sought to restrict and even prohibit the patenting of plant and animals ('life-patenting'). Proposals on that issue focused on Art. 27.3b, calling for the non-patentability of micro-organisms and microbiological processes. Moreover, developing countries and LDCs demanded that Art. 27.3b should ban the patenting of any life-form, including natural biological materials. Lastly, and quite controversially, a few developing countries and LDCs proposed that Art. 27.3b should include the WHO model of essential drugs list, consequently making drugs on that list non-patentable.

Clearly, the sudden shift of attitude towards the TRIPs agreement, in contradistinction to the period of 1996–1998, needs to be further investigated. Yet it is quite plausible that the trigger for this kind of activism was the forthcoming

deadline of TRIPs implementation by developing countries (2000) combined with the growing understanding that carrying out the entire range of TRIPs obligations would pose serious difficulties for these countries.

Nevertheless, while developing countries and LDCs were highly active in the TRIPs arena during Seattle, they lacked a strategy, and to a certain extent also tactics, for achieving their IP goals. As we shall see later, these were the main strengths of the advanced European pharmaceutical industry and its IP allies, and were well reflected in the activities of the EU during the period 1995–1999.

NOTES

1. For the various statements concerning the Singapore ministerial meeting, see WTO documents series WT/MIN(96)/ST
2. Vice Minister of Foreign Trade, Colombia (WTO – Ministerial Conference 1996a), document number: WT/MIN(96)/ST/23
3. Minister of Commerce and Industry, Botswana (WTO – Ministerial Conference 1996b), document number: WT/MIN(96)/ST/76
4. Minister of Foreign Relations, Paraguay (WTO – Ministerial Conference 1996c), document number: WT/MIN(96)/ST/75
5. Minister of Commerce and Industry, Bangladesh (WTO – Ministerial Conference 1998b), document number: WT/MIN(98)/ST/60
6. Minister of Trade, Kenya (WTO – Ministerial Conference 1998c), document number: WT/MIN(98)/ST/43
7. Minister of Commerce and Industry, Botswana (WTO – Ministerial Conference 1998d), document number: WT/MIN(98)/ST/110
8. Secretary of State for Industry and Trade, Dominican Republic (WTO – Ministerial Conference 1998e), document number: WT/MIN(98)/ST/117
9. Communication from Kenya (WTO – General Council 1999h), document number: WT/GC/W/302
10. Ibid.
11. Communication from Venezuela (WTO – General Council 1999e), document number: WT/GC/W/282
12. Ibid.
13. Ibid.
14. Communication from Colombia (WTO – General Council 1999i), document number: WT/GC/W/316
15. Communication from India (WTO – General Council 1999l), document number: WT/GC/W/352
16. Ibid., p. 2
17. Ibid., p. 3
18. Communication from the CEFTA and Latvia (WTO – General Council 1999g), document number: WT/GC/W/275
19. Ibid.
20. Communications from the African Group (WTO – General Council 1999h), Colombia (WTO – General Council 1999i) and Venezuela (WTO – General Council 1999e); see also: communication from Canada (WTO – General Council 1999f), document number: WT/GC/W/256
21. Communication from Canada (WTO – General Council 1999f)
22. Minister of Commerce, Industry and Production, Pakistan (WTO – Ministerial Conference 1999b), document number: WT/MIN(99)/ST/9; Minister of Commerce and Industry, Bangladesh (WTO – Ministerial Conference 1999c), document number: WT/MIN(99)/ST/17; Minister of

Industry and Trade and Development, Cameroon, (WTO – Ministerial Conference 1999g), document number: WT/MIN(99)/ST/88; Minister of Commerce, Industry and Handicrafts, Morocco (WTO – Ministerial Conference 1999d), document number: WT/MIN(99)/ST/29; Minister of Commerce and Handicrafts, Senegal (WTO – Ministerial Conference 1999e), document number: WT/MIN(99)/ST/61

23. Minister of Commerce, Industry and Production, Pakistan (WTO – Ministerial Conference 1999b), document number: WT/MIN(99)/ST/9
24. Minster of Commerce and Handicrafts, Senegal (WTO – Ministerial Conference 1999e), document number: WT/MIN(99)/ST/61
25. WIPO (2000: 15–18); see also: WIPO – International Bureau (2000), document number: WIPO/IPTK/RT/99/7; WIPO Secretariat (2001), document number: WIPO/GRTKF/IC/1/3
26. WIPO (2000: 11–18)
27. WIPO – UNESCO (1985); for an overview of the model see: WIPO Secretariat (2001: 28–33)
28. Blakeney (1999: 2–3)
29. WIPO – UNESCO (1985) Model Section II; WIPO Secretariat (2001: 28–33 and Annex 3, p. 4)
30. Blakeney (1999: 2–3)
31. WIPO – International Bureau (1999), document number: WIPO/IPTK/RT/99/2
32. WIPO – International Bureau (2000: 12–31); WIPO Secretariat (2001: Annex 3)
33. Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru (WTO – General Council 1999n), document number: WT/GC/W/362; Communication from Cuba, Honduras, Paraguay and Venezuela (WTO – General Council 1999k), document number: WT/GC/W/329; Minister of Commerce and Industry, India (WTO – Ministerial Conference 1999a), document number: WT/MIN(99)/ST/16; Communication from Cuba, Honduras, Paraguay and Venezuela (WTO – General Council 1999k), document number: WT/GC/W/329; Communication from Venezuela (WTO – General Council 1999e: 2)
34. Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru (WTO – General Council 1999n: 1)
35. Ibid.
36. Ibid., pp. 1–2; see also Communication from Cuba, Honduras, Paraguay and Venezuela (WTO – General Council 1999k)
37. Statement by Pakistan (WTO – Ministerial Conference 1999b: 4)
38. WIPO (1998b), document number: WIPO/INDIP/RT/98/4E
39. Ibid., pp. 2–3
40. Ibid., p. 2
41. Ibid., p. 3
42. Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru (WTO – General Council 1999n: 2); see also Communication from Cuba, Honduras, Paraguay and Venezuela (WTO – General Council 1999k: 2)
43. Ibid.
44. Secretary of State for Industry and Trade, Honduras (WTO – Ministerial Conference 1999f), document number: WT/MIN(99)/ST/40; Communication from Venezuela, (WTO – General Council 1999e: 2); Communication from India (WTO – Ministerial Conference 1999a: 2)
45. Communication from Kenya on behalf of the African Group (WTO – General Council 1999h: 3–4)
46. Ibid.; see also: Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri-Lanka and Uganda (WTO – General Council 1999m: 4), document number: WT/GC/W/355
47. Communication from Kenya on behalf of the African Group (WTO – General Council 1999h: 3)
48. McGirk (1998: 48)
49. For a popular overview on the subject see: *The Economist*, *The Human Genome – Survey* (2000: 14–16); *the Economist* (2001a: 19–20); Lemonick and Golden (2000: 73–8)
50. Office of the Prime Minister, United Kingdom, (2000); Griffith and Wrong (2000)
51. Griffith and Wrong (2000)

52. Communication from India (WTO – General Council 1999b), document number: WT/GC/W/225; Communication from Venezuela (WTO – General Council 1999e: 2); Communication from Kenya on Behalf of the African Group (WTO – General Council 1999h: 3–4)
53. United Nations, *Convention on Biological Diversity* (1992) Website: www.biodiv.org; for the IP protection of patents via a *sui generis* system see: Lele, Lesser and Horskotte-Wesseler (1999); OECD (1996)
54. Communication from Venezuela (WTO – General Council 1999e: 2); Communication from Cuba, Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda (WTO – General Council 1999m: 27)
55. WHO (2001); Hogerzeil (2000), document number: WHO/EDM/PAR
56. For an overview of WHO's Essential Drug activities see: WHO (2000c; 2000b)
57. WHO (2000c)

8. Protecting the international pharmaceutical IP agenda of TRIPs: strategies and activities of the advanced pharmaceutical industry in Europe between 1995 and 1999

8.1 INTRODUCTION

Although the establishment of the TRIPs agreement clearly required a considerable effort on the part of IP advocates, exploiting TRIPs benefits and preserving its achievements proved to be an equally challenging task. As the controversy surrounding TRIPs intensified, particularly from 1999, IP advocates, such as the advanced pharmaceutical industry in Europe, were, for the first time, on the defensive. In the light of the new situation, the advanced pharmaceutical industry in Europe found itself pursuing two contradictory goals: (1) exploiting the benefits derived from the TRIPs agreement, and (2) preventing TRIPs from being downgraded to a lower level of IP protection.

This chapter links the industry's strategies and activities concerning the exploitation and preservation of TRIPs to the EU's IP approach and operations between 1995 and 1999. First, the chapter focuses on the declarative level, describing the views of the EU and of its member states (UK, Germany) concerning IPRs and the TRIPs agreement. Second, the chapter analyses the operational level, assessing TRIPs-related activities of both the advanced pharmaceutical industry in Europe and the EU. It does so by focusing on two periods: (1) 1995–1998, during which operations were aimed at exploiting TRIPs benefits, and (2) end of 1998 up to the Seattle ministerial meeting, when industry–EU activities shifted towards the preservation of the TRIPs agreement. Finally, the chapter puts great emphasis on the combined efforts of the industry and of its regional and international IP allies, such as IFPMA, UNICE, CEFIC, TABD and US-IPC. This emphasis is essential, since the advanced pharmaceutical industry in Europe did not perform alone but rather as a 'team-player'. More importantly, this provides a more comprehensive insight into the common sentiments, goals and strategies shared by IP advocates globally.

8.2 EU ADVOCACY OF IPRS AND THE TRIPS AGREEMENT

The IP 'doctrine' of the advanced pharmaceutical industry in Europe has already been described in great detail in Chapters 4 and 5. Special attention was also given to the rhetoric used by the industry in order to express its IP position. This section looks at the governmental end of the IP equation, describing the views expressed by the EU (with specific reference to the UK and Germany) on IPRs generally and on TRIPs in particular. The result, as portrayed below, shows a high level of similarity between the IP views and rhetoric of the EU and that of the industry.

8.2.1 The Views of the EU on IPRs

Examining various documents, position papers, statements and website information concerning the EU's approach towards IPRs, it is possible to argue that the EU is an enthusiastic supporter of IPRs.

Most notably, the EU adheres to the assumption that IP protection is an important element which positively affects its economic performance and competitive abilities. To cite a few examples: in a special 1998 report on IPRs, the European Commission (henceforth, the Commission) argued that 'Industrial property (IPRs) is no longer regarded as just a complex area reserved for experts alone, but as a strategic issue of importance to growth in the community'.[1] A different report, dated October 1998, by the Committee on Legal Affairs and Citizen's Rights of the European Parliament, argued that 'intellectual property is an essential factor in the promotion of innovation, and is basic to competitiveness in an advanced society such as that which exists in Europe'.[2] The same notion was emphasized by the European Commissioner for Internal Market, Frits Bolkestein:

> The need for the protection of industrial property rights for innovation and employment and its impact on competition is crucial. My short presentation of what the Commission has already achieved and the on-going activities clearly shows the importance the Commission attaches to the protection of Intellectual Property Rights within the EU and at a global level.[3]

The language used by the Commission concerning IPRs and future innovation closely resembles the rhetoric of the advanced pharmaceutical industry in Europe. As illustrated by DG Trade:

> Numerous industries in the Union are heavily dependent on an effective adequate protection of intellectual property rights in order to guarantee reasonable return on investment for their expenses in research development creativity. For example, the

> invention of a pharmaceutical product can require substantial investments in the order of several hundreds million ECUs while costs for the production of a film can easily amount to tens of millions of ECU and in some cases, may exceed one hundred million ECU.[4]

An additional example can be found in an Annexe Draft to the 1998 Conference of Accession to the European Union, in which the EU argued that 'patent protection in the field of pharmaceuticals is of vital importance as the main means of encouraging and protecting in investment and research of new products'.[5] The Commission's views on the relationship between patents and industrial competitiveness are best expressed in a 1997 Green Paper entitled *Promoting Innovation Through Patents*: 'It is vital to protect the fruits of innovation. In economic terms, it has been clearly established that companies with specialized know-how which sell branded products and patented products or processes have a competitive advantage when it comes to maintaining or expanding their market share.[6]

Leading country members, such as the UK and Germany, have also expressed their solid support for IPRs, emphasizing their contribution to innovation and investment in Europe. When referring to various types of IPRs (patents, copyrights and trademarks) the DTI argued that 'a strong system for protecting these measures is key to encouraging innovation and technology transfer in developed and developing countries alike'.[7] In a White Paper concerning world poverty published in December 2000, the UK put particular emphasis on IPRs and investment in pharmaceuticals: 'Intellectual Property Rights – for instance, conferring copyright, patent or trademark protection – provide an essential incentive for private investment in research and development. This is particularly so in medicine and agriculture, where research can be costly and long term, and where the results are uncertain.'[8] A similar view was expressed by the President of the German Patent Office, Hans Georg Landfermann, concerning the increase in pace and volume of patent applications in Germany: 'This growth evidences the great importance that industry attaches to the protection of industrial property rights. Inventive talent and innovativeness are the basis for success particularly in today's knowledge society.'[9]

Also, the EU tends to attach positive features to IPRs with respect to their welfare and economic implications for society as a whole. As noted by the Director of the Industrial Property Unit in the Commission DG Trade (DG I/D/3), Paul Vandoren: 'I have yet to come across a convincing paper suggesting that not having intellectual property laws will enhance long term growth. Also, the limitation in time of the protection granted for inventions inevitably implies that in due course their benefits will be truly shared by all citizens.'[10]

Similarly, the Committee on Research, Technological Development and Energy of the European Parliament, called for the inclusion of an IP system in

the EU's 1996 annual research programme (referred to as the 5th Framework), expressing the view that IP 'encourages, rather than inhibits, the transfer of technologies'.[11] The Commission, in one of its position papers, chose to link IPRs to neo-liberal and democratic ideals, arguing that the 'protection of these rights is a basic feature of democratic legal systems and market economies'.[12]

8.2.2 The Views of the EU on the TRIPs Agreement

The EU is a prominent advocate of TRIPs and emphasizes the precedent established by the agreement in terms of the global protection of IPRs and the prevention of IP piracy. The Commission describes TRIPs as a 'major step forward in the global protection of intellectual property rights through establishing minimum rights for right-holders and adequate enforcement mechanisms'.[13]

More specifically, the EU emphasizes the IP achievements secured by the TRIPs agreement, including the basic principles of national treatment and most favoured nation mechanisms for the settlement of disputes, TRIPs enforcement procedures and the detailed protection standards embodied in the agreement.[14] As explained by the Commission:

> The binding nature of the obligations accepted by its members is a particular strength, since the WTO has been able to go further to secure enforcement than specialised agencies such as the World Intellectual Property Organisation (WIPO), with which the WTO cooperates closely. Significant trade friction caused by international piracy and the sale of counterfeited goods was one of the driving forces behind the efforts to get a WTO agreement on IPRs.[15]

Indeed, in 1998 the Commission's Vice President, Sir Leon Brittan, elaborated on the achievements secured by the WTO, including those in the field of IPRs:

> The track record of the WTO since the conclusion of the Uruguay Round has been extremely positive for us all, bringing better business certainty and better market access. Tariff and non-tariff barriers have been slashed, our intellectual property has started to benefit from global protection, and our services industries are opening up new markets.[16]

The EU openly admits that developed countries were the driving force behind TRIPs, noting that 'industrialised countries have long shared a common appreciation of the necessity to secure the protection of intellectual property rights through the provision of administrative measures and civil and criminal legal procedures for their protection'.[17] In fact, according to the Commission, the EU played a leading role in the creation of the TRIPs agreement.[18] Also, the Commission explicitly acknowledges that the EU's international activities are closely linked to the interests of European IP-based industries. For instance,

the Commission argues that its 'prolific activity is due to the need, clearly felt nowadays, to provide European firms doing business in non-Community countries with an adequate legal framework within which to enjoy effective, genuine protection of know-how and innovation'.[19] Similarly, in its 1996 report to the European Parliament concerning the WTO, the Committee on External Economic Relations concluded that with the implementation of the TRIPs agreement 'EU enterprises enjoy similar conditions in third markets to those enjoyed by foreign enterprises in the EU since the completion of the internal market'.[20] The Committee also called for 'further rules and sanctions to protect intellectual property because in the era of globalisation and information technologies the competitiveness of undertakings and economies depends on the knowledge and skills of people'.[21]

In parallel to expressing its views on TRIPs, the EU argues that developing countries and LDCs would also benefit from the agreement. In this case, the EU places IPRs within the general sphere of trade liberalization, linking developing countries' commitments to a higher level of IP protection to the perceived benefits derived from free-trade and investment.[22] According to the Commission, developing countries should internalize the fact that domestic regulation of IPRs and trade liberalization are 'interlinked and mutually supportive'.[23]

Likewise the UK argues that 'developing countries have an important interest in providing intellectual property protection, as a way of encouraging more investment, research and innovation from which they should benefit'.[24] When referring specifically to TRIPs it adds that 'the UK government believes that the agreement allows WTO members sufficient flexibility to implement domestic IPR regimes which take adequate account of their national circumstances'.[25]

Furthermore, aware of the obvious gap between developed and developing countries in the distribution of IP gains, the EU emphasizes the long-term benefits the latter may expect from adopting a protective regime of IPRs.[26] To quote the Director of the Industrial Policy Unit of DG Trade: 'While it is true that the benefits of intellectual property protection take time to bear fruit, notably in developing countries, we should remain mindful of the fact that those countries which have the highest growth in the last fifty years all have good IP protection laws.'[27]

Germany, however, expressed a more cautious view on the subject. For instance, in 1999 the Federal Minister for Economic Cooperation and Development, Heidemarie Wieczorek-Zeul, referred to the potentially harmful effects of IP monopolies in developing countries:

> The current dispute in the WTO over the protection of intellectual property shows the amount of power linked to knowledge and the political and economic interests at stake. Industry in the rich countries is demanding better protection in marketing the results of its research and inventions…From a business point of view that makes sense.

> However, it also understandable that the developing countries fear being excluded from important technical developments, and often even being denied the benefits that others are deriving from local knowledge and genetic material from their own countries, for instance in the field of medicine.[28]

Notwithstanding the above, the IP views of the EU are not a result of an institutional reality in which common sets of ideas and beliefs were translated into a highly protective IP perspective. Nor is it a pluralist process that reconciles the divergent views and interests concerning IPRs. In Chapters 1 and 6 it was suggested and demonstrated that there is no single and transparent institution responsible for the IP international policy-making of the EU and that the IP views of different interest groups are conveyed through a multitude of channels.

Consequently, lobbying on IPRs is not exclusive to the advanced pharmaceutical industry in Europe or to IP advocates in general. For example, important consumer groups such as the Trans Atlantic Consumer Dialogue (TACD) and the BEUC (the European Consumers' Organisation), have expressed strong reservations about the TRIPs agreement.[29] The TACD, for example, lobbied DG Trade directly in order to influence the Commission to take a much more moderate and flexible view regarding the implementation of the TRIPs agreement in developing countries and in LDCs.[30] In fact, the Commission explicitly responded to the proposals made by the TACD concerning IPRs and access to medicines from February 2000, concluding that these recommendations 'are not justified for legal and practical reasons'.[31] This rejection of the IP proposals by the TACD indicates that the Commission is aware of other views, but none the less chooses to support the industry's position. In this respect the above data suggests that an interest-based approach seems to provide a better explanatory route for the IP views of the EU as compared with an institutional approach.

Having examined the declarative level we can persuasively argue that the EU is highly supportive of IPRs and of the TRIPs agreement. The EU regards IPRs as an important factor contributing to its overall economic performance, most notably to its ability to compete against other industrial countries and to its attractiveness for future investments. As for the TRIPs agreement, the EU is equally enthusiastic, considering the agreement to be a major step forward in the creation of a global IP regime, which would naturally benefit its IP-based industries. Interestingly, the language used by the EU, and by the Commission in particular, is very similar to the rhetoric used by the advanced pharmaceutical industry in Europe. The EU tends to over-emphasize the potential benefits arising from IPRs. At the same time it downplays the implications deriving from the agreement, particularly for developing countries and LDCs.

8.3 INDUSTRY'S EFFORTS FOR EXPLOITING TRIPS ACHIEVEMENTS AND THEIR IMPACT ON THE IP-RELATED ACTIVITIES OF THE EU – 1996 TO 1998

Dealing with the operational level, this section records the goals, strategies and activities of the advanced pharmaceutical industry in Europe concerning TRIPs and considers their implications on EU actions in this field.

8.3.1 Industry's Activities between 1996 and 1998 – Demands for the Rapid Implementation of TRIPs

Although the creation of the TRIPs agreement was clearly revolutionary, the advanced pharmaceutical industry did not rest on its laurels. Eager to reap the benefits of TRIPs, it focused primarily on the timely implementation of the agreement, particularly in specific developing countries such as India, Pakistan, Argentina and Brazil. Whilst pursuing this strategy the industry and its IP allies relied on their vast and well-coordinated organizational set-up in order to emphasize the need for TRIPs implementation, even using identical language.

In a 1995 paper entitled *GATT TRIPs and the Pharmaceutical Industry: a Review* the IFPMA argued that 'it is essential that having come so far in achieving consensus on a minimum level of intellectual property rights that the WTO comes into existence and that the TRIPs Agreement is implemented'.[32] The IFPMA added that a close watch is required to ensure that 'there is no deterioration in the implementation of the transitional provisions'.[33] The VFA noted that 'TRIPs must be implemented by all WTO members countries fully and according to schedule'.[34] Similarly, EFPIA argued that 'for the European R&D- based pharmaceutical industry, the paramount objective is to ensure the complete (and) timely implementation of the current TRIPs agreement by all WTO countries as well as its appropriate enforcement'.[35]

Inter-industry alliances and organizations also emphasized the importance of TRIPs implementation. UNICE, for instance, argued that 'the priority for strengthening intellectual property protection at the international level is to ensure effective and timely implementation of the TRIPs Agreement and pursue the work programme embodied in the built-in agenda'.[36] Identical language was used by the TABD which called for a 'proper and timely implementation' of TRIPs.[37] The US-based IPC has also stressed that the efficacy of TRIPs is heavily dependent upon the acceleration of TRIPs implementation in developing countries and in LDCs.[38] Additionally, the European Committee of the American Chamber of Commerce argued that the successful implementation

and enforcement of TRIPs is of fundamental importance to the fight against IP piracy.[39]

Furthermore, the efforts of the advanced pharmaceutical industry in Europe and its IP allies to promote the implementation of the TRIPs agreement were not restricted to statements alone. Using all avenues, these actors issued detailed position papers and reviews concerning the state of play of TRIPs implementation in developed, developing and least developed countries. One example is a 1997 paper titled: 'The Importance of Third World Implementation of TRIPs', written by a senior corporate IP consultant of the pharmaceutical company, Zeneca (today AstraZeneca).[40] The paper provided an inter-country analysis, naturally from an industry perspective, of TRIPs implementation in different WTO members. As examples referring to developing countries, the paper argued that Brazil did not provide any protection to trade secrets and pharmaceutical registration data (Art.39.3); Argentina excluded pharmaceutical and biotechnological products from patentability; and India did not carry out the obligations specified under Art.70.8, that is so-called 'mailbox' provisions for patent applications in pharmaceutical and agro-chemical products.[41]

Information regarding TRIPs implementation in the pharmaceutical field was also issued by PhRMA, the TABD, the VFA and by EFPIA.[42] EFPIA, for instance, argued that the amendments to South Korea's 1998 Pharmaceutical Affairs Law Enforcement were in contradiction to its TRIPs obligations for the protection of pharmaceutical registration data (Art. 39.3).[43]

8.3.2 Translating Industry's Inputs to European Action – EU Activities Relating to the Implementation and Enforcement of TRIPs Pharmaceutical IP Provisions

Two WTO disputes can best describe the EU's approach and activities concerning the TRIPs agreement: the first was between the EU and India on the granting of patent protection to pharmaceutical inventions with respect to Art. 70.8 and 70.9 of TRIPs. The second was between the EU and Canada concerning clinical tests in patented pharmaceutical products. In both disputes, the EU's actions reflected, to a considerable extent, the interest of the advanced pharmaceutical industry in Europe.

WTO dispute between the EU and India concerning patent protection in pharmaceutical and agricultural–chemical products – 'mailbox' procedures and exclusive marketing rights

On 28 April 1997, the EU (originally referred to as the EC and its member states) requested consultations with India, in accordance with the WTO dispute settlement procedures (DSU), concerning India's lack of patent protection for pharmaceutical and agricultural chemical (agro-chemical) products.[44]

The key arguments raised by the EU were as follows:[45]

1. The TRIPs agreement requires all WTO members to grant patents for the subject matter specified in Art. 27 of the agreement, including pharmaceutical and agro-chemical products.
2. Pursuant to Art 70.8, WTO members that do not grant patent protection for pharmaceutical and agro-chemical inventions as at the date of coming into effect of the agreement (1995), and that are benefiting from the transitional provisions specified in Art. 65 and 66 of TRIPs, must provide for measures that allow parties to file patent applications concerning such inventions ('mailbox' procedures).
3. Once patent protection for pharmaceutical and agro-chemical inventions has been granted, the above members must examine these applications according to the criteria for patentability set forth in TRIPs. Patents granted for such applications must be fully compatible with the provisions specified in the agreement.
4. Subject also to the provisions of Art.70.9, WTO members are required to grant exclusive marketing rights (EMRs) for a period of five years to any pharmaceutical or agro-chemical product using the mailbox procedures and to which marketing authorization was approved. That is on the condition that the said product has received patent and marketing approval from another WTO member.
5. Contrary to the provisions laid down in Art. 27, India does not provide patent protection for inventions covering pharmaceutical and agro-chemical products, nor does it provide adequate rules and mechanisms that conform to the obligations specified in Art. 70.8 and 70.9 – mailbox provisions and EMRs. Hence, India's legal regime is not compatible with its TRIPs obligations.
6. In light of the above, the EU requested that India amend its domestic law – the Patents Act of 1970 – in order to align it to the provisions of the TRIPs agreement.

During the consultations held on14 May 1997, the parties did not reach a mutually acceptable solution. As a result the EU formally requested the DSB (9 September 1997) to establish a panel to examine and to resolve the dispute. At its meeting of 16 October 1997, the DSB agreed to establish a panel with standard terms of reference in accordance with Art. 6 of the DSU.[46] The United States reserved third party rights. The official name for the dispute was: 'India – Patent Protection for Pharmaceutical and Agricultural Chemical Products'.[47]

The arguments raised by the EU were based on the findings of an earlier panel dealing with the same dispute between the US and India. On 20 November 1996, following a request by the US, the DSB established a panel to examine this

issue.[48] Acting as a third party to the dispute, the EU expressed its full support for the request made by the US to find that India did not carry out its obligations under Art. 70.8 and Art. 70.9 of the agreement.[49] In a report dated 5 September 1997, the appointed panel found that India had violated Art. 70.8(a) and Art. 70.9.[50] India appealed, stating its objections which dealt mainly with some of the panel's legal interpretations.[51] Although the Appellate Body modified to an extent the reasoning of the panel, it essentially upheld the conclusions of the panel report concerning these articles.[52] On 16 January 1998, the DSB adopted the Appellate Body report, and at the DSB meeting, on 22 April 1998, India and the US agreed on an implementation period of 15 months.[53]

The EU argued that since the Appellate Body had issued its report, India had not taken meaningful steps to amend the Patents Act of 1970 in order to provide for an appropriate means for mailbox applications, as well as EMRs, to pharmaceutical and agro-chemical products.[54] It further added that pursuant to Art. 3.8 of the DSU, the breach of the relevant WTO rules by India had an adverse effect on the EU and its member states as the other party to this dispute.[55] Hence, the onus fell on India to rebut the presumption that its present domestic patent regime nullified or impaired the benefits accruing to the EU as specified under Art. 70.8 and 70.9 of TRIPs.

India's principal arguments for rejecting the complaints raised by the EU were mostly technical and were based on the following:[56]

1. The complaint brought by the EU is inconsistent with DSU provisions dealing with multiple complainants (Art. 9.1 and 10.4 in particular), according to which multiple complaints should be submitted to a single panel 'whenever feasible' or 'whenever possible'. India argued that, given that the same matter has already been the subject of a dispute between the US and India, the EU should have raised its complaints either jointly with the US, or at least simultaneously.
2. There is insufficient evidence to demonstrate that mailbox applications can be challenged in India's courts or that India's mailbox system does not provide a sound legal basis for preserving the novelty of the inventions and the priority of the date of such applications.
3. Because the previous panel did not rely on Art. 31 of the Vienna Convention on the Law of Treaties it wrongly interpreted Art. 70.9 of the TRIPs agreement. Consequently, it incorrectly concluded that Art. 70.9 requires implementation of EMRs, regardless of the sequence of events according to which such rights should be granted.

The panel's report, issued on 24 August 1998, ruled in favour of the EU. It rejected India's request for dismissal of the complaints raised by the EU on the basis of multiple complaints.[57] It also found that India had not successfully

rebutted the prima facie case of violation of Art. 70.8(a) that has been established by the EU and had, therefore, failed to take the action necessary to implement its obligations (mailbox procedures) under that article.[58] Concerning the granting of ERMs (Art. 70.9), the panel stated that, following the rules in terms of Art. 31 of the Vienna Convention, the implementation of Art. 70.9 should have commenced on 1 January 1995.[59] Accordingly, the panel found that India had failed to implement its obligations under Art. 70.9 to establish a system for the granting of exclusive marketing rights to be available at any time after the WTO agreement came into force.[60] The panel also endorsed the EU's position, according to which India's actions, or lack of action, constituted a case of prima facie nullification or impairment of benefits accruing to the EU under the TRIPs.[61] In its report the panel recommended that 'the Dispute Settlement Body request India to bring its transitional regime for patent protection of pharmaceutical and agricultural chemical products into conformity with its obligations under the TRIPS Agreement'.[62] The report was adopted by the DSB on 22 September 1998.[63] At the DSB meeting on 25 November 1998, India issued a joint statement with the EU in which India agreed to comply with the panel ruling and to implement its recommendations by 16 April 1999.[64] India presented its final status report, concerning the implementation of both the DSB rulings, on 28 April 1999.[65]

Obviously, the dispute between the EU and India, as well as that between the US and India, in which the EU participated as a third party, was about the interests of pharmaceutical multinationals in the Indian market. Indeed, both the EU and the US relied on evidence provided by the industry itself. For instance, in order to demonstrate that European-based pharmaceutical companies were ready to apply for EMRs in India, the EU provided the panel with a copy of a letter, dated 28 April 1998, which it had received from the Glaxo-Wellcome Director of Global Intellectual Property:

> We have a product called Valaciclovir for which we have patents on a tablet formulation and a crystalline form. These applications have been filed in the mailbox procedure. A marketing approval application has been filed in India and we expect launch to occur in early 1999. We will therefore be making an application for marketing exclusivity before that time. This is certainly not a comprehensive list, but I hope it provides some evidence that the marketing exclusivity provisions will need to be in place in India this year.[66]

The US also referred to a letter it had received from Dr Harvey Bale, Senior Vice President, PhRMA, emphasizing the importance of India's compliance with TRIPs:

> As you know, PhRMA companies are experiencing great losses in India because of its failure to provide patent protection for pharmaceutical products. Unless India

> establishes a mechanism to ensure that mailbox applications can be filed and given the legal status required by the TRIPS Agreement (i.e., all applications that would have been filed after 1 January 1995, had a system been in place), they will continue to face enormous losses for decades to come. Furthermore, without a system for the grant of exclusive marketing rights in place, at least one company and perhaps many others will incur significant additional losses.[67]

It should also be noted that the EU participated as a third party in another dispute concerning mailbox procedures and EMRs between the US and Pakistan. On 6 May 1996, the US requested the Government of Pakistan to enter into consultation on the matter.[68] In a communication dated 28 May 1996, the EU asked to be included in the consultation.[69] The EU argued that 'the European pharmaceutical and agro-chemical industry has an important export interest in the Pakistan market' and that 'the actual amount of this interest is, at this stage, difficult to evaluate because Pakistan does not provide for either patent protection or the above-mentioned filing and marketing systems'.[70]

Having failed to reach a mutually acceptable solution, on 4 July 1996 the US asked the DSB to establish a dispute panel.[71] However, on 28 February 1997, the parties announced that they had reached a mutually agreed solution, according to which, with effect from 1 January 1995, Pakistan would provide for mailbox procedures and EMRs to pharmaceutical and agro-chemical patents.[72] The official notification also specified the terms and timetable for implementing these provisions.[73]

The WTO dispute between the EU and Canada concerning the scope of patent protection in the pharmaceutical field – commercial tests and 'Bolar' exemptions

On 19 December 1997, the EU requested Canada to hold consultations regarding the implementation of amendments to Canada's Patent Act in relation to TRIPs provisions concerning the protection of patented inventions in the pharmaceutical field.[74] During the consultation meetings (13 February and 12 June 1998) they failed to reach a mutually satisfactory solution. Consequently, the EU requested DSB, in a communication dated 11 November 1998, to establish a panel to examine the matter and at its meeting, on 1 February 1999, the DSB approved that request.[75] Australia, Brazil, Columbia, Cuba, India, Israel, Japan, Poland, Switzerland, Thailand and the US reserved third party rights.[76]

An overview of the nature and scope of the dispute The dispute between the EU and Canada was one of the most interesting disputes concerning TRIPs pharmaceutical IP agenda for three reasons. First, although based on the question of TRIPs implementation, the purpose of the dispute was to deal with the interpretation of the agreement, namely defining the scope of patent protection in pharmaceuticals. Second, it was a dispute between WTO developed-country

members. Third, the dispute reflected the clash of interests between the two major segments of the pharmaceutical industry, that is between R&D-based companies and generic-orientated companies.

In essence, the dispute concerned the scope of patent protection and its influence on the effective term of market monopoly granted to patent holders. As already mentioned in Chapters 4 and 5, the advanced pharmaceutical industry in Europe is interested in broadening and extending the scope of patent rights and the term of patent protection. One way to do so is to establish that no tests or experiments be carried out in patented drugs without the consent of the patent owner. In other words, by establishing that commercial tests and experiments commence only after patent expiry, research-based companies would be able to extend their market monopoly vis-à-vis generic competitors beyond the patent term (20 years).

The scope and term of patent rights are not identical across developed countries. Two factors are particularly relevant:

1. The extent to which patent laws in these countries prohibit commercial testing in patented products.
2. Whether legislation exists which provides a supplementary term of protection for patents.

In this regard, EU legislation is the most favourable to pharmaceutical research-based companies. First, it prohibits the commercial testing of patented drugs. According to Cornish, patent provisions, such as Art. 27b of the Community Patent Convention (CPC) that allow for experiments to take place in the subject matter of the patented invention, are not valid for commercial purposes. These experiments are generally aimed at obtaining marketing authorization, usually for generic substitutes.[77] Citing various court rulings across Europe, Cornish argues that 'in Europe it is almost universally accepted that the experimental use defence does not permit such (commercial) testing to take place in advance of expiry'.[78] Second, and as discussed in Chapter 5, EU regulations provide for an additional term of protection (an average of five years) using supplementary protection certificates (SPCs – EEC Directive No. 1768/92).

In the US, the 1984 Drug Price Competition and Patent Term Restoration Act (known as the Waxman–Hatch Act) provided a compromise between the interests of research-based and generic-based companies. It removed regulatory obstacles in the process of granting marketing authorization for generic drugs and, simultaneously, increased the effective patent term of protection by an additional maximum period of five years.[79] Legalizing, *inter alia*, commercial testing in patented medicines, the Waxman–Hatch Act was ultimately linked to the ruling of the Court of Appeals for the Federal Circuit in the case of Roche Products Inc. v. Bolar Pharmaceuticals Co. Inc.[80] In that case, a generic

manufacturer, Bolar Pharmaceuticals Co. Inc., conducted experiments in Roche's patented medicine as part of its efforts to receive market authorization for its own generic version of the patented drug. The Court ruled that the common law 'experimental use' defence only covered experimentation for scientific purposes and not for commercial ones. Thus, Bolar's activities amounted to an infringement of the relevant patents.[81] Nevertheless, the Waxman–Hatch Act reversed the ruling, as amended in Section 271(e)(1) of Art. 35 of the US Patent Code, and allowed for such experiments to take place.[82] This amendment received the popular name of 'Bolar exemptions'.

Finally, in contrast to the pharmaceutical IP policy of the EU, the Canadian Patent Act, as amended in 1992, is more beneficial to generic-based companies, providing for Bolar exemptions (Section 55.2–2), without granting any supplementary term of protection to pharmaceutical patent holders.[83]

By bringing the issue of Bolar exemptions before a WTO dispute panel, the EU presented a tough IP stand, which was clearly in contradiction to Canada's position, but also in collision with that of the US. In doing so, the EU became a 'spokesman' for the European IP-based pharmaceutical industry. Specifically, the EU fully supported the position expressed by EFPIA regarding the experimental-use exception (Art. 30 of TRIPs): 'Any commercially relevant or significant use of a patented technology during the life of the patent, including the generation of data for marketing approval and, of course, the commercial scale manufacture, inventory, stockpiling and distribution of copied drugs should be explicitly excluded from this exemption.'[84]

Relying on data provided by EFPIA, the EU argued that the European research-based pharmaceutical industry had made an analysis of its alleged losses suffered in Canada due to Bolar exemptions, which exceeded the amount of C$100 million per year.[85] According to the EU, the analysis was based on the 'conservative' assumption that, while Bolar exemptions would allow generic companies to market the product immediately upon patent expiry, in the absence of these provisions effective marketing would only be possible, at the earliest, two years after the patent has expired.[86]

The position expressed by the EU and EFPIA concerning the Bolar exemptions was also supported by regional and global IP-based organizations. The IPFMA, for instance, argued that the experimental use of patented material should be the only exception allowed under TRIPs Article 30 and that any other commercial use, including development of data, manufacture, stockpiling, should be explicitly excluded.[87] The 1997 TABD Action Plan for IPRs included the 'avoidance of any expansion, and preferably elimination, of regimes permitting the commercial testing of products during the term of the patent'.[88] That was also the position of UNICE which called for the 'prohibition of Bolar type exclusion and introduction of indirect infringement as in the Community Patent Convention'.[89]

In contrast, the generic-based pharmaceutical industry expressed its opposition to the action taken by the EU. The International Generic Pharmaceutical Alliance (IGPA) argued that the Bolar exemption was 'the very sort of provision that typifies the "balance" which is expressed in TRIPs and to which signatory countries were agreeing' and that 'it is very damaging to the spirit of TRIPs that certain interests seek to undermine this provision'.[90] That was also the position of the European Generic Medicines Association (EGA).[91]

Arguments presented by the parties and conclusions of the panel During the dispute process, the EU presented the following arguments:[92]

1. According to Art. 27.1 patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Pursuant to Art. 28 of the TRIPs agreement, a patent shall confer on its owner the exclusive right to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling or importing the patented product.
3. Art. 30 states that the term of protection available for patents shall not end before the expiry of a period of 20 years counted from the filing date.
4. Despite the above provisions, in the case of pharmaceutical patents, Canada does allow a third party to use the patented invention without the consent of the patent-holder in two instances:
   4a. When a third party carries out experiments and tests (proof of safety and bioequivalency) in order to obtain marketing approval for a copy of an innovative medicine before the expiry of the relevant patent (Section 55.2 (1) of the Canadian Patent Act). Consequently, this would ensure that the generic drug would be available to the market immediately after the patent expiry of the original drug.
   4b. When a third party wishes to manufacture and stockpile patented products for a period of up to six months before patent expiry for sale after expiry (in particular, Section 55.2 (2) of the Patent Act read in conjunction with the manufacturing and Storage of Patented Medicines Regulation).
5. Thus, Canada's legal regime appears to be inconsistent with its obligations under TRIPs, particularly with respect to Art. 27, 28 and 33 of the agreement.

Canada, on the other hand, based its counter-arguments on a more lax interpretation of the TRIPs agreement, as well as on social justification:[93]

1. The exceptions to the exclusive patent rights in the Canadian Patent Act are consistent with the 'limited exceptions' provision in Art. 30 of the

agreement. These exceptions did not conflict in any mode or manner with the 'normal exploitation' of a patent. Nor did they prejudice or 'unreasonably prejudice' (as phrased in Art. 30) the 'legitimate interests' of a patent-holder. In parallel, and in accordance with Art. 30, the exemptions took into account the 'legitimate interests' of third parties.

2. That Art. 27.1 of TRIPs prohibits discrimination of inventions in the basic fields of technology did not apply to 'limited exceptions', as provided for by Art. 30. And, in any event, Canada's limited exceptions to the exclusive rights conferred by a patent did not discriminate against other fields of technology. Such exemptions relate to products subject to laws regulating the manufacture, construction, use or sale of a product and not to any particular field of technology.
3. Therefore, Canada's limited exceptions to the exclusive rights conferred by a patent did not reduce the patent term of protection, nor did they impair the patentee's right to exploit its patent for the full term of protection by working the patent for its commercial advantage.
4. Socially speaking, Canada argued that the Bolar and stockpiling provisions adopted under its Patent Act aimed to achieve a balance between IP rights and obligations, both of which were recognized objectives of the TRIPs agreement (Art.7). In practice, the above provisions enabled competition to take place immediately after patent expiration and, in doing so, they were consistent with Art. 40 of TRIPs – adopting measures for preventing IPRs from having an adverse effect on competition. Canada also noted that the Bolar and stockpiling provisions sought to protect and to promote public health (in accordance with Art 8.1) by increasing access to cost-effective generic medicines, following patent expiry.

Moreover, as a counter measure, Canada requested the EU to hold consultations concerning what Canada regarded as the positive discrimination of patented pharmaceutical products by the EU.[94] Canada argued that the granting of SPCs (patent extensions) via Council Regulation (EEC No. 1768/92) and European Parliament and Council Regulation (EU No. 1610/96) were inconsistent with the anti-discrimination principle provided by Art 27.1 of TRIPs, since they only applied to pharmaceutical and agricultural chemical products.[95]

The US supported Canada's position with respect to the Bolar provisions, arguing that 'pre-expiration testing' (Bolar type tests) was a reasonable exception to the exclusive rights provided by Art. 28, and justified under Art. 30 of the agreement.[96] However, the US rejected Canada's 'stockpiling' legislation, arguing that it did not fall within the scope of 'limited-exceptions' of Art. 28. The US noted that stockpiling activities during the patent term merely 'facilitated the avoidance by generic manufacturers of the normal manufacturing and

distribution start-up time after patent expiration that was faced by all competitors of producers of all patented products'.[97]

The DSB panel published its conclusions in a report dated 17 March 2000, noting that 'the legal issues in this dispute primarily involve differences over interpretation of the key TRIPS provisions invoked by the parties, chiefly Articles 27.1, 30 and 33'.[98] Concerning Canada's Bolar exemption, the panel found that it was indeed a 'limited exception' within the meaning of Art. 30 of TRIPs.[99] As to Canada's stockpiling provisions, the panel found that they constituted a substantial curtailment of the exclusive rights that patent owners are entitled to under Art. 28.1 of the agreement.[100] The panel based its conclusion both on legal interpretation and economic reasoning. With respect to the latter, the panel noted that given the exclusive rights granted under the patent system it is reasonable to expect that patent owners would enjoy an additional period of exclusivity after patent expiry. The panel thus concluded that stockpiling activities, aimed at reducing post patent-expiry market exclusivity, were inconsistent with expected market effects that can only be perceived as an affirmation of the patent system itself. Accordingly, the panel recommended that Canada should bring Section 55.2(2) into conformity with its obligations under the TRIPs agreement.[101] At the DSB meeting of 23 October 2000, Canada informed the participating country members that it had implemented the panel's recommendations with effect from 7 October 2000.[102]

The advanced pharmaceutical industry in Europe, represented by EFPIA, was clearly disappointed by the ruling[103] and continued to argue fiercely against Bolar orientated experiments.[104] Similarly, the EU also maintained its position concerning Bolar exemptions despite the DSB ruling, although using less explicit language. As submitted in a communication dated 13 June 2001 ('The Relationship Between the Provisions of the TRIPs Agreement and Access to Medicines'):

> The EC and its Member States consider that Article 30 amounts to a recognition that the patent rights contained in Article 28 ('Rights Conferred') may need to be adjusted in certain circumstances. The provisions of Article 30 should be fully respected, and be read in light of Articles 7 and 8…They should not be interpreted as allowing for any substantial or unjustified curtailment of patent rights. However the EC and their Member States are not opposed in principle to exemptions being made, for example, for purpose of research, provided of course that such exemptions are non-discriminatory.[105]

As we have seen, with the coming into effect of the TRIPs agreement in 1996, the advanced pharmaceutical industry in Europe, as well as its IP allies, were highly alert as regards to reaping the potential benefits deriving from the agreement. Between 1996 and 1998 the industry followed a strategy according to which TRIPs implementation was the most important element of the agreement.

In doing so, the industry and its IP allies treated TRIPs as a minimum-standard agreement that must be implemented at all cost. The advanced pharmaceutical industry in Europe also functioned as a 'watch-dog', providing data regarding the state of TRIPs implementation in WTO members, particularly in developing and least-developed countries such as India, Pakistan, Argentina, Brazil and Korea. Simultaneously, the industry made an effort to ensure that TRIPs is interpreted in a more protective manner (dispute against Canada), considering this type of action as a value-added goal.

It is highly plausible that the industry's efforts were translated into action by the EU, as observed in two WTO disputes launched by the EU. In the dispute with India, the EU argued that India did not implement TRIPs provisions concerning (1) The establishment of 'mailbox' procedures to patent applications concerning pharmaceutical and agro-chemical products, and (2) the granting of exclusive marketing rights (EMRs) to such products (Art. 70.8 and 70.9 of TRIPs). *Inter alia*, the EU argued that European-based companies would suffer economic losses if India did not fully implement the above provisions. The DSB report issued by the panel fully supported the EU's position. It should also be noted that the EU participated as a third party in additional disputes (US vs. India, US vs. Pakistan) concerning mailbox applications and ERMs in the field of patented pharmaceuticals.

While the dispute with India was about implementation, the one against Canada concerned the interpretation of the TRIPs provisions, dealing with the scope of patent protection. Basing its arguments on a highly protective IP approach, the EU argued against patent legislation in Canada providing for Bolar exemptions (commercial tests in patented pharmaceutical products prior to patent expiry) and for 'stockpiling' activities in the field of pharmaceuticals. According to the EU, such legislation was inconsistent with the rights granted to patent owners under TRIPs (Art. 28 and 30). In its report, the DSB found that Canada's legislation concerning stockpiling was in contradiction to the agreement. However, regarding the more important issue of Bolar exemptions, the DSB found that Canada's legislation was a 'limited exception' to patent rights, and therefore consistent with the provisions of Art. 30 of the TRIPs agreement.

Regardless of the result, both cases, particularly the Bolar exemption case, suggest that the actions taken by the EU reflected to a great extent the IP interests of the advanced industry in Europe, as well as its perspective and interpretation of the TRIPs agreement. However, it must be noted that in this research it was not possible to gain full access to the different discussions and protocols leading to the decisions of the EU to initiate two disputes against India and Canada. Therefore, further research is needed in order to fully establish that the actions taken by the EU with respect to pharmaceutical patents were indeed a result of direct lobbying by the advanced pharmaceutical industry.

8.4 'SEATTLE'-RELATED ACTIVITIES – INDUSTRY'S EFFORTS FOR PRESERVING TRIPS INTERNATIONAL PHARMACEUTICAL IP AGENDA

The advanced pharmaceutical industry in Europe considered the Seattle ministerial meeting of the WTO to be an important test of the robustness of the TRIPs agreement. The industry was well aware of the harsh criticism expressed by developing countries and LDCs concerning the agreement (as discussed in the previous chapter). Accordingly, the industry and its IP allies focused chiefly on adopting a coherent and unified strategy for preserving their interests in the agreement.

The industry's efforts concerning the above commenced as early as September 1998. In an internal circular dated 11 September 1998, EFPIA's Director General, Brian Ager, asked members of EFPIA's Intellectual Property Committee to formulate an opinion on the possible inclusion of IPRs in the Millennium Round.[106] The circular emphasized the need to cooperate with other organizations such as the IFPMA, PhRMA, JPMA (Japan Pharmaceutical Manufacturers Association) and UNICE.[107] Correspondence between EFPIA, Novartis, and UNICE during November 1998 also suggests that the industry sought to coordinate its position with other European IP-based groups.[108]

For the advanced pharmaceutical industry in Europe, the most problematic aspect of the meeting in Seattle was its closeness to the deadline for implementing TRIPs by developing countries (year 2000). In other words, the industry was highly aware of the risks involved in 're-shuffling the cards', particularly vis-a-vis developing countries and LDCs, should TRIPs be open to negotiations in Seattle. As put forward by EFPIA in a letter addressed to Sir Leon Brittan, Vice President – European Commission, dated 4 January 1999:

> Global improvement of intellectual property is more than ever a key issue for the European research-based pharmaceutical industry. EFPIA had therefore made an in-depth assessment of this issue (TRIPsII). We have identified a number of relevant improvement issues in areas such as patents, registration data and trademarks, but at the same time we had to clearly recognise that re-opening intellectual property in the WTO negotiations entails important risks. …By 2000 the TRIPs Agreement will take effect for many countries and we are very concerned that its implementation would be affected by the negotiations.[109]

UNICE, which played a pivotal role in presenting the interests of the entire European IP-based industries, also expressed the same concern:

> UNICE notes that several developing countries feel that because of the Uruguay Round single undertaking principle, they have had obligations imposed on them in the field of intellectual property that they would like to re-negotiate downwards.

> The attitude of some leading LDCs towards the year 2000 deadline and their TRIPs obligations clearly shows their current thinking on the subject.[110]

As a result, the industry focused primarily on preserving the level of IP protection provided by the TRIPs agreement. Working closely with its IP allies (IFPMA, PhRMA, UNICE, CEFIC, TABD, US IPC), both regionally and internationally, the industry pursued a strategy which consisted of two layers:

1. Core strategy – according to which negotiations on IPRs (referred to as TRIPsII) should not by any means reduce the current level of protection provided by the agreement.
2. External or complementary strategy – presenting a list of highly protective demands for TRIPsII in order to negate the attempts of developing countries and LDCs to downgrade the level of IP protection provided by TRIPs. These two elements are discussed below.

8.4.1 Core Strategy – Preventing any Downgrading in the Level of IP Protection Provided by the TRIPs Agreement

The industry and its IP allies used all available channels (position papers, conferences, press releases, personal meetings, and so on) in order to emphasize the principle of the non-downgrading of TRIPs, doing so repeatedly and simultaneously.

In a June 1999 position paper, EFPIA argued that 'if the TRIPs Agreement is included on the agenda of the Millennium Round, the mandate for negotiation must be clearly limited to improvements in the level of intellectual property protection'.[111] In another position paper dated October 1999, EFPIA added that the 'Commission's general commitment of principle that such negotiations should in no way lead to lowering standards or affect the ongoing work in the TRIPs Council (built-in agenda) and that the current transitional periods for TRIPs implementation must not be delayed is pivotal'.[112] Similarly the IFPMA urged all countries to 'keep faith with the Uruguay Round Agreement and with all those countries that are making the substantial effort to align their legislation and practices with their TRIPs obligations'.[113] CEFIC, the chemical equivalent of EFPIA, in its position paper of October 1998, concluded that 'in view of the negotiations that took place on the occasion of the Uruguay Round, and the TRIPs Agreement resulting from it, the chemical industry could not accept any weakening of TRIPs in reply to unrealistic demands'. The TABD, in its 1999 mid-year report, recommended that 'the US and the EU should vigorously oppose any efforts to weaken or otherwise renegotiate the protection achieved in the TRIPs Agreement'.[114] Identical language was used by the US IPC, which argued that 'it is critical that the United States make it clear that, for

the United States, the TRIPs Agreement provides a baseline for the protection and enforcement of intellectual property rights and that it will not be party to any weakening of the agreement'.[115]

In order to express its opinions more directly and effectively, the IP 'alliance' also held personal meetings with key officials from the EU, the US, the WTO and WIPO. For instance, between 19–21 October, a joint UNICE and US IPC delegation held a series of meetings concerning TRIPs II negotiations. The delegation met with key officials such as Rita Hayes, Deputy US Trade representative, Roderick Abbott, Head of EU permanent delegation to the International Organizations in Geneva, Paul Vandoren, Director of Unit /D/3 (New Technologies, Intellectual Property and Public Procurement) at DG Trade of the European Commission and Pascal Leardini, DG Internal Market, both of the European Commission, Adrian Otten, Director of the WTO Intellectual Property and Investment Division, Dr Kamil Idris, Director of WIPO, as well as other officials.[116] During these meetings, representatives of the advanced pharmaceutical industry in Europe and its IP allies underscored the need for TRIPs implementation by developing countries and the possibility of limiting IP negotiations in Seattle to TRIPs built-in-agenda.[117]

Moreover, in order to ensure that TRIPs implementation would not be disrupted by the negotiations, EPFIA, UNICE and the US IPC also asked the Commission to strongly oppose demands for extending the moratorium on non-violation disputes (Art. 64.2).[118] UNICE, highly sceptical about the prospects of TRIPsII, took the extreme position that the EU should avoid negotiating on IPRs in Seattle.[119] Nevertheless, it argued that negotiations, should they take place, must be limited to the implementation of TRIPs and to the work-programme embodied in TRIPs built-in agenda.[120] With respect to pharmaceuticals, TRIPs built-in agenda required the Council for TRIPs to reach a decision by the year 2000 regarding the non-patentability of inventions based on plants and animals (Art. 27.3b).

Pharmaceutical companies also chose to forward their message individually. At an FT conference concerning TRIPs (30 September 1999), a senior Pfizer patent consultant called for the rejection of any proposal aimed at weakening TRIPs level of IP protection, such as in the cases of parallel trade and compulsory licences: 'Such proposals must be resisted such that there is no re-opening of existing agreements to further delay the implementation by developing countries, or to permit any back-sliding with respect to substantive levels of protection.'[121]

Finally, the advanced pharmaceutical industry in Europe also chose to respond to accusations made by relevant NGOs, such as Médecins Sans Frontières (MSF), that the TRIPs pharmaceutical IP agenda restricts access to quality medicines in the developing world. As argued by EFPIA and the IFPMA in a joint press release dated 23 November 1999: 'A serious look at the WTO TRIPs

agreement indicates its global social benefits in terms of health and economic development, spreading R&D and related investment to more countries – making globalisation of the fight against disease a reality.'[122]

8.4.2 Complementary Strategy – Presenting Tough IP Demands for the Possible Negotiations on 'TRIPsII'

The advanced pharmaceutical industry in Europe was also prepared for full-scale negotiations on TRIPsII, in the event that the primary strategy of the non-downgrading of TRIPs failed. Its intention was to convince the Commission to introduce a list of highly protective IP demands that would negate any demands presented by developing countries and LDCs for the downgrading of TRIPs, particularly in the field of pharmaceuticals. As before, its vast organizational scope allowed the industry to coordinate its position with the rest of its IP allies. The industry's demands with respect to TRIPs pharmaceutical IP agenda focused on five major issues:[123]

1. Prohibiting the principle of international exhaustion, as provided by Art. 6 and the footnote to Art. 28 of TRIPs. As discussed in Chapter 6, international exhaustion was one of the few issues in TRIPs that was totally contrary to the interests of the advanced pharmaceutical industry in Europe. The industry deeply opposes the principle of international exhaustion as it allows for the parallel importation of patented pharmaceuticals.
2. Providing for a 10-year exclusivity period for data submitted for the purpose of obtaining marketing approval for pharmaceutical and agro-chemical products (Art.39.3). By making this demand, the industry sought to broaden the scope of its market monopoly, in addition to that granted by patents vis-à-vis generic-based companies.
3. Extending the effective patent term of protection by:
   - 3a. Introducing in TRIPs a supplementary term of protection for patents (SPCs in the case of the EU and Patent Term Restoration in the case of the US). According to the industry such a term was required to enable patent owners to recoup the period of market exclusivity lost as a result of the process of applying for marketing approval.
   - 3b. Prohibition of any type of commercial testing in patented products – Bolar exemptions – other than solely for experimental purposes.
   - 3c. Creating a linkage between the granting of marketing approval of generic copies and the use of the relevant patent. The industry demanded that regulatory authorities seek affirmative proof that all relevant patents that were the basis for the generic version had expired or were used with the patentee's permission. This, of course, would delay the launch of the generic version to the market, as it would

make the process of approving the generic drug more complicated and time-consuming.

4. Removing the exemption from patentability of plants and animals, as specified in Art. 27.3b. Taking the opposite position of developing countries and LDCs, the industry argued for the patenting of inventions based on all types of animal and plant varieties that meet TRIPs criteria for patentability.
5. Increasing sanctions and criminal penalties for counterfeiters, particularly where health and drug safety are concerned. Also to create and to provide for a model anti-counterfeiting law, as a reference for WTO members.

Despite the above demands, it is reasonable to assume that the advanced pharmaceutical industry in Europe did not expect that the EU, or the US for that matter, would adopt these demands in full. For example, the industry's demand to allow the patentability of plants and animals seemed to be quite unrealistic in the light of the huge resistance of developing countries and LDCs, as well as the opposition of NGOs based in the developed world, to the issue of 'life patenting'. In fact, it seems that EFPIA, UNICE and CEFIC became quite worried about NGOs activities, which were aimed at presenting the TRIPs agreement in a negative light, and their eventual implications on the Commission's IP position.[124]

On the contrary, these demands signalled to the EU, the US and also developing countries, that for IP-based industries, such as in the pharmaceutical and chemical fields, the level of IP protection provided by TRIPs can be significantly strengthened. In other words, the advanced pharmaceutical industry in Europe wanted to ensure that demands for the downgrading of TRIPs would encounter demands for upgrading the agreement, which would eventually lead to keeping TRIPs in its current level of protection.

It should also be noted that the industry did not present any demands with respect to the protection of trademarks. This is probably because developing countries did not raise any objections regarding trademarks and pharmaceuticals, something that may come as a surprise given their solid opposition to this issue during the 1970s.

8.4.3 The IP Position of the EU Concerning the Seattle Ministerial Meeting

The EU presented its position on IPRs resulting from Seattle in a communication to the WTO, dated 2 June 1999: *EC Approach to Trade-Related Aspects of Intellectual Property in the New Round*.[125] Quoted below is the full text of the communication:

1. The inclusion of intellectual property in the Uruguay Round was a major breakthrough in the field of multilateral rules on trade-related aspects of intellectual property rights. For the first time, intellectual property benefited from basic WTO principles such as most-favoured-nation. It also made the provisions subject to the integrated dispute settlement system of WTO in the field of substantive standards as well as in the field of enforcement.
2. The TRIPS Agreement was not meant to be a static instrument, but one capable of adaptation to new realities. It provides for a 'built-in agenda'. Furthermore, the launching of a new round offers the opportunity for examining areas in which the TRIPS Agreement should be amended. However, the launching of the new round will take place at a time when the transitional periods, which developing countries can avail themselves of for implementing TRIPS, will expire.
3. It should of course be kept in mind that the TRIPS *acquis* is a basis from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods.
4. The pursuit of amendments to TRIPS should be undertaken whilst preserving a balance between the interests of all countries as well as between the users and the right holders. First, issues which were left aside because of lack of consensus at the end of the Uruguay Round, require further examination. In the patent area, for example, the two existing systems for filing patent applications ('first-to-file' versus 'first-to-invent') lead to unnecessary burdens for inventors. Second, one may be able to build upon a number of new developments on intellectual property that have taken place outside the WTO and on which international consensus has made progress. For example, in the area of copyright, international consensus was reached in WIPO on several issues relating to copyright and related rights in the context of the Information Society.
5. In addition, it will be necessary to take decisions on the follow-up of the 'built-in agenda', which will almost certainly not be terminated by the time of the Ministerial Conference in Seattle, notably in the area of geographical indications (multilateral register for wines, spirits and other products).

Based on the above, particularly points 2 and 3, it is quite easy to conclude that the EU's approach to IPRs reflected to a great extent the primary objective of IP-based industries in Europe: the advanced pharmaceutical industry for example the non-downgrading of the TRIPs agreement. Moreover, the US and Japan used almost identical language in their communications. The former argued that 'the priority TRIPS issue is the full implementation of TRIPS obligations by developing-country WTO Members no later than 1 January 2000'.[126] The US also stated that 'Article 71 also provides that amendments to the TRIPS Agreement may be referred to the Ministerial Conference if they serve the purpose of incorporating higher levels of intellectual property rights that have been achieved in other multilateral agreements and accepted by all WTO Members'.[127] Japan submitted a similar statement:

> Taking into account the nature of the TRIPS Agreement, that is, a minimum standard of intellectual property protection, we should not discuss the TRIPS Agreement with

a view to reducing the current level of protection of intellectual property rights. To the contrary, the TRIPS Agreement should be improved properly in line with new technological development and social needs. For example, the TRIPS Agreement should deal with higher protection of intellectual property rights which has been achieved in other treaties or conventions in other fora appropriately.[128]

Thus, in a well-coordinated operation, at least in terms of language and dates of submission of communications to the WTO, the Triad expressed an IP position that was highly compatible with the interests of the international IP-based community. Differing completely from developing countries and LDCs, the IP approach of the US, the EU and Japan intentionally avoided getting into the 'nuts and bolts' of TRIPs provisions. Instead they emphasized the non-downgrading of TRIPs as a precondition for future negotiations on TRIPsII.

Once again it should be noted that it is not currently possible to conclude that the similarity in views and strategies between the EU and the advanced pharmaceutical industry in Europe and its IP allies is subject to causality. Lack of sufficient information as to why and how the EU adopted its IP objective prevents one from doing so. Moreover, in terms of internal coherence, the EU approach to this issue was not entirely homogeneous. The Commission clearly supported the IP approach described above. Yet compared with its 1996 approach the European Parliament adopted a more moderate view on TRIPs, as described in its resolution of 18 November 1999.[129] The resolution was issued in response to a communication by the Commission: *The EU Approach to the Millennium Round*, dated 8 July 1999. This resolution was based on the recommendations of the Committee on Industry, External Trade Research and Energy, of 16 October 1999.[130] In its resolution the European Parliament called upon the Commission to offer comprehensive technical aid for developing countries facing difficulties in implementing TRIPs. It also argued that, given the objections to the patenting of living organisms, the Commission should evaluate the agreement (Art. 27.3b) and act accordingly, should this evaluation necessitate change. The resolution also supported the possibility of granting longer transitional periods to LDCs for implementing TRIPs, and called for the transfer of technologies and know-how to developing countries. However, the European Parliament explicitly rejected the conduct of comprehensive negotiations on the TRIPs agreement, as well as 'insisting' (used in the original text) on the 'need for effective protection of intellectual property, which is a vital element of fair trade'.[131]

Since the Seattle ministerial meeting failed to produce an agenda for negotiations, it is difficult to foresee which approach would have been eventually adopted in Europe. Still, the pivotal role played by the Commission in respect of the European decision-making process for trade agreements via the Article

133 Mechanism, enables it to exert great influence on WTO-related matters, including IPRs.[132]

Post-Seattle events suggest that the Commission remains an enthusiastic supporter of IPRs in general and of the TRIPs pharmaceutical IP agenda in particular. This can be seen in a series of position papers issued by the Commission concerning compulsory licensing, data exclusivity, patenting of plants and animals and access to medicines.[133] More impressively, the Commission reiterated its commitment to the protection of pharmaceutical IPRs in forums that were quite hostile to the subject, such as at the Trans Atlantic Consumer Dialogue Conference, focusing on patents and pharmaceuticals (10–12 February 2000), and the Fourth Civil Society Meeting on Trade and Access to Medicines, dated 6 November 2000.[134]

We conclude that, to a great extent, the EU's IP approach to the WTO Millennium Round reflected the interests of the advanced pharmaceutical industry in Europe. Most importantly, the EU endorsed the principle of non-downgrading of the TRIPs agreement. That was also the case for the US and Japan. The above principle was aggressively advocated by the industry and its IP allies (IFPMA, UNICE, CEFIC, TABD, US IPC, and so on). It was selected carefully and intentionally, being part of an overall strategy that focused on the preservation of the TRIPs agreement, rather than on its improvement. For the industry and its IP allies, the close proximity of the Seattle negotiations to the implementation deadline of TRIPs in developing countries (year 2000), imposed serious risks to the level of IP protection provided by the agreement. The ambitious demands presented by developing countries and LDCs convinced the industry that its main goal was to protect the TRIPs agreement (core strategy) instead on focusing on its improvement. In the event that the negotiations on the TRIPs agreement had proceeded on a full-scale basis, the industry and its IP allies also adopted a complementary strategy aimed at negating the demands for the downgrading of the agreement.

With respect to the pharmaceutical IP agenda, the advanced pharmaceutical industry in Europe and its IP allies presented five major demands: (1) prohibiting international exhaustion; (2) placing a 10-year protection period for data exclusivity; (3) extending the effective term of patent protection via a supplementary term of protection and the exclusion of Bolar provisions; (4) allowing for the patentability of plant and animals, and (5) adopting and enforcing more restrictive measures against counterfeiters.

Thus, the IP position of the EU with regard to the WTO meeting in Seattle was fully compatible with the industry's primary goal of the non-downgrading of the TRIPs agreement. Evidence suggests that even after Seattle and despite the increasing opposition to the issue of IPRs by developing countries and NGOs, such as Oxfam and Médecins Sans Frontières, the Commission remains a solid supporter of pharmaceutical IPRs.[135] This support is very important

to the advanced pharmaceutical industry in Europe particularly in the light of the increasingly moderate IP views expressed by the European Parliament towards Seattle.

8.5 CONCLUSION

This chapter explored and described the interaction and cooperation between the advanced pharmaceutical industry in Europe and the EU, regarding the TRIPs agreement during the period of 1995 to 1999. It was not before the creation of the agreement in 1995, that the consequences of the establishment of a highly protective international IP system began to unfold. Consequently, from 1998 and towards the Seattle ministerial conference of November 1999, developing countries and LDCs severely questioned the legitimacy of the TRIPs agreement.

Nevertheless, it is because of these attacks that the ability of IP advocates, such as the advanced pharmaceutical industry in Europe and its IP allies, to exploit and preserve the TRIPs agreement was such an impressive achievement, particularly with respect to its rather controversial pharmaceutical IP agenda.

In order to demonstrate the above, this chapter focused first on the declarative level, providing an overview of the EU position concerning IPRs in general and the TRIPs agreement in particular. In comparing this position to that of the advanced pharmaceutical industry in Europe and its IP allies, as described in detail in previous chapters, one can conclude that the EU holds similar or almost identical IP views. Even more so, when expressing its IP views, the EU (particularly the European Commission) and its member states, such as the UK and Germany, used a language that was very similar to that used by the industry.

In essence, the EU stressed the importance of IPRs to its economic performance, competitive abilities, level of innovation and attractiveness to corporate investment. The EU also attached positive features to IPRs with respect to their welfare and economic implications for society as a whole, with the Commission even describing IPRs as an essential element of democracy and market economies.

Regarding the TRIPs agreement, the EU prided itself on being one of the driving forces behind the agreement. It emphasized the achievements secured by the TRIPs agreement, namely the inclusion of the basic principles of national treatment and most favoured nation, dispute settlement mechanisms and enforcement procedures and, most importantly, the detailed protection provisions embodied in the agreement. The EU also explicitly admits that the primary goal of the TRIPs agreement was, and still is, to serve IP-based companies, such as pharmaceutical multinationals. As to the criticism expressed

by developing countries and LDCs, the EU noted that, although these countries may expect short-term costs, over the long-run the TRIPs agreement would benefit all WTO members.

That the EU, and particularly the Commission, expresses IP views that are very similar to those of the advanced pharmaceutical industry does not imply that there is an institutional process through which interests, beliefs and ideas are translated into common views about IPRs in the EU. On the contrary, given the complex mechanism for international IP policy making in the EU, it is logical to assume that different views about IPRs are conveyed via multiple channels across the national and regional level. In fact the EU, and the Commission (including DG Trade) have been exposed to antagonistic views about IPRs and the TRIPs agreement by groups such as the BEUC and the TACD. In other words, it seems that views expressed by the EU about IPRs reflect specific interests (research-based pharmaceutical industry) rather than a pluralist and consensual view originating from a coherent institutional process.

Next, the chapter focused on the operational level, studying the linkage between the advanced pharmaceutical industry in Europe and EU operations concerning the TRIPs agreement. Relating industry activities to EU operations concerning TRIPs was a complex task that required a two-stage analysis. The first looked at the way in which the industry and its regional and international IP allies strategized and used their sophisticated organizational infrastructure in order to provide a unified and coherent input across the national, regional and transnational levels. The second assessed the TRIPs-related operations by the EU, reaching the conclusion that these actions reflected, to a great extent, the IP interests of the advanced pharmaceutical industry in Europe, as well as that of its IP allies.

Focusing on TRIPs IP pharmaceutical agenda, the chapter identified two major periods:

1. 1995 to 1998 – during which the industry's actions were aimed at reaping the benefits of the TRIPs agreement. In order to do so, the industry and its IP allies adopted a strategy that focused on the full and timely implementation of the agreement, particularly in key developing countries such as India, Pakistan, Argentina, Brazil and South Korea. As a tactic, the industry and its IP allies kept treating TRIPs as a minimum-standard agreement that must be implemented at all cost, as well as providing current data about the state of TRIPs implementation by WTO members such as those mentioned. Furthermore, as a value-added goal, the advanced pharmaceutical industry in Europe and its IP allies also wanted to ensure that TRIPs is interpreted in a more protective manner.

   Two disputes handled by the EU suggest that the efforts of the advanced pharmaceutical industry in Europe and its IP allies were fruitful.

In the dispute against India (September 1997), the EU argued that India did not implement its obligations under TRIPs concerning patented pharmaceuticals because it failed to: (i) provide adequate facilities for accepting and processing patent applications of pharmaceutical and agro-chemical products ('mailbox' procedures, Art. 70.8 of TRIPs), and (ii) grant exclusive marketing rights (EMRs) to such products as provided by Art. 70.8 and 70.9 of the agreement. The EU argued, *inter alia*, that European pharmaceutical companies would experience considerable economic losses if India did not fully implement the above provisions. In this case, the WTO ruled in favour of the EU (August 1998). Moreover, the EU also participated as a third party in additional disputes concerning the same issues (US vs. India, US vs. Pakistan).

In a different dispute against Canada (November 1998), the EU focused not only on TRIPs implementation but also, and more importantly, on the interpretation of TRIPs provisions dealing with the scope of patent protection. The EU, basing its position explicitly on the views of the advanced pharmaceutical industry in Europe, argued against Canada's Patent Act, which provided for Bolar exemptions (commercial testing of drugs with patent protection in place) and for 'stockpiling' activities in patented pharmaceuticals. The EU argued that such legislation was inconsistent with the rights granted to patent owners under Art. 28 and 30 of the TRIPs agreement. In this case, the WTO ruled in favour of Canada's Bolar legislation (March 2000), arguing that it was a 'limited exception' to patent rights, and therefore consistent with the provisions of Art. 30 of TRIPs. However, the WTO also found that Canada's legislation concerning stockpiling activities was inconsistent with its obligations under the TRIPs agreement. Thus, although the advanced pharmaceutical industry in Europe failed to secure a more protective interpretation of TRIPs with respect of the scope of patent protection in pharmaceuticals, it was clearly able to convince the EU to pursue this goal. The EU did so even when it meant going against a developed country such as Canada, and to some extent also against the US, which provided a more moderate version of Bolar exemption (1984 Waxman–Hatch Act). However, because it was not possible to gain full access to the entire decision-making protocols of the EU with respect to the above disputes, the chapter could not establish whether the EU pursued the interests of the advanced pharmaceutical industry in Europe because of the latter's lobbying activities. Still, because of the unique nature of these disputes and given that the EU relied on data provided by the industry, such a causality is quite plausible.

2. 1999 up to the Seattle ministerial meeting – here the advanced pharmaceutical industry in Europe concentrated primarily on preserving the level of protection provided by the TRIPs agreement. This strategy was selected

carefully and intentionally by the industry and its IP allies as a response to the fierce criticism and ambitious demands presented by developing countries and LDCs. The industry mainly feared that developing countries would use negotiations on IPRs in Seattle (TRIPsII) as an excuse for not carrying out their obligations to implement the agreement by the year 2000. Therefore, the industry and its IP allies used all available channels (position papers, conferences, press releases, personal meetings, and so on) in order to convey a single simple message – that in any event, the TRIPs agreement must not be downgraded.

The advanced pharmaceutical industry in Europe and its IP allies were also well prepared for a situation in which negotiations on TRIPs proceeded on a full-scale basis. Adopting a complementary strategy aimed at negating demands for the downgrading of TRIPs, the industry and its IP allies presented their own list of highly protective demands.

Concerning TRIPs pharmaceutical IP agenda, the advanced pharmaceutical industry in Europe focused on five major issues: (i) prohibiting international exhaustion, that is preventing parallel imports; (ii) placing a 10-year protection period for data exclusivity; (iii) extending the effective term of patent protection using supplementary term of protection, while prohibiting 'Bolar' type legislation; (iv) legalizing the patentability of plants and animals, and (v) adopting and enforcing stricter measures against counterfeiters.

As in the previous period, the advanced pharmaceutical industry in Europe and its IP allies were able to secure their international IP objectives. Quite noticeably, the official IP position of the EU to the WTO Millennium Round reflected, to a great extent, the interests of the industry and its IP allies. That was also true in the cases of the US and Japan. Most importantly, these countries endorsed the non-downgrading of the TRIPs agreement level of IP protection. However, in terms of internal European coherence, it should be noted that the views of the EU concerning the negotiations on IPRs in Seattle were not completely homogeneous. While the European Commission expressed a view highly compatible with that of the advanced pharmaceutical industry in Europe, the IP position of the European Parliament became more moderate and in favour of developing countries, though not in a manner that seriously conflicted with the industry's interests.

Still, evidence suggests that, even after Seattle, the Commission remained a solid supporter of pharmaceutical IPRs despite increasing opposition to the issue by developing countries and NGOs, such as Oxfam and Médecins Sans Frontières. Given the key role of the Commission in devising European IP trade policy, that support was, and still is, crucially important to the advanced pharmaceutical industry in Europe and its IP allies.

Overall, it is quite evident that the interests and operations of the advanced pharmaceutical industry in Europe regarding the TRIPs agreement between 1995 and 1999 were substantially reflected in EU actions in that field.

NOTES

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7. Department of Trade and Industry, UK (2000)
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9. German Patent and Trade Mark Office (2000)
10. Vandoren (1999: 11)
11. European Parliament Committee on Research, Technological Development and Energy, (1996: 4) document number: A4–0376/96
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13. Commission of the European Communities (1999: 16); Commission of the European Communities - DG Trade (1999b; 2000b)
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27. Vandoren (1999: 11–12)
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29. BEUC (2000); Trans Atlantic Consumer Dialogue (1999)
30. Commission of the European Communities – DG Trade (2000a)
31. Ibid., p. 4
32. IFPMA (1995a: 16)
33. Ibid.
34. VFA, 1999 Annual Report (2000a: 19)
35. EFPIA (1999h: 2)

36. UNICE (1999: 6)
37. TABD, 'Charlotte Statement of Conclusion' (1998b: 22)
38. Intellectual Property Committee, US (1994b: 7–8)
39. Zueco (1999: 6)
40. Beton (1987), in author's notes
41. Ibid. Annex 1B, pp. 15–17
42. PhRMA (1999: 88–92); VFA, 1999 Annual Report (2000a: 18–20); TABD (1998: pp. 6–34); EFPIA (1999g); EFPIA (June 1999e)
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44. WTO – Dispute Settlement Body, *India – Patent Protection For Pharmaceutical and Agricultural Chemical Products – Request for Consultations by the European Communitie* (1997b) document number: WT/DS79/1
45. WTO – Dispute Settlement Body, *India – Patent Protection For Pharmaceutical and Agricultural Chemical Products – Request for the Establishment of a Panel by the EC* (1997c), document number: WT/DS79/2; for a detailed overview of the arguments raised by the EU see: WTO – Dispute Settlement Body, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products: Complaint By the European Communities and Their Member States* (1998c: 8–33), document number: WT/DS79/R
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71. WTO – Dispute Settlement BodyDispute, *Pakistan – Patent Protection For Pharmaceutical and Agricultural Chemical Products – Request for the Establishment of a Panel by the United States* (1996c), document number: WT/DS36/3
72. WTO – Dispute Settlement Body, *Pakistan – Patent Protection For Pharmaceutical and Agricultural Chemical Products – Notification of a Mutually-Agreed Solution* (1997a), document number: T/DS36/4
73. Ibid.
74. WTO – Dispute Settlement Body, *Canada – Patent Protection of Pharmaceutical Products: Complaint by the European Communities and their Member States* (2000a: 1), document number: WT/DS114/R
75. Ibid., p. 1
76. Ibid.
77. Cornish (1999: 249–50); Council Agreement Relating to Community Patents (89/695/EEC) (1989)
78. Cornish (1999: 250)
79. For an overview of the Waxman–Hatch Act see: Mossinghoff (1999: 187–94); Grabowski and Vernon (May 1986: 95–198)
80. Unites States Court of Appeals For The Federal Circuit, (1984)
81. EC–Canada patent dispute, DSB report (WTO – Dispute Settlement Body 2000a: 37–8)
82. US Patent Code, Art. 35, Section 271(e)(1) reads in part that 'It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products'; See also Correa (2000: 75–81)
83. EC–Canada patent dispute DSB report (WTO – Dispute Settlement Body 2000a: 1–7, 12–15 and Annex I)
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96. EC–Canada patent dispute DSB report (WTO – Dispute Settlement Body 2000a: 138–42)
97. Ibid., p. 143
98. Ibid., p. 149
99. Ibid., pp. 157–60
100. Ibid., p. 157
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103. EFPIA – Press Release (2000a)
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105. Communication from the European Communities and their Member States to the TRIPs Council (2001: 3)
106. Director General EFPIA, circular addressed to members of EFPIA Intellectual Property Committee (11 September 1998); in author's records
107. Ibid.

108. Letter from the Head of Corporate Intellectual Property, Novartis, addressed to UNICE (5 November 1998); letter from EFPIA's Manager of Intellectual Property and Environment to UNICE (10 November 1998), in author's records
109. Letter from EFPIA's President to Sir Leon Brittan, Vice President European Commission (January 1998), in author's records
110. UNICE (13 November 1998: 29)
111. EFPIA (June 1999d: 2)
112. EFPIA (1999h: 1)
113. IFPMA (1999: 1)
114. TABD, Mid Year Report (1999: 72)
115. Intellectual Property Committee (US) (Gorlin and Levi 1998: 1); in author's records
116. Intellectual Property Committee (US) and UNICE (1998); Beton (1998); both available in author's records
117. Ibid., pp. 1–2
118. EFPIA (1999h: 1); Intellectual Property Committee (US) (Gorlin and Levi 1998: 4); UNICE (13 November 1998: 30)
119. UNICE (13 November 1998: 30)
120. Ibid., pp. 30–31
121. Richardson (1999: 8)
122. EFPIA – Press Release (1999i).
123. The description of the IP position of the advanced pharmaceutical industry in Europe and its IP allies is based on the following documents: EFPIA position papers (June 1999d; 1999f; 1999h); IFPMA (1999); UNICE (January 2000h; 2000f), Intellectual Property Committee (US) (Gorlin and Levi 1998: 3); TABD (1999: 72)
124. In a circular to EFPIA's Priority Action Team concerning the Millennium Round, the Director of EFPIA noted the following: 'If, due to NGO activity at national level, Member States are moving on some important issues, such as TRIPs, this would have huge implications on the EU negotiating position (and influence the current strong opposition of the Commission regarding any weakening of TRIPs). This should be viewed in a context where TRIPs is presented by the activists as a "weapon" used against developing countries and that traditionally the EU defined as a strong supporter of these countries' (Ager, Director General EFPIA, 1999);
125. Communication from the European Communities (WTO – General Council 1999a), document number: WT/GC/W/193
126. Communication from the United States (WTO – General Council 1999j), document number: WT/GC/W/323
127. Ibid.
128. Communication from Japan (WTO – General Council 1999c), document number: WT/GC/W/242
129. European Parliament, External Trade Committee on Industry, Research and Energy (1999), document number A5–0062/1999
130. European Parliament, Committee on Industry, Research and Energy (1999), reference A5–0062/1999, PE 231. 700/fin
131. European Parliament (1999)
132. See Chapter 5, section 5.3.3; see also: Woolcock (2000: 401–27)
133. Commission of the European Communities, *Legal Issues Related to Compulsory Licensing Under the TRIPs Agreement* (2001a); Commission of the European Communities, *Questions on TRIPs and Data Exclusivity – an EU Contribution* (2001b); Commission of the European Communities, *Review of the Provisions of Article 27.3(b) of the TRIPs Agreement – Draft Communication by the European Communities and Their Member States on the Relationship Between the Convention on Biodiversity and the TRIPs Agreement*, submitted by the European Commission to the Article 133 Committee (2001c)
134. Commission of the European Communities – DG Trade (2000a); Commission of the European Communities (November 2001)
135. For anti-patent views in the field of pharmaceuticals see: t'Hoen (2000); Oxfam (2001a; 2001b)

9. The dynamics of change within the framework of IPRs

9.1 ANSWERING THE FUNDAMENTAL QUESTION

The author of this book was motivated and challenged by one key question: why is such strong international intellectual property protection in place and how did this come about? More specifically, the book explores the manner in which the advanced pharmaceutical industry in Europe and its IP allies helped in shaping and preserving the global intellectual property system of the TRIPs agreement between 1995 and 1999.

The key conclusion is that the advanced pharmaceutical industry was successful in mobilizing national and regional authorities, such as the EU, and thereby played a significant role in the creation, preservation and exploitation of this strong international system of pharmaceutical IPRs. The process and rationale leading to this conclusion as enumerated in previous chapters is described below.

9.1.1 The Inadequate Economic Justification for the Establishment of IPRs

The overall goal of this book has been to investigate the international economic phenomenon of IPRs by using political tools. Accordingly, the theoretical framework was selected by a process of elimination, that is by assessing the feasibility of economic explanation of IPRs before moving to the political dimension.

Initially, it was necessary to consider the economic desirability of IPRs and their implications on society as a whole (so-called IPRs in a closed economy). Economists should tell us whether, on balance, a system of IPRs, or more accurately a system of intellectual monopoly rights, generates a net loss or a net benefit to society. Unfortunately thus far, or at least for the past 80 years, economists have been unable to provide an answer to this question, notwithstanding the availability of rich and in-depth literature on the economics of IPRs.

This was described in Chapter 2, which surveyed and assessed the economics of patents and trademarks – two major expressions of IPRs. The economics

of patents is particularly problematical, since it does not provide a coherent theory for assessing the benefits and costs deriving from this type of IPR. In order to increase the amount of knowledge products in the future, a patent system ultimately monopolizes, and therefore restricts, the efficient use of knowledge products that are currently available. That is the patent system's greatest inherent flaw which, at present, cannot be reconciled by economic theory or by any empirical data.

Other factors in the patent system are also very problematic. The extent to which patents either optimize or detract from the allocation of resources for the creation of knowledge products, as well as their effect on the subsequent distribution of such products as a new resource, are some of these problematic factors. The optimal term of patent protection is also unknown.

We seem to be on safer ground with the economics of trademarks, since this is based on the logic of product differentiation. Trademarks can provide consumers with information about the product's origins and sometimes information about its quality. If the information is accurate then trademarks are of benefit to consumers. However, if not accurate, as for example in cases where the reputation of trademarked product (brands) exceeds its actual quality, then trademarks can actually cause harm to consumers.

Trademarks can also provide irrelevant and even false information, as for example when they differentiate between products that are identical in all but name. This phenomenon is particularly acute in the field of pharmaceuticals, where generic products have to compete with brand-based products (naturally the two are identical in their substance and purpose).

9.1.2 Rival Economic and Political Explanations for the Internationalization of IPRs – Politics 'Prevails'

In Chapter 3, the book explores possible explanations for the internationalization of IPRs, that is the decision of countries to commit themselves to a legally binding international IP system.

The chapter studied the economic implications of such a system on international trade and technology-transfer (licensing, joint ventures and foreign direct investment). It unveiled a deep conflict of interests between countries with strong IP capabilities (developed countries) who benefit enormously from such a system and countries with weak IP capabilities (developing countries and LDCs) that are likely to suffer considerable economic losses, certainly in the short term.

With respect to trade in IP-based products, the equation is quite simple. The more capable a country is in the creation of IP-based products, the more it would benefit from an international system of IPRs. The main problem here is that the overwhelming majority of IP-based products have been consistently owned by a

few developed countries. For example, the US, Japan, the UK, Germany, France and Switzerland own about 80 per cent of patents and trademarks world-wide. Thus, there is no theoretical and empirical justification for countries with weak IP capabilities to enter into an international agreement that would increase the level of protection of IPRs. This would worsen their terms of trade and is also likely to increase the prices of IP-based products in their territory. In fact, it is against the economic interest of countries with low IP capabilities to join such a system.

We also find that a stronger commitment to the protection of IPRs does not guarantee countries with low IP capabilities greater access to innovative technologies or investments. For example, the cost of having stronger patent protection in a given developing country, particularly one with reverse-engineering capabilities, is probably greater than the benefits, if any, from the disclosed information concerning the patented invention in that country. Economically it is better if that country would simply free-ride the patent, especially when it can retrieve information about the patent in the country of origin. Currently, it is also empirically unclear whether a stronger commitment to the protection of IPRs is positively linked to different forms of technology transfer, such as licensing, joint ventures and foreign direct investment.

Subsequently, other explanations had to be considered and the book shifted its focus to the political dimension. It examined the effectiveness of trade retaliation as a political tool for forcing countries to protect IPRs both domestically and internationally.

We reviewed three historical examples involving pharmaceutical and chemical patents: Switzerland (1888–1907), South Korea (1983–1987) and Brazil (1988–1990). Until 1888, Switzerland was one of the few developed countries in Europe that did not have a patent system in place. Switzerland's decision to enact patent legislation in that year was to a great extent the result of external pressures from key interest groups, notably the chemical industry in Germany. The threat of trade retaliation from Germany drove Switzerland to amend its patent legislation further to include protection of chemical processes in 1907.

During the second half of the 1980s, the US and the EC used the threat of trade retaliation to force countries such as South Korea and Brazil to grant patent protection to pharmaceutical patents and processes. Following threats by the US and the EC to impose trade sanctions on South Korea, the government agreed in 1986/7 to protect the pharmaceutical patents of foreign companies, despite fierce domestic opposition. The US actually imposed 100 per cent *ad valorem* taxes on Brazilian goods, forcing the Brazilian government to amend its patent laws in 1990. Ultimately, the threat of trade retaliation by the US and the EC against developing countries in these years was also essential to the inclusion of IPRs in the Uruguay Round negotiations.

Thus, Chapter 3 concluded that the internationalization of IPRs may be attributed to the political behaviour of countries with strong IP capabilities, that is developed countries, and not to the mutual economic interest of all member countries. This notion had to be explored more accurately by looking at the way in which the current international system of IPRs (the TRIPs agreement) is linked to the interests of powerful sectors in developed countries.

9.1.3 The International Political Economy of IPRs – Linking Interests with International Systemic Outcomes: the Advanced Pharmaceutical Industry in Europe and the TRIPs Agreement

The importance of an IPE framework which links interest groups to international systemic outcomes, such as trade agreements and financial accords, has already been outlined in Chapter 1. Yet this approach was not tested on international agreements concerning IPRs. Therefore it was necessary to examine empirically the extent to which an IPE interest-based approach can provide an answer to our basic question. This process of empirical examination was carried out in Chapters 4 to 8, which focused on the advanced pharmaceutical industry in Europe and the TRIPs agreement. It consisted of four stages, as described below.

Stage 1 – establishing that IPRs provide the advanced pharmaceutical industry in Europe with a powerful incentive for collective action

The term 'advanced pharmaceutical industry' refers to pharmaceutical companies that are able to create new products by undertaking extensive R&D projects. Chapter 4 establishes that the pharmaceutical industry as a whole is dominated by a relatively small number (30–50) of research-based pharmaceutical MNCs based in a few developed countries (the US, the UK, Germany, Switzerland, France and Japan). The chapter also concluded that the advanced pharmaceutical industry in Europe is one of the two most dominant actors in this field (together with the US). For example, during the past four decades European-based companies have discovered more than half of the new chemical entities that are used for developing new drugs. European-based companies also account for approximately 40 per cent of the leading pharmaceutical drugs that were developed between 1975 and 1995. Moreover, the advanced pharmaceutical industry in Europe is the largest producer of pharmaceuticals, accounting for more than 30 per cent of world production. Together with its US counterpart, the industry in Europe is also the biggest investor in pharmaceutical R&D projects.

The chapter then elaborated on the importance of IPRs to the advanced pharmaceutical industry, focusing again on European-based companies. Patents, data exclusivity and trademarks are crucial to research-based pharmaceutical MNCs. Obviously, the monopoly embodied in patent protection enables

pharmaceutical MNCs to generate exceptional revenues from the sales of their innovative drugs. Equally important, during the pre-marketing stage of pharmaceutical drugs, patents and trade secrets are used as an insurance tool protecting potentially successful pipeline drugs. Data exclusivity grants pharmaceutical MNCs an additional period of protection vis-à-vis generic-based competitors. Trademarks are an extremely effective tool for pharmaceutical MNCs, since they allow these companies to reduce losses once patent expiry occurs. Empirical evidence suggests that by promoting brand-based prescription drugs, particularly to doctors, research-based pharmaceutical companies are able to charge higher prices for their products even when generic substitutes are available on the market.

Stage 2 – identifying the core IP interest of the advanced pharmaceutical industry in Europe and describing the organizational structure through which the industry operates to secure these interests

Chapter 5 identifies the specific IP interests of the advanced pharmaceutical industry in Europe:

1. Securing strong patent protection (monopoly) that is both long-term and wide-ranging in scope.
2. Granting a period of exclusivity to information submitted to regulatory authorities for the purpose of obtaining marketing approval (data exclusivity).
3. Securing brand-loyalty of doctors and patients via extensive protection of trademark rights.

The rhetoric used by the industry in order to express its views has two distinctive features. First, it is melodramatic with respect to the ability of IPRs to stimulate future inventive activities. Secondly, it tends to downplay and even to ignore the monopolistic effects of IPRs.

Subsequently, the chapter mapped the intra-industry (vertical) as well as the inter-industry (horizontal) IP-organizational structure, through which the advanced pharmaceutical industry in Europe operates in order to further its objectives and goals.

Most importantly, pharmaceutical MNCs are the building blocks of the entire intra-industry organization in the field of IPRs. At the corporate level, each company has its own department responsible for securing, exploiting and enforcing IPRs. Similar academic and professional experience creates a strong sense of 'epistemic community' amongst corporate IP directors of pharmaceutical MNCs.

Intra-industry structures at the national level include pharmaceutical organizations such as the Association of the British Pharmaceutical Industry

(ABPI) and the Verband Forschender Arzneimittelhersteller (VFA) in Germany. These associations are guided by the same international IP inputs and pursue similar IP objectives. Both have specific committees dealing with IPRs (the Intellectual Property Committee in the case of ABPI, and the sub-committees for patents and trademarks, hierarchically located under the Legal Affairs Committee, in the case of VFA).

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the focal point for intra-industry organization at the regional level. It has a major role in initiating and facilitating the advanced pharmaceutical industry's entire IP objectives and strategies. This is done via EFPIA's Intellectual Property Policy Committee (IPPC) and by its IP Priority Action Teams (PATs) that are responsible for the dominant portion of pharmaceutical IP objectives in Europe. EFPIA's importance derives not only from its unique structure which allows pharmaceutical companies to maintain their voice at the regional level, but also because of the way in which the EU formulates and carries out its international IP objectives and operations.

In 1994 the European Court of Justice ruled that the EU and its member states share joint competence with regard to multilateral IP trade-related negotiations and agreements. The joint process of decision making ultimately feeds into the '133 Committee', in charge of formulating the communities' international commercial policies, including those relating to IPRs. Accordingly, the European Commission is particularly important to the EU's decision-making process in the field of IPRs. EFPIA is therefore required to operate directly at the regional level, particularly vis-à-vis the Commission, in order to secure a more favourable environment for research-based companies. Indeed, EFPIA was able to derive the benefits of these interests with respect to the granting of a supplementary term of protection to patents (known as SPCs) in 1992 and the patenting of biotechnological inventions in 1998.

Internationally, the advanced pharmaceutical industry in Europe takes part in two major forums: the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and INTERPAT. The former represents the world-wide research-based pharmaceutical industry (more than 50 national associations in 2000). It is guided by the Intellectual Property Protection Coordination Committee and uses its special consultative position with institutions such as the World Bank, WTO and WIPO in order to promote awareness of the IP demands of pharmaceutical MNCs. INTERPAT is a much more specialized forum focusing solely on IPRs. Its membership is exclusively pharmaceutical MNCs, and as such it allows corporate IP directors to feed homogeneous and well-coordinated inputs to their representatives at the various levels.

The advanced pharmaceutical industry in Europe also attaches great importance to inter-industry alliances on IP issues. At the regional level it maintains close contacts with the European Chemical Industry Council

(CEFIC) – the key representative of the chemical industry in Europe – and the Union of Industrial and Employer's Confederations of Europe (UNICE) – the umbrella organization of industry associations and federations in Europe. At the international level, European-based pharmaceutical MNCs form IP alliances with companies from other industries (telecommunications, films, software) via forums such as the Trans Atlantic Business Dialogue (TABD). The industry in Europe also cooperates with the Intellectual Property Committee (IPC) in the US – an organization representing the IP interests of dominant US-based companies across the board (IBM, Pfizer, Texas Instruments and so on).

Regional and international inter-industry cooperation takes place through meetings, consultations, joint position papers (sometimes jointly with Keidanren, Japan), and direct lobbying of the European Commission, the WTO, WIPO, and so on. This allows European-based pharmaceutical companies to be part of a global IPR front that promotes its specific interests and objectives.

Stage 3 – examining the international system of pharmaceutical IPRs established by the TRIPs agreement

Chapter 6 deals with the aspect of the case study regarding international systemic outcomes, that is the TRIPs agreement.

Negotiations on the TRIPs agreement, and in particular on pharmaceutical IPRs, during the Uruguay Round were characterized by a deep north–south divide. Developed countries (mostly the US, the EC, Switzerland and Japan) sought to establish an obligatory rule-based agreement. Developing countries (led by India, Brazil and Argentina) fiercely opposed that idea and even questioned the entire legitimacy of including an agreement on IPRs under a GATT/WTO framework.

Without a doubt, the result was highly favourable to the interests of developed countries. The TRIPs agreement revolutionized the global protection of IPRs. The agreement included the basic principles of national treatment and most favoured nation, dispute settlement mechanisms and enforcement procedures, a system of notifications, and a detailed set of provisions for each and every form of IPRs.

On the other hand, the TRIPs agreement offered few prospects for countries with weak IP capabilities that would experience substantial costs in implementing the agreement. Specifically, the TRIPs provisions concerning the supply of technological, technical and financial assistance to developing countries and LDCs, as well as the transfer of know-how to these countries, are vague and impractical.

The TRIPs agreement's pharmaceutical IP provisions (patents, trademarks, trade secrets) mirror to a great extent the objectives and goals of the advanced pharmaceutical industry. The TRIPs agreement secures and increases the global protection of patented pharmaceuticals. It guarantees that patents will

be granted, on a non-discriminatory basis, to all fields of technology, including pharmaceuticals. That patented pharmaceuticals are entitled to a 20-year period of protection is particularly revolutionary. During the pre-TRIPs era many countries, mostly developing and least developed countries, granted much shorter terms of protection, if at all, to pharmaceutical patents.

The trademark system established under the agreement also greatly enhances the ability of pharmaceutical IP owners to exploit their branded products internationally. For example, pharmaceutical trademark owners have the exclusive right to prevent the use of identical or similar signs for generic-based substitutes. The agreement also prohibits WTO members from placing special requirements on the use of trademarks for pharmaceuticals, such as the obligation to use a second mark that would make the exterior of brand-based drugs less distinctive.

The TRIPs agreement also acknowledges that pharmaceutical and agro-chemical data submitted to regulatory authorities for the purpose of obtaining market approval should be treated as a trade secret (data exclusivity). The agreement requires that WTO members protect this data, particularly when it is subject to unfair commercial use.

One must also note that some elements in the TRIPs agreement are not fully compatible with the interests of the advanced pharmaceutical industry. For example, it prohibits member countries from bringing cases concerning the international exhaustion of IPRs to the WTO's Dispute Settlement Body, thereby implicitly allowing for parallel imports of patented products to take place under its international IP regime.

Stage 4 – linking interest groups activities to international systemic outcomes: strategies and activities of the advanced pharmaceutical industry in Europe between 1995 and 1999 concerning the TRIPs agreement

Lastly, the book focuses on the attempts by the advanced pharmaceutical industry in Europe to exploit and to preserve the TRIPs agreement between 1995 and 1999, relating them to EU operations in this field.

Here, it was necessary to describe at the outset (Chapter 7) the emerging opposition to the TRIPs agreement from developing countries and LDCs. It was not before 1998 that these countries became actively hostile to the TRIPs agreement. As part of their preparations for the Seattle ministerial conference (30 November – 3 December 1999) developing countries and LDCs joined forces, seeking to modify the agreement and to accommodate it to accord with their own interests. Overall, developing countries and LDCs requested that the provisions of the TRIPs agreement dealing with the supply of financial, technical and technological assistance should become more operational and binding. Specific requests were also put forward with respect to the TRIPs

agreement pharmaceutical IP agenda including: the establishment of IPRs in the field of traditional knowledge, the 'non-patenting of life', and the exclusion of essential drugs from patentability.

However, as Chapter 8 points out, the actions of the advanced pharmaceutical industry in Europe, which aimed at exploiting and preserving the TRIPs agreement despite the above opposition, were much more organized and sophisticated. As soon as the TRIPs agreement came into effect, the advanced pharmaceutical industry in Europe and its IP allies were ready to exploit the benefits arising from the agreement. In order to do so, they had to make the EU work in their favour.

Between 1995 and 1998, the primary strategy of the advanced pharmaceutical industry in Europe and its IP allies was to emphasize the need for the full and timely implementation of the TRIPs agreement, particularly in key developing countries and LDCs, such as India, Pakistan, Argentina and Brazil. The industry also acted as a 'watchdog', providing up-to-date information about the state of the implementation of the TRIPs agreement in WTO members. Furthermore, the advanced pharmaceutical industry in Europe and its IP allies wanted to ensure that the TRIPs agreement be interpreted in a manner suited to their own objectives, considering it a value-added goal.

EU operations during this period suggest that the strategy and efforts of the advanced pharmaceutical industry in Europe and its IP allies were productive and successful. The EU was involved in a series of patent disputes, notably against India and Canada, in which it explicitly pursued the commercial interests of the advanced pharmaceutical industry in Europe.

In the dispute against India (September 1997), the EU argued that India did not implement its obligations under the TRIPs agreement concerning patented pharmaceuticals. Specifically, the EU argued that India did not provide adequate facilities for accepting and processing patent applications of pharmaceutical and agro-chemical products, as well as denying exclusive marketing rights for such products. On August 1998 the WTO ruled in favour of the EU. The EU also participated as a third party in additional disputes concerning the same issues (US vs. India, US vs. Pakistan).

In the dispute against Canada (November 1998) the EU focused on the scope of the monopoly granted to pharmaceutical patents, explicitly adopting the position of the advanced pharmaceutical industry in Europe. The EU argued that Canada had violated its obligations under the agreement, since it enabled generic-based companies to conduct commercial testing in patented drugs (Bolar exemptions), as well as to 'stockpile' generic-based drugs, before patent expiration took place. In this case the WTO ruled in favour of Canada's Bolar legislation (March 2000). Yet the WTO also ruled that Canada's legislation concerning stockpiling activities was inconsistent with its obligations under the TRIPs agreement.

From the second half of 1998, the possibility of negotiating on IPRs in Seattle put the advanced pharmaceutical industry in Europe and its IP allies on the defensive for the first time. In the light of the fierce criticism expressed by developing countries and LDCs, the industry was very concerned about the implications of re-opening negotiations on the TRIPs agreement (so-called TRIPsII). The industry also feared that developing countries would use the negotiations on TRIPsII as an excuse for not carrying out their obligations to implement the agreement by January 2000. This time, the primary strategy of the advanced pharmaceutical industry in Europe and its IP allies was to emphasize the non-downgrading of the TRIPs agreement, that is that the current level of IP protection provided by the TRIPs agreement would be considered a 'floor' for any future negotiations on IPRs.

The industry and its IP allies were also well prepared for a worst-case scenario, in which negotiations on TRIPsII would proceed on a fully-fledged basis without any pre-conditions. In this instance, the advanced pharmaceutical industry in Europe presented a list of highly protective pharmaceutical IP demands, the purpose of which was to negate the demands of developing countries and LDCs for the downgrading of the TRIPs agreement. The industry stressed five major issues: (1) the exclusion of the principle of IE from the TRIPs agreement; (2) extending the scope and term of patent protection by prohibiting Bolar activities and by adding a supplementary term of patent protection; (3) having a five-year period of data exclusivity; (4) legalizing the patentability of plants and animals, and (5) strengthening provisions of the TRIPs agreement dealing with enforcement and penalties. Although the meeting in Seattle ended in failure, the advanced pharmaceutical industry in Europe and its IP allies were able to secure their primary objective. Towards the meeting in Seattle the EU (and also the US and Japan) officially endorsed and emphasized the principle of the non-downgrading of the TRIPs agreement as a pre-condition for the negotiations.

9.1.4 Probing the Plausibility of Rival Explanations – the Role of Institutions and Ideas in the Internationalization of IPRs

Overall this book focuses on two theoretical channels. On the one hand, it examines the economic spectrum of IPRs and concludes that there is a fundamental difficulty in explaining the reality of such a strong international system of IPRs by using a purely economic approach. On the other hand, using an IPE interest-based approach, the book suggests that the internationalization of IPRs, as well as the international IP system in its current form, is driven by the IP interests of key groups, such as the advanced pharmaceutical industry in Europe. Naturally, this hypothesis requires further research and plausibility tests.

Notwithstanding the above, it has already been argued in Chapter 1 that there may be other factors and perspectives that can provide additional, and possibly

even rival, explanations to the key question, that is why and how is such a strong international IP agenda in place? During the course of the investigation it was possible to consider, and subsequently to discount, the plausibility of both the pluralist and the institutional-based perspectives. Considering the former, it became quite evident that the international IP system is not a balanced result of a confluence of interests. Given that the bias towards the interests of key IP-based industries is so apparent in the TRIPs agreement, it is very difficult, if not impossible, to analyse the agreement from a pluralist or even a neo-pluralist perspective. This is also the case in the IP approach of the EU. Clearly, the IP views and activities of the EU, and particularly the Commission, are beneficial to the advanced pharmaceutical industry and its IP allies, and possibly even derives from these interests. It is also apparent that the European Commission (particularly DG Trade) is one of the most prominent advocates of IPRs. Yet the Commission is also exposed to antagonistic views about IPRs, such as those expressed by the TACD and BEUC. Therefore, the pro-IP activities adopted by the EU between 1995 and 2000 are probably a result of a specific and focused interest-based perspective rather than a pluralist process leading to the adoption of these views and activities.

An institutional approach can add valuable information and insight about the manner in which the international IP system manifests itself. It may also help us to identify the mechanisms through which the international IP system is maintained and preserved. In this respect an institutional approach may provide an important contribution as to the 'how' component of the research question. However, an institutional approach falls short of contributing to the 'why' component, that is why there is such a strong international IP system in place. In fact, it may even lead to inaccurate and possibly misleading conclusions. As described in Chapter 1, an institutional approach assumes a priori that the central role of IP institutions is to protect IPRs. That is because IP institutions by definition are designed to protect intellectual property rights. Consequently, any explanation developed on the basis of an institutional approach, be it of rational choice or of an historical perspective, builds upon the notion that there is a need to establish and protect IPRs. This research suggests that the logic for establishing IPRs is far from clear. Therefore, an interest-based approach which identifies the different groups and interests concerning IPRs contains an important critical element that is lacking in part in the institutional perspective.

Empirically speaking, we find that although IP institutions such as the WTO TRIPs agreement are clearly essential to the international protection of IPRs, they still lack a critical mass which would make them pivotal to the agenda-setting dimension of IPRs. The TRIPs agreement was created because developed countries, notably the US and the EC, thought that WIPO did not provide effective tools for the enforcement of IPRs. The decision to make IPRs part of the WTO (TRIPs) suggests that the developed countries pursued their own

individual interests at the expense of one of the most impressive international IP institutions at the time (WIPO). Looking at the regional level, we find that the complex process through which international IP policy-making is taking place in the EU cannot be attributed to a single and transparent institution. On the contrary, the joint competence between the European Commission and the member states concerning the international negotiations on IPRs (ultimately via the 133 Committee) makes the process of IP policy truly multi-dimensional. It also seems that the primary channel is the Commission (DG Trade) which plays a pivotal role in reaching the IP negotiating position of the EU. Evidence suggests that both IP advocates and antagonists are aware of the role of the Commission and lobby it directly.

Thus, all the above suggests that an interest-based approach provides a better starting point for explaining why and how such a strong international IP system is in place. However, it must also be noted that in this study it was not possible to gain full access to the decisions leading the EU to initiate WTO disputes against India and Canada, nor to the process leading the EU to adopt its IP position at the Seattle Ministerial Conference. Therefore, although we suggest that such actions are motivated by specific IP interests, rather than by pluralist or institutional processes, these options still remain within the boundaries of possibility.

9.1.5 Key Findings and Conclusions

Based on the theoretical and empirical process described above, the following conclusions regarding the research question are drawn:

- Conclusion no. 1 – the field of economics does not provide an adequate basis for the establishment of IPRs, nor does it provide a satisfactory explanation for the decision of countries with weak IP capabilities to commit themselves to a strong international system of IPRs. In fact, the political use of trade retaliation by developed countries, notably the US and the EU, against countries with weak IP capabilities is much more likely to force these countries to protect IPRs domestically and internationally.
- Conclusion no. 2 – an international political economy framework that is based on interest groups and international systemic outcome has better prospects for explaining why and how such a strong international system of IPRs (the TRIPs agreement) is in place. This framework must ultimately rely on empirical case studies.
- Conclusion no. 3 – the advanced pharmaceutical industry in Europe is a dominant actor in the field of pharmaceuticals world-wide. It also considers IPRs as vitally important to its existence, particularly with regard to its ability to continue to produce new products and to generate

profits. In other words, IPRs provide a powerful incentive for collective action in the hands of the advanced pharmaceutical industry in Europe.

- Conclusion no. 4 – the advanced pharmaceutical industry in Europe uses an impressive vertical and horizontal build-up in order to enforce its IP interests. This build-up is based on an intra-industry IP organizational structure throughout the corporate, national, regional and international levels, as well as on horizontal alliances with powerful IP-based industries and associations.
- Conclusion no. 5 – the TRIPs agreement revolutionized the global protection of IPRs. In its current form (at least until the end of 1999) the agreement is overwhelmingly biased in favour of the interests of developed countries. Accordingly, the agreement's pharmaceutical IP provisions create an environment that is highly favourable to the advanced pharmaceutical industry.
- Conclusion no. 6 – commencing in 1999, developing countries and LDCs became much more antagonistic to the TRIPs agreement, seeking to modify its provisions in order to make them more balanced.
- Conclusion no. 7 – between 1995 and 1999 the advanced pharmaceutical industry in Europe and its IP allies engaged in prolific activities aimed at exploiting and preserving the pharmaceutical IP agenda deriving from the TRIPs agreement. Using its impressive IP build-up, the advanced pharmaceutical industry and its IP allies were successful in mobilizing the EU to protect their interests vis-à-vis developing countries and generic-based companies. These activities explain, at least in part, the reason that such a controversial international system of pharmaceutical IPRs is still in place.

9.2 PHARMACEUTICAL IPRS IN THE NEW MILLENNIUM – THE ROAD AHEAD

Attacks on the TRIPs agreement and on its pharmaceutical intellectual property agenda have intensified since the WTO ministerial meeting in Seattle (November 1999). Recent developments in the field of pharmaceutical IPRs have served to highlight to a greater extent the different conflicts built into the patent system. Three cases are particularly relevant for this purpose: (1) the case of patented AIDS medicines in South Africa in which 40 pharmaceutical MNCs sued the government for violating their patent rights; (2) the controversy surrounding 'Cipro', Bayer's patented drug against anthrax, following the 11 September attacks on the US; and, most importantly (3) the negotiations and outcome of the WTO ministerial meeting in Doha (November 2000).

9.2.1 Patented AIDS Medicines in South Africa – the 'Hubris' of Pharmaceutical Multinationals

On 23 November 1997 the South African parliament passed a new law titled 'Medicines and Related Substances Control Amendment Act'.[1] The amendment act (section 15C) provided for the local production of patented medicines, via tools such as compulsory licensing or patent revocation, and authorized the parallel importation of such medicines.[2] The government of South Africa, justifying its actions on the basis of a national emergency, argued that the prices of patented medicines against AIDS were too expensive for the millions of South Africans infected by the disease.[3]

The response of the advanced pharmaceutical industry rapidly followed. On 18 February 1998, 40 pharmaceutical companies together with the South African Pharmaceutical Manufacturers Association (PMA) filed a lawsuit against the new act.[4] The companies argued that the amendment act was unconstitutional, since it granted excessive powers to the Minister of Health, as well as violating South Africa's obligations under the TRIPs agreement.[5] The companies asked for, and obtained, an interim interdict preventing the government from implementing the contested amendments until a final ruling is made.

The industry used its impressive political resources, particularly in the US, to influence the government of South Africa to re-amend the Medicines Amendment Act. During 1998 and 1999 the companies received the full backing of the US and the EU. In June 1997, the US suspended the granting of GSP benefits to the government of South Africa.[6]

The EU also operated to ensure that South Africa would comply with the provision of the TRIPs agreement, though in a more general context. The result was presented in Art. 9 of the 'Agreement on Trade, Development and Cooperation' between the EC and South Africa, dated 9 July 1999:

> The Parties shall ensure adequate and effective protection of intellectual property rights in conformity with the highest international standards. The Parties apply the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) from 1 January 1996 and undertake to improve, where appropriate, the protection provided for under the Agreement.[7]

However, from the year 2000 the circumstances surrounding the dispute changed dramatically and the decision of pharmaceutical companies to enforce their patent rights turned out to be a public-relations disaster. The state of the AIDS epidemic in South Africa is grave. It is estimated that 20 per cent (4.2 million people) of South Africa's population is HIV positive (year 2000).[8] According to UNAIDS, about 250 000 South Africans died of AIDS in 1999.[9] The Sub-Saharan African region as a whole has the largest population infected with HIV (about 24.5 million people out of 34.4 million world-wide).[10]

In the light of the above, the increased anti-patent activities of local and western-based NGOs, such as Treatment Action Campaign (TAC), Médecins Sans Frontières (MSF) and Oxfam, proved highly effective. These organizations sought and succeeded to publicly connect the patent policy of pharmaceutical companies to the AIDS epidemic in South Africa. MSF, for example, published a petition in its website calling for the 40 pharmaceutical companies to drop their lawsuit because it was 'blocking the implementation of legislation that aims to improve access to essential medicines by making drugs more affordable'.[11] Oxfam was even more blunt in its approach, particularly in two 2001 publications titled: *Patents Injustice: How World Trade Rules Threaten the Health of Poor People* and *Fatal Side Effects: Medicine Patents under the Microscope*.[12]

Nevertheless, the industry, miscalculating the dramatic change in atmosphere, decided to proceed with its legal action. Once the case was brought before the High Court of Justice in Pretoria, on 5 March 2001, it was subject to huge public scrutiny. The industry found itself being accused of denying the South African people a cure for AIDS.[13] The pressure of NGOs and of the media encouraged the government of South Africa to continue with its plans. More importantly, it drove the US, and the USTR in particular, to reduce its involvement in the dispute.[14] Thus, pharmaceutical companies had little choice but to withdraw their lawsuit on 18 April 2001.[15]

9.2.2 Patents, Cipro and Anthrax – Questioning the Fundamentals of Patents

The attacks of 11 September were followed by the delivery of anthrax-infected envelopes to key institutions in the US. The panic surrounding the possibility of bio-terror attacks also provoked a high-profile debate about the social legitimacy and efficacy of patents in times of crisis.

The focus of the debate was Cipro – a patented drug owned by the German pharmaceutical company Bayer AG. The threat of a full-scale outbreak of anthrax caught developed countries, including the US, completely unprepared. These countries did not have enough antibiotics in stock to handle an outbreak of such proportions, should it occur. In order to increase its supply of antibiotics, the US had two choices: to purchase more drugs from Bayer or to allow generic-based companies to manufacture the drug, thus overriding Bayer's patent.[16] Both alternatives were far from optimal.

The former, whilst preserving Bayer's patent rights, risked the under-supply of Cipro, since it was not clear how quickly the company could meet the new demand. Bayer itself announced on October 2001 that its plans to triple the production of Cipro to a quantity of 200 million tablets would be spread over a period of three months, starting from November of that year.[17] The second

alternative, which in theory provided an immediate solution to the threat of anthrax in terms of time and supply, ultimately violated Bayer's patent.

For a short while the US flirted with the idea of overriding Bayer's patents.[18] On 16 October 2001, a senior New York senator, Charles Schumer, issued a press release, according to which the 'United States could significantly increase its supply of Cipro by purchasing the drug's generic version directly from manufacturers'.[19] Eventually, the US chose not to pursue this course of action. However, that was not before Bayer agreed on 24 October 2001 to reduce the price of Cipro from $1.77 (which was already sold at a discount price to the Federal Government) to 95 cents per tablet.[20]

Canada went one step further. On 18 October 2001 the government announced its intention to order one million generic tablets of Cipro from the local generic-based company Apotex, which is also Canada's largest pharmaceutical company.[21] Bayer argued that Canada's decision was illegal since it violated its patent rights.[22] The dispute between the parties was settled on 22 October 2001, when both sides announced that Bayer would provide one million tables of Cipro to the government within 48 hours of request.[23]

The somewhat hysterical behaviour of the US and Canada provided a golden opportunity for developing countries to emphasize even more the negative consequences of patent monopolies, particularly in times of health crises. Developing countries, such as Brazil and India, highlighted the contrast between developed countries' support of intellectual property protection in the case of AIDS, and the way in which the US and Canada considered the idea of overriding patent rules in the case of anthrax.[24]

9.2.3 The TRIPs Agreement and the WTO Ministerial Meeting in Doha (9–14 November 2001)

For the advanced pharmaceutical industry, the WTO ministerial meeting in Doha could not have come at a worse moment. To a large extent the industry was a victim of its own success. The TRIPs agreement set such a high standard of global protection of pharmaceutical IPRs that, once the events of 2001 took place, it was no longer possible to ignore the profound imbalances embodied in the agreement and in the agenda it had established. Even before the meeting in Doha it was clear that the negotiations on the TRIPs agreement would focus almost exclusively on the issue of patented drugs and access to medicines.[25] This issue was described as one of the meeting's 'deal-breakers'.[26]

Demands of developing countries, LDCs and NGOs concerning the TRIPs agreement and public health

On 4 October 2001, a group of developing countries, led by Brazil, India and Kenya, submitted to the Council for TRIPs a joint proposal for a ministerial

declaration on the TRIPs agreement and pharmaceutical IPRs.[27] The four-page proposal was highly aggressive and daring in terms of the modifications it sought to make in the agreement with regard to pharmaceutical IPRs.

The most controversial element in the proposal was the statement that 'nothing in the TRIPs Agreement shall prevent Members from taking measures to protect public health'.[28] This statement essentially allowed WTO members to ignore the agreement whenever health issues were involved. The proposal also aimed to substantially reduce the level of protection granted to patented pharmaceuticals, mostly by providing for the free use of parallel imports and compulsory licences. It also called upon the WTO to grant developing and least developed countries an additional five-year period for implementing the agreement (for example 2005 for developing countries, 2010 for LDCs).[29]

Quite naturally, NGOs, such as Médecins Sans Frontières (MSF), Oxfam and Third World Network, fully supported the position of developing countries.[30]

The intellectual property position of the advanced pharmaceutical industry and developed countries

The advanced pharmaceutical industry was well aware of its poor negotiating position for the upcoming meeting in Doha. Its biggest problem was the ability of developing countries and NGOs to link the TRIPs agreement (patents in particular) to the under-supply of medicines in poor countries.

Accordingly, the industry had modified its objectives. Before the meeting in Seattle (November 1999), the industry's key objective was to preserve the level of protection provided by the agreement. In Doha (November 2001), the industry's key goal was to ensure that pharmaceutical IPRs remain an integral part of the TRIPs agreement, thereby preserving its structural and agenda-setting framework. For that purpose the industry was willing to accept, although not explicitly, a temporary reduction in the level of protection granted by the agreement to pharmaceutical IPRs.

More specifically, the industry argued that the TRIPs agreement was flexible enough to accommodate 'adjustments' in the level of intellectual property protection granted to pharmaceutical products. As argued by EFPIA in a July 2001 position paper:

> Nor, in EFPIA's view, is it [at] all necessary for TRIPs to be re-opened in order to clarify its terms. The terms of the agreement already contain important flexibility with respect to such matters as the extension of transitional periods for Least Developed Countries, the use of licensing under conditions of national emergency, and the prevention of abuse of monopoly power.[31]

The advanced pharmaceutical industry wanted to ensure that, in the event of a ministerial declaration in Doha, the TRIPs agreement and pharmaceutical patents in particular would not be portrayed as an obstacle to public health nor

as an impediment to medicine access. For that purpose the industry focused on three elements. First, it reported that the majority of medicines for the most deadly pandemics in developing countries and LDCs, such as malaria and tuberculosis, are not patented.[32] Secondly the industry argued that other factors, such as healthcare facilities, staff and equipment as distribution channels, are the major contributors to the health crises in these countries.[33] Thirdly, the industry accused developing countries, particularly those with industrial capabilities, such as India and Brazil, of using the TRIPs agreement as a 'scapegoat' and as an excuse for not carrying out their public obligations.[34] Interestingly, prior to the meeting in Doha, PhRMA – the major representative of the advanced pharmaceutical industry in the US – did not publish any position papers with regard to this issue.

The EU continued to advocate the protection of pharmaceutical IPRs. Once again the Commission was the most enthusiastic supporter of patented pharmaceuticals and the TRIPs agreement. For example, in its position paper for the negotiations on IPRs in Doha: *Towards Better Recognition of Intellectual Property Rights* (October 2001) the Commission clearly sided with the approach of the advanced pharmaceutical industry in Europe.[35] In another report dated October 2001 concerning the negotiations in Doha, the Commission emphasized the efforts of research-based pharmaceutical companies to reduce the prices of patented medicines.[36]

As to the European Parliament, we saw in the previous chapter that since 1999 its approach towards IPRs has been more reserved. Nevertheless, in its resolution submitted to the WTO meeting in Doha, the European Parliament was still quite supportive of the TRIPs agreement.[37]

Other developed countries, particularly the US, were even more enthusiastic in their support for pharmaceutical IPRs. This can best be seen in the joint proposal by the US, Switzerland, Australia and Canada that was submitted to the WTO on 4 October 2001.[38] In sharp contrast to the proposals of developing countries, this proposal stated that the TRIPs agreement 'contributes to the availability of medicines'.[39] According to the US and its allies a ministerial declaration on the TRIPs agreement and public health should 'recognise that strong, effective and balanced protection for intellectual property is a necessary incentive for research and development of life-saving drugs and, therefore, recognise that intellectual property contribute to public health globally.[40] The proposal also emphasized the flexibility of the TRIPs agreement.

Negotiating towards a ministerial declaration on TRIPs agreement and public health

Negotiations on pharmaceutical IPRs in Doha were much less contested than initially anticipated. On 11 November 2001 it became more evident that the parties were aiming at finding a solution within the parameters of the agreement.

In particular, the parties negotiated on the extent to which the proposed declaration should cover public health as a whole or focus on specific problems such as pandemics.[41] On 12 November 2001 a new draft was issued and on 13 November the parties were close to an agreement.[42] During that time other issues, such as anti-dumping, export subsidies and market access in agriculture remained unresolved.[43]

The meeting in Doha ended on 14 November 2001 with two distinct successes: China (and Taiwan) became a member of WTO, and a 'green light' was given to the launch of a new round of trade negotiations, to be completed by January 2005. The agenda for the negotiations was outlined by two ministerial declarations: a main-text declaration, covering all WTO topics, including IPRs, and a detailed declaration on the TRIPs agreement and public health.[44] The latter is discussed below.

The ministerial declaration on the TRIPs agreement and public health includes two major parts. The first part (Art. 1–4) refers to the structural efficacy and the social legitimacy of the agreement. Aside from its 'diplomatic' formulations, which emphasize the importance of public health concerns, the declaration suggests that the TRIPs agreement is flexible enough to accommodate measures aimed at promoting public health and access to medicines. In other words, the declaration re-affirms the legitimacy of the TRIPs agreement, rather than stating that it is irrelevant in times of health crises. In this respect the declaration is much closer to the primary goal of the advanced pharmaceutical industry and to the position of developed countries.

The second part of the declaration (Art. 5–7) provides some operational clarification to the provisions in the agreement that relate to pharmaceutical IPRs. Inevitably, these clarifications lead to a temporary reduction in the protection of patented medicines. Specifically, Art. 5(b, c) allows WTO members to use compulsory licences, without pre-conditions, in times of national emergency (to be determined by each and every member).[45] Art. 5d re-affirms the right of WTO members to adopt the principle of international exhaustion, that is to deal with the parallel importation of patented medicines.[46] The declaration also acknowledges that countries with insufficient manufacturing capabilities would not be able to use the tool of compulsory licences (that would allow local companies to manufacture original patented drugs). It instructs the council for the TRIPs agreement to find an expeditious solution to this problem by the end of 2002.[47] Finally, Art. 7 of the declaration grants LDCs an additional period of ten years to implement the agreement (January 2016).[48]

The ministerial declaration on the TRIPs agreement was widely perceived as a victory of developing countries and NGOs over the powerful and influential pharmaceutical MNCs. The headlines were quite melodramatic; for example, 'How activists outmanoeuvred drug makers in WTO deal' (Wall Street Journal Europe, 15 November 2001), and 'Declaration on patent rules cheers developing

nations' (Financial Times, 15 November 2001).[49] That was also the approach of developing countries and NGOs.[50]

The advanced pharmaceutical industry welcomed the declaration in a manner that was more 'politically correct' than genuine. All the statements released by the leading Pharma organizations – EFPIA, the IFPMA and PhRMA (the US-based organization) – focused on the recognition that the TRIPs agreement is a 'legitimate tool for developing new medicines and for promoting public health'.[51] The industry ignored the possible implications of the declaration on patented pharmaceuticals, or at best, downplayed its significance.[52] The industry's perception of the outcome in Doha is best described by the director of the IFPMA: 'Representatives of some governments and NGOs sought to effectively take the TRIPs agreement out of the WTO; however, the consensus opinion rejected that counterproductive approach.'[53]

Developed countries also expressed their satisfaction with the declaration. Similarly to the advanced pharmaceutical industry, both the EU and the US emphasized the importance of the TRIPs agreement to public health and access to medicines.[54] The EU argued that 'the adoption of the ministerial declaration on TRIPs and Public Health is an indication that the WTO is supportive of public health matters and that intellectual property is part of the solution to the tension between public health objectives and the interests of private companies'.[55]

The significance of the Doha declaration to the advanced pharmaceutical industry – short term losers; long term gainers

The meeting in Doha produced two major results that are relevant to the TRIPs agreement and to its pharmaceutical intellectual-property agenda:

1. The level of intellectual property protection granted to pharmaceutical products was eroded (for example allowing for the free use of compulsory licences and parallel imports).
2. It established that pharmaceutical IPRs are an integral part of the TRIPs agreement, and in turn part of the WTO.

At first glance these two results seem mutually supportive, that is that in order for pharmaceutical IPRs to remain part of the TRIPs agreement their level of protection should be reduced. In fact, they are not.

Despite the temporary erosion in the protection of patented drugs, the pharmaceutical intellectual property agenda of the TRIPs agreement is still highly protective and demanding. For example, notwithstanding the Doha declaration, developing countries are required to follow the timetable outlined in the agreement (year 2000). By now, these countries should have a fully operational patent system in place (including pharmaceuticals), with 20 years of protection and extensive monopoly rights. Over the longer run the intellectual

property agenda established by the TRIPs agreement is even more tilted towards the interest of the advanced pharmaceutical industry. Before the meeting in Doha, pharmaceutical IPRs were scrutinized not only by developing countries and NGOs but also by the media. In turn, the declaration of Doha reduced the level of protection granted to pharmaceutical IPRs to its lowest point since the formation of the WTO.

However, that pharmaceutical IPRs remain an integral part of the TRIPs agreement and of the WTO is highly important for the advanced pharmaceutical industry. By their own admission, developing countries and NGOs acknowledge that the TRIPs agreement and its pharmaceutical intellectual property agenda do not now obstruct efforts to promote public health and access to medicines. In other words, they essentially terminated the damaging equation according to which pharmaceutical IPRs equal the inability to provide medicines to the poor and weak citizens of developing and least-developed countries. By doing so, developing countries and NGOs put the advanced pharmaceutical industry in a much more comfortable negotiating position on pharmaceutical IPRs in the future. That would be true particularly if the widespread epidemics that now hit entire populations, such as in the sub-Saharan region, were not contained, or if they became even worse. In that case the industry could ask for the upgrading of the TRIPs agreement using the argument that a weak international system of pharmaceutical IPRs does not help to cure widespread epidemics.

9.3 IMPLICATIONS OF THE BOOK'S FINDINGS AND SUGGESTIONS FOR FURTHER RESEARCH

Primarily, this book suggests that the international political-economy of IPRs can increase our understanding of the ways in which IPRs are established, managed and exploited at the regional and international levels. Arguably, the political-economy of IPRs is a necessary stage between the economic study of IPRs and the legal interpretation of such rights. The reason is that placing IPRs in a political context enables us to understand the process by which economic interests are translated into legal realities.

An IPE framework that is based on interest groups and international systemic outcomes treats the field of IPRs as an ongoing battlefield of interests between those who create knowledge on the one hand and those who consume it on the other. Accordingly, it does not take the international system of IPRs for granted. Rather it explores and unveils the political route by which such a system is constituted and associates its outcome to the particular interests of different groups.

Consider for example the debate about the patenting of life (for instance, whether genetic-engineering techniques for isolating embryonic stem-cells

or for cloning may be patentable).[56] Economists would have to consider the consequences of obtaining a patent monopoly on such a sensitive and unique element (the same applies to the patenting of genes or proteins in the future). A legal perspective would focus, *inter alia,* on the definitional differences between discoveries (non-patentable) and inventions (patentable) in this field. An IPE approach would look at the different interests (economic, political, social and ethical) motivating the debate over life-patenting. It would explore the manner in which these interests are translated into collective action, as well as examining the international institutional process (TRIPs agreement, Art. 27.3b) through which the debate is managed and concluded. In doing so, an IPE, interest-based, framework would add invaluable insight into the essence of the debate and its implications on the entire field of IPRs.

More importantly, by politicizing the study of IPRs it is possible to place them in a much broader context. Here, IPRs would become highly relevant to the old cliché of 'knowledge equals power'. The politics of IPRs provide a concrete example of the manner in which the ownership and control over knowledge is legally translated to the monopolistic behaviour that affects our lives in almost every aspect.

Looking at the international trade arena as a whole, the book finds considerable risk in including agreements that are not based on trade-liberalization (or even on some form of 'benign' mercantilism) under a WTO framework. In this regard the TRIPs agreement is highly problematic. Contrary to other WTO agreements which define what member countries should refrain from doing, particularly in terms of barriers to trade, the TRIPs agreement does exactly the opposite. It provides an accurate prescription for what countries ought to be doing, that is, it raises the level of protection granted to IPRs and therefore leaves little space for manoeuvre and interpretation. Consequently any attempt to resolve the ongoing north–south tensions is based either on making the agreement more general and vague, or by redefining its specific provisions in order to make them less contested. It is quite plausible that every adjustment in the global level of IP protection, be it upwards or downwards, would require WTO members to redefine the relevant provisions in the TRIPs agreement. The ministerial declaration in Doha is one example in which specific provisions in the agreement were re-defined in order to make them more internationally balanced.

Furthermore, and as discussed previously, the book suggests that the WTO is not necessarily the optimal institution for the management of IPRs. Evidently, the different mechanisms of the WTO did not reduce the tension between developed and developing countries in this field. In the case of pharmaceuticals, the dispute settlement mechanism of the WTO was ultimately used by developed countries as a tool for enforcing and exploiting the different provisions of the TRIPs agreement. As a result, developing and least developed countries sought to exclude pharmaceutical IPRs from the dispute settlement mechanism. It

becomes clear that in order to reduce the inherent north–south tensions built into the TRIPs agreement, member countries had to rely on political solutions (negotiations) rather than on the WTO day-to-day institutional process.

Considering other aspects, the author used an interest-based approach in order to explain IPRs, rather than using the field of IPRs as a way of explaining interest-group behaviour. Nevertheless, the book also makes a small contribution in this regard. For one, European IP-based interest groups consider the regional level as vitally important to decisions concerning IPRs in terms of internal legislation and the conduct of international IP agreements. The author highlights the complex European decision-making processes in this field. De jure the EU and its member states are jointly responsible (competent) to conclude international negotiations on IPRs. De facto the European Commission plays a prominent role in forming and executing the intellectual property objectives and negotiating strategies of the EU. This in turn implies that regional collective action is essential to the field of IPRs, hence the importance of EFPIA.

That pharmaceutical MNCs maintain their voice and influence, both formally and operationally, is also important to our understanding of the relationship between different interest-group players. Moreover, the way in which the advanced pharmaceutical industry in Europe and its IP allies organized themselves and operated in order to obtain their IP goals may be used as a model for assessing the operations of international alliances in other areas.

Certain issues concerning the study itself require further investigation. First, there is a need to understand the process which led developing and least developed countries to 're-discover' the problems embodied in the TRIPs agreement. This work has shown that, during the Uruguay Round negotiations and as at the end of 1998, developing and least developed countries had serious reservations about the agreement. It would be particularly interesting to explain why these countries reduced their opposition to TRIPs, at least officially, during the interim period of 1996 to 1998.

Second, in order to obtain a more accurate and complete picture of the TRIPs agreement and pharmaceuticals, it is also essential to focus on the advanced pharmaceutical industry in the US. The US industry is one of the most influential actors in the field of IPRs, and its contribution to the creation and preservation of the TRIPs agreement during this period is particularly important.

Third, it is necessary to identify the factors leading to what would appear to be the divergence of views between the Commission and the European Parliament since 1999. We can evaluate the extent to which the allocation of European lobbying efforts by the advanced pharmaceutical industry in Europe (prima facie the industry put greater emphasis on lobbying the Commission) affected the IP views of these two bodies.

As to researching the field in general, it is crucial to learn the behaviour of other IP-dependent groups, such as the software, music and film industries. This

would allow one to assess the goals, strategies and operations of the IP-based industry as a whole.

Equally interesting is the intensifying debate about IPRs and the internet. Examples such as the patenting of the 'one-click' method by the electronic bookshop giant Amazon.com, the ruling against the internet music company Napstar concerning copyright violations and the problem surrounding trademarks and e-commerce demonstrate how complex this issues is.[57] Currently, the debate is confined to companies based in developed countries and so is not about north–south tensions. Hence, comparing 21st century arguments for and against internet IPRs with arguments concerning IP monopolies during the 19th century can shed valuable light regarding the historical dynamics of IPRs.

Also, as we have seen, trademarks are a source of great market power, possibly even more so than patents. This unique and fascinating form of IPRs has traditionally been 'sidelined' in comparison with the study of patents and copyrights. It requires further investigation.

Most importantly, the field of IPRs is truly multi-dimensional. It is a dynamic and constantly changing field, which has the capacity to affect political, economic, social and even ethical modes of behaviour. For researchers of social sciences it is a rich source of data, as well as a worthy challenge.

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Appendix – Interviews

INDUSTRY

26 October 1998 – Mr Alan Hunter, Director of Law and Intellectual Property, Association of British Pharmaceutical Industry (ABPI); Place of interview: London, UK.

28 October 1998 – Mr Terry Crowther, Director, European Patent Operations, Lilly; Place of interview: Surrey, UK.

16 November 1998 – Mr Bill Tyrrell, European Patent Attorney, Corporate Intellectual Property, SmithKline Beecham; Place of interview: Brentford, Middlesex, UK.

25 November 1998 – Dr Alan Hesketh, Manager of Global Intellectual Property, GlaxoWelcome; Place of interview: Greenford, Middlesex, UK.

26 November 1998 – Mr David Wood, Director, European Patents Department, Pfizer; Place of interview: London, UK.

6 January 1999 – Mr Manual Campolini, Manager, International Intellectual Property & Environment Division, European Federation of Pharmaceutical Industries and Associations (EFPIA); Place of interview: Brussels, Belgium.

5 February 1999 – Ms Lynne Sailor, Public Policy Consultant (freelance), Pfizer; Place of interview: London, UK.

15 February 1999 – Dr John Beton, Consultant Patent Attorney (Retired from ICI), Chairman of TRIPs Workgroup, Union of Industrial and Employers' Confederation of Europe (UNICE); Place of interview: Maidenhead, UK.

31 August 1999 – Second interview with Mr Bill Tyrrell, SmithKline Beecham; Place of interview: Brentford, Middlesex, UK.

31 August 1999 – Second interview with Dr Alan Hesketh, GlaxoWelcome; Place of interview: Greenford, Middlesex, UK.

16 November 1999 – Dr Harvey E. Bale, Director, International Federation of Pharmaceutical Manufacturers and Associations (IFPMA); Place of interview: Geneva, Switzerland.

18 November 1999 – Mr Brian A. Yorke, Head of Corporate Intellectual Property, Novartis; Place of interview: Basel, Switzerland.

24 November 1999 – Second interview with Mr Terry Crowther, Lilly; Place of interview: Surrey, UK.

31 May 2000 – Dr Brigit Reiter, Director, Pharmaceutical Law, Patent and Trademarks, Verband Forschender Arzneimittelhersteller (VFA), by telephone and email.
13 June 2000 – Mr Weiler, European Affairs, Verband Forschender Arzneimittelhersteller (VFA), by telephone.
13 June 2000 – Dr Dieter Laudien, Director of Patents Division, Boheringer-Ingelheim (also director of VFA's Patents Committee), by email.

GOVERNMENT

European Commission

6 January 1999 – Mr Pascal Leardini, Directorate E (Free Movement of Information, Intellectual Property, the Media, Data Protection), DG Internal Market; Place of interview: Brussels, Belgium.
30 August 2000 – Ms Gunaelius, Directorate E – Intellectual Property Section, DG Internal Market, by telephone.
30 August 2000 – Mr Stephan Beslier, Directorate M – Intellectual Property, DG Trade, by telephone.
31 August 2000 – Ms Nina Hvid, Directorate M – Intellectual Property, DG Trade, by telephone.

Germany

8 August 2000 – Mr Clause Peter Leier, Directorate General V, External Economic Policy and European Integration Policy, Federal Ministry of Economics and Technology, by telephone.
9 August 2000 – Mr Karchler, Patent Section, Trade Law Division, Federal Ministry of Justice, by telephone.
10 August 2000 – Mr Clause Rudolff Schaffer, Industrial Property Section, Trade Law Division, Federal Ministry of Justice, by telephone.

United Kingdom

2 November 1998 – Mr Paul Hawker, Director of WTO Unit, Trade Policy Directorate, Department of Trade and Industry; Place of interview: London, UK.
1 September 1999 – Second interview with Mr Paul Hawker, DTI, Place of interview: London, UK.

3 September 1999 – Mr Karl Whitfield, TRIPs Division, Intellectual Property Policy Division, Patent Office; Place of interview: Newport, South Wales, UK.
31 May 2000 – Third interview with Mr Paul Hawker, DTI, by telephone.

INTERNATIONAL ORGANISATIONS

World Trade Organization

16 November 1999 – Mr Adrian Otten, Director Intellectual Property and Investment Division; Place of interview: Geneva Switzerland.
16 November 1999 – Mr Yair Shiran, Deputy Permanent Representative to the WTO; Place of interview: Geneva, Switzerland.
17 November 1999 – Mr Matthijs Geuze, Counsellor, Intellectual Property Division and Secretary to TRIPs Council; Place of interview: Geneva, Switzerland.

World Intellectual Property Organization

15 November 1999 – Mr Nuno Carvalho, Senior Legal Officer, Global Intellectual Property Issues Division; Place of interview: Geneva, Switzerland.
15 November 1999 – Mr Richard Owens, Director of Global Intellectual Property Issues Division; Place of interview: Geneva, Switzerland.

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