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.