ICTSD Intellectual Property and Sustainable Development Series



Intellectual Property and Competition Law

Exploring Some Issues of Relevance to Developing Countries

By **Carlos M. Correa,** University of Buenos Aires, Argentina

ICTSD
International Centre for Trade and Sustainable Development

Issue Paper No. 21

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ACRONYMS

ANVISA	Agencia Nacional de Vigilancia Sanitaria
ARV	Anti-retroviral
BI	Boehringer Ingelheim
Bt	Bacillus thuringiensis
CFI	Court of First Instance
CISAC	International Confederation of Societies of Authors and Composers
DDR	Double Data Rate
DES	Drug-Eluting Stent
EEA	European Economic Area
ECJ	European Court of Justice
EPIP	European Policy for Intellectual Property
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FTA	Free Trade Agreement
FTC	Federal Trade Commission
GSK	GlaxoSmithKline
ICA	Italian Competition Authority
IP	Intellectual Property
IPO	Intellectual Property Owners Association
IPR	Intellectual Property Right
ITP	Independent Television Publications Limited
LDC	Least-developed Country
NDA	New Drug Application
OECD	Organisation for Economic Co-operation and Development
OS	Operating System
PTO	Patent and Trademark Office
PC	Personal Computer
RTE	Radio Telefis Eireann
SDRAM	Synchronous Dynamic Random Access Memory
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
WTO	World Trade Organization

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FOREWORD

Intellectual Property and Competition Law is one further contribution of the ICTSD Programme on Intellectual Property Rights and Sustainable Development to a better understanding of the proper role of intellectual property in a knowledge-based economy. The objective of the study is to generate and increase understanding of the relationship between intellectual property (IP) and competition law and policy. The study explores a number of issues that could be relevant to developing countries in addressing the interface between these two disciplines where the understanding of law and economics poses unique analytical challenges to policy-makers.

As stressed in the study, the relationship between intellectual property and disciplines regulating competition has attracted growing attention, particularly as a result of the expansion and strengthening of IP protection at the global scale. While IP law deliberately subjects intellectual assets to the exclusive control of right owners, competition law seeks to avoid market barriers and benefit consumers by encouraging competition among a multiplicity of suppliers of goods, services and technologies. Such challenges are particularly complex in developing countries, the majority of which have little or no tradition in the application of competition law and policies. In fact, in most of these countries intellectual property rights have been expanded and strengthened in the absence of an operative body of competition law, in contrast to developed countries where the introduction of higher levels of IP protection has taken place in normative contexts that provide strong defences against anti-competitive practices.

This study commissioned to Professor Carlos Correa (University of Buenos Aires), notes that the TRIPS Agreement (Article 40) specifically provides for the possibility of regulating anticompetitive practices in licensing agreements. As highlighted in the paper, this is crucial to ensure the right balance between competition and the protection of intellectual property rights (IPRs). However, it does not specifically address this issue, as there is abundant literature on national experiences on this matter, as well as on the interpretation of the TRIPS Agreement and the legal approaches that developing countries may adopt. The paper, on the contrary, explores a number of issues where not much work has yet been done in developing countries but that could be of relevance in tackling the interface between IP and competition policies. Notably, the paper deals with some competition law issues specifically relating to technology markets, as distinct from product or service markets. It thus discusses the extent to which the refusal to license an intellectual property right to a third party may be deemed anti-competitive. The paper considers, further, anti-competitive situations arising from the acquisition and enforcement of intellectual property rights. The use of compulsory licences to remedy anti-competitive practices is also examined together with a number of state interventions that determine key aspects of their competition policies.

The premise of ICTSD's work in this field, together with its joint project with UNCTAD, is based on the understanding that IPRs have never been more economically and politically important – or controversial – than they are today. Patents, copyrights, trademarks, industrial designs, integrated circuits and geographical indications are frequently mentioned in discussions and debates on such diverse topics as public health, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, and the entertainment and media industries. In a knowledge-based economy, there is no doubt that a better understanding of IP is indispensable to informed policy making in all areas of development. The relationship between competition law and policy and IP stands high in the WIPO Development Agenda recently adopted by the WIPO General Assembly.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth remains inconclusive. Diverging views also persist on the impacts of intellectual property rights on development prospects. Some point out that, in a modern economy, the minimum standards laid down in TRIPS will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, technology transfer and private investment flows. Others stress that IP, especially some of its elements, such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by: raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers.

It continues to be urgent, therefore, to ask how can developing countries use IP tools to advance their development strategy? What are the key concerns surrounding the issues of IP for developing countries? What are the specific difficulties they face in IP negotiations? Is IP directly relevant to sustainable development and to the achievement of agreed international development goals? How we can facilitate technological flows among all countries? Do they have the capacity, especially the least developed among them, to formulate their negotiating positions and become well-informed negotiating partners? These are essential questions that policy makers need to address in order to design IP laws and policies that best meet the needs of their people and negotiate effectively in future agreements.

To address some of these questions, the ICTSD Programme on Intellectual Property and Sustainable Development was launched in July 2000. One central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries – including decision makers, negotiators but also the private sector and civil society – who will be able to define their own sustainable human development objectives in the field of IP and effectively advance them at the national and international levels.

We hope you will find this study an additional contribution to the debate on IP and sustainable development and particularly in responding to the need for increased awareness and better understanding of the interface between IP and competition policy. An underlying assumption of our work on IP has been the pursuit of a proper balance between the different interests at stake in designing appropriate regimes compliant with international commitments. These regimes, as in the case of countries with strong traditions in IP, are designed taking into account adequate checks and balances. Competition law and policies are essential components of these checks and balances.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

Intellectual property (IP) law subjects intellectual assets to the owner's exclusive control. Competition law on the other hand, seeks to avoid market barriers and benefit consumers by ensuring that a multiplicity of suppliers of goods, services and technologies may effectively compete against each other. The relationship between these two areas of law poses uniquely difficult challenges to policy-makers, particularly in developing countries, the majority of which have little or no tradition in the application of competition law and policies.

A number of regulations linked to the acquisition and exercise of intellectual property rights, such as those dealing with the marketing approval of pharmaceuticals and agrochemicals, directly influence market entry and contestability. Such regulations integrate what may be called a country's "competition policy". Given the lack of legislation, weak implementation or absence of policies to deal with the IP-competition relationship in developing countries, a competition policy approach may be particularly useful to ensure a pro-competitive exercise of intellectual property rights (IPRs).

Developing countries can follow their own approach to competition law and IPRs since there are no international rules (with the exception of Article 40 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that constrain the capacity of such countries to discipline IP-related anti-competitive behaviour. In the absence of international rules on the matter, countries may have different views about what constitutes undesirable anti-competitive effects as a result of the exclusivity granted under IPRs.

Although competition law has usually dealt with markets for goods, markets for technologies exist separately from those for products or services and may also be subject to competition law. Competition law may, in particular, address situations in which IP is used to charge excessive prices for or prevent access to protected technologies. Competition provides a strong incentive for developing new technologies in certain fields. In cases where IPRs are granted, governments can adopt measures to mitigate the monopolisation of technologies and promote competition. Thus, although Article 31(b) of the TRIPS Agreement only refers to the refusal of a voluntary licence as a *condition* for the granting of a compulsory licence, the unilateral refusal to license a patent (generally known as "refusal to deal") can be considered grounds for granting a compulsory licence and has been contemplated in a number of national patent laws.

The possibility of allowing third parties to use IPRs in cases of refusal to deal has also been considered in some countries under competition law in the context of the "essential facilities" doctrine. This doctrine applies when one firm, which controls an essential facility, denies a second firm reasonable access to a product or service that the second firm must obtain in order to compete with the first. While some US court decisions have suggested that information may constitute an essential facility, the extent of application of this doctrine to intellectual property cases is uncertain. Under European Community law, an "essential facility" may include an intellectual property right. An IPR holder is not entitled to exclude competitors from the use of his/her rights when a licence is essential for competition, such as where the refusal to license prevents the introduction of a new product or allows the intellectual property holder to monopolise a secondary market. Developing countries may draw interesting lessons from the application of the concept of refusal to deal and the essential facilities doctrine in developed countries. However, there are no rigid models and developing countries can elaborate their own approaches on the matter in order to respond to their public interests.

It is generally accepted in developed countries that holding IPRs does not necessarily confer market power *per se*. However, the respect of IPRs under competition law is premised on the assumption

that the intellectual property is properly obtained. Competition law may be applied when particular intellectual property rights have not been obtained in the proper manner or are not deserved, for instance, when patents have been obtained by deceiving the patent office. In addition, low standards of patentability and shortcomings in patent examination may lead to the granting of "poor quality" patents that can hamper competition. Acquiring patent rights for frivolous developments or with overbroad claims can provide grounds for anti-competitive intervention even in jurisdictions where IP is essentially seen as compatible with competition law.

The accumulation of patents in the form of "package patents" may have anti-competitive effects if used, for instance, to inappropriately extend market power from legitimate patent claims to illegitimate patents, or to coerce a party into licensing patents that it might not have otherwise done. "Patent thickets" may also raise competition law concerns, as co-operation among competitors in different forms (including cross-licensing) may be necessary to navigate the patent thicket, ultimately limiting competition. "Sham petitioning" may equally form the basis for a claim under competition laws. The US Federal Trade Commission, for instance, has intervened in some cases of fraudulently-obtained patents.

While much of the literature on IPRs and competition law focuses on patents, anti-competitive behaviour may be based on or facilitated by other modalities of IPRs. Thus, copyrights have been involved in important competition law cases. Several studies have shown that copyright creates monopoly power and that the majority of markets on information goods follow a pathway of progressive concentration at both the national and international levels. The anti-competitive effects of copyright protection of software, particularly of interfaces, have been central in several cases, notably involving the dominant software provider, Microsoft. Competition law concerns have also frequently arisen in relation to copyright collecting societies. A fundamental tension between the goals of trademark and competition laws has also been observed in some cases.

Undue *enforcement* of IPRs can also amount to anti-competitive conduct. In particular, preliminary injunctions may be effectively used to prevent legitimate competition. This is why courts in the United States and Europe have generally taken a very cautious approach towards the granting of injunctions in patent cases. Border measures can also be used with an anti-competitive intent. Enforcement measures should allow the protection of the IPR holder's legitimate interests, but equally protect against abuses that may unjustifiably distort competition. In the US the concept of "sham" litigation may be applied in cases of abuses of legal procedures, notably when a legal action is based on fraudulently acquired IPRs or on an obviously incorrect legal theory, on valid rights that are known to be unenforceable or where the plaintiff knew that there was no infringement.

Compulsory licences can be used, both in the context of IPRs and of competition laws, to remedy anti-competitive practices. Article 31(k) of the TRIPS Agreement, explicitly provides for the granting of such licences in the case of patents. For example, in the US the grounds for granting compulsory licences under competition law have included the use of patents as a basis for price-fixing or entry-restricting cartels, the consummation of market-concentrating mergers in which patents played an important role and practices that extended the scope of patent restrictions beyond the bounds of the patented subject matter. Compulsory licences may be used in cases of cross licensing that unduly limit competition, particularly when they involve substitute technologies, that is, technologies that actually or potentially compete with each other, independently of their intrinsic characteristics.

"Patent pools" represent another situation that may be subject to analysis from a competition policy perspective. Such pools may be used for pro-competitive purposes. However, they may facilitate tacit collusion in a multiplicity of markets and allow the pool members to impose abusive terms on non-members wishing to get access to technologies.

Finally, there are a number of areas in which IPRs play an important role and where actions taken by governments decisively shape competitive relations. This is, for instance, the case of regulations determining the requirements for marketing approval of pharmaceutical and agrochemical products. The *sui generis* system of "data exclusivity" applied in some countries – and promoted through free trade agreements – confers a temporary right to the exclusive use of such data by the first applicant (generally the company that developed a new product), thereby excluding generic competition during the period of exclusivity. Restrictions to competition may also arise from the so-called "patent-registration linkage" under which a national health authority cannot approve a medicine, or is obliged to take other measures, when there are patents relating to the medicine and the applicant has not obtained the patent owner's consent.

In conclusion, IP law cannot be designed and applied in isolation from other legal disciplines, particularly competition law. The "competition policy" approach suggests that creating and preserving the conditions for competition and market contestability in the area of IPRs, is not only the task of "competition law" or "antitrust" authorities. Defining the right balance between competition and IPRs is an objective to be achieved through a diversity of policies and regimes. A number of recommendations can be made to developing countries, namely:

- establish or strengthen competition laws in order to control, *inter alia*, possible abuses emerging from the acquisition and exercise of IPRs;

- consider the competition implications of various policies and regimes that determine market entry, such as marketing approval of pharmaceutical and agrochemical products;

- ensure an adequate coordination among the competition law agency and other agencies whose decisions may influence market structure and operation, with the aim of maintaining a competitive environment;

- fully use the flexibilities allowed by the TRIPS Agreement to determine the grounds for granting compulsory licences to remedy anti-competitive practices relating to IPRs;

- consider, in particular, the granting of compulsory licences in cases of refusals to deal;

- conceptualise and apply the essential facilities doctrine as required to address situations of control of essential technologies, taking into account the relevant market conditions and public needs;

- develop policies, including guidelines, to prevent and correct abuses in the acquisition and enforcement of IPRs;

- address situations that may normally lead to anti-competitive conduct such as "package" and "thicket" patents;

- adopt guidelines for use at the patent offices to prevent the granting of frivolous or low quality patents, as well as patents containing overly broad claims, which may be used to unduly restrain legitimate competition and block innovation;

- avoid "linkage" provisions and data exclusivity in order to promote competition in markets of regulated products.

INTRODUCTION

The relationship between intellectual property (IP) and disciplines regulating competition has attracted growing attention, particularly as a result of the expansion and strengthening of IP protection at the global scale. While IP law deliberately subjects intellectual assets to the exclusive control of right owners, competition law seeks to avoid market barriers and benefit consumers by encouraging competition among a multiplicity of suppliers of goods, services and technologies. Dealing with such a relationship poses unique analytical challenges to policy-makers (Kovacic, 2005, p. 2).

Such challenges are particularly complex in developing countries, the majority of which have little or no tradition in the application of competition law and policies. In fact, in most of these countries IPRs have been broadened and strengthened in the absence of an operative body of competition law, in contrast to developed countries where the introduction of higher levels of IP protection has taken place in normative contexts that provide strong defences against anti-competitive practices.

The analysis of the relationship between IP and competition disciplines may be limited to the interactions between laws relating to the acquisition and exercise of IP, on the one hand, and competition law[1], on the other. However, this perspective ignores the impact of a number of regulations linked to the acquisition and exercise of IPRs that directly influence market entry and contestability. This broad set of regulations integrates what may be called a country's "competition policy".[2] They include, for instance, regulations dealing with the marketing approval of pharmaceuticals and agrochemicals, inter-firm mobility of personnel, standard setting, and other measures and policies applicable in sectors where IP is significant in determining relationships among competitors.

The study of competition policy, as defined, requires the consideration of various forms of state interventions affecting the acquisition and use of IPRs. Although competition law can be an important instrument to limit the harmful effects of IPRs[3], most developing countries do not apply such laws to correct anti-competitive uses of IPRs, due to the lack of legislation, weak implementation or absence of policies to deal with the IP-competition relationship.[4] Hence, a broader competition policy approach may be particularly useful in developing countries to ensure a pro-competitive use of IPRs.

Until 1990 only 16 developing countries had formal competition legislation. With technical assistance from international institutions, particularly the United Nations Conference on Trade and Development (UNCTAD), around 50 countries completed legislation for competition in the 1990s and many others were in the process thereafter. However, as noted by Gal, "the mere adoption of a competition law is a necessary but not sufficient condition for it to be part of market reform. Just as ecological conditions determine the ability of a flower to bloom, so do some preconditions affect the ability to apply a competition law effectively" (Gal, 2004, p. 21). Many such conditions are missing in developing countries. Enforcing agencies generally lack the financial and human resources, as well as the legal mechanisms (such as investigative tools and the capacity to impose high penalties) required for an effective application of the laws to correct anti-competitive distortions. This may be particularly true in situations where IPRs are involved, as enforcing agencies normally have no expertise in this area.[5]

Even in those developing countries where competition law exists, clear criteria or guidelines to deal with the anti-competitive acquisition and use of IPRs have not been established.[6] In adopting such guidelines, developing countries can obviously follow their own conceptions about competition law and IP as there are no international rules[7] (with the exception of Article 40 of the TRIPS Agreement) that constrain the capacity of such countries to discipline IP-related anti-competitive behaviour. The attempts, mainly sponsored by the European Union, to bring competition policy into the WTO have failed and are unlikely to surface again in the short term.

Competition laws can adopt different approaches, such as an efficiency or welfare approach, or a purely "economic freedom" approach (Drexl, 1999, p. 228). Countries may also elaborate a development-oriented approach by emphasising, for instance, the generation or preservation of competitive capabilities or social benefits. Thus, in South Africa, competition law seeks to "promote and maintain competition" for a range of purposes, including the promotion of "the efficiency, adaptability and development of the economy" and the advancement of social and economic welfare.[8] It may also be in the national interest for firms to increase their market power, for instance, through mergers to achieve economies of scale, even though, as a result, consumer prices may rise (Scherer, 1994, p. 61). Conversely, competition policies focusing on consumers' welfare may give preference to static over dynamic efficiency and may be vigilant about the impact of pricing.

In examining the relationship between IP law and competition policy, consideration should also be given to the different territorial spans of IP and competition policy. Intellectual property policy is to a great extent shaped by international law, particularly in the case of developing countries. These countries are induced by various means to adopt the standards of IP protection elaborated in developed countries[9], often through coercion or as a pre-condition to preserve or get access to larger markets in the context of free trade agreements (FTAs). Such standards are decisively influenced by the industries that may benefit from new or strengthened forms of IP protection (Sell, 2003).

Competition policy – as opposed to competition law – has important implications for the analysis of the interaction with IP policies. Two such implications are of particular relevance. First, different state agencies may assume important pro-competition roles, independently of the interventions by specific competition law-enforcing agencies, where they exist. Second, such roles are relevant not only with regard to private behaviour, but also with regard to competitive distortions introduced by various government bodies.

For instance, there is growing concern that the failings in the procedures for examining and granting patents have led to the proliferation of "low quality" or trivial patents which have deleterious effects on competition, as examined below. While some of the distortions created by such failings may be corrected by courts, their intervention may be too costly and too late. Some state agencies have, hence, taken action in order to prevent the erection of undue market barriers through the acquisition of patents. Such agencies may include bodies with specific competences in areas apparently distant from competition policy.[10]

The courts can also play a pro-competition role. In some countries (e.g. Germany) they are in charge of granting compulsory licences. In other cases, they can take an active role in avoiding anti-competitive behaviour by limiting the rights conferred by IPRs. For instance, in a recent decision in *eBAY INC. et al v. MERCEXCHANGE*[11], the US Supreme Court denied a permanent injunction in a case of patent infringement. It stated that "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts." This decision effectively amounts to granting a compulsory licence on "equity" grounds.

It is important to recall that Article 8.2 of the TRIPS Agreement stipulates that "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 the international transfer of technology." This provision recognises the Member State's right to subject the exercise of intellectual property rights to competition laws.[12]

This paper deals, first, with some competition law issues specifically relating to technology markets, as distinct from product markets. Second, it discusses the extent to which the refusal to license

an intellectual property right to a third party may be deemed anti-competitive practice. Third, it considers anti-competitive practices arising from the acquisition and enforcement of intellectual property rights. Fourth, the use of compulsory licences to remedy anti-competitive practices is examined. Fifth, the paper addresses a number of state interventions that determine key aspects of their competition policies.

Given the limited experience existing in developing countries in the application of competition policies in general, and more specifically, in addressing the relationship between competition law and IPRs, this paper relies heavily on precedents from developed countries. Although the doctrines, legislation and jurisprudence found in these countries should be adapted to the specific contexts of developing countries, they allow us to draw some useful lessons for policy-making in this area.

It is also to be noted that Article 40 of the TRIPS Agreement specifically provides for the possibility of regulating restrictive practices in licensing agreements. This is crucial to ensure the right balance between competition and the protection of IPRs. This paper, however, does not specifically address this issue as there is abundant literature on national experiences on the matter, as well as on the interpretation of Article 40 of the TRIPS Agreement and the legal approaches that developing countries may adopt.[13]

TECHNOLOGY MARKETS

Competition policy may be applied both to circumstances surrounding the *access* to IP protected technology, as well as to the conditions under which that access is eventually conferred. Possible anti-competitive behaviour relating to access to technology has received little attention until recently and is of crucial importance for developing countries.

Although competition law has usually dealt with markets for goods, markets for technologies exist separately from those for products or services (Arora *et al,* 2001) and may be subject to competition law. Thus, the guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements (2001/C 3/02)[14] distinguish between "product markets" and "technology markets" and define the latter as:

"When rights to intellectual property are marketed separately from the products concerned to which they relate, the relevant technology market has to be defined as well. Technology markets consist of the intellectual property that is licensed and its close substitutes, i.e. other technologies which customers could use as a substitute (2.2(b)47)."

In addition[15], the Commission Notice - Guidelines on the application of Article 81 of the "EC Treaty to technology transfer agreements" indicates that:

"Technology is an input, which is integrated either into a product or a production process. Technology licensing can therefore affect competition both in input markets and in output markets. For instance, an agreement between two parties which sell competing products and which cross license technologies relating to the production of these products may restrict competition on the product market concerned. It may also restrict competition on the market for technology and possibly also on other input markets (para. 20)."[16]

Similarly, the Anti-trust Guidelines for the Licensing of Intellectual Property issued by the Department of Justice and the Federal Trade Commission[17] of 6.4.1995 indicate that:

"Technology markets consist of the intellectual property that is licensed (the "licensed technology") and its close substitutes – that is, the technologies or goods that are close enough substitutes significantly to constrain the exercise of market power with respect to the intellectual property that is licensed. When rights to intellectual property are marketed separately from the products in which they are used, the Agencies may rely on technology markets to analyze the competitive effects of a licensing arrangement (para. 3.2.2)."

The differentiation between product and technology markets means that anti-competitive behaviour may take place with regard to either or both. Competition policy may, in particular, address situations in which IP is used to charge excessive prices for or prevent access to protected technologies.

It may be argued that the very purpose of IPRs is to restrict third parties' use of technologies and other protected assets and that, therefore, such exclusionary right should be preserved unfettered and exempted from competition law challenges. However, "[T]he fact that intellectual property laws grant exclusive rights of exploitation does not imply that intellectual property rights are immune from competition law intervention."[18] Intellectual property rights are, in effect, not absolute but subject to higher public interests. Moreover, IPRs are granted to serve public interests *through* inventors and creators and not just to benefit them.[19] Thus, in an important case, the US Supreme Court stated that "[T]he basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility."[20] Article 7 of the TRIPS Agreement also stipulates that:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users

of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

The critical point is not whether competition policy may interfere with IPRs, but rather when such intervention is justified. In the absence of international rules on the matter, countries may have different approaches about the situations in which the exclusivity granted under IPRs may lead to undesirable anti-competitive effects. In fact, the impact of IPRs on the market substantially varies depending upon the legal and socio-economic contexts in which they apply. Thus, the static-dynamic efficiency rationale applicable to a developed country does not necessarily hold in low income countries. High levels of IPR protection may have significant negative distributive consequences in the latter without contributing – or even impeding – their technological development (Stiglitz, 1999, p.315). As a result, competition authorities may legitimately give static efficiency precedence over dynamic efficiency considerations and challenge, for instance, situations of excessive pricing emerging from the exercise of IPRs.[21]

This may be particularly the case in developing and least-developed countries (LDCs) where IP protection may provide little or no incentive to domestic innovation, while it may only contribute marginally to innovation elsewhere. In these cases, the present sacrifice of static efficiency finds no justification in future gains of dynamic efficiency as domestic innovation is unlikely to occur and foreign innovation depends on larger markets in developed countries.[22] Moreover, the static-dynamic efficiency rationale for IP is questionable in more general terms: "[T]here is first of all the logical difficulty of accepting the concept of injecting a certain amount of inefficiency into an economic system today to promote only its possible efficiency tomorrow; this is in effect an anomalous passage for the economic theory…" (Ramello, 2003, p. 124).

Both static and dynamic efficiency may be affected by the granting and exercise of IPRs. The exclusionary rights conferred can lead to under-utilisation of information and jeopardise the generation of subsequent innovation. Cumulative forms of innovation prevail in most sectors of the economy, including in the biomedical field. Since information is both an *output* and an *input* in the production process, a conflict arises between first and second generation innovators, because the greater the rights (and hence incentives) of the first generation, the greater the costs (and hence the lower the incentives) of the second generation producers: since every generation is both "the first" to future producers and "the second" to prior producers, the conflict is pervasive and sets limits on the extent to which, even in a dynamic analysis, it is efficient to recognise and enforce rights in information products. As Arrow put it, "precisely to the extent that [property rights in information are] successful, there is an under-utilisation of the information" (in Benkler, 2001, p. 271).

In fact, competition is not necessarily incompatible with and, on the contrary, can effectively lead to dynamic efficiency through increased innovation. Competition can be a powerful incentive to introduce product, process or organisational innovations, as noted by the Federal Trade Commission (FTC):

"Competition can stimulate innovation. Competition among firms can spur the invention of new or better products or more efficient processes. Firms may race to be the first to market an innovative technology. Companies may invent lower cost manufacturing processes, thereby increasing their profits and enhancing their ability to compete. Competition can prompt firms to identify consumers' unmet needs and develop new products or services to satisfy them (Federal Trade Commission, 2003a, p. 1-2)."

Many important innovations are the result of stiff competition, particularly when different technological options may be pursued. One well known example is the case of the semi-conductors industry, where IPRs play a marginal role as an incentive for innovation.[23] Many studies also indicate that patent protection is not always, or even usually, the driving force behind research and development.[24] In the area of software, for

instance, non-appropriation mechanisms, such as "open source" schemes, have proven to promote a vibrant process of innovation. Some studies also indicate that software patents are not associated with increased research and development, but rather those firms that increased patenting in software tended to reduce their research and development expenditures (Bessen and Hunt, 2003). Professor Boyle also noted that:

"In fact, it is remarkable to consider that the areas where the Internet has succeeded most readily – for example as a giant distributed database of facts on any subject under the sun – are traditionally those in which there are little or no intellectual property rights. The software on which the Internet runs is largely open source, another Internet-enabled method of innovation to which policy-makers have been slow to adapt. The Internet offers us remarkable opportunities to achieve the real goals that intellectual property policy ought to serve: encouraging innovation and facilitating the dissemination of cultural and educational materials. Yet policy making has focused almost entirely on the Internet's potential for illicit copying." (Boyle, 2004 p. 6).

In sum, competition provides a strong incentive for developing new technologies in certain fields. Governments may influence the shape of technology markets, notably through the adoption of IPRs. As discussed in the next section, in cases where IPRs are granted, governments can adopt measures to mitigate the monopolisation of technologies and promote competition.

REFUSAL TO DEAL[25]

A key issue in establishing the relationship between intellectual property and competition law is the extent to which a third party may be authorised to use protected subject matter without the consent of the intellectual property right-holder. In the United States, the European Union and other jurisdictions, intellectual property is regarded as equivalent to other forms of property and, hence, right-holders have the power to refuse third party use. For instance, the Competition Tribunal of Canada stated in the *Tele-Direct* case (1997)[26] – where it was alleged that selective refusals by the respondent to license its trademark constituted an abuse of its dominant position – that Tele-Direct's refusal to license its trademarks fell squarely within its legal prerogative: "[I]nherent to the very nature of the right to license a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom to grant a license; selectivity in licensing is fundamental to the rationale behind protecting trade-marks."[27]

However, intellectual property is not absolute and in some circumstances a third party may obtain access to and use the protected subject matter in order to compete in an otherwise monopolised market.[28] Thus, the unilateral refusal to voluntary license a patent (generally known as "refusal to deal") can be sufficient grounds for granting a compulsory licence under some national laws. Although Article 31 b) of the TRIPS Agreement only refers to the refusal of a voluntary licence as a *condition* for the granting of a compulsory licence, the WTO Secretariat has expressly recognised the possibility of articulating a "refusal to deal" as grounds for granting such licences[29] and this has been contemplated in a number of national laws, for instance, in China[30], Argentina[31] and Germany.[32] In the United Kingdom, a compulsory licence may be granted based on a refusal to deal that causes some specific effects, such as when, as a result of the refusal to grant a licence, an export market is not being supplied, the working of any other patented invention which makes a substantial contribution is prevented or hindered, or the establishment or development of commercial or industrial activities in the country is unfairly prejudiced (Section 48.3.d of the UK Patent Act, as revised in 1977).[33] In Canada, a compulsory licence can be granted under the Patent Act in cases of refusal to license when some negative effects arise[34] (anti-competitive effects are apparently not necessary to establish this type of abuse). Similarly, in South Africa, a licence can be granted in the case of the refusal to grant a licence on reasonable terms, where trade or industry or agriculture or the establishment of a new trade or industry in the country is prejudiced and it is in the public interest that a licence be granted (section 56(2)(d), Patents Act No. 57 of 1978).

Compulsory licences based on "refusal to deal" can also be granted in intellectual property cases under competition laws. Thus, in Australia, a compulsory licence for "refusal to deal" may be granted unless the patentee can prove that the licence would equally be refused in a competitive situation (O'Bryan, 1992, p. 10). A decision by Belgian courts in 1995 also imposed a compulsory licence on two copyright collecting societies in favour of two cable distributors that had been refused the right to transmit by cable the German Cable SATI in Belgium. Refusing the authorisation for a reasonable remuneration was deemed to be abusive (Latham, 1996, p. 25). In Canada, section 32 of the Competition Act[35] gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licences and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been used to cause undue damage to trade or commerce or to prevent or lessen competition.

US approach to refusal to deal

In the US, the Federal Circuit asserted *In re Independent Service Organizations Antitrust Litigation* that there was "no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent"[36], but held that a patentee's right to refuse to license its intellectual property right was limited in certain circumstances: where the patent was obtained

through fraud, where a lawsuit to enforce the patent was a sham, or where the patent holder uses his right to refuse to sell patented parts to gain a monopoly in a market beyond the scope of the patent (Hovenkamp *et al*, 2005, p. 28).

In the case of copyrights, US courts have admitted to investigate the reasonableness of a refusal by a copyright's owner to license his/her rights.[37] While a refusal to license is presumed to be legal, in *United States v. Microsoft* the district court held that "copyright does not give its holder immunity from laws of general applicability, including the antitrust laws."[38]

The possibility of permitting third party use of IPRs in cases of refusal to deal has been considered in some countries under competition law in the context of the "essential facilities" doctrine.[39] This doctrine, as defined by a US appellate court[40], "imposes liability when one firm, which controls an essential facility, denies a second firm reasonable access to a product or service that the second firm must obtain in order to compete with the first."

In the US, this doctrine has been mainly applied with regard to the access to vertically-integrated natural monopolies under Section 2 of the Sherman Act. The US federal courts have analysed refusal to deal either by expressly referring to this doctrine or just applying similar reasoning. In *Otter tail Power Co v. the United States,* the US Supreme Court ruled that a dominant firm that controls an infrastructure or an asset that other companies need to make use of in order to compete has the obligation to make the facility available on non-discriminatory terms (Rahnasto, 2003, p. 144). In *MCI v. AT&T*, the US Seventh Circuit Court designed a four-step test for determining whether access should be granted to a particular facility on the basis of the essential facilities doctrine:

(1) control of the essential facility by the monopolist;
(2) a competitor's inability, practically or reasonably, to duplicate the essential facility;
(3) denial of the use of the facility to a competitor; and
(4) feasibility of providing the facility.[41]

The US patent law, as amended in 1988, provides that "no patent owner otherwise entitled to relief for infringement… of a patent shall be denied relief or deemed guilty of a misuse or illegal extension of the patent right by reason of his having… refused to license or use any rights to the patent…" This amendment protects a patentee from a counterclaim of misuse; in applying it, courts have held that a patentee cannot be held liable for unilaterally refusing to sell or license a patent (Taladay and Carlin, 2002, p. 445). Alleged monopolists' refusals to deal, and conditional refusals to deal with respect to exclusive intellectual property rights continue, however, to be the subject of litigation and debate in the US[42], although in no case has a US court explicitly conceded so far that an intellectual property can be deemed an essential facility for the purposes of granting a non-voluntary licence to allow competition (Hovenkamp *et al*, 2005, p. 20).

In *Intergraph Corp. v. Intel Corp* the plaintiff argued that Intel's chips and technical know-how constituted an essential facility, as access thereto was vital to the plaintiff's business. The district court agreed that Intel's intellectual property rights relating to its chips were an essential facility and that Intel should be compelled to license its patents and trade secrets to Intergraph on reasonable and non-discriminatory terms.[43] However, the decision was reversed on appeal[44] on the argument that "an essential facilities claim could not be made out unless the owner of the essential facility and the antitrust plaintiff competed in a market that required access to the facility."

A detailed analysis of US case law by Hovenkamp *et al* (2005) indicates that while some US court decisions have suggested that information may constitute an essential facility[45], the extent of the application of this doctrine to intellectual property cases is uncertain.[46] Although a presumption of legality of a unilateral refusal to license applies, particularly in the patent area, such presumption may not be deemed as absolute but intended rather to hold a *per se* legality only when the challenged conduct is "within the legitimate scope of the intellectual property right" (Hovenkamp *et al*, 2005, p. 20, 42).

European approach

The European Commission and courts have examined in several cases whether the refusal to give third parties access to an essential facility constitutes an abuse of a dominant position, contrary to Article 82 of the EC Treaty.[47] Under EC law, an "essential facility" may be "a product such as a raw material, an intellectual property right, a service, information, infrastructure or access to a physical place such as a harbour or an airport, or a part of a telecommunications network, or a software interface" (Lang, 2005, p. 62).

In an early precedent (*Volvo AB v. Erik Veng (UK) Ltd*)[48] the European Court of Justice (ECJ) had considered that "the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design, constituted the very subject matter of exclusive rights. It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right." The Court, however, provided three examples of situations where a refusal to license may be abusive, if coupled with (1) an arbitrary refusal to supply spare parts to independent repairers, (2) overcharging for spare parts, or 3) ceasing to produce spare parts for a particular model when there were many vehicles of that model still on the road. In *Renault* the ECJ confirmed the judgment given in *Volvo* (Rahnasto, 2003, p. 145).

The decision of the ECJ of 6 April 1995 in *Magill*[49] established an important precedent in relation to refusal to deal in the context of intellectual property rights. The Court held that Radio Telefis Eireann (RTE) and Independent Television Publications Limited (ITP) could not rely on national copyright provisions to refuse to provide information on programme scheduling to third parties. Such a refusal, the Court argued, constituted the exercise of an intellectual property right beyond its specific subject matter and, thus, an abuse of a dominant position under Article 86 of the EC Treaty. The court reasoned that RTE and ITP held a dominant position, because they were the only source in Ireland of the basic information necessary to produce weekly television programming guides and were thus in a position to exclude all competition from that market.

The Court considered that whilst refusal to grant a licence in exercising an intellectual property right is not in itself an abuse of a dominant position, it may be an abuse where special circumstances exist. Such circumstances included the lack of an actual or potential substitute for a weekly television guide, the existence of a specific, constant and regular demand for such a guide and the fact that the refusal to grant a licence to Magill to produce such a guide prevented the appearance of a new product on the market which RTE and ITP did not offer (Latham and Geissmar, 1995, p. 9):

"The appellants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article 82 of the Treaty (para. 54)."

Though some legal commentators have argued that the *Magill* Court required a finding of two markets, there is nothing in *Magill* which suggested that the application of Article 82 to an intellectual property right necessarily required market leveraging (Fine, 2003, p. 2). The ECJ, in fact, considered that each broadcasting station was dominant over the information needed by the plaintiffs to compile a comprehensive TV guide. The doctrine elaborated in *Magill* may be the basis for the granting of a compulsory licence of the basic patent to the holder of an improvement patent, but it also lays the ground for consideration of other cases of anti-competitive conduct. An abuse may be found even where the intellectual property holder has never licensed the intellectual property in question (Taladay and Carlin, 2002, p. 451-452). The ECJ's judgment in *Magill* clearly points to the acceptance of the application of the essential

facilities doctrine to intellectual property anti-trust cases (Rahnasto, 2003, p. 145).

In *Tiercé Ladbroke*[50] the Court of First Instance (CFI) of the EC held that the company PMI, which licensed the copyright of 12 race-course operators in France, was not obliged to license live film coverage of the races to a firm that provided betting services (in fact, it was the leading provider of such services in Belgium). The court found that the refusal to license the applicant did not fall within the prohibition of Article 82 because it did not involve a product or service which was (a) essential for the exercise of the activity in question (that is, for which there was no real or potential substitute), or (b) a new product whose introduction could be prevented and for which there was specific, constant and regular potential demand.

The facts in this case "were hardly supportive of an infringement of Article 82, even on a broad reading of *Magill*, since it was clear to the CFI that broadcasts of French horse races were not essential to the betting organisation, Ladbroke, where bets were placed prior to any broadcast of the race in question. This decision, however, confirmed that preventing the emergence of a *new product* was not a *sine qua non* condition to compel access to an essential facility under Article 82. What really mattered was whether the IP holder, by refusing to license, was preventing access to an essential facility" (Fine, 2003).

The essential facilities doctrine was also at stake in *Oscar Bronner.*[51] In this case, Mediaprint refused to distribute the papers of a smaller specialist firm, which alleged that the only nationwide home delivery service in Austria was an essential facility. The ECJ rejected the complaint since there were other ways of delivering the applicant's newspapers and there were no proven technical, legal or economic obstacles to establish another national home delivery scheme (even if less efficiently). Again in this case, the decision – even if negative for the applicant – indicated that Article 82 did not require that the dominant firm prevent the emergence of a new product, but rather that its refusal of access to an essential facility be likely to eliminate competition on the relevant market. Interestingly, the advocate general stated in this case that the role of competition law was to protect consumers rather than competitors:

"… it is important not to lose sight of the fact that the primary purpose of Article 82 is to prevent distortion of competition – and in particular to safeguard the interests of consumers – rather than to protect the position of particular competitors" (para. 58).

The European Commission also applied the essential facilities doctrine to adopt interim measures requiring IMS (the world's largest supplier of data on pharmaceutical markets)[52] to license to competitors the use of copyrighted information[53] in which IMS was deemed to hold a dominant position. Two competitors in the data business, who used IMS' "bricks" model to compile and present their own information, were sued by IMS (which also obtained an injunction), for infringement of the data bases regime established under European law.[54] In the Commission's view, the "bricks" model had become a *de facto* industry standard. It held that the refusal of access to the brick structure (an essential one with no substitute) was likely to eliminate all competition in the relevant market and was not objectively justified. It also argued that IMS could obtain fees from the compulsorily licensed companies and thereby its legitimate interest would not be prejudiced.[55]

In examining the case law in the EC, two experts have noted that:

"The development of the essential facilities doctrine has been different in the EC and the US. Unlike in the US, EC competition law imposes upon dominant firms a general duty to share as well as to supply competitors. Indeed, if a dominant firm tries to deny access to a facility as a means of deterring competition, it may be found to abuse its dominant position even if the facility is not "essential." Moreover, the EC is more likely to consider the effect of exclusion on a competitor, rather than on competition as a whole, in evaluating whether access to a facility is required …" (Taladay and Carlin, 2002, p. 450-451).

In sum, under EC law an intellectual property holder may reserve for its exclusive use an intellectual property right even when it generates an important competitive advantage and creates a dominant position. However, the same holder cannot exclude competitors from the use of his/her rights when a licence is essential for competition – even if a licence to the product has never been granted. This is the case for instance where the refusal to license prevents the introduction of a new product or allows the intellectual property holder to monopolise a secondary market. Although the ECJ has not defined precisely what is meant by an "essential facility", the test seems to require only that the facility be in some way essential. While the court is restrictive in identifying a facility as essential, requiring access seems to follow automatically if the existence of such a facility is determined. Under this interpretation, a refusal to license an intellectual property right is prohibited if it leads to a dominant position, "even if no other abuse or additional abusive conduct has occurred: in other words, dominance without abuse can be illegal" (Lang, 2005, p. 73).

The Italian Competition Authority (ICA) decided to grant a compulsory licence[56] in a case brought before it for an alleged abuse of a dominant position through the refusal by Merck to grant Dobfar (a chemical pharmaceutical manufacturer) a licence to produce an active ingredient (ceimipenem/cilastatina-IC) needed for the production of an antibiotic (carbapenems) used in the treatment of infectious diseases.[57] The ICA considered that Merck's refusal to license its product (covered by a Certificate of Complementary Protection[58]) amounted to an abuse of dominant position "since it prevented Dobfar from producing the IC and enabled Merck to maintain its dominance over the relevant pharmaceutical markets, cutting out potential competitors. Namely, the IC was deemed to be an essential resource for the production of generics by Merck's potential competitors, whereas Dobfar was considered an indispensable supplier for such competitors and in turn, Merck was seen as an indispensable supplier for Dobfar" (Coco and Nebbia, 2007, p. 452).

This decision reflects a particular application of the essential facility doctrine, under which "the active ingredient was deemed to be "essential" not for the requesting firm, as one would expect, but for its customers, i.e. the generics producers, although the indispensability referred not to the asset but to the relationship between the claimant and the defendant" (Coco and Nebbia, 2007, p. 454).[59]

Lessons for developing countries

The analysis made in this section reveals that compulsory licences can be used, under certain conditions, in the EC and possibly to a more limited extent in the US, to allow third parties access to technologies protected by IPRs in cases of refusals to deal. The "essential facilities" doctrine may be applied to ensure access to protected technologies particularly, but not only, for their exploitation in secondary markets, even in the absence of an otherwise abusive conduct. The refusal to grant third parties access to an essential technology (such as to manufacture a medicine) may provide sufficient grounds, as shown by the ICA decision, for compelling a dominant firm to grant licences on non-discriminatory and reasonable terms.

Interestingly, the South African Competition Commission had set a precedent in this regard in 2003. It found that pharmaceutical firms GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) had contravened the Competition Act of 1998. The firms were found to have abused their dominant positions in their respective anti-retroviral (ARV) markets, in particular, the firms had "denied a competitor access to an essential facility."[60] Although the Commission decided to refer the matter to the Competition Tribunal for determination, the case was later settled as the firms accepted to grant voluntary licences.[61] As a result, there was no further elaboration on the application of the essential facilities doctrine.

In sum, interesting lessons may be drawn from the experiences in the application of the concept of refusal to deal and the essential facilities doctrine in developed countries. However, there are no rigid models and developing countries can elaborate their own approaches on the matter in order to respond to their public interest.

ACQUISITION AND ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

It is generally accepted in developed countries that holding IPRs does not automatically confer market power *per se*[62]. The predominant concept is that IP and competition laws are complementary: they both aim at promoting innovation and competition (Ghidini, 2006, p. 5). However, the respect of IPRs under competition law:

"is premised on the assumption that the intellectual property is properly obtained. Problems arise when particular intellectual property rights have not been obtained in the proper manner or are not deserved. Patent protection in the absence of novelty and non-obviousness can harm innovation by eliminating the incentives for the patent holder and others to engage in further pursuit of something that is novel and non-obvious" (Azcuenaga, 1995).

The case of patents

The anti-competitive effects of the granting of IPRs, particularly patents, have raised growing concerns. An OECD (Organisation for Economic Co-operation and Development) report regarding biotechnology patents, for instance, noted that "the rising tide of biotechnology patents has brought concerns that they are being granted too freely and too broadly. Too many patents that cover too much ground will not only harm competition, but will also stifle innovation by making further research riskier, more difficult or more expensive" (OECD, 2004, 15).

The problem, however, is not limited to biotechnology patents but extends to other fields, such as pharmaceutical and software patents. Jaffe and Lerner have documented how the US current patent system:

"provides incentives for applicants to file frivolous patent applications, and for the patent office to grant them. It likewise encourages patent holders to sue, and those accused of patent infringement to give in and pay under threat, even if the patent at issue is of dubious validity. It does not provide good incentives for the information necessary to resolve questions about patent validity to be brought forward and analysed appropriately" (Jaffe and Lerner, 2004, p. 6).

The extent to which the application for patents and their acquisition may be deemed anti-competitive crucially depends on the room left to obtain patents on minor developments. Such room has greatly expanded in the last twenty years in some jurisdictions such as in the US[63] where the FTC has found:

"significant concerns that, in some ways, the patent system is out of balance with competition policy. Poor patent quality and legal standards and procedures that inadvertently may have anticompetitive effects can cause unwarranted market power and can unjustifiably increase costs. Such effects can hamper competition that otherwise would stimulate innovation" (FTC, 2003a, p. 5).

The situation in the US patent office – one of the largest in the world – exemplifies the weaknesses of patent prosecution and the possible abuses by skilled applicants willing to acquire patents as an anti-competitive tool rather than as a reward for genuine innovation. The FTC has noted that presumptions in Patent and Trademark Office (PTO) rules tend to favour the issuance of a patent: "[I]f the examiner does not produce a *prima facie* case [of obviousness], the applicant is under no obligation to submit evidence of nonobviousness." *(footnote omitted)* Similarly, "[O]ffice personnel ….must treat as true a statement of fact made by an applicant in relation to [the asserted usefulness of the invention], unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement." Likewise, "[T]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." *(footnote omitted)* The PTO's resources also appear inadequate to allow efficient and accurate screening of questionable patent applications (FTC, 2003a, p. 9).

Acquiring patent rights for frivolous developments or with overly broad claims can provide grounds for anti-competitive intervention even in jurisdictions where IP is essentially seen as compatible with competition law. This means that the granting of a patent does not exclude the possibility of considering that a misconduct has taken place. A patent is granted on the basis of an examination that is often limited to prior patent documents and which only confers a presumption of validity that can be challenged by third parties before the same patent offices or courts. However, the presumption of validity should be taken with caution.[64] As noted by the FTC, the shortcomings of the procedures to evaluate patent applications "suggest that an overly strong presumption of a patent's validity is inappropriate. Rather, courts[65] should require only a "preponderance of the evidence" to rebut the presumption of validity" (FTC, 2003a, p. 8).[66]

The increase in the number of patent applications and the relaxation of patentability standards, has led to a proliferation of "poor quality" patents in some countries.[67] This trend has been fuelled in the US by the pro-patent trend inaugurated in 1982 with the creation of a Federal Circuit Court specialised in intellectual property cases (Jaffe and Lerner, 2004, p. 10). However, patents are often held invalid by US courts.[68]

The lax standards of patentability applied by some patent offices have encouraged applications on trivial developments, generally known in the pharmaceutical industry as "ever-greening".[69] They are the result of various patenting strategies[70], such as "blanketing", "flooding", "fencing", "surrounding" (Granstrand, 1999, p. 221-222), under which firms seek patent protection to block or delay competition in either innovation[71], technology or product markets.

The creation of "packages" of patents by a company around a given technology or product has become increasingly common. In the pharmaceutical field, for instance, ten or more patents are often acquired around the same active ingredient, even after it has already fallen into the public domain. The accumulation of patents may be the result of different patent strategies. As examined by Rubinfeld and Maness (2005), package patents may be used:

- to inappropriately extend market power from legitimate patents claims to illegitimate patents;[72]
- to coerce a party into licensing patents that it might have chosen to avoid or design around (especially when the licence fee is not dependent on the number of patents);
- to reduce a competitor's incentive to challenge individual patents since as "the cost of challenging patents increases with the number of patents included in the bundle, a firm may have an incentive to include weak patents in the package";
- to misuse patents if the bundle is used "to extend a firm's monopoly power from the "space" covered by a strong patent to the space encompassed by strong and weak patents together" (Rubinfeld and Maness, 2005, p. 90).

Mandatory package licensing have been generally deemed anti-competitive by the US Department of Justice and the courts in the US, although in some cases they may arguably reduce transaction costs as there is no need to negotiate individual licences (Rubinfeld and Maness, 2005, p. 90).

"Patent thickets" may also raise competition law concerns. When an overlapping set of patent rights (belonging to various companies) exists, those seeking to commercialise new technology need to obtain licences from multiple patentees. Co-operation among competitors in different forms (including cross-licensing) may be necessary to navigate the patent thicket, ultimately limiting competition.[73]

Low standards of patentability and the expectation of acquiring patent rights in order to harass competitors, increase the likelihood of "sham petitioning". This is:

"the situation in which a person uses the governmental process, as opposed to the outcome of that process, as an anti-competitive weapon…such as the filing of a large number of patent applications that are not well founded,

that claim the technology of others, or that are otherwise frivolous" (Sankaran, 2000).

Sham petitioning may form the basis for a claim under antitrust laws. Moreover, whether the petitioning is a "sham" or not, no immunity protects one who attempts to enforce a patent that is known to be invalid or procured by inequitable conduct (Sankaran, 2000). In Australia, legislation passed in implementing the FTA signed with the US provides for the imposition of penalties of up to 10 million Australian dollars on pharmaceutical patent holders that are found to have filed frivolous suits to extend their patents and prevent generic copies of patented drugs from being marketed.

The granting of a US patent is often invoked before smaller patent offices in developing countries as evidence that the invention meets high patentability standards. The pro-patent approach promoted by the US PTO has led many patent offices to apply very loose criteria to establish novelty and inventive steps, particularly in the pharmaceutical field where patents are granted in some cases with regard to, inter alia, pharmaceutical formulations[74], combinations of known products[75], optical isomers[76], polymorphs[77], salts of known substances[78] and variants of manufacturing processes. Presenting drugs in slightly different ways to secure new patents and layering several patents on different aspects of the drug to secure perennial monopoly rights is one of the main ways that pharmaceutical firms employ to artificially extend the patent life of their drugs (Glasgow, 2001).[79] As a result, there is a proliferation of pharmaceutical patents over a myriad of minor modifications (Correa, 2001), while the development of new chemical entities has drastically decreased since the 1990s. Such entities account for a small fraction[80] of the thousands of patents obtained every year around known drugs, including those in the public domain.

In view of the distortions caused by wrongly granted patents, the OECD has recommended a more active role for competition law enforcing agencies:

"… to strive to limit the anti-competitive aspects of IPR while respecting its necessity. It appears that the wisest course of action for an agency wishing to influence IP policy is either to challenge the validity of invalid or overly broad patents through litigation or by requesting patent re-examinations, or to open a dialogue with the IP agency and take an advisory role (or both)" (OECD, 2005, p. 16).

Although the OECD suggests that "[F]or several reasons, such as a lack of relevant technical expertise and limited resources, it does not appear to be prudent for competition authorities to assume responsibilities related to the initial review of IP applications" (OECD, 2005, p. 7), the direct intervention of such authorities may be contemplated where they may contribute to improve the functioning of the IPR system.

In the US, courts have considered that extending patent rights beyond the scope of the grant violates the antitrust laws.[81] The FTC has intervened in some cases of fraudulently obtained patents. In the 1960s it challenged agreements between Pfizer and American Cyanamid relating to tetracycline patents and ordered the compulsory licensing of the patent in question at a fixed royalty.[82] Pfizer and American Cyanamid were found to have made mis-representations to and withheld essential information from the patent examiner, thereby deceiving him into granting a patent that otherwise would not have been approved (Azcuenaga, 1995).

In a more recent case, the FTC also found and condemned practices aimed at deceiving the US patent office to unduly obtain patent protection:

"Through Bristol's [Bristol-Myers Squibb Company] decade-long pattern of alleged anti-competitive acts, Bristol avoided competition by abusing federal regulations in order to block generic entry; deceived the US Patent and Trademark Office (PTO) to obtain unwarranted patent protection; paid a would-be generic rival over USD 70 million not to bring any competing products to market; and filed baseless patent infringement lawsuits to deter entry by generics" (FTC, 2003b)[83].

Similar abuses were found and condemned in Europe. Thus, the European Commission determined that AstraZeneca misused government procedures in order to exclude generic firms and parallel traders from competing against its product Losec. The abuses consisted, in particular, in the misuse of the patent system by knowingly making misrepresentations to patent offices with a view to extending the basic patent protection for Losec. The misleading information "was initially provided by AstraZeneca in the context of its applications to several patent offices in June 1993 and December 1994 within the EEA [European Economic Area] for extra protection for omeprazole (the active substance in AstraZeneca's product Losec) in the form of so-called supplementary protection certificates."[84]

In Canada, the Intellectual Property Enforcement Guidelines state that:

"If an IP owner licenses, transfers or sells the IP to a firm or a group of firms that would have been actual or potential competitors without the arrangement, and if this arrangement creates, enhances or maintains market power, the Bureau may seek to challenge the arrangement under the appropriate section of the Competition Act."

The Competition Bureau intervened in an Appeal Court case involving three pharmaceutical companies, Eli-Lilly, Shionogi and Apotex, around the question of whether the assignment of a patent can constitute an agreement or arrangement to lessen competition unduly, contrary to section 45 of the *Competition Act*. In accordance with **Sheridan Scott,** Canadian **Commissioner of Competition:**

"This is a critical question which brought into play the relationship between the Competition Act's authority vis-à-vis the Patent Act. A lower court judge had, in effect, held that a simple assignment of a patent in whatever circumstances would not run afoul of the Competition Act because the assignment of patents is expressly authorized by section 50 of the Patent Act and Parliament must be taken to have understood that patents confer market power.

If this interpretation had stood, the capacity of the Competition Act to deal with cases involving intellectual property, for example, where a company buys up all the competing intellectual property thereby creating a true monopoly, would have been seriously compromised, and the effects may have carried over to other forms of property and related laws" (Scott, 2006).

On appeal, the Federal Court of Appeal found that the right to assign a patent recognised by the Patent Act:

"does not immunize an agreement to assign a patent from section 45 of the Competition Act when the assignment increases the assignee's market power in excess of that inherent in the patent rights assigned" (Scott, 2006).

While the FTC has advanced some proposals to deal with the anti-competitive effects of patent grants and a bill to reform the US patent law and increase patent quality is pending before the Congress[85], the OECD has suggested a number of measures against the patenting of trivial inventions:

i) stricter examination: low-quality applications would be deterred by a low probability being granted; *ii) reduction of fees once a patent is granted (as opposed to rejected*): such a discount would encourage self-selection by patentees so that the number of low-quality applications would decrease; *iii) second-tier patent protection*: enhance the use of so-called petty patents or utility models systems as an alternative to standard patents for minor and less novel inventions (such a system has been working for a long time in many countries; it was recently modernised in Australia); and *iv) setting up a credible public domain alternative:* for example, encouraging firms to publicise their inventions on dedicated Internet sites at low cost when the only purpose for patenting is to avoid others patenting first (a practice referred to as defensive patenting) (OECD, 2004, p. 29).

Copyright

While much of the literature on IPRs and competition law focuses on patents, anti-competitive behaviour may be based on or facilitated by other modalities of IPRs.

Although the smaller breadth of copyright protection as compared to patents would suggest that individual copyright material is rarely the source of significant monopoly power (Régibeau and Rockett, 2004, p. 52), copyrights have been involved in important competition law cases, such as Napster's digital distribution[86], Magill and IMS Health.[87] In many cases, competition authorities have focused on market power stemming from the concentration of copyrighted materials as a result of corporate mergers, such as the USD 109 billion AOL-Time Warner approved by the FTC in December 2000.[88]

Several studies have shown that copyright creates monopoly power and that the majority of information goods markets follow a pathway of progressive concentration at both the national and international levels. It has also been found that several characteristics of such markets – such as the existence of economies of both scale and scope on the supply side and network externalities on the demand side – are self-reinforcing and contribute to creating and strengthening dominant positions and consolidations in the copyright area (Ramello, 2003, 126).

As a result, copyrights operate in a significantly altered competitive scenario where one "persistent trait is the existence of non-price competition, in which the sunk cost component has the dual role of consolidating and increasing demand and/or creating barriers to entry for potential competitors" (Ramello, 2003, 126-127).

The anti-competitive effects of copyright protection of software, particularly of interfaces (which allow the inter-operability of different pieces of software or hardware) have been central in several cases, notably involving the dominant software provider, Microsoft.[89] The main concern in these cases has been the possible leveraging of the monopoly power enjoyed in one market to other markets through the control of interfaces. Thus, on 24 March 2004, the European Commission concluded, after a five-year investigation, that Microsoft Corporation broke European Union competition law by using its near monopoly in the market for operating systems (OS) for personal computers (PCs) to take over the markets for operating systems for work group servers and for media players. The Commission ordered Microsoft to disclose to competitors the interfaces required for their products to be able to communicate with the Windows OS and to offer a version of its Windows OS without Windows Media Player to PC manufacturers (or when selling directly to end users). In addition, Microsoft was fined Euro 497 million for abusing its market power in the EU.[90]

Competition law concerns have also frequently arisen in relation to copyright collecting societies. Thus, the European Commission opened formal proceedings against the International Confederation of Societies of Authors and Composers (CISAC) and its individual national members. The Commission's concerns included the fact that the royalty collectors were trying, by various methods[91], to ensure that each of them maintained exclusive access to broadcast royalties in the countries in which they operate. By obliging commercial users to get a licence only from the domestic collection society, limited to the domestic territory, collective societies may ensure a monopoly on their domestic markets and prevent the new entrants from getting into the copyright management market.[92] In July 2007, CISAC offered to grant multi-territory licences for performing rights over the Internet, satellite and cable (not including the so-called "mechanical rights"[93]) in order to settle the case with the Commission.[94]

Trademarks

The relationship between competition law and trademark law was tested in a case decided in 2005 by the Canadian Supreme Court, where it examined whether trademark rights relating to LEGO blocks could be extended on functional

features, such as the geometrical pattern of raised studs on the top of the bricks. The last of LEGO's Canadian patents on its blocks had expired in 1988. The Court held that:

"Trademark law should not be used to perpetuate monopoly rights enjoyed under now-expired patents… The fact is... that the monopoly on the bricks is over and Mega Bloks and Lego bricks may be interchangeable in the bins of the playrooms of the nation – dragons, castles and knights may be designed with them, without any distinction."[95]

A fundamental tension between the goals of trademark and competition law has also been observed in some cases.[96] In the US, some case law has dealt with the trademark-antitrust relationship (Chang, 1997). Acquiring a trademark may violate Section 2 of the Sherman Act if a trademark is fraudulently registered or monopolisation or probability of monopolisation is shown, or Section 7 of the Clayton Act, if a threat of substantial lessening of competition is found.

Abusive enforcement of intellectual property rights

Finally, undue *enforcement* of IPRs can also amount to anti-competitive conduct. In particular, preliminary injunctions may be effectively used to prevent legitimate competition. This is why courts in the US and Europe have generally taken a very cautious approach towards the granting of injunctions in patent cases.[97]

Enforcement measures should allow the protection of legitimate interests, but equally protect against abuses that may unjustifiably distort competition. For instance, in Chile in 1993, a local company was sued for infringement of a patent on a certain process (relating to fluconazole) which was not actually used in the country (the product was imported from countries where no patent protection on processes and/or products existed). The Chilean law permitted the title-holder to request and obtain a judicial ban on the activities of the alleged infringer until the case was finally decided. This allowed the patent holder to block the commercialisation of products by local companies for several years, during which the price of the corresponding medicine increased significantly. Later on the case was dismissed, but nobody reimbursed patients for the higher prices paid or lack of access to the medicine. There are many examples of abusive requests of interlocutory injunctions in Latin America. In Argentina, for instance, Bristol Myers Squibb obtained such an injunction against a local firm on the basis of a patent (AR 017747B1) protecting a formulation of didanosine, a drug administered to HIV patients that was not developed by Bristol Myers Squibb and which is in the public domain.[98]

In Venezuela, the competition authority found that Laboratorios WYETH S.A. had abused a patent on a pharmaceutical formulation of venlafaxine to threaten a local company and block its entry into the market with a competing medicinal product, thereby violating Article 6 of the Venezuelan competition law.[99]

Border measures can also be used with an anti-competitive intent. One case relating to soymeal imports to the European Union is illustrative of the potential misuse of provisions aimed at protecting legitimate interests. The European Regulation **1383**/2003 empowers customs authorities to detain goods suspected of infringing IPRs. Unlike the obligation under Article 50 of the TRIPS Agreement, which is limited to trademark counterfeiting and copyright piracy, the Directive applies to other IPRs, including patents.

Argentina is one of the main world exporters of soymeal produced from soybeans genetically modified to resist a particular herbicide (glyphosate). Monsanto did not obtain a patent on its herbicide resistant "RR" technology in Argentina, as it filed the respective application after the expiry of the applicable legal terms. Around 95 percent of soybean currently produced in Argentina is derived from varieties (developed by different companies) incorporating the RR gene. Although Monsanto obtained royalties for the RR technology under private contracts with seed companies, it tried to obtain an additional payment from Argentine farmers, who refused to pay any extra charge for a technology that is in the public domain. Monsanto then targeted

the importation of Argentine soymeal into Europe, on the basis of two patents (EP0218571 and EP 546090) that protect the gene and gene constructs, as well as the transformed cells, in a soybean plant. Despite the fact that the patents cannot extend to industrially processed products where the genes in question, even if hypothetically found intact, cannot perform their functions[100], Monsanto obtained orders from customs authorities in several European countries to detain the importation of Argentine soymeal. It filed lawsuits against importers in the Netherlands, Denmark and Spain, that were bound to deposit substantial guarantees to get the imported soymeal dispatched.

This case illustrates an attempt to expand the legal powers conferred by patents through an overly broad interpretation of patent claims. If these attempts were successful, they could have a major adverse effect on competition in secondary markets (e.g. shirts made out of Bt (*Bacillus thuringiensis*) cotton), as the patent owner would exercise undue market power on products not covered by patents.

In the US, the concept of "sham" litigation may be applied in cases of abuses of legal procedures. Sham suits violate Section 2 of the Sherman Act or Section 1 of the same Act if done collectively. Section 2 of the Sherman Act may be applied when a legal action is based on fraudulently acquired IPRs or on an obviously incorrect legal theory, on valid rights that are known to be unenforceable or where the plaintiff knew that there was no infringement. In *Grip-Pak Inc. v. Illinois Tool Works Inc.*[101] Judge Posner stated that "litigation could be used for improper purposes even when there is probable cause for the litigation; and if the improper purpose is to use litigation as a tool for suppressing competition in its antitrust sense, it becomes a matter of antitrust concern."[102] As mentioned above, in *re Independent Service Organizations Antitrust Litigation*, the court held that where the patent was obtained through fraud or where a lawsuit to enforce the patent was a sham, a patentee's right to refuse to license its intellectual property right may be limited.[103]

In *Professional Real Estate Investors, INC., et al, v. Columbia Pictures Industries, INC., et al.*, however, the Supreme Court set a high standard to admit the existence of sham litigation. Justice Stevens held that:

"the distinction between "sham" litigation and genuine litigation is not always, or only, the difference between lawful and unlawful conduct; objectively reasonable lawsuits may still break the law. For example, a manufacturer's successful action enforcing resale price maintenance agreements, (footnote omitted) restrictive provisions in a license to use a patent or a trademark, (footnote omitted) or an equipment lease, (footnote omitted) may evidence, or even constitute, violations of the antitrust laws. On the other hand, just because a sham lawsuit has grievously harmed a competitor does not necessarily mean that it has violated the Sherman Act… The rare plaintiff who successfully proves a sham must still satisfy the exacting elements of an antitrust demand."

In accordance with this decision, hence, an antitrust violation should be determined in addition to the existence of sham litigation. Nevertheless, Justice Stevens cautioned that "I would not, however, use this easy case as a vehicle for announcing a rule that may govern the decision of difficult cases, some of which may involve abuse of the judicial process."[104]

In sum, abusive practices can often be found in the acquisition and enforcement of IPRs. Governments can apply competition laws or other measures to prevent and punish such practices, which have a significant deleterious effect on competition and social welfare. Intellectual property right law may, in particular, contain specific provisions and remedies to deal with such abuses. In fact, the TRIPS Agreement does not limit but requires governments to ensure that abuses committed through the enforcement of IPRs be subject to adequate control.[105]

COMPULSORY LICENCES TO REMEDY ANTI-COMPETITIVE PRACTICES

Compulsory licences can be used, both in the context of IPRs and of competition laws, to remedy anti-competitive practices. Article 31(k) of the TRIPS Agreement, explicitly provides for the granting of such licences.[106] Unlike other compulsory licences allowable under the Agreement and following the previous US practice, in the case of anti-competitive practices:

(a) there is no need to previously negotiate a voluntary licence with the patent owner;
(b) the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration;
(c) the compulsory licensee is not subject to the limitation imposed by Article 31;
(d) the licence shall be predominantly for the supply of the domestic market of the member granting it.

The existence of anti-competitive practices is also considered as grounds for the granting of compulsory licences under the laws of Chile (1991), Argentina (1995) and the Andean Group countries (Decision 486, 2000), among others. There is, in particular, a long experience in applying such a remedy in the US. As noted by Scherer and Watal (2002):

"The United States has led the world in issuing compulsory licenses to restore competition when violations of the antitrust laws have been found, or in the negotiated settlement of antitrust cases before full adjudication has occurred (footnote omitted). By the end of the 1950s, compulsory licenses had been issued in roughly 100 antitrust cases covering an estimated 40 to 50 thousand patents, including AT&T's basic transistor concept patents, IBM's computer and tabulating card machine patents, General Electric's fluorescent and incandescent lamp patents, Du Pont's nylon patents, and Eastman Kodak's color film processing patents. Additional cases since then have led to the licensing of Xerox's plain paper copying machine patents, the tranquilizer Meprobamate, synthetic steroids, the antibiotic Griseofulvin, Cytokine biopharmaceutical patents owned by Novartis and Chiron, and the 9-AC cancer drug patent rights assembled under the merger of Pharmacia AB with Upjohn. Some of the U.S. antitrust decrees, such as those covering General Electric's incandescent lamp patents and the 8,600 patents in AT&T's portfolio, required licensing at zero royalty rates. Most provided for "reasonable" royalties…" (Scherer and Watal, 2002, p. 16).

In the US the grounds for granting compulsory licensing under competition law have included the use of patents as a basis for price-fixing or entry-restricting cartels, the consummation of market-concentrating mergers in which patents played an important role and practices that extended the scope of patent restrictions beyond the bounds of the patented subject matter (Scherer and Watal, 2002, p. 17). Compulsory licences have recently been granted in the US as a part of mergers reviews and to address other anti-competitive situations (see Box 1).

Notwithstanding the US' extensive experience with the use of compulsory licences as an anti-competitive remedy, Reichman notes that the interface between antitrust law and intellectual property law appears more rigid in the US than in the European Community, in part because the US has not adopted the European doctrine of abuse of a dominant position (Reichman, 2006).[107] Compulsory licences have been granted in the EC in cases relating to patents[108] and copyrights, as noted above.

Compulsory licences for trademarks were also granted in exceptional cases in the US. In *FTC v. Cereal Companies*, the Federal Trade Commission proposed to create five completely new companies and required the major existing firms (Kellogg, General Mills and General Food) to license their trademarks. In *FTC v. Borden Company*, the FTC found market dominance in the lemon juice market and the judge decided to compulsorily license the "Realemon" trademark (Goldstein, 1977, p. 124). After these precedents,

Box 1. Recent Compulsory Licences to Remedy Anti-Competitive Practices in the US

Merger reviews

In 2002, the US FTC granted a compulsory cross-licence of the Immunex tumor necrosis factor (TNF) patent to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States."

In 2005, the FTC ordered a compulsory licence of Guidant's intellectual property surrounding the RX delivery system for Drug-Eluting Stents (DES) as a condition of Guidant's acquisition by either Johnson & Johnson or Boston Scientific.[13] Boston Scientific, which eventually won the bidding to acquire Guidant, was required to license DES patents to a potential entrant, Abbott.

Remedies to anticompetitive practices

In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows.[14]

In February 2007, in a case involving a failure to disclose patents on the standard, an FTC antitrust remedial order compelled memory chipmaker Rambus to license its patented technology on certain specified terms and limited the maximum royalty rates that Rambus can collect for use of its patents to 0.25 percent for Synchronous Dynamic Random Access Memory (SDRAM) products; 0.5 percent for Double Data Rate (DDR) SDRAM products, as well as SDRAM memory controllers or other non-memory chip components; and one percent for DDR SDRAM memory controllers, or other non-memory chip components. After three years, the royalty rate will be zero percent.

Source: Love, 2007.

the policy became less flexible and compulsory licences for trademarks have been prohibited by the TRIPS Agreement (Article 21).[109] The TRIPS Agreement seems to rely on the concept that the trademark owner has an absolute right to license or not his/her trademark.

It is to be noted that the effect on competition of granting one or more compulsory licences will depend on the market structure and particular competitive conditions. In some cases, the market share that compulsory licensees may obtain may be small and even insignificant, on account of the reputation and dominant presence of the patent owner in the market (Watal, 2000). Hence, the granting of compulsory licences should be accompanied by other measures to effectively promote competition. It is important, in particular, that – as permitted by Article 31(k) of the TRIPS Agreement – the compulsory licensee be allowed to export in order to achieve economies of scale.

Compulsory licences may be used in cases of cross-licensing that unduly limit competition, particularly when they involve substitute technologies (that is, technologies that actually or potentially compete with each other) independently of their intrinsic characteristics.[110] The anti-competitive effects of cross-licensing

may stem from tacit collusion between rivals or from the determination of the levels of royalty payments even in the absence of an explicit or tacit coordination, as "the cross-licensing agreement simply modifies the firms' incentives to ensure that the uncoordinated equilibrium is less competitive than before" (Régibeau and Rockett, 2004, p. 36).

Patent pools[111] represent another situation that may be subject to analysis from a competition policy perspective. Such pools may be used for pro-competitive purposes. For example, the United States Patent and Trademark Office identified a number of advantages of patent pools in the area of biotechnology which, it argued, "could serve the interests of both the public and private industry, a win-win situation" (Clark *et al*, 2000). Among the benefits cited for this approach to licensing were: efficiency in obtaining rights to patented technology through "one stop" licensing mechanisms; the distribution of risks associated with research and development; and the elimination of "blocking" patents or "stacking" licences and the consequent encouragement of co-operative efforts.

However, there are also reasons for concern about the anti-competitive effects of patent pools since they may facilitate tacit collusion in a multiplicity of markets and allow pool members to impose abusive terms on non-members to get access to the technologies. Moreover, if access is permitted, it may be conditional upon payment for the whole set of pooled patents, thereby leveraging the monopoly power enjoyed by pool members in one market to another (Régibeau and Rockett, 2004, p. 39-40).

Finally, a compulsory licence may not be required to address an anti-competitive situation when parallel imports are admitted (when a product is imported into a country without the authorisation of the title holder of his/her licensees) provided that the product has been put on the market elsewhere by the right holder, his/her licensee or other authorised person.

Article 6 of the TRIPS Agreement recognises the possibility of legally admitting parallel imports, based on the principle of "exhaustion of rights". This principle was extensively developed in the framework of European integration in order to avoid the fragmentation of markets and the exercise of discriminatory pricing by title-holders within the Community. It has been incorporated, with an international reach, in many national laws. However, WTO Members are free to establish a different solution and partially or totally ban parallel imports. This is the policy adopted in many developed and some developing countries.

Parallel trade may also be impeded by private arrangements that unduly distort competition. In a number of cases, the anti-competitive effects of restraints on parallel imports have been considered. Thus, the European Commission applied Article 81 of the EC Treaty in cases relating to the parallel trade of pharmaceutical products within the Community. In *Sandoz* (1987) and *Bayer* (1996), also known as the *Adalat* case, the Commission fined the pharmaceutical companies for having agreed on an export ban with their wholesalers.[112] The Commission considered that national price control regulations were an insufficient justification for impeding parallel trade. Banning of parallel trade was also found to be anti-competitive in the already mentioned case relating to Astra Zeneca's anti-acid product, Losec.[113] The Peruvian competition law enforcing authority, INDECOPI, which is also competent in industrial property matters, denied a trademark owner the right to exclude parallel imports, based on Article 157 of Decision 486 ("Common Regime on Industrial Property") (Barbosa, 2005, p. 118).

GOVERNMENT INTERVENTIONS AFFECTING COMPETITION

As mentioned above, there are a number of areas in which IPRs play an important role and where actions taken by governments decisively shape competitive relations. This section considers some of these areas.

Data exclusivity

Regulations determining requirements for marketing and approval of pharmaceutical, agrochemical and other products represent a significant component of a state's competition policy. Such requirements may be linked in some areas to IPR protection, thereby defining the room for competition by innovators and generic companies.

Governments have had considerable leeway to determine the conditions to be met by market entrants in the area of pharmaceuticals.[114] The first marketing approval of a pharmaceutical product normally depends on the supply of evidence on quality, efficacy and safety (test data). National health authorities can follow different models for the approval of the second (and subsequent) marketing application. The authority may:

(a) require the second entrants to produce their own test data or to obtain an authorisation of use from the "originator" of the data;
(b) allow the second entrants to rely on the "originator's" test data against payment of a compensation;[115]
(c) use the "originator's" test data in order to examine subsequent applications of similar products; in this case, the authority reviews and relies on the originator's data;
(d) rely on the approval given in a foreign country and require the second entrants to prove only that their product is similar to an already registered product (the authority does not receive nor review the originator's test data).

In some jurisdictions, the test data necessary for the registration of pharmaceutical products are subject to a *sui generis* system of "data exclusivity", which confers a temporary right to the exclusive use of such data by the first applicant (generally the company that developed a new product). This means that the competent health authority will not be able, for a certain period, to use or rely on the data submitted by the first applicant in order to approve a second entrant's application for the commercialisation of a similar product. This model is based on the argument that without data exclusivity, private firms would have no incentive to bear the considerable costs of producing the required data. The exclusive period of use would permit the originator of the data to recover the investment made for their development.

In other countries, however, it is possible for health authorities to approve a second entrant application by relying on data submitted by the first applicant or on the approval granted by a foreign authority. The rationale for this approach – which is consistent with the TRIPS Agreement[116] – is that marketing approval should not erect barriers to otherwise legitimate competition and that investment for developing test data will not be jeopardised, especially in cases where the approval is granted in a developing country.[117] This model of marketing approval can promote price competition and access to more affordable medicines.

The data exclusivity and the unfair competition approach obviously have very different implications for competition. While the first eliminates generic competition – even in the absence of patent protection – during the exclusivity period,[118] the second promotes it. In addition, procedures relating to the marketing approval of pharmaceutical products are liable to be misused. For instance, Astra Zeneca was found to have misused such procedures and infringed Article 82 of the EC Treaty by de-registering the original capsule version of Losec in Denmark, Norway and Sweden with a view to preventing the authorisation of generic versions thereof.[119]

Linkage

Restrictions to competition may arise from other aspects of regulatory procedures for the approval of medicines and other products. One example is the so-called "patent-registration linkage" applied in some countries[120] and actively promoted by the US in free trade agreements. Under such linkage, a national health authority cannot approve a medicine, or is obliged to take other measures when there are patents relating to the medicine, and the applicant has not obtained the patent owner's consent to use the patent in question.

There are different forms of linkage, with various degrees of state intervention. In the case of the US,[121] the linkage system operates through the so-called "Orange Book" of the Food and Drug Administration (FDA). Patent holders must register information[122] on all patents, including their expiry dates, relevant to products for which they have obtained marketing approval. The patents to be listed include those which claim a drug or a method of using the drug that is the subject of a new drug application (NDA) or amendment, or with respect to which patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use or sale of the drug product. Process patents are not required to be registered in the Orange Book.

The FDA has repeatedly argued that it lacks the knowledge and resources to undertake to review patent claims to ensure that listings in the Orange Book have been correct, relying rather on the patent holder's declaration. The FDA must inform patent owners who registered their patents in the Orange Book about the existence of a third party's application on the same drug, but it is the patent owner who needs to act before the courts if s/he wants to interfere with the application procedures of a non licensed third party.[123] If a lawsuit is filed, the FDA's approval of the generic drug is automatically stayed for 30 months, regardless of the merits of the case.

A US FTC study found that for nearly 75 percent of the drugs covered by the study, brand-name companies initiated patent infringement litigation against the first generic applicant.[124] A court decision had been made (at the time of conclusion of the study) for 53 drug products out of 75. For 30 drug products, a court decision resolved the patent infringement claims. Generic applicants prevailed 73 percent of the time. Settlements were reached in 38 percent of the instances. Nine of these settlements obliged the brand-name company to pay a certain amount of money to the generic applicant. In seven cases the brand-name company licensed the generic applicant to use the patents for the brand-name drug product prior to patent expiration and in two cases the settlements allowed the generic applicant to market the brand-name drug product as a generic product, under the brand-name company's own marketing approval. In 18 instances, a court held that the brand-name company's patents were either invalid or not infringed (FTC, 2002).

In addition, litigation took place against the second generic applicant in cases where the first generic applicant settled its patent infringement litigation. Out of a total of 20 drug products with first generic settlements, nine drug products involved litigation with the second generic applicant. In four cases, there was also settlement with the second generic applicant; in three cases the second generic applicant won the patent infringement suit, while brand-name companies only prevailed in one infringement suit (FTC, 2002).

There has been considerable evidence on the abuse of the marketing approval procedures and Orange Book listings through patents that only specify a new feature or function of the drug that was not covered by a patent at the time the drug was first approved by the FDA (FTC, 2002) or by including non-eligible patents. Such patents have been used to delay the entry of generics, as each new patent could be used to obtain a new automatic stay for 30 months.[125]

In a case decided by the FTC against Bristol Myers, for instance, the company was found to have made wrongful listings "because the FDA does not review patents presented for listing in

the Orange Book to determine whether they do, in fact, meet the statutory listing criteria. Once listed in the Orange Book, improperly-listed patents have the same power as any validly listed patent to trigger a 30-month stay of generic approval, thereby delaying generic entry and potentially costing consumers millions, or even billions, of dollars without valid cause" (FTC, 2003b). The FTC claimed that Bristol conspired to list improperly an invalid patent in the Orange Book regarding its product "Taxol". Bristol was also alleged to have paid its potential buspirone rival over USD 70 million to withhold competition until patent expiration, eliminating the only potential generic threat to BuSpar for the entire patent period (FTC, 2003b).

In order to avoid some of these abuses, in 2003 the FDA introduced new regulations allowing for only one opportunity to obtain the 30-month stay and excluding patents claiming packaging, metabolites and intermediates. In the case of patents that claim a polymorph that is the same as the active ingredient described in the NDA, the NDA applicant is required to certify in a prescribed declaration that it has test data which demonstrates that a drug product containing the polymorph will perform the same as the drug product described in the NDA (Greenblum, 2003, p. 86).

The linkage provisions promoted by the US in foreign countries, mainly through free trade agreements, require in some cases the direct intervention of health authorities to refuse marketing approval applications, even without a judicial order. Such a broad intervention contradicts the concept that patents are "private rights", as stated in the preamble of the TRIPS Agreement and that, whether a given product infringes or not a patent is a legal matter entirely separate from the technical issues concerning safety and efficacy of drugs. Health authorities have no knowledge or experience whatsoever to assess the claims of a patent, especially given the vast number of patents obtained on marginal developments around existing drugs, such as formulations and compositions, dosage forms, polymorphs, etc.[126]

CONCLUSIONS

Intellectual property law cannot be designed and applied in isolation from other legal disciplines, particularly competition law. A basic premise of this study is that the relevant trade-offs between "static" and "dynamic" efficiencies are not necessarily embedded in the design of IP regimes nor in other regimes that affect competition and that can be broadly deemed part of a country's competition policy.

The "competition policy" approach articulated in this study suggests that creating and preserving the conditions for competition and market contestability in the area of IPRs, is not only the task of "competition law" or "antitrust" authorities. Through a diversity of policies and regimes, the right balance between competition and IPRs can be reached.

The implementation of an effective competition policy is likely to require a multiplicity of institutional actors. The existence and effective operation of a competition authority may be crucial, but insufficient to ensure competition in areas where IP plays a significant role and where state regulations may limit market entry.

Government agencies should assume an active role in the promotion of effective competition in areas, such as pharmaceuticals, where IPRs and other regulations are significant determinants of competitive behaviour. Co-operation and coordination among various agencies may be essential to create and maintain a competitive environment.

As discussed in this paper, the essential facilities doctrine provides a basis to limit the monopoly power associated with IPRs, particularly when the exercise of such power results in an unacceptable loss of welfare. Although this doctrine has been mainly applied to allow third parties' access to tangible assets, as examined above, it can be applied to intellectual property since both situations are basically the same: a competitor is prevented from accessing something essential to compete.

The most clear cut situation where the essential facility doctrine may be used is when the refusal to license prevents other parties from competing in a downstream market. Competition authorities may consider that a refusal to license an intellectual property right is unlawful if the lack of permission to use the right leads to a monopoly or near-monopoly, particularly when the dominant position allows the title-holder to charge excessive prices. The doctrine may be applied, however, even in cases where no additional abusive conduct is determined. Moreover, exclusionary conduct may trigger a compulsory licence simply on the grounds of refusal to deal. As the decision commented above by the Italian Competition Authority shows, there is considerable flexibility to conceptualise and grant compulsory licences in cases of refusal to deal and to apply the essential facilities doctrine to ensure, *inter alia*, access to technologies essential for production of competing products.

In the light of the previous analysis, a number of recommendations[127] can be made to developing countries, namely:

- establish or strengthen competition laws in order to control, *inter alia*, possible abuses emerging from the acquisition and exercise of IPRs;
- consider the competition implications of various policies and regimes that determine market entry, such as marketing approval of pharmaceutical and agrochemical products;
- ensure adequate coordination among the competition law agency and other agencies whose decisions may influence the market structure and operation, with the aim of maintaining a competitive environment;
- fully use the flexibilities allowed by the TRIPS Agreement to determine the grounds for granting compulsory licences to remedy anti-competitive practices relating to IPRs;
- consider, in particular, the granting of compulsory licences in cases of refusals to deal;
- conceptualise and apply the essential

facilities doctrine as required to address situations of control of essential technologies, taking into account the relevant market conditions and public needs;

- develop policies, including guidelines, to prevent and correct abuses in the acquisition and enforcement of IPRs;

- address situations that may normally lead to anti-competitive conduct such as "package" and "thicket" patents;

- adopt guidelines for use at the patent offices[128] to prevent the granting of frivolous or low quality patents, as well as patents with overly broad claims, which may be used to unduly restrain legitimate competition and block innovation;

- avoid "linkage" provisions and data exclusivity in order to promote competition in markets of regulated products.

ENDNOTES

1 Understood as the body of law specifically aimed at regulating market power, such as antitrust legislation.

2 "Competition policy" refers here to the full set of policies and institutions that affect a country's competitive environment. This concept has been used with a different meaning, as encompassing competition laws in addition "to other measures aimed at promoting competition in the national economy, such as sectoral regulations and privatisation policies. Also supervision over the government policies through competition advocacy" (SICE Dictionary of Trade Terms, http://www.sice.oas.org/dictionary/CP_e.asp).

3 This has been one of the points of consensus reached at the WTO Working Group on the Interaction between Trade and Competition Policy. See Petersman, 1999, p. 45.

4 The case brought before the South African Competition Commission by COSATU, the TAC, CEPPWAWU, Hazel Tau, Nontsikelelo Zwedala, Sindiswa Godwana, Sue Roberts, Isaac Skosana, William Mmbara, Steve Andrews, Francois Venter and the AIDS Consortium against GlaxoSmithKline South Africa Ltd and Boehringer Ingelheim was one of the few cases in which competition law authorities intervened in an IP-related case in a developing country. See Berger, 2005.

5 See, e.g. in Barbosa, 2005, an analysis of the Latin American case.

6 Some countries have adopted such guidelines, particularly in the area of licensing practices. See, e.g. *Antitrust Guidelines for the Licensing of Intellectual Property*, available online at: http://www.usdoj.gov/atr/public/guidelines/0558.htm; Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements. Guidelines for reviewing the exercise of IPRs were also issued by the Korean Fair Trade Commission.

7 There is also little international co-operation on this subject, except among the enforcing agencies of a few developed countries.

8 Sections 2(a) and (c) of the Competition Act, 89 of 1998.

9 The protection of traditional knowledge may be the sole and noticeable exception of standards elaborated in developing countries to meet their own objectives. See, e.g. Dutfield, 2000.

10 For instance, the Brazilian *Agencia Nacional de Vigilancia Sanitaria (*ANVISA) was empowered by a Provisional Measure, later confirmed by Law 10.196 of February 14, 2001, to review and refuse the granting of pharmaceutical patents. In accordance with the amended article 229-c of the Industrial Property Code, "[T]he grant of patents for pharmaceutical products and processes shall be subject to prior consent by the National Sanitary Supervision Agency - ANVISA"

11 L. L. C. of May 15, 2006.

12 The consistency requirement introduces an ambiguous standard which should not be interpreted, however, as subjecting national antitrust laws to any TRIPS-supremacy (UNCTAD-ICTSD, 2005, p. 551).

13 See, e.g., Gutterman, 1997; Keeling, 2003; Korah, 2006; UNCTAD-ICTSD, 2005; Berger, 2005; Correa, 2007; Roffe and Spennemann, forthcoming.

14 Guidelines on the applicability of Article 81 of the EC Treaty to horizontal co-operation agreements (2001/C 3/02), Official Journal of the European Community, 6.1.2001.

15 See also Article 1(j) of the Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements. This article provides that: "the relevant technology market includes technologies which are regarded by the licensees as interchangeable with or substitutable for the licensed technology, by reason of the technologies' characteristics, their royalties and their intended use" (Official Journal of the European Union, 27.4.2004)

16 Official Journal of the European Union 27.4.2004

17 Available online at: http://www.usdoj.gov/atr/public/guidelines/0558.htm,

18 Commission Notice - Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, Official Journal of the European Union 27.4.2004. The quoted statement is qualified by the Commission as follows: "Indeed, both bodies of law share the same basic objective of promoting consumer welfare and an efficient allocation of resources. Innovation constitutes an essential and dynamic component of an open and competitive market economy. Intellectual property rights promote dynamic competition by encouraging undertakings to invest in developing new or improved products and processes. So does competition by putting pressure on undertakings to innovate. Therefore, both intellectual property rights and competition are necessary to promote innovation and ensure a competitive exploitation thereof" (idem). See also Barbosa, 2005.

19 For an instrumental analysis of IPRs (as opposed to a propetarian conceptualisation) see Drahos, 1996.

20 *Brenner v. Manson,* 383 U.S. 519, 534-35 (1966).

21 For instance, "excessive pricing to the detriment of consumers" may be condemned under the South African Competition Act (section 8(a)) and under Article 82 of the EC Treaty. In accordance with the latter "[A]ny abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in: (a) directly or indirectly imposing unfair purchase or selling prices or unfair trading conditions". Excessive prices can also be an anti-competitive practice under Brazilian law No. 8.888/94 (Article 21). See Rosenberg, 2005.

22 Research and development in the pharmaceutical sector is illustrative of this situation. Scherer has shown that the extension of pharmaceutical product patents to developing countries under the TRIPS Agreement is likely to have no significant impact on the development of new medicines (Scherer, 2004). In accordance with PhRMA's Pharmaceutical Industry Profile 2005 – "From Laboratory to Patient: Pathways to Biopharmaceutical Innovation" (available online at: http://international.phrma.org/publications/publications/17.03.2005.1142.cfm, developing countries are responsible for only about 10 percent of global sales (in value) and for 5-7 percent of the global industry's profits. See also the report of the Commission on Intellectual Property Rights, Innovation and Public Health (2006), Public Health, Innovation and Intellectual Property Rights, World Health Organization (available online at: www.who.int).

23 See, e.g. the classical study by Levin *et al*, 1987, which found that firms in 130 lines of business reported that patents were the least important means of securing competitive advantage for new products.

24 This certainly does not exclude the possibility of obtaining a patent even where the innovation would have taken place without it. In this case, a patent represents a windfall gain for the firm at the expense of social efficiency.

25 This section is partially based on Correa, 2004

26 73 C.P.R. (3d) 1.

27 Quoted in Grover, 2001, p. 14.

28 There are, of course, other circumstances, such as lack of or insufficient working, emergencies, public interests, in which the use of protected subject matter may be authorised on the basis of compulsory licences. See, Correa, 1999.

29 See WTO Secretariat, 1995.

30 The Chinese law, as revised in 1992, establishes that "[W]here any entity which is qualified to exploit the invention or utility model has made requests for authorisation from the patentee of an invention or utility model to exploit his or its patent reasonable terms and conditions and such efforts have not been successful within a reasonable period of time, the patent Administration Department under the State Council may, upon the request of that entity, grant a compulsory license to exploit the patent for invention or utility model" (Article 48). Rule 72 of the Implementing Regulations subjects the request of a compulsory licence according to Article 48 of the Law, to the expiration of three years from the date of the granting of the patent, and further stipulates that the licence should be predominantly for the supply of the domestic market.

31 The Argentine patent law provides that a compulsory licence may be granted if the patent owner does not grant a voluntary licence after 150 days of a request by a third party on reasonable commercial terms and conditions (Article 42).

32 The German Patent Law (Text of December 16, 1980, as amended by the Laws of July 16 and August 6, 1996) provides that "[A] non-exclusive authorization to commercially exploit an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory licence) if …1. the applicant for a licence has unsuccessfully endeavoured during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade …" (Section 24-(1)). See also the laws of Israel, Austria (Patent Law of 1970, as amended by the Law of May 23, 1984, Section 36(2)); Ireland (Patents Act 1992 of February 27, 1992, Section 70(2)).

33 Further, pursuant to the UK Patents Act, 1977, section 51, a licence "as of right" could be ordered as a consequence of a report by an Anti-Trust Authority that a patent holder had refused to grant licences on reasonable terms against the public interest.

34 See, e.g. Canadian Patent Act, R.S.C., ch. P-4, s 65(2)(c), (d), (e) and (f).

35 No case has ever been brought to a trial under this section. The Canadian Commissioner of Competition reported that the Bureau of Competition will "examine Canada's existing provisions for compulsory licensing, that is, sections 19 and 65 of the *Patent Act*, and section 32 of the *Competition Act*, to determine whether these have met their legislative intent. The study will also explore other models for compulsory licensing and the appropriate division of responsibility among the Commissioner of Patents, the Commissioner of Competition and the Courts" (Scott, 2006).

36 203 F.3rd 1322 (Fed. Cir. 2000), at 1326.

37 See *Rural Tel. Serv. Co. v. Feist Publications, Inc.,* 957 F. 2d 765, 767-69.

38 1998 WL 614485 (DDC Sept. 14, 1998), quoted in Hovenkamp *et al,* 2005, p. 36.

39 The following is partially based on Correa, 2004.

40 In *Alaska Airlines, Inc. v. United Airlines, Inc.*, 948 F.2d 536, 542 (9th Cir. 1991).

41 See Rahnasto, 2003, p. 144.

42 See, e.g., Gleklen and MacKie-Mason in the July 2002 edition of Antitrust Source: http://www.abanet.org/antitrust/source/july.html

43 *Intergraph Corp. v. Intel Corp.,* 3F. Supp. 2d 1255 (N.D. Ala. 1998).

44 195 F. 3d at 1356-59.

45 *Bellsouth Advertising v. Donnelley Information*, 719 F Supp. 1551 (S.D. Fla. 1988).

46 In *Verizon Communications v. Law Offices of Curtis V. Trinko* 540 US 398 (2004) the Supreme Court stated that it had never recognised the essential facilities doctrine (Hovenkamp *et al*, 2005, p. 20).

47 Article 82. "Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States. Such abuse may, in particular, consist in: (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; (b) limiting production, markets or technical development to the prejudice of consumers; (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts."

48 (238/87), [1988] ECR 6211, [1989] 4 CMLR 122, CMR 14498. An almost identical judgment was given at the same time in *Renault Maxicar* 53/87, [1988] ECR 6039 [1990] 4 CMLR 265 [1990] 1 CEC 267.

49 Cases C-241-242/91P [1995] ECR I-743.

50 *Tiercé Ladbroke v. Commission*, T504/93, [1997] ECR II 923, [1997] 5 CMLR 309.

51 *Oscar Bronner GmbH & Co. KG v. Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG and Other*, (C-7/97), [1998] ECR I-7817, [1999] 4 CMLR 112, [1999] CEC 53.

52 Interim order of the European Commission, 3 July 2001, O.J. 2002, L59/18, [202] 4 CMLR 58, [2002] CEC 2234.

53 The information consisted of data about the German territory, which was divided into 1860 zones ("bricks"), including at least four pharmacies in each zone. This information allowed pharmaceutical companies to closely monitor sales, while avoiding the identification of sales made by individual pharmacies.

54 European Directive 96/9, O.J. 1996, L77/20.

55 *IMS Health v. Commission* (T-184/01RI), 10 August 2001 and *IMS Health v. Commission* (T-184/01R II), 26 October 2001. The Commission's measures, however, were suspended by interim order of the court of first instance, which indicated that there was at least a serious doubt whether there was a duty for IMS to license its intellectual property rights, given that it was itself offering the same service as the companies requesting access.

56 Decision A364 Merck—*Principi Attivi in Boll*. 11/2007 available online at: www.agcm.it

57 ICA also granted an interim measure, which was confirmed by the Italian Regional Administrative Tribunal (TAR) of Lazio (TAR Lazio 7 March 2006, n 1713).

58 Certificates of Complementary Protection are granted under EU law to extend the duration of a patent concerning an approved medicinal (or phytosanitary) product in order to compensate (up to five years) for the time passed between the date of the patent application and the marketing approval of the product.

59 The same authors note that ICA brought a similar action, based on comparable facts, against GSK, who after the opening of the proceedings, admitted to licensing an active ingredient. As a result, the issuance of a compulsory licence was not required (Coco and Nebbia, 2007, p. 452).

60 See http://www.compcom.co.za/resources/Media%20Releases/MediaReleases%202003/Jul/Med%20Rel%2030%200f%2016%20Oct%202003.asp

61 For instance, under the settlement agreement, GSK undertook to: "extend the voluntary licence granted to one firm in 2001 in respect of the public sector to include the private sector; grant up to three more voluntary licences on terms no less favourable than those granted to the first licensee, based on reasonable criteria; permit the licensees to export the relevant antiretroviral drugs to sub-Saharan African countries; where the licensee does not have manufacturing capability in South Africa, GSK would permit the importation of the drugs for distribution in South Africa; permit licensees to combine the relevant ARV with other antiretroviral medicines; and charge royalties of no more than 5 percent of the net sales of the relevant ARVs." See http://www.compcom.co.za/resources/Media%20Releases/MediaReleases%202003/Jul/Med%20Rel%2034%200f16%20Dec%202003.asp

62 The US "Antitrust Guidelines for the Licensing of Intellectual Property", for instance, state that "the Agencies do not presume that intellectual property creates market power in the antitrust context" (para. 2.0.b). Some authors have stretched this concept and hold the extreme view that intellectual property and competition law have to be treated as independent bodies of law: IP law should limit itself to properly *assigning* and *defending* property rights while Competition Law should be concerned with the *use* of such property rights. More precisely, Competition Law should be concerned only with the use and abuse of property rights that are sources of monopoly power. This principle of separation also applies to the enforcement of the law" (emphasis in the original) (Régibeau and Rockett, 2004, p. 3).

63 A survey conducted among large companies (with annual revenues exceeding USD 10 billion) by the Intellectual Property Owners Association (IPO) in August 2005 showed that its corporate members "perceive the quality of patents granted by the US Patent and Trademark Office to be less than satisfactory. Over half (51.3 percent) of respondents rated the quality of patents issued in the US today as less than satisfactory or poor (47.5 percent rated it as less than satisfactory and 3.8 percent as poor). Those rating quality as more than satisfactory or outstanding totalled 8.8 percent of all respondents (8.8 percent rated as more than satisfactory and 0 percent as outstanding). Respondents' prognosis for the future was not encouraging. Over two-thirds of respondents said they "…would be spending more, not less, on patent litigation over the coming years" (Patent Litigation Costing More, *PR Newswire* (press release), New York - Sep 13, 2005)

64 See Cassagne, 2006 who distinguishes the presumption of validity of the administrative active granting a patent from the substantive validity of the patent.

65 For a discussion of how antitrust courts might use antitrust doctrine against improvidently granted IPRs, see Kovacic and Reindl, 2005.

66 Under US law, "If both sides in a lawsuit produce evidence of equal relevance and weight, then whoever bears the burden of proof loses. If the weight of the evidence tips, even if only slightly, in one party's favor, she wins under a preponderance of evidence standard, but not under a clear and convincing evidence standard. Clear and convincing evidence lies in between the "beyond a reasonable doubt" burden of proof used in criminal cases, and the preponderance standard" (Samuelson, 2004).

67 "A poor quality or questionable patent is one that is likely invalid or contains claims that are likely overly broad" (FTC, 2003a, p. 5).

68 "Approximately 40% of those patents challenged on validity grounds are found invalid on summary judgment. Assuming summary judgment of validity is survived, approximately 30% are found invalid at trial… There are also equitable challenges so the cumulative effect of all validity and equitable challenges results in a patent surviving a challenge to its validity approximately 55% of the time" (Philip Brooks' Patent Infringement Updates, "Is it Worth it for Generics to Challenge Branded Drugs?", available online at: http://infringement.blogs.com/philip_brooks_patent_infr/2007/01/is_it_worth_it_.html).

69 "Ever-greening" is the strategy that consists in acquiring patents on minor or trivial developments with the aim of extending the length of the exclusive rights beyond the 20-year original patent term.

70 For the description of "patent hoarding" and "the détente strategy", see OECD, 2005, p. 40-43.

71 In accordance with the US "Antitrust Guidelines for the Licensing of Intellectual Property", "[A]n innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development" (para. 3.2.3).

72 As noted by the US Court of the Third Circuit in *American Security*, and subsequently by the US Supreme Court in *Zenith V. Hazeltine*

73 See e.g., Shapiro, 2001.

74 That is, a particular form given to an active ingredient for administration to the patient, for instance, micronised particles.

75 They often consist in the simple mixture of known drugs (e.g. aspirin, carisoprodol and codeine phosphate).

76 Many chemical compounds present a molecular structure comprising two mirror forms. Frequently, after the mixture ("racemic" mixture) of both forms has been patented, an application is made for a patent for the most active isomer.

77 Different crystalline forms of the same compound.

78 For example, besilates.

79 Other means include: "(a) using legislative provisions and loopholes to apply for a patent extension; (b) suing generic manufacturers for patent infringement; (c) merging with direct competitors as patent rights expire in an effort to continue the monopoly; …(e) using advertising and brand name development to increase the barrier to entry for generic drug manufacturers" (Glasgow, 2001, p. 234-235). It has also been noted that "Hoechst Marion Roussel (Aventis) paid Andrx several million US dollars to delay the introduction of a generic version of the drug Cardizem CD. The Federal Trade Commission settled a case in 2000 between Abbott Laboratories and Geneva Pharmaceuticals over charges of payments to delay the introduction of generic versions of patented drugs. Civil charges for anti-competitive practices have also been brought against Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products, on grounds that the companies entered into anti-competitive arrangements with the motive of delaying generic versions of a drug, K-Dur 20 potassium-chloride supplement" (Sampath, 2003).

80 In 2005, for instance, only twenty "new chemical entities" were approved by the US Federal Food and Drug Administration.

81 See, eg, *Atari Games Corp. v. Nintendo of Am.*, 897 F. 2d 1572, 1576 (Fed. Cir. 1990).

82 The decision was confirmed by the court in *Charles Pfizer & Co. v. Federal Trade Commission*, 401 F.2d 574 (6th Cir. 1968), cert. denied, 394 U.S. 920 (1969).

83 The FTC reported that Bristol "has settled charges that it engaged in a series of anti-competitive acts over the past decade to obstruct the entry of low-price generic competition for three of Bristol's widely-used pharmaceutical products: two anti-cancer drugs, Taxol and Platinol and the anti-anxiety agent BuSpar. According to the FTC's complaint, Bristol's illegal conduct protected nearly USD 2 billion in annual sales at a high cost to cancer patients and other consumers, who

– being denied access to lower-cost alternatives – were forced to overpay by hundreds of millions of dollars for important and often life-saving medications" (FTC, 2003b).

84 Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — *AstraZeneca*), Official Journal of the European Union 30.11.2006. The "relevant market" in this case was the national markets for so-called proton pump inhibitors sold on prescription. The Commission imposed a fine of EUR 60 million.

85 See Leahy-Hatch/Berman Smith, *The patent reform Act of 2007*, available online at: http://leahy.senate.gov/press/200704/041807a.html.

86 See *A&M RECORDS v. NAPSTER* (2001).

87 See above.

88 FTC concern was "that the merger of these two powerful companies would deny to competitors access to this amazing new broadband technology" (Robert Pitofsky, chairman of the FTC, available online at: http://news.com.com/2100-1023-249897.html).

89 The legality under competition law of leveraging copyright-based market power in one market (PC operating systems) to gain a dominant position in another market (workgroup server operating systems) was, for instance, one of the key issues in the case initiated by Sun Microsystems against Microsoft in 1998, which the European Commission decided in 2004 finding Microsoft guilty (Lévêque, 2005, p110). See COMP/C-3/37.792, *EC Commission v. Microsoft*.

90 See http://europa.eu/rapid/pressReleasesAction.do?reference=IP/04/382&format=HTML&aged=1&language=EN&guiLanguage=en.q

91 For instance, the contracts include membership restrictions obliging the authors to transfer their rights only to their own national collecting society as well as territorial restrictions. See European Digital Rights, "European Commission starts antitrust procedure against CISAC", available online at: http://www.edri.org/edrigram/number4.3/cisacantitrust.

92 Idem.

93 Mechanical right allows creators to claim royalties when their works are recorded on CDs, cassettes or other devices.

94 International Herald Tribune, July 12, 2007.

95 The case was initially filed in 1996 by LEGO Canada and Kirkbi AG against Mega Bloks Inc. of Montreal. See http://scc.lexum.umontreal.ca/en/2005/2005scc65/2005scc65.pdf.

96 See, eg., Statement of FTC Commissioner Sheila F. Anthony, in General *Mills Inc./Diageo PLC/ The Pillsbury Company*, File No. 001-0213, available online at: http://www.ftc.gov/os/2001/10/gmstmtant.htm.

97 See, e.g., Strauss, 2000. In France, for instance, only 19 provisional measures were granted out of 6000 requests filed in twenty years (between 1984 and 2004). See Bird & Bird *et al*, 2006, p. 63

98 *Bristol Myers Squibb Company s/medidas cautelares*, 22 February 2007.

99 Superintendencia para la Promoción y Protección de la Libre Competencia, Resolución Nº SPPLC/0076-06, Caracas, 26 de Diciembre de 2006.

100 In accordance with Article 9 of the Directive on Biotechnological Inventions, the protection with regard to patents on a product containing or consisting of genetic information extends "to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained *and performs its function*" (emphasis added).

101 Court of Appeals for the Seventh Circuit no. 82-1119.

102 See also *Yankee Candle Co v. Bridgewater Candle Co.*, 140 F. Supp. 2d (D. Mass. 2001 *Ferraris Medical, Inc. v. Azimuth Corp.*, 2002 U.S. Dist. LEXIS 13589 (D.N.H. 2002); *Hangards, Inc. v. Ethicon*, 743 F.2d 1282 (9th Cir. 1984),

103 203 F.3rd 1322 (Fed. Cir. 2000), at 1327. See also *Atari Games Corp. v. Nintendo of Am.*, 897 F. 2d 1572, 1576 (Fed. Cir. 1990) (extending patent rights beyond the scope of the grant violates the antitrust laws).

104 Available online at: http://www.law.cornell.edu/supct/html/91-1043.ZC1.html.

105 As mentioned, Article 41 of the TRIPS Agreement requires that enforcement procedures be applied "in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."

106 Article 31(k): "Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur."

107 See also Reichman and Hasenzahl, 2003.

108 For instance, "a company that controlled patented processes used to produce a key chemical intermediate for a drug effective against tuberculosis was found under Article 86 of the European Community treaty to be abusing its monopoly power when, after entering into production of the drug through its subsidiary, it subsequently refused to sell or license the intermediate to an independent pharmaceutical manufacturer" (Scherer and Watal, 2002, p. 17).

109 Article 21: "Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs."

110 Thus, as observed by Régibeau and Rockett, "two patents on separate pain relievers are substitute even though the chemical compounds and the physiological mechanisms involved might be very different" (Régibeau and Rockett, 2004, p. 35).

111 A "patent pool" is an agreement between two or more patent owners to license one or more of their patents to one another or to third parties.

112 The first decision was upheld by the European Court of Justice while the second one was reversed. Although the Court did not question that contractually agreed obstacles to parallel trade within the Community fell foul of Article 81, the Court found that the Commission failed to establish that the wholesalers agreed (even tacitly) to a ban imposed by Bayer to prevent parallel imports of Adalat into the UK. See, eg., http://www.hhlaw.com/files/Publication/937ed0df-08d0-4722-9cae-914d168747b8/Presentation/PublicationAttachment/1429ab35-1c2b-440f-a59a-def47e41c464/1701_EPC_Summer_2004_p30-31.pdf; see also Monti, 2001, p. 8-9.

113 Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca), Official Journal of the European Union 30.11.2006.

114 This section will focus on pharmaceutical products. The considerations made are applicable, *mutatis mutandi*, to agrochemicals.

115 This approach – equivalent to a compulsory licence – is the one applicable, under certain circumstances, in accordance with the US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for the marketing approval of agrochemicals.

116 Article 39.3 of the TRIPS Agreement requires protection of test data against unfair competition; it does not mandate the grant of an exclusivity period. See, eg., Correa, 2002.

117 Developing countries account for only about 10 percent of global sales (in value) and for 5 to 7 percent of global industry's profits. See PhRMA's Pharmaceutical Industry Profile 2005 – "From Laboratory to Patient: Pathways to Biopharmaceutical Innovation" (available online at: http://international.phrma.org/publications/publications/17.03.2005.1142.cfm).

118 This period is of five years in the US and countries that have signed free trade agreements with that country, six years in Canada and China and extends up to 11 years in the European Community.

119 Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 — AstraZeneca), Official Journal of the European Union 30.11.2006.

120 Many countries do not accept the "linkage" concept. In Europe, for instance, there is complete independence between intellectual property protection and registration. Health authorities have no legal capacity to look into IPR issues or to deny approval for an application that conforms to the relevant technical standards, even if there is an infringement of IPRs.

121 For a description of the drug approval procedures, see FTC, 2002.

122 Patents to be registered include those claiming active ingredients, formulations, compositions and methods of use. The forms require information, *inter alia,* on whether the patent claim is to a polymorph that performs the same as the active ingredient described in the application, to a metabolite of the approved active product and whether the patent is a process-by-product patent. See the Code of Federal Regulations, Title 21, Food and Drugs, Part 314 particularly Section 314.53.

123 A generic firm can claim that a listed patent is invalid or will not be infringed by a generic product (Paragraph IV certification).

124 The brand-name company generally sued all generic applicants if the drug product had annual sales larger than USD 500 million in the year the first generic applicant filed its marketing approval (FTC, 2002, p. 18).

125 Senators John McCain (Republican) and Charles Schumer (Democrat) introduced legislation in 2002 (the "Greater Access to Affordable Pharmaceuticals Act", S.812) that would have reduced the 30-month automatic injunction to 45 days. This reform did not find, however, Congressional support.

126 In order to prevent abuses based on the enforcement of such patents, in Mexico the linkage only applies with regard to patents claiming an *active ingredient* (*Decreto por el que se reforma el Reglamento de Insumos para la Salud y el Reglamento de la Ley de la Propiedad Industrial*). [Decree reforming the Regulation of the Health Supplies and the Regulation of the Law of Industrial Property], Diario Oficial de la Federación, 19 de septiembre de 2003, 106-107, available online at: http://www.gobernacion.gob.mx/dof/2003/septiembre/dof_19-09-2003.pdf (limiting the linkage to patents on "*la sustancia o ingrediente activo*" [the active substance or ingredient], thereby narrowing down the linkage's restriction on competition).

127 It is also important to recall, in addition, the need to establish regulations to control restrictive practices in licensing agreements, as expressly permitted by Article 40 of the TRIPS Agreement.

128 See in particular Correa, 2006.

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