THE STRENGTHENING OF IPRs IN DEVELOPING COUNTRIES AND COMPLIMENTARY LEGISLATION

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Introduction

In designing a national intellectual property system, policymakers need to consider cross-cutting issues, such as the protection of public health and consumers' interests, the conservation and sustainable use of genetic resources, the promotion of competition, and innovation and technology transfer, and the support of small local inventors. The protection of intellectual property is not an end in itself, but a tool that each society should use in order to attain higher public interests.

These kinds of considerations are particularly relevant for developing countries. In these countries, with a limited or no tradition in competition law and a weak scientific and technological infrastructure, the strengthening of intellectual property rights "could markedly raise market power and invite its exercise" (Lahouel and Maskus, 1999).

This paper considers several areas of legislation and a number of aspects relating to the implementation of IPRs that should accompany the introduction or reform of IPRs laws in developing countries. Its purpose is to highlight areas in which there is a need to enact, and effectively enforce, legislation that should compliment IPRs laws.

1. Competition policy

While the strengthening of IPRs has taken place in developed countries in a framework of effective application of a competition policy\footnote{\textsuperscript{2}} in developing countries, the process is qualitatively different. While the latter have been obliged to meet the TRIPS Agreement's standards, very few of them have in place a competition law regime that would allow them to control and remedy abuses in the exercise of IPRs. This asymmetry is likely to put developing countries in a very unfavorable position once the TRIPS Agreement becomes fully effective. They in general have no or weak competition policies in place, including instruments to prevent and remedy possible abuses by IPRs right-holders.

\textsuperscript{2} "Competition policy" may be defined as "a body of laws, administrative rules and case law which are employed to deter restrictive business practices so as to maintain fair competition. Competition policy also includes rules and regulations governing mergers and acquisitions" (Singh and Dhumale, 1999, p. 2)
The TRIPS Agreement has expressly recognized the right of Member States to adopt measures in relation to such abuses (article 8.2). However, it does not prescribe any concrete means therefor. For most developing countries, which lack a tradition in competition law, to develop an effective system to avoid IPRs-related anticompetitive practices is not a simple task.

The relationship between IPRS and competition policy has received growing attention in recent academic work (UNCTAD, 1999a; Dumont and Holmes, 1999). The basic point is how to reconcile the right to exclude (ius excludendi) conferred under IPRs, with the need to preserve some degree of competition in the relevant markets. The complementarity of these two areas of regulation has been expressly recognized by the TRIPS Agreement in the specific area of licensing agreements (see below).

Competition policies are generally well established in developed countries. However, there is no unique concept of “competition policy”. It varies across countries and over time. It is well recognized that varying economic, social and cultural needs and interests influence and separate national systems of competition law (Ullrich, 1998, p. 12). It is also recognized that “competition policies cannot be identical in different countries and that each market needs to be assessed in its own context” (Brittan and van Miert, 1996, Annex, p. 2).

In fact, differences in national competition policies are significant. For instance, current US and European approaches, despite common elements, considerably differ, particularly with regard to the treatment of abuses of dominant position and vertical restraints. The EC system is seen in the United States as more interventionist than US law (Fox, 1997).

Such differences in national policies often reflect themselves in the goals of competition laws. In some countries, for instance, the interests of competition are on a par with those of consumers, like in France (Brault, 1995, p. 13). In South Korea, the aims of the competition law (as amended in 1992) include to stimulate “business activities and protecting consumers as well as promoting a balanced development of the national economy” (article 1). In Japan, the purpose of the law is not only to promote free competition but also ensuring fairness in the competitive process (article 1 of the Antimonopoly Act). In Europe the integration of the various member nations of the European Union has been a dominant objective of competition law.

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The evolution that has taken place in the United States is illustrative of how the approaches to competition law may also vary over time. In its origin and till the 1970’s the antitrust law was seen in that country as a weapon against monopolies and oligopolies as well, as a means to protect the weak from exclusion by the powerful (Merges et al, 1997, p. 1040). This “structuralist approach” -mainly concerned with the government role in maintaining competitive market structures- substantially changed under the influence of the “Chicago school”, and was replaced by a “process oriented approach” (Scheyrer, 1992, p. 100). The “Chicago school” persuasively advocated that the purpose of antitrust is to promote social welfare by ensuring that markets work freely and without interference. Under “modern antitrust” the objective is to increase aggregate wealth, not distributing it (Fox, 1996) by promoting efficiency.

An evolution in thinking on competition law has also occurred in the European Economic Community. In the early 1980’s the Community redefined its interests and relaxed its policies, partially in response to the perceived failure of some member governments’ strategies to build up “national champions” (Sell, 1998, p. 161).

1.1. IPRs and competition law in developed countries

Despite these differences in the approaches, goals and implementation of competition policies in developed countries, competition law has often been applied in different countries to remedy anticompetitive practices based on the exercise of IPRs.

The experience of United States is illustrative. Antitrust laws have been applied in that country in a significant number of cases in order to limit the powers conferred to IPRs owners.

Although in the United States the patent law does not provide for compulsory licenses, this is probably the country with the richest experience in the granting of compulsory licenses to remedy anti-competitive practices. More than one hundred of such licenses have been granted (Scherer, 2000). Compulsory licenses have been granted in the United States in relation to present and future patents. Generally such licenses have been granted against a reasonable royalty, generally determined on the basis of the "willing-buyer, willing-seller" formulation (Finnegan, 1977, p. 140). However, in some cases the compulsory licenses were conferred royalty free. In some cases, moreover, the patentee was required to make the results of its

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4 Thus, blanket provisions for horizontal R&D arrangements, including commercialization, were adopted and joint ventures were exempted from enforcement under Article 85(1) of the Treaty of Rome.
5 For instance, in FTC v. Xerox Corporation (Goldstein, 1977, p. 124).
Box 1
Some compulsory licenses granted by courts in the United States

1. Hartford-Empire Company v. U.S., 65 USPQ 1 (1945). The Supreme Court held that the defendants violated the antitrust law (Sherman Act and Clayton Act), and it required them to grant licenses under their glassmaking machinery patents at “uniform reasonable royalties.” In dieta, the court stated that it had no authority to order dedication of the patents which would be equivalent to royalty free compulsory licensing.

2. U.S. v. National Lead Company, 73 USPQ 498 (1947). The Supreme Court used compulsory licensing with royalty payments to promote competition where the defendants conspired or combined to restrain trade in titanium products. The court stated that royalty-free compulsory licensing was an open matter to be decided in a future case. The decree did provide for the licensing of technology at a reasonable charge and limited to a three year period.


4. U.S. v. Glaxo Group Limited, 176 USPQ 289. The U.S. Supreme Court held that the government may litigate the validity of a patent, despite the fact that the defendant did not rely on the patent in defence against antitrust claims, where patent licenses and pooling agreements are per se unreasonable restraints of trade, and where the government’s claims for further relief are substantial. The court stated that mandatory sales and reasonable royalty licensing are well established forms of relief when necessary to an effective remedy, particularly where patents have provided leverage for or have contributed to an antitrust violation.

5. U.S. v Cooper Development Association, Inc. The government charged 11 copper fabricating companies and their trade association with violating Section 1 of the Sherman Act by conspiring to unlawfully restrict rights granted under jointly-owned patents for a single stack plumbing system. The government proposed a Consent Decree wherein the defendants agreed to license their patents and furnish technical data upon request at royalties not to exceed 3% of the net selling price of certain components of the system.

6. U.S. Manufacturers Aircraft Association, Inc. The government charged the defendants with violating Section 1 of the Sherman Act by utilising

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6 Hartford -Empire case (Finnegan, 1977, p. 139).
7 For instance, in FTC v. Xerox Corporation (Goldstein, 1977, p. 124). See also Correa and Bergel, 1996.
patent pooling and cross-licensing arrangements to eliminate competition in research and development of aircraft inventions. The consent decree dissolves the association, cancels the cross-licensing arrangement, and provides for compulsory licensing of about 1,500 U.S. patents at reasonable royalties.


US government has, through the Federal Trade Commission, also granted recently (see Box 2) a number of compulsory licenses, thus indicating that the system is broadly used in that country as a recourse to ensuring competition.

Box 2
Compulsory licenses in recent decisions in the United States

Ciba-Geigy and Sandoz merger

The U.S. Federal Trade Commission's (FTC) issued on March 24, 1997 a Decision and Order concerning the merger between Swiss companies Ciba-Geigy and Sandoz into Novartis. The combined entity would also control Chiron, a biotechnology company. The FTC concluded that the merger would violate U.S. antitrust laws, because the merged companies are current or potential competitors for several products. The FTC required divestiture of several products, and ordered compulsory licenses of intellectual property rights for a number of other healthcare inventions. For example, Ciba-Geigy, Sandoz and Chiron were required to license a large portfolio of patents, data and known-how relating to HSV-tk products, hemophilia gene rights and other products to Rhone-Poulenc Rorer. The new merged entity and Chiron were also required to grant non-exclusive licenses to all requesters for patent and other rights to Cytokine products.

In the case of the non-exclusive Cytokine licenses (which involve gene therapy), and the Anderson gene therapy patent, the FTC specified that the royalties can be no greater than three percent (3%) of the net sales price.

Gargoyles, Inc. and Pro-Tec, Inc. v. The United States

On May 20, 1997, a decision was given by the United States Court of Appeals for the Federal Circuit (96-5089-5094 ;113 F.3 d 1572). In this case the private plaintiff -who owned a patent subject to compulsory licenses- sought “lost profits” rather than a “reasonable royalty” as compensation. The royalty set by the Court of Federal Claims was 10 percent. The government considered this excessive and sought a reduction. The dispute involved US patent 4.471,611 for protective eyewear, which had been used by American Optical to provide US Army with several thousand pairs of ballistic/laser protective spectacles. The Appeals court upheld the lower court decision and argued that "because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained."

Acquistion of shares of Rugby-Darby Group Companies by Dow Chemical Co.

The FTC required Dow to license to a potential entrant intangible dicyclomine assets, including " all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information
systems, software, the Drug Master File, all information relating to the United States Food and Drug Administration Approvals\textsuperscript{7} that are not part of the acquired company's physical facilities or other tangible assets.

**Upjohn and Pharmacia Aktiebolag merger**

Upjohn was required to divest certain intellectual property (including patents), or the FTC would appoint a trustee to issue an exclusive United States license and a non-exclusive rest-of-the-world license for Pharmacia's research and development assets related to 9-AC. These requirements would protect consumers from reduced competition and higher prices for topoisomerase I inhibitors.


Compulsory licenses for trademarks have also been granted in exceptional cases in the United States. 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).

In Canada, the Competition Act (section 32 of the Competition Act) gives the Federal Court power to expunge trademarks, to license patents (including setting all terms and conditions), to void existing licenses and generally to abridge or nullify normal patent or trademark rights where the trademarks or patents have been used to injure trade or commerce unduly or to prevent or lessen competition unduly (Grover, 1992, p. 14). The Australian Trade Practices Act has been invoked in cases of refusal to deal (O'Bryan, 1992, p.10).

In Europe, competition laws have also been applied to remedy anticompetitive practices by IPRs right-holders. Though the exercise of exclusive rights is regarded as an essential part of the very subject matter of IPRs, in cases where the holder enjoys a dominant position and abuses it, for instance, when the holder unjustifiably refuses to grant a voluntary license\textsuperscript{9}.

1.2 Options for developing countries

\textsuperscript{8} No cases had been brought under this section at least until 1997 (McFetridge, 1998, p. 90).
\textsuperscript{9} See the considerations and decision by the European Court of Justice in the *Magill* case (Korah, 1999, p. 75-81).
Though some proposals have been made (notably by the European Union) to develop new disciplines on competition law in the framework of the WTO, in the absence of international binding standards, all countries are so far free to exercise their sovereign rights in the regulation of competition, including when it is affected by the exercise of IPRs.

Currently over 70 countries worldwide have competition laws, half of them in the category of developing countries (UNCTAD, 1997a, p. 189).

The number of developing countries that has adopted competition laws has increased significantly in the 1990s. Many Latin American countries (Brazil, Colombia, Peru, Venezuela, Mexico, Costa Rica, Panama) introduced or amended legislation in that period. The Andean Group countries approved a common regime (Decision 285 of 1991), and a “Protocol” was concluded within MERCOSUR though it is not still in force.

In Asia, some countries (e.g. India) have a considerable tradition in antitrust policies. However, many Asian countries do not have a competition policy, but legislation to prevent misleading advertising, and to provide for price control where necessary. They do not have a body of legislation which addresses anti-competitive practices (Waverman and Wu, 1996, p.135).

This was also the typical situation in most developing countries before the liberalization process of the 1980’s and 1990’s. The application of classical antitrust policies were, in practice, replaced by a wide range of State measures aimed at controlling economic power, such as price control regimes, establishment of State-owned enterprises, and the prior screening and approval of foreign direct investment and transfer of technology agreements (UNCTAD, 1978, p. 1).

The slow adoption of competition laws in developing countries may be attributed, in part, to the lack of a perceived need for them since governments felt to some extent that a similar role could be played, as mentioned above, by other forms of State intervention. It may also be that, unlike in the case of intellectual property rights—an area in which developed countries, particularly the United States, have exerted strong pressures for the adoption of high standards of protection—developing countries have not been under coercion by developed countries to adopt competition laws.
Though there is a growing number of developing countries that apply competition laws, in many of them serious enforcement problems remain. Moreover, many developing countries have no legislation at all. Unlike the case of intellectual property rights, industrial lobbies do not play a significant role in demanding for legislation; in most cases the demand for policy change come from technocratic groups within the State (Sell, 1998, p. 199). The fact that there is no requirement within WTO on competition law leaves Member countries with the freedom to shape their own legislation at their will, according to their needs and objectives.

Developing countries, in sum, can tailor competition policies, including specific regulations on the interface between IPRs and competition, to their own conditions and goals, unrestricted by international rules and so far free from demands or coercion by developed countries. In doing so they need not to mechanically adopt the models of competition policies applied in industrialized countries. Such policies should be simpler in developing countries than in such countries in order to be capable of being enforced by much weaker States, and essentially aim at the promotion of long term growth of productivity, that is, of dynamic rather than static efficiency (Singh and Dhumale, 1999, p. 12).

The existence of anti-competitive practices is considered a ground for the granting of compulsory licenses in the patent laws of Chile (1991), Argentina (1995) and the Andean Group countries (Decision 344, 1993), among other countries. In South Africa, a compulsory license can be granted if the demand of a protected product is being met by importation and the price charged by the patentee is "excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title" (section 56(2)(e)). In these cases, the anticompetitive rules are included in the patent laws themselves, an option that may be more practical and straightforward for countries with weak or no competition laws. So far, however, there is no evidence about the actual application of these provisions.

In sum, developing countries should consider the adoption of competition rules to deal with abuses of IPRs as an integral part of the new legislative framework resulting from the implementation of the TRIPs Agreement. The control of such abuses may be done under general competition laws or under specific provisions incorporated in IPRs laws. This latter

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10 In the case of Argentina, for example, where an amendment to the legislation is under consideration, the adoption of a new law that permits the control of mergers has gained impetus in Parliament and among government officials, as a result of the acquisition of a dominant control in the largest Argentine oil company by a Spanish firm.
approach may be preferable in those countries lacking tradition in the area of competition law, or where enforcement mechanisms still need to be strengthened.

2. Registration of pharmaceutical and agricultural products

Another area that needs to be carefully considered relates to the conditions for the registration of pharmaceutical and agrochemical products. Certainly, such products need to comply with adequate standards of efficacy and toxicity in order to be safe for consumers and the environment. In the registration process, as required by the TRIPS Agreement (article 39.3) it is also necessary to protect against unfair competition the undisclosed data submitted with the application for registration.

Though these regulations are necessary to protect public health and/or the environment, they may in certain cases erect barriers to legitimate competition and limit access to protected products, particularly by the poor.

In some jurisdictions, the data submitted for the registration of pharmaceutical and agrochemical products, are subject to a *sui generis* protection, based on the exclusivity in the use of such data for a certain period. This system excludes the possibility that the sanitary authority and a third party rely on the information already submitted to that authority for the approval of a second and subsequent applications of "generic" versions of the same product.

Thus, in the United States data submitted for the registration of a new chemical entity enjoy five years of exclusivity: another application on the same product cannot be filed before the expiration of such period. If the chemical entity is not new, but the data are based on new clinical investigations, the protection is given for three years. In Europe, exclusive rights are granted for ten years (Cook, 2000).

In other countries, however, it is possible to rely on a previous registration and on the data related thereto, in order to process and approve subsequent applications, based on the "similarity" of the products. This approach, which promotes a competitive environment, is particularly suitable to developing countries that wish to foster an improved access by their people to pharmaceutical products.

11 See below, however, the limitations imposed by the TRIPS Agreement with regard to the control of restrictive practices in licensing agreements.
This issue is addressed by article 39.3 of the TRIPS Agreement, which leaves considerable room to Member countries to implement the obligation to protect said data against unfair competition practices.

Section 7 of Part II of the TRIPS Agreement contains specific provisions on "undisclosed information". According to article 1.2 of the Agreement, this is a category of "intellectual property" as patents, trademarks and other modalities dealt with by the Agreement. Article 39.1 stipulates that "in the course of ensuring effective protection against unfair competition as provided in Article 10.bis of the Paris Convention", Parties shall protect undisclosed information and the "data submitted to governments or governmental agencies" as a condition of approving the marketing of pharmaceutical and agrochemical products.

The Agreement provides that "undisclosed information" is regulated under the discipline of unfair competition, as contained in article 10 bis of the Paris Convention. With this approach, the Agreement clearly avoids the treatment of undisclosed information as a "property". The fact that the "undisclosed information" is deemed to be a "category" of intellectual property does not imply the existence of a property right. It is generally accepted that unfair competition is one of the disciplines of industrial property, and in this sense is article 1.2 to be interpreted. Article 39 does not imply any obligation to confer exclusive rights on undisclosed information, but just to protect it against unfair commercial practices.

Although article 39.1 refers to "undisclosed information" and to "undisclosed test" or other "data submitted" to governments as two separate issues, it seems clear that in the latter case the data also need to be "undisclosed" in order to be covered under the terms of the Agreement. The scope of Article 39.2 is sectorally limited: it only protects data which are submitted as a condition for obtaining approval for the marketing of pharmaceutical or of agricultural chemical products "which utilize new chemical entities". This means, that

1. information that is already public (e.g., because it has been published in scientific journals) and which is submitted for a marketing approval does not fall within the scope of this Section
2. a "new" entity may be deemed as one which is not yet comprised in the state of the art.

The protection to be granted is against "unfair commercial use" of the relevant protected information. This means that a third party could be prevented from using the results of the test undertaken by another company as background for an independent submission for
marketing approval if the respective data were acquired through dishonest commercial practices. Such a party could, obviously, independently develop the relevant data and information or obtain them from other sources. However, the duplication of tests (often involving suffering of animals) to reach results that are already known will certainly be highly questionable from a cost-benefit social point of view. This provision would also permit the competent authority to rely on data in its possession to assess a second and further applications relating to the same drug, since this would not imply an “unfair commercial use”.

Finally, the obligation not to disclose under article 39.3 is addressed to government authorities. Two exceptions to that obligation are provided for:

a) when disclosure is necessary to protect the public; and
b) when steps are taken to ensure that the data will not be used in a commercially unfair manner.

Under these exceptions, disclosure would be permissible, for example, to allow a compulsory licensee to obtain a marketing approval, particularly when the license is aimed at remediying anti-competitive practices or satisfying public health needs.

Some developed countries, notably the USA, have tended to interpret article 39.3 of the TRIPS Agreement as requiring a period of exclusivity for data protection. This interpretation, however, is not supported - neither by the text of article 39.3 nor by its negotiating history. Developing countries wishing to promote access to drugs and chemical products for agriculture at competitive prices, may foster generic competition by providing for the protection of test data as required by the TRIPS Agreement. Thus, a generic producer could not be prevented from applying and obtaining registration of a product when the authority relies on information it already possess on a similar product.

In sum, developing countries should carefully consider the scope of regulations on registration of pharmaceutical products and of products for agriculture. Such regulations should be enacted with a pro-competitive intent, in a manner that maximizes legitimate competition by generic producers, while respecting the standards of protection imposed by the TRIPS Agreement.

3. Transfer of technology regulations

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12 This section is substantially based on a study prepared by the author for UNIDO in 1995. See UNIDO, 1996.
Many developing countries (e.g. Argentina, Brazil, South Korea, Nigeria, Malaysia, Philippines, Vietnam) established during the 1970’s and the 1980’s specific regulations for the control of transfer of technology transactions and, in particular, of restrictive practices that are common in licensing agreements.

Such regulations -first adopted under Decision 24 of the Andean Pact (1971)- were largely inspired by US antitrust policies as applied during the 1960’s and by the draft International Code of Conduct on Transfer Of Technology unsuccessfully negotiated under the auspices of UNCTAD. The regulations generally identified a number of practices that would be deemed condemnable, either *per se* or on the basis of an evaluation of their effects case-by-case. Many of such laws were substantially modified or repealed during the 1990s, as part of a process of liberalization of the economies.

Transfer of technology regulations have generally operated on the basis of a registration system. The validity or certain clauses of licensing and other transfer of technology contracts was made conditional upon their review and approval by a national authority.

Such regulations have been applied to different modalities of technology transfer, including licensing agreements, know-how contracts and supply of technical services. In some cases, they have also been extended to turn-key agreements, franchising contracts and other contractual modalities. Trade-mark licenses have in general been covered, often including special provisions and requirements. In most cases, regulations have dealt only with technology transfer contracts with foreign parties (i.e., with international contracts), although internal transactions have also been regulated in some countries (e.g. Brazil).

A key issue in technology transfer regulations has been the control over royalties and other payments to foreign licensors, as well as on practices that restrict the research, commercial or industrial activities of the licensee. Regulatory regimes also commonly determine a maximum duration for technology transfer agreements.

Most of the technology transfer regulations specified the clauses that were considered “restrictive”. Though they varied significantly among countries, in general the list of banned clauses included:

* Grant-back provisions
* Exports restrictions
*Post-agreement use of the technology
*Price and volume fixation by the licensor
*Tie-in clauses

During the 1980s many transfer of technology laws were made less interventionist and restrictive or were repealed outright (e.g. Mexico), in the context of broader trade liberalization policies. In most cases, however, this process was not accompanied by the establishment of competition laws that could be effectively applied to control restrictive practices and other abuses in technology transfer transactions.

It is important to note that Section 8 of the TRIPS Agreement contains a set of rules aimed at the control of "anti-competitive practices" in voluntary licenses. These rules are one of the concrete applications of the general principle stated in article 8.2 of TRIPS, according to which "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".

The text in article 40.1 recognizes that some licensing practices pertaining to intellectual property rights which restrain competition "may have adverse effects on trade and impede the transfer and dissemination of technology". Article 40.2 expressly allows countries to adopt measures to control or prevent certain licensing practices, but while doing so establishes limits for national action. The test to judge the practices to be controlled or prevented should be based on three elements:

i) the assessment of practices should be made in particular cases;

ii) practices should constitute an "abuse" of intellectual property rights, a concept which will probably vary among different countries;

iii) they should have an "adverse effect on competition in the relevant market".

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13 Another application of this principle is article 31 k) relating to compulsory licensing to remedy anticompetitive practices.
Based on the referred elements, article 40.2 clearly adopts the competition test and the rule of reason to assess anticompetitive effects, and thus settles a debate that divided developed and developing countries during the long and unsuccessful negotiations on an International Code of Conduct on Transfer of Technology. The TRIPS Agreement is the first international agreement to contain rules on restrictive practices in licensing contracts of a binding nature. The Code of Conduct had been conceived, instead, as based on merely voluntary compliance. Article 40.2 of the TRIPS Agreement, however, falls short in respect to the Code’s objectives. The said article only allows national legislation to adopt measures, but (with the exception of a few examples considered below) does not contain internationally agreed rules on the practices that may be deemed anti-competitive.

The examples given by Article 40.2 include the following:

a) exclusive grant back provisions, i.e. those that oblige the licensee to transfer the improvements made on the licensed technology exclusively to the licensor;

b) obligations imposed on the licensee not to challenge the validity of licensed rights;

c) coercive package licensing, i.e. the obligation for the licensee to acquire from the licensor other technologies or inputs he does not need or desire.

Previous negotiating versions of the Agreement included a significantly longer list where restrictions on research and on use of personnel, price fixing, exclusive sales or representation agreements, tying agreements, exports restrictions and other practices were mentioned\(^\text{14}\). In any case, an advantage of the provision is that any restrictive clause could be subject to scrutiny, provided of course, that the stipulated test is applied.

One peculiar feature of section 8 is, finally, that it establishes a consultation system applicable for cases where a Member considers that a national or domiciliary of other Member is undertaking practices in violation of the former laws and regulations on anti-competitive practices. This consultation system, based on the concept of "positive commity" developed

\(^{14}\) See the text of 22 November 1990, which was discussed at the Montreal Mid-Term Review of December 1990. See also the list of practices as negotiated by the U.N Conference on a Code of Conduct on Transfer of Technology (Unctad TD/CODE TOI/47).
under antitrust law aims to promote the cooperation of Member countries in controlling anticompetitive practices. However, this system has had so far little application, if any.

In sum, developing countries have considerable room to enact and apply special laws to regulate transfer of technology transactions, including rules on prices and restrictive practices, subject to the general conditions imposed with regard to the latter by the TRIPS Agreement. The control of the terms of conditions in such transactions may also be done through general competition law. Given that developing countries are strongly dependent for their industrialization on foreign technologies, the modalities of access to such technologies are of crucial importance.

4. Implementation of patent laws

The implementation of the TRIPs Agreement has led to a significant increase in the amount and complexity of the tasks faced by Patent Offices in developing countries. Mainly as a result of the required protection of pharmaceuticals—previously excluded in many of those countries—the number of applications has jumped and put tremendous pressure on offices which are generally under-staffed and lack the resources to properly and timely undertake the examination of patent and other applications.

The emerging situation is most worrying in the area of patents. The patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations. The restriction on the free movement of ideas that the granting of a patent entails is usually justified by the inventor’s contribution to society and by the need to recover the investment necessary for invention (Gutterman, 1997; Granstrand, 1999; Le Bas, 1999). There is no doubt that the development and exploitation of numerous contributions to technology have been closely linked to, although not necessarily determined by, the possibility of obtaining exclusive rights to exploit inventions (Archibugi and Malaman, 1991).

Nonetheless, it is apparent that attainment of the main objectives of the patent system is increasingly frustrated by serious shortcomings in the system’s design and management. For many observers, there is a danger the patents system stifles the very innovation it is supposed to

15 This section is partially based on a study prepared for the World Health Organization (2000).
The National Academies of the United States, for instance, have taken up the criticism raised by many academics and sectors of industry (Barton 2000), and have expressed their concern at a possible decline of standards, especially as regards non-obviousness and usefulness, in the examination and granting of patents, as a result of which far more “low quality” patents with broad coverage are being granted.

Lester Thurow, an economist at MIT, has also expressed serious doubts about the efficacy of the patents system for ensuring a satisfactory rate of innovation at the lowest social cost. He wonders why patent rights of equal effect and duration should be granted to inventors who have made different contributions, some of them significant and others less so, and how it is possible to ensure that patents actually encourage, rather than hold back innovation. He also advocates differential treatment for the developing countries, which are basically dependent on technology from outside (Thurow, 1997).

In actual fact, thousands of patents are granted each year by patent offices in the world for minor, purely trivial developments or for substances (including genes) that already exist in nature and which have merely been discovered but not invented by their would-be “owner”. In 1999, the United States Patent Office, for instance, granted over 160,000 patents, twice the number granted ten years before.

This is the fruit of loose criteria for patentability, of the excessive flexibility of the Patents Office in assessing the degree of inventiveness, novelty and usefulness of the applications submitted to it and of shortcomings in the examination procedures. In addition, new areas have emerged, such as software and “business methods”, for which the number of patents have surged; in the view of some, this trend seriously jeopardizes the so called “new economy” (Gleick, 2000, p.44).

Other patent offices throughout the world are following suit, occasionally in the mistaken belief that an examination conducted by the patent office of a highly industrialized

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16 See, Gleick, 2000, p.44; The Economist, April 8, p. 17.
18 The adoption of a notion of local innovation for knowledge disseminated by media other than publication outside the United States has led, for example, to the patenting of plants and knowledge developed and widely used in the developing countries (Correa, 1999c; The Crucible, 2000)
19 For example, less than 50% of the examinations conducted by the US Patent and Trademark Office refer to relevant background bibliography; the examination is by and large limited to analyzing previous patents. See, Aharonian, 2000.
country is a sound guarantee. Many of the patents granted are astounding, not so much for their inventiveness as for their triviality.  

Nevertheless, patents for some trivial inventions may not create great concern if their economic value is scant or limited. The problem arises, however, when these same lax criteria and deficient examinations affect areas of greater economic and social importance. Even when the patent granted is weak and questionable, if the patent owner is sufficiently strong, in many cases it will aggressively assert its rights against potential competitors, and will elbow out of the market small and medium-sized firms without the means to take on costly and lengthy litigation.

For instance, in the pharmaceutical field, only a few (several dozen) “new chemical entities” (i.e. molecules not pre-existing) are developed and patented each year. Nonetheless, thousands of patents are granted annually in this sector. This paradox can be explained by the enormous capacity that this sector’s major firms have built up not only for developing “authentic” inventions, but also for taking out patents on secondary, occasionally trivial developments, in order to extend their monopoly over a product or process, beyond that allowed by the original patent. One example will illustrate this type of problem.

Some five years after having patented cimetidine, SmithKline & French obtained a new patent for a polymorph (a particular crystalline form of the molecule), which had in fact actually been described in the original patent. The effect of this patent would have been to delay for several years the marketing of generic products. The patent was challenged – with success – before the courts in several countries on grounds of lack of novelty, thereby aborting the attempt to extend the monopoly of the original patent. Had the additional patent remained in force, the public would have been denied access to the drug at more competitive prices when the original patent had expired.

There are various ways in which barriers are frequently raised around products in the public domain, or patents on the point of expiring, with the aim of preventing legitimate competition. One of them is the patenting of polymorphs, described above. Other means employed artificially to delay the marketing of competing products include patenting of:

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21 Barton has drawn attention to the use of these “strategic litigation” practices. See, Barton, 1995.
22 The chemical and pharmaceutical industry accounts for about one third of the patents granted each year in the USA (Aharonian, 2000).
a) **Pharmaceutical formulations**, i.e. a particular way of administering an active ingredient, which may be unpatented in combination with certain additives;

b) “Selective” inventions: these occur when a single element or group of elements of an already known large group are selected in order to take out a patent based, for example, on a feature that was not specifically described in an earlier patent for the larger group;

c) “Analogous” processes: this relates to processes that are not in themselves inventive, but which allow a product with innovative features to be obtained;

d) **Combinations** of known products;

e) **Optical isomers**: this takes advantage of the property of many chemical compounds to present two mirror forms. Frequently, after the mixture of both forms has been patented (“racemic” mixture) an application is made for a patent for the most active isomer.

f) **Active metabolites**: this involves patenting the active metabolite of a particular compound that produces the desired effect in the body;

g) **Prodrugs**: these are compounds which, although themselves inactive, produce a therapeutically active ingredient when metabolized in the body;

h) New **salts** of known substances;

i) Variants of known **manufacturing processes**;

j) New **uses** for known products;

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24 The practical consequences of this type of patent may be significant. For example, in Thailand—where there are serious problems of HIV infection—there is no current patent for didanosine (“ddl”) as such. Nevertheless, the firm Bristol Myers Squibb (which did not discover the product, but obtained it under licence from a federal United States laboratory) patented a formulation of “ddl” thereby blocking the Thai Government’s attempts to purchase the drug at a price that was more affordable to its population. The Thai Government is currently examining the possibility of granting a compulsory licence or applying for the patent to be declared void.

25 For example, after terfenadine had been on sale for several years, a patent was obtained for the relevant active metabolite. The courts decided that it was an unacceptable attempt to extend the original patent.

26 An example of a patent for the use of a known drug is AZT (Retrovir), which was synthesized in 1964 by the Michigan Cancer Foundation as a possible anti-cancer drug. Another more recent example is sildenafil (“Viagra”).
The legal outcomes and administrative and judicial practices observed in respect of these different forms of protection vary significantly in different jurisdictions. There is considerable margin for manoeuvre to allow each country to determine its own policy. Ideally, it should seek to afford protection to developments that are truly inventive, and reject those that are designed to block competition and delay the marketing of alternative products that are cheaper for consumers.

This is not, however, an easy task for patent offices in developing countries given their limited financial and human resources. UNCTAD found in a study on the implementation of the TRIPS Agreement (UNCTAD, 1996b) that developing countries will face a substantial cost in order to upgrade their IPRs systems. Such costs include those generated by the patent and trademark offices, as well as by customs, police and other authorities involved in the enforcement of IPRs. However, such countries have received little support from developed countries –the main beneficiaries of such implementation- despite the specific obligations contained in said Agreement.

There is a large scope for cooperation and assistance from developing countries in order to strengthen developing countries’ patent offices and procedures. While assistance is already provided by the UN specialized body on the matter (the World Intellectual Property Organization), particularly in terms of training, infrastructure and access to databases, additional cooperation is needed in these areas as well as to increase the number of examiners and retain them in local patent offices27. Any assistance to be provided should take into account the particular conditions and needs of the country concerned, in order to ensure that IPRs policies are as functional as possible to the national innovation system.

To sum up: the enactment of a “good” patent law is not enough to ensure that IPRs are protected in a manner that balances the patent owner’s and society interests. The actual implementation of the law will determine the scope for the diffusion of existing technologies and for innovation thereon. Current practices in some countries indicate that patents are often granted to minor or trivial developments, that may block legitimate competition and limit the access by developing countries to technologies needed for their development.

27 Given that salaries in patent offices are lower than in the private sector, it is generally very difficult for such offices to retain qualified personnel. Patent offices may also be supported to develop a network of researchers (in universities and other institutions) that may provide technical advice for the evaluation of patent applications.
5. Access legislation

Another component of IPRs complementary legislation relates to “access legislation”, that is, legislation aimed at regulating access to genetic resources residing in a country. Some countries have started to adopt legislation based on or inspired by the CBD\footnote{Since the entry into force of the CBD, over 30 countries have drafted and/or enacted new legislation regulating access to genetic resources (Glowka, 1999). With only a few exceptions, these are all developing countries.} which has delineated a number of mechanisms to exercise such rights, namely through subordinating access to prior informed consent, mutually agreed terms and the sharing of benefits.

The principles of the CBD relating to access have been implemented at the national level through different types of regulations\footnote{The following categorization is partially based on Glowka, 1999.}. A first category includes general environmental laws (such as those adopted in Australia and several African countries\footnote{For instance, the National Environment Management Act, 1994 (Law No. 13/94) of Gambia empowers the competent national authority to prohibit or restrict any trade or traffic in any component of biological diversity (article 32.g). It contains a specific provision (article 35) on access to genetic resources, according to which “the genetic resources of the Gambia shall constitute and essential part of the natural wealth of resources of the people of the Gambia”. A Council created by the law may make regulations and prescribe guidelines regarding access to the genetic resources of The Gambia, including measures (a)measures regulating the export of germplasm; b)measures for sharing of benefits derived from germplasm originating from The Gambia; and c) fees to be paid for access to germplasm”.} which are only “enabling” in nature, in the sense that they charge a competent national authority to examine the issue and provide specific guidelines or regulations in the future.

A second category includes framework sustainable development, nature conservation, national parks, sectoral or biodiversity laws, which generally contain access provisions more detailed than laws in the first group\footnote{For example, in Cameroon, law 94/01 of 20.1.94 sets forth rules for an integrated management, conservation and sustainable utilization of forests, fauna and fisheries. It provides that genetic resources of Cameroon belong to the State. Nobody is allowed to exploit them for scientific, commercial or cultural purposes without authorization. The financial or economic benefits resulting from their utilization are subject to a royalty to be paid to the State, at a rate and upon modalities of payment to be determined by the Minister of finances, on the basis of proposals by the competent ministers (article 12).}. Most of these laws establish the principles of mutually agreed terms and prior informed consent for access, in some cases in great detail such as the Biodiversity Law of Costa Rica (Law No. 7788 of 1998).

Finally, a third category comprises “dedicated” regulations, that is, those specifically aimed at regulating access to genetic resources. Very few regulations fall within this category: the Philippines Executive Order 247 (1995), Decision 391 of the Andean Group, and the regulations issued to implement said Decision in some of the Andean countries.
Though there are draft regulations in the three mentioned categories under consideration in many countries, overall the number of countries that have actually adopted legislation to incorporate the CBD provisions is rather small. The slow pace of implementation of the CBD is in sharp contrast to the speed and depth of changes in the area of IPRs.

The basic provisions of the “dedicated” regulations as well of other regulations that specifically deal with access (such as the Biodiversity law of Costa Rica) are quite similar. They generally reaffirm the principle of national sovereignty, institute prior informed consent procedures and specify the conditions for granting of permits. Among such provisions the following are generally found (Byström, Einarsson and Axelsson Nycander, 1999):

- full information about new products and/or knowledge developed from accessed materials,
- priority access to such new products and/or knowledge,
- a share in financial and other benefits accruing,
- obligatory deposit of a specimen of each accession,
- transfer to third parties only after authorization,
- involvement of local scientists in collection/research.

In some cases (e.g. Andean Group Decision 391) it is also established that any IPR or other claims to the resource in question shall not be considered valid if it was obtained or used in violation of the terms of the permit. Another common feature of regulations on access is their broad scope: they apply to all genetic resources in all sectors of biodiversity, as well as those maintained in in situ and in ex situ conditions.

The implementation of access legislation is an important tool to implement the CBD. It should, however, appropriately distinguish among different sectors of biodiversity. Thus, given the interdependence on plant genetic resources for agriculture, a restrictive system of access may limit the flow of germplasm that is essential to a sustainable agriculture. For this reason, a multilateral system of access to and exchange of such resources is in the process of development under the auspices of FAO.

32 The Organisation of African Unity has also prepared a draft model legislation covering access and community rights.
33 In some cases, moreover, the State is declared as “owner” of all genetic resources under its jurisdiction.
In sum, access legislation may contribute to prevent unauthorized access to and use of genetic resources, and provide a basis for challenging (at least at the national level) IPRs obtained on such resources without the consent of the country of collection. However, such legislation should not erect obstacles for the exchange of germplasm in the area of agriculture, where it is most needed to ensure a sustainable food production.

6. Main conclusions

The implementation of IPRs in developing countries requires to carefully consider other areas of legislation that may directly or indirectly influence the exercise of such rights. The impact of IPRs on society will substantially depend upon the interaction of IPRs laws and such other legislation.

The availability of adequate legal means to control anticompetitive practices is an essential element to build up a fair and balanced framework for the recognition and protection of IPRs. IPRs, as any other rights, may be abused, particularly in countries with weak or no tradition in the area of competition law, as it is currently the case of most developing countries. These countries not only need to enact competition laws; they need to ensure an effective enforcement thereof, a task that is increasingly difficult in a global economy.

Other areas of legislation may significantly affect the competitive environment for the exercise of IPRs. This is the case of the registration procedures for certain products, such as pharmaceuticals and chemicals for agriculture. While competent authorities should ensure that the required standards of quality, efficacy and toxicity are met, regulations should not unduly restrict genuine competition. The registration of non-patented products on the basis of “similarity” to those already approved by a sanitary authority (and without using otherwise protected undisclosed information), may enhance competition and access to such products, specially by the poor.

The regulation of transfer of technology, quite popular in many developing countries during the 1970’s and early 1980’s is another important complimentary area, particularly as a means to avoid restrictive practices in licensing agreements. Though the control of such practices may be exercised in the framework of competition laws, specific regulations (as existing in Europe) may contribute to the predictability and effectiveness of the legal regime.
Similarly, the proper implementation by the patent office of existing legislation has turned to be an important aspect. In many countries, patents are currently granted to minor or trivial developments lacking an actual inventive step. This practice, if followed by developing countries, may considerably limit their room to foster the diffusion of existing technologies, and erect barriers to the access of essential products, such as pharmaceuticals. The way in which patent examination is conducted should be subject to careful scrutiny. Patent offices should not blindly accept the results of examinations made elsewhere and should act with a view to protect the public interest.

Finally, there is an important interaction between IPRs and access legislation that should be taken into account in the design and implementation of the respective laws. Since few developing countries have adopted access legislation so far, there is significant room to develop such interface in order to ensure, for instance, that genetic resources are not appropriated as such under IPRs and that the flows of germplasm for agriculture is not unduly restricted.

Based on the analysis made, the following actions by DFID and donors may be recommended to assist developing countries in the implementation of IPRs policies:

- To thoroughly examine the interaction between IPRs laws and legislation in areas such as competition, product registration, promotion of innovation and transfer of technology.
- To develop, as a component of IPRs or competition laws, effective rules to address anticompetitive practices of IPRs rightholders.
- To examine and suggest options for implementing procedures for the registration of pharmaceutical and agrochemical products in a manner that foster legitimate generic competition.
- To develop a legal framework for the control of restrictive business practices in transfer of technology agreements, and to support local companies for the acquisition and use of technology.
- To support local patent offices in developing appropriate methods and criteria for examination of patent applications, and in establishing a well qualified technical staff as well as networks to improve the examination process.
- To develop access legislation consistent with the CBD, including provisions in order to prevent the misappropriation of genetic resources and ensure the flows of germplasm for food and agriculture.
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