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**Training Module on the WTO  
Agreement on Trade-Related  
Aspects of Intellectual Property  
Rights (TRIPS)**



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## **Abbreviations**

CBD	Convention on Biological Diversity
EC	European Commission
EMR	exclusive marketing rights
FDI	foreign direct investment
FTA	free trade agreement
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product
GNP	gross national product
IPR	intellectual property right
LDC	least developed country
MFN	most favoured nation
R&D	research and development
TRIPS	trade-related intellectual property rights
UPOV	International Union for the Protection of New Varieties of Plants
WHO	World Health Organization
WTO	World Trade Organization

## **Acknowledgements**

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The purpose of this training module is to inform trade experts and negotiators of developing countries about key aspects relating to intellectual property rights (IPRs) and more specifically, the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

This module is for information and training purposes only and does not intend to state the official negotiating positions of World Trade Organization (WTO) member States. It aims to provide training materials and inputs for developing country trainers, lectures and government officials involved in training and research tasks.



## **Introduction**

Since the 1980s, the availability and enforcement of intellectual property rights (IPRs) have become a major issue in international economic negotiations and, in many cases, the subject of trade disputes between countries.

Intellectual property allows for controlling the commercial exploitation of the results of scientific, technological and cultural creation. The ability to develop and use such results is a key factor of economic growth. The results of scientific, technological and cultural creation also have crucial importance for international competition, especially for the production and trade of technology-intensive goods and services: “Knowledge is critical for development, because everything we do depends on knowledge. For countries in the vanguard of the world economy, the balance between knowledge and resources has shifted so far toward the former that knowledge has become perhaps the most important factor determining the standard of living – more than land, than tools, than labour. Today’s most technologically advanced economies are truly knowledge-based.” (World Bank, 1998: 17)

The international framework on IPRs, established by the TRIPS Agreement and an increasing number of regional trade agreements with IPR provisions, is likely to affect the conditions for access to and use of technology and, therefore, the patterns of industrial and technological development in developing countries.

This module commences by providing background – including a historical perspective – on IPRs and the TRIPS Agreement. Then, chapter II offers a brief overview of different IPRs followed by chapter III, which discusses the interlinkages between IPRs and development. In so doing, chapter III looks at key aspects, including sector-specific impacts of IPRs, the impact of IPRs on gross domestic product (GDP) and the impact of IPRs on the private sector and on key public policy issues. Chapter IV provides a short description of the TRIPS Agreement and its main cross-cutting and IPR-specific provisions. Finally, chapter VI sketches out how the TRIPS Agreement evolves, most importantly through dispute settlement and the built-in agenda.





## Chapter I. Background

***Intellectual property: allows for controlling the commercial exploitation of the results of scientific, technological and cultural creation.***

Technology has been recognized as an essential element in any developmental strategy (Commission for Intellectual Property Rights (CIPR), 2002). Although different technological packages are needed at different levels of development, it seems clear that even for mature sectors, the access to appropriate technical knowledge is key, not just to succeed in the marketplace, but also to survive in a context of trade and investment liberalization.

***The ability to develop and use the results of scientific, technological and cultural creation is a key factor of economic growth.***

The capabilities to develop science and technology are, however, very asymmetrically distributed in the world. Research and development (R&D) expenditures showed a steady increase since the 1970s in industrialized countries, with a growing participation of the private sector in total R&D. In many countries, half and more of R&D expenditures is funded or executed by private firms.

Developing countries, however, only account for a small proportion of global expenditures on R&D. The deep asymmetry existing in the distribution of capabilities to generate new science and technology is illustrated by international patent registration. Industrialized countries hold 97 per cent of all patents worldwide (United Nations Development Programme (UNDP), 1999: 67–68). It should be borne in mind, however, that within the category of “developing countries” there are countries with sharp differences in their technological capabilities. Some of them (e.g. the Republic of Korea) invest heavily in R&D and have been able to enter into sophisticated technical fields, such as the production of semiconductors.

During the 1980s, the expansion of trade in the framework of the globalization of the economy created strong demands by firms from developed countries for an expansion and universalization of IPR protection. These firms actively sought to ensure certain levels of IPR protection worldwide with a view to capturing the rents generated by the intangible components of traded products and services. The strengthening of IPRs was also seen as an important condition for foreign direct investment (FDI) and technology transfer.

In 1994, a new and comprehensive treaty on IPRs was established within the WTO framework, adopted as an outcome of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). It is called the Agreement on Trade-Related Aspects of Intellectual Property Rights – the TRIPS Agreement. It requires all WTO member countries to adopt in their laws minimum standards of protection for patents, trademarks, copyrights and other IPRs. It has substantially limited the freedom that countries enjoyed until then to design and implement their own intellectual property systems.

TRIPS obliges all WTO members to establish minimum standards for most categories of IPRs. The adopted standards mirror to a great extent those in force in industrialized countries at the time of the negotiation of the agreement. Under the agreement’s rules, most developing countries have been bound to amend their legislation in order to introduce higher standards of protection or extend it to new areas, such as software, biotechnology and integrated circuits. Importantly, according to article 1 of the TRIPS Agreement, members cannot be obliged to provide a higher level of protection than the one required in the minimum standard.

***Minimum standards: members cannot provide a level of protection lower than the one set forth by those standards.***

The adoption of the TRIPS Agreement represented a major step towards the harmonization of certain aspects of the protection of IPRs. Complying with the TRIPS Agreement in these respects has posed a special challenge for developing countries and raised considerable concerns from different perspectives, notably with regard to access to technologies needed for development and access to drugs. However, WTO members have been left a certain amount of manoeuvre room to adopt, in certain cases, different approaches and legal solutions.

The explicit aim of the agreement is to ensure that the protection and enforcement of IPRs contributes “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 the balance of rights and obligations” (article 7). The idea of balancing the benefits of title holders and the public should be a key concept in the design and implementation of IPR legislation. However, while substantive obligations and enforcement measures were stipulated with considerable detail, the main concerns and positions of developing countries, i.e. technology transfer and cooperation, capacity-building and the limitations to exclusive rights, were provided for in a rough, sometimes ambiguous, and non-binding manner.

The new international framework on IPRs established by the TRIPS Agreement is likely to affect the conditions for access to and use of technology and, therefore, the patterns of industrial and technological growth in developing countries. Reverse engineering and other methods of imitative innovation will be restricted, thereby making technological “catching up” more difficult than before. Strengthened IPRs are also likely to increase the negotiating position of right holders to determine the royalties to be paid for needed technologies, in case they agree to part with them. IPR holders also exclude direct competition, and charge higher prices for their protected technologies and products. Hence, states need to enact or adequately enforce competition policies.

#### **Box 1. TRIPS in short**

TRIPS establishes a common set of standards for all countries, without differentiating on the basis of socio-economic and technological development. The obligations that the agreement sets forth to protect inventions include: recognizing patents for pharmaceuticals without distinction between imported and locally produced products; granting patent protection for at least 20 years from the date of application; limiting the scope of exemptions from patent rights; and effectively enforcing patent rights through administrative and judicial mechanisms. In the area of copyright, the protection of computer programs became mandatory. The agreement also makes it mandatory to protect secret know-how, trademarks, geographical indications, industrial designs and integrated circuits.

Since most developing countries may be excluded from the benefits of protection for inventions because they lack the scientific infrastructure and the capital needed for R&D, they also need to devise IPR systems that fit their local conditions, to the extent allowed by their international obligations. This may be done by adopting protection for incremental innovations and by sui generis regimes for traditional knowledge, including plant varieties developed by farmers in the fields.

***Options for a pro-development implementation of TRIPS obligations include adopting protection for incremental innovations and sui generis regimes for traditional knowledge, such as plant varieties developed by farmers in the fields.***

These considerations do not mean that patents cannot help stimulate local research and development. They do suggest, however, that strengthened IPRs will affect developing countries differently than technologically advanced ones. In the latter IPRs may lead to more innovation, in the former only to higher prices in many cases.

The TRIPS Agreement does not impose uniform legal requirements upon WTO member countries. Countries must meet the minimum standards it calls for, but are left with considerable leeway within which to develop their own laws according to the characteristics of their legal systems, public health situations and development needs. In implementing the TRIPS provisions, they can adopt measures aimed at promoting social and economic welfare (article 7 of the agreement) and preventing the abuse of intellectual property rights (article 8.2).

***Articles 7 and 8 of TRIPS: two provisions crucial for realizing development benefits.***

Developing countries can also adopt measures that mitigate the impact of exclusive rights and thereby promote competition. This is the case, for instance, of the principle of “international exhaustion”, under which “parallel imports” can be allowed. These may apply, for example, to the import of products from the countries in which they are cheapest. This is not a means of denying the patentee’s right to remuneration (which is received with the first sale of the product), but rather of ensuring that patents work to the mutual advantage of the producers and the users of technological knowledge.

Another important measure to promote competition may be the so-called “Bolar” exception. This makes it possible to use an invention to conduct tests on a drug and obtain marketing approval for it before the expiry of the patent, so that a generic version of the drug can be marketed as soon as the patent expires. Argentina, Australia, Canada, Israel, the United States and many other countries have legalized this exception.

In addition, article 31 of the TRIPS Agreement allows governments to issue compulsory licenses to address emergencies, counteract anti-competitive practices, for governmental use and in other cases determined by the national law, subject to the conditions (particularly with regard to the compensation of the patent holder) set forth by the agreement.

In 2001 WTO members adopted by consensus an important declaration – the Doha Declaration on the TRIPS Agreement and Public Health – that confirmed the flexibilities available to interpret and implement the TRIPS Agreement, particularly to protect public health. Pursuant to this declaration, a system has been adopted to facilitate the importation of drugs by countries with no or insufficient manufacturing capacity in pharmaceuticals. A revision of the agreement has been agreed upon in order to formally incorporate such a system, and it has been submitted for ratification.

***The 2001 Doha Declaration: a unique decision confirming the flexibilities available for WTO members.***

However, the free trade agreements (FTAs) promoted by a number of developed countries have significantly eroded the TRIPS flexibilities, particularly in the area of public health, through the adoption of “TRIPS-plus” provisions that, inter alia, may further limit access to drugs at affordable prices for the poor.

The Uruguay Round left open a number of issues (protection of biotechnological inventions, protection of geographical indications, disputes in cases of “non-violation”) on which further negotiations were called for as part of the “built-in agenda” of the WTO. Little progress has been made on these issues, despite the interest of developing countries in clarifying, in particular, the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). Several proposals have been tabled to enhance the protection of geographical indications of agricultural products, with the support of some (but not all) developed and developing countries.

In summary, the ways in which the TRIPS Agreement is implemented through national laws can have a significant impact on development and the attainment of public policies objectives, including in the area of health and food. Developing countries have some flexibility under the agreement, which they can use to design national laws that respond to public policy objectives. Other WTO members must respect this flexibility, and not use unilateral threats in order to obtain TRIPS-plus levels of protection.

## Chapter II. Intellectual Property Rights – A Brief Overview<sup>1</sup>

Intellectual property is a category of property on intangibles that may be claimed by individuals, enterprises or other entities. The peculiar feature of this kind of property is that it relates to pieces of information that can be incorporated in tangible objects. Protection is conferred to ideas, technical solutions or other information that have been expressed in a legally admissible form, subject, in some cases, to registration and approval procedures.

*Intellectual property: a category of property on intangibles.*

*Holders of IPRs include individuals, enterprises or other entities.*

Though the content of intellectual property is the information as such, IPRs are exercised – generally as exclusive rights – with respect to the products that carry the protected information. Thus, the owner of a patent can prevent the manufacture, use or sale of the protected product in the countries where the patent has been acquired. Those who create certain intangibles may, via the enforcement of such rights, regulate the use of the creation and the commercialization of the goods that contain them. Control over an intangible therefore translates itself into control over markets.

*IPRs are generally exclusive rights: the holder of an IPR over e.g. an invention can preclude others from doing certain acts (and obtaining attendant benefits) relating to the invention (ius excluendi).*

Intellectual property rights include the following categories:

**Copyright and related rights.** Copyright protection is provided to authors of original works of authorship, including literary, artistic and scientific works. Copyright has also been extended to protect software and databases. Copyright protects the expression of an idea, not the idea itself. This means that, in principle, protection is only extended to the form in which an idea is expressed (e.g. the particular writing of instructions in a computer program), but not to the underlying concepts, methods and ideas. The owner of a copyright can generally prevent the unauthorized reproduction, distribution (including rental), sale and adaptation of the original work. Protection generally lasts for the life of the author plus at least 50 years, or for at least 50 years in case of works belonging to juridical persons. Neighbouring (or related) rights are accorded to phonogram producers, performers and broadcasting organizations. In some countries, the expressions of folklore are also subject to copyright protection.

**Trademarks.** Trademarks are signs or symbols (including logos and names) registered by a manufacturer or merchant to identify goods and services. A valid trademark allows the owner to exclude imitations where this would mislead the public about the origin of a product. Protection is usually granted for ten years, and renewable as long as the trademark is actually used. The domain names used in cyberspace do not constitute trademarks per se, but may be used as signs for commercializing or promoting goods and services.<sup>2</sup>

**Geographical indications.** These are signs or expressions used to indicate that a product or service originates in a country, region or specific place. There are different types of geographical indications. They are called “appellations of origin” when the characteristics of the product can be attributed exclusively or essentially to the natural and human factors of the place in which the product originates.

<sup>1</sup> This section is partially based on South Centre (1997).

<sup>2</sup> See on this subject the work done by WIPO at [www.wipo.int](http://www.wipo.int).

**Industrial designs.** An industrial design protects the ornamental or aesthetic aspect of an industrial article. In some countries there is specific protection for industrial designs, while in others it coexists with or can be accumulated with copyright or trademark protection. The term of protection generally varies between five and 15 years (including renewal).

**Patents.** Patents confer the exclusive right to make, use or sell an invention, generally for a period of 20 years (counted from the filing date).<sup>3</sup> In order to be patentable, an invention usually needs to meet the requirements of novelty, inventive step (or non-obviousness) and industrial applicability (or usefulness). Patents may be granted for processes and products. Patent-like protection is conferred for functional models and other “minor” innovations under utility models (see definition below).

**Layout designs of integrated circuits.** The protection of the layout (or topography) of integrated circuits is a sui generis form of protection that allows the owner of the design to prevent the unauthorized reproduction and distribution of such designs. Reverse engineering is generally allowed. (“Reverse engineering” is a method of evaluation of a product to understand its functional aspects and underlying ideas. This technique may be used to develop a similar product.) The duration of protection is shorter than under copyright (typically 10 years).

**Undisclosed information.** Trade secrets protection covers confidential information of commercial value, including business information as well as know-how. Trade secrets are generally protected under the discipline of unfair competition. No exclusive rights are granted. Trade secrets are protected as long as the information has commercial value and is kept secret. This category also includes data submitted for the registration of pharmaceutical and agrochemical products. According to the TRIPS Agreement, they must be protected against disclosure and unfair commercial use. In some countries, the data cannot be relied on by national authorities to approve subsequent requests of market authorization for certain periods (five to 10 years).

**Breeders’ rights.** This is a sui generis form of protection conferred on plant varieties that are new, stable, uniform and distinguishable. Exclusive rights include, in principle, the sale and distribution of the propagating materials. Breeders’ rights generally permit the use by other breeders of a protected variety as a basis for the development of a new variety (the “breeder’s exception”) and the re-use by farmers of seeds obtained from their own harvests (the “farmer’s privilege”).

**Utility models.** This title protects the functional aspect of models and designs, generally in the mechanical field. Though novelty and inventiveness are generally required, the criteria for conferring protection are less strict than for patents. The term of protection also is shorter (typically up to 10 years).

**Databases.** While protected under general copyright rules, some countries have adopted a sui generis regime for the protection of databases (even if not original), including the right to prevent the extraction of data.

**Unfair competition.** The discipline of unfair competition, which has generally been deemed a chapter of industrial property, provides a remedy against acts of competition contrary to honest business practices, such as confusing or misleading the customer and discrediting the competitor. An act of unfair competition is defined as “any act that a competitor or another market participant undertakes with the intention of directly exploiting another person’s industrial or commercial achievement for his own business purposes without substantially

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<sup>3</sup> In some countries (e.g. the United States) the term of protection may be extended for an additional period in order to compensate the title holder for delays in patent examination or for the period required for the marketing approval of pharmaceuticals.

departing from the original achievement” (WIPO, 1994: 55). In some cases, the discipline of unfair competition supplements the protection of trademarks<sup>4</sup> and patents.

**Community rights on traditional knowledge.** Some countries have developed or are in course of developing sui generis regimes for the protection of traditional knowledge on the basis of collective rights, including, for instance, the rights to participate in the benefits arising from the commercial exploitation of their knowledge.

The TRIPS Agreement contains minimum standards on all the categories described above, except for the expressions of folklore, utility models, breeders’ rights<sup>5</sup> and community rights. The area of unfair competition is only dealt with in relation to undisclosed information.

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<sup>4</sup> In common law countries, the doctrine of “passing off” (misrepresenting of one’s business goods or services as another’s, to the latter’s injury, generally by using a confusingly similar trademark or trade name) may also be applied.

<sup>5</sup> However, under the TRIPS Agreement, members are obliged to protect plant varieties by means of patents, an effective sui generis regime, or a combination of both (article 27.3 (b)).





## Chapter III. What is the Impact of IPRs on Development?

The international framework on IPRs established by TRIPS and other agreements affects the conditions for access to and use of technology and, therefore, the patterns of industrial and technological development in developing countries. For example, reverse engineering and other methods of imitative innovation will be restricted, thereby making technological catching up more difficult than before. Strengthened IPRs are also likely to increase the negotiating position of right holders to determine the royalties to be paid for needed technologies, in case they agree to part with them. It is crucial for policymakers and affected stakeholders to carefully consider the implications of different IPRs on their country's economic, social and technological development.

***Important implications for policymakers to consider include the impact of IPRs on investment, local innovation transfer of technology, conservation and use of biodiversity, foreign trade and public health.***

This section aims to assist policymakers in this task. It commences with a short overview of different sectoral implications as they emanate from different IPRs, then reviews select studies on the potential contribution of IPRs to GDP. Thirdly, it offers some analysis of the economic value of IPRs for private sector actors and finally discusses key public policy issues that arise from select IPRs.

### ***1. Sector-specific implications of IPRs***

The introduction or strengthening of IPRs resulting from the implementation of the TRIPS Agreement may have an important and varied impact on different industries.

***There is a sectoral dimension to IPRs: with the exception of trademarks, each type of IPR affects different sectors of the economy to varying degrees.***

Patents are most relevant to sectors where innovative capabilities exist or can be established. In countries with low investment in R&D, the patent system generally allows for the protection of foreign-made inventions, while few applications originate domestically. The use of the patent system may be promoted through awareness programmes addressed to local researchers and firms, including the diffusion of patent documents.

Trademarks have an overriding impact across industries (except for producers of commodities). The acquisition and development of trademarks is extremely important in certain sectors for value creation in both domestic as well as international markets. The increased levels of protection for trademarks required by the TRIPS Agreement (arising from the enhanced protection of well-known trademarks and more effective enforcement measures, including at the border) put higher barriers to the manufacture and sale of counterfeiting products than before the adoption of the agreement.

Copyright protection enables the extraction of economic value from the commercial exploitation of artistic and literary (including scientific) creations. The economic importance of "copyright industries" varies considerably among developing countries. Thus, the film and software industries are particularly strong in India, while Caribbean countries may benefit from the worldwide acceptance of their musical creations. In many developing countries, however, the main value generated by copyrighted works is likely to be associated with the distribution rather than the creation of such works.

Geographical indications usually apply to wines, spirits and food products, but they may also identify handicrafts and other industrial articles. Some developing countries have advocated an enhanced protection for such indications in the Council of TRIPS. Some of these countries believe that their economies may benefit from an expansion of protection to the same level conferred under

the TRIPS Agreement to wines and spirits (Vivas Eugui, 2000). Careful assessment is needed, however, as the successful development of geographical indications requires considerable investment and coordination among producers.

Industrial designs are particularly relevant for some consumer-oriented industries, such as clothing and automobiles. They may be an important means for increasing the value of products for domestic consumption and exports.

Utility models are not subject to the rules of the TRIPS Agreement. They can be of particular importance for developing countries, since they protect minor innovations that predominate in the innovative process of such countries. However, only some developing countries have adopted this modality of protection.

Undisclosed information/trade secrets may be of importance in many industries, particularly those where process innovation prevails, such as the chemical industry.

Integrated circuits protection is particularly relevant for the countries that design and produce integrated circuits, although such protection may affect the importation of a wide range of industrial articles that incorporate semiconductors.

Plant breeders' rights are relevant to the commercial development of seeds. However, in many countries the production and distribution of commercial seeds play a marginal role, while the informal seed system (based on the production and exchange of farmers' varieties) is the main channel for the diffusion of improved varieties. More than 80 per cent of crops cultivated in such countries are planted with seeds from the informal seed system.

In sum, IPRs take very different forms and apply to a broad range of activities. The importance of various types of IPRs varies considerably according to the types of industries involved, their R&D intensity and the rate and nature of their innovative activities. Table 1 summarizes the subject matter of different categories of IPRs and indicates the main sectors and activities that are affected by their availability and enforcement.

**Table 1. Subject matter and main fields of application of intellectual property rights**

Type of intellectual property right	Subject matter	Main fields
Patents	New, non-obvious, industrially applicable (useful) inventions	Chemicals, drugs, plastics, engines, turbines, electronics, industrial control and scientific equipment
Trademarks	Signs or symbols to identify goods and services	All industries
Copyright and related rights	Original works of authorship, artistic performances, broadcasting and phonograms production	Printing, entertainment (audio, video motion pictures), software, broadcasting
Integrated circuits	Original layout designs	Microelectronics industry
Breeders' rights	New, stable, homogeneous, distinguishable varieties	Agriculture and food industry
Trade secrets	Secret business information	All industries
Industrial designs	Ornamental designs	Clothing, automobiles, electronics, etc.
Geographical indications	Geographical origin of goods and services	Wines, spirits, cheese and other food products
Utility models	Functional models/designs	Mechanical industry

Table 1 suggests that, in terms of industrial and technological policies, the relevance of IPRs for a particular country is dependent on the type of goods and services that it produces and trades, and on the characteristics of its national innovation system. In assessing the economic impact of different forms of IPRs, consideration should be given to the benefits that producers and traders may derive from them, as well as to their impact on competition and consumer welfare. National policies should strike a balance between the benefits that accrue to right holders and the costs associated with protection, notably when IPRs are mostly in the hands of companies that do not produce locally.

## ***2. IPRs and GDP – an attempt to quantify the impact of IPRs on the national economy***

Given the pervasiveness of IPRs it is difficult to determine their impact on the generation of value added. Several methodologies have been developed in order to estimate the “economic value” of different types of IPRs for individual companies, as well as the importance of IPRs in terms of GDP. These methodologies have been mainly applied to copyrights and neighbouring rights. The value added by the production and commercialization of copyrights is easier to calculate than in the case of other IPRs, since the author’s work is the very basis of some industries, which would not otherwise exist.<sup>6</sup> Some studies have also been carried out on the contribution of patents and trademarks to GDP.<sup>7</sup>

An analysis of the contribution of copyrights to GNP (gross national product) was first undertaken in the United States at the end of the 1950s. According to the study, the industries based on copyrights accounted for a 2 per cent share of GNP. About twenty years later a new study indicated a 2.8 per cent share. In quantitative terms, the industries involved, taken together, were second only to the medical and health services, and ahead of agriculture, the automobile industry and electrical equipment. In a later study, in 1982, the percentage of GNP attributable to the copyright-based industries amounted to 4.6 per cent (Cohen Jehoram, 1989). In the case of Canada, copyright industries account for 4.5 per cent of the economy.<sup>8</sup>

Some studies on the economic importance of copyright have also been conducted in developing countries. For instance, a study found that copyright-related industries have considerable importance in the Southern Common Market (MERCOSUR) member countries<sup>9</sup> and Chile. Such industries accounted for around 6 per cent of GDP. However, the most value added was from the distribution of imported copyrighted works rather than the local production thereof; significant trade deficits were also found (OMPI-Universidade Estadual de Campinas, 2002: 14).

The assessment of the current impact of IPRs in terms of GNP may be an important indicator for public action on the matter, including the design of IPR legislation and participation in international negotiations. This kind of study, however, may only provide a static picture, and does not necessarily capture the dynamic effects of changes in IPR protection in various sectors.

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<sup>6</sup> The core group of copyright industries includes newspapers and magazines, publishing of books and related industries, radio and television, cable television, discs and tapes, plays, advertising, computer programs (software) and data processing. It also includes manufacturing, business practices, architecture and design, distribution (transport of goods, bookshops, record stores and other forms of wholesale or retail distribution of products protected by copyright) and copyright-related industries (production and technical assistance involving equipment used solely with copyright-protected material, for example, computers, radio and television equipment, and other listening or recording equipment). See OMPI-Universidade Estadual de Campinas (2002: 11).

<sup>7</sup> Raymond, 1986; Silberston, 1987; Higgins and James, 1996.

<sup>8</sup> See The economic impact of Canadian copyright industries – sectoral analysis, final report, submitted to the Copyright Policy Branch, Department of Canadian Heritage, 31 March 2006, [http://www.pch.gc.ca/progs/ac-ca/progs/pda-cpb/pubs/copyright/03\\_e.cfm](http://www.pch.gc.ca/progs/ac-ca/progs/pda-cpb/pubs/copyright/03_e.cfm).

<sup>9</sup> Argentina, Brazil, Paraguay and Uruguay.

### ***3. IPRs and private sector – the economic value of intellectual property for firms<sup>10</sup>***

The new emerging framework on IPRs is likely to affect the conditions for access to and use of technology and, therefore, the patterns of industrial and technological development in developing countries. Reverse engineering and other legitimate methods of imitative innovation will be restricted, thereby making technological catching up more difficult than before. Strengthened IPRs will most probably increase royalty payments required by technology holders, if they agree to transfer their technology at all.

Local firms should pay adequate attention to the IPR situation of the processes that they employ as well as that of the products they manufacture, import or distribute. Companies operating in areas where IPRs are of particular importance (such as pharmaceuticals, clothing and audio-visual works) should obtain expert advice in order not to be exposed to possible legal actions. The infringement of IPRs may lead to lengthy and costly litigation and, in some cases, criminal sanctions.

At the same time, the use of IPRs generates value to its possessor. The various intangible assets embodied in intellectual property are of different value according to the activity sector in question. Moreover, the economic importance of IPRs varies when it is examined from an intrasectoral angle, depending on factors such as: (a) the type of product or service on offer; (b) the technological level and rate of innovation of the enterprise; (c) marketing strategies; and (d) conditions of demand. Within one and the same sector, then, there will be firms for which certain intangible assets have a greater (or lesser) value than for other enterprises in the same sector.

***Four methods for evaluating benefits for firms: price of the final product; market value approach; cost-based approach; and contribution to profits.***

There are many possible ways of evaluating the economic value of intellectual property for an enterprise. Insofar as it represents an asset, which may even be entered into the accounts as such, evaluating it is of particular importance, especially to assess the net worth of an enterprise or to carry out certain transactions (for example assignments, licenses, mergers and acquisitions) involving the rights in question.

#### **Price of the final product**

A series of studies on the economic value of intellectual property has sought to quantify its importance on the basis of the final value of the protected products or services, that is to say, the price that the consumer pays in the marketplace for the product or service. This provides an approximate, albeit rather rough, estimate of the value of the intangible asset linked to the product or service in question.

In fact, prices depend on the costs of production, distribution and marketing, including advertising, and also on the firm's profit margin. The greater the firm's market power (depending on the number of other suppliers, product differentiation and the promotion and advertising undertaken) the greater the cost/benefit ratio is likely to be, though this does not necessarily reflect a greater value of the intellectual property. Conversely, an efficient producer who competes on the basis of price may charge a final price lower than that of his competitors, but this does not necessarily mean a smaller intellectual property content. In other words, the final price of the product that incorporates an intellectual property component is a poor indicator of the value of the intellectual property itself.

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<sup>10</sup> This section is substantially based on Correa (2000b).

If this methodology is used in the case of commercially available products or services, it will also be necessary to introduce indicators that reflect the differences in the levels of per capita income and in the prices in different countries.

### **The market value approach**

This approach is based on an examination of the price at which an IPR is exchanged within a context where the parties have freedom to contract (that is, where there is no compulsion to do so) and have reasonably full information, and where the price fixed is fair to both parties (i.e. the terms obtained do not give one party an advantage over the other) (Smith and Parr, 1994: 144–145).

For this method to be applied, there should ideally be an “active” market with a certain number of transactions that can be taken as a basis of reference, information must be accessible on the terms of such transactions and the values must be adjusted over a period of time with, in particular, adjustments made to allow for a lack of comparability between various transactions on intellectual property.

In the examination of comparability, the following factors need to be taken into account:

- The sector in question, especially if the cases used for comparison cover various sectors;
- Different expectations of profitability that can be attributed to the IPRs, even within one and the same sector;
- Market share;
- R&D that may yield a product providing an alternative to competitors’ products;
- Barriers to entry (e.g. distribution chains);
- Expected growth of sales;
- The strength and coverage of legal protection (e.g. in response to applications for nullity by third parties);
- Expected remaining term of the right that is being evaluated. (Smith and Parr, 1994: 171–173)

### **The cost-based approach**

This method is based on the calculation of what would it cost to construct a “replica” of the asset in question. The replacement or reproduction cost is frequently used in the insurance sector for purposes of providing indemnification for a damage or loss incurred.

The cost of an intellectual property asset may be calculated on the basis of an examination of the values corresponding to: (a) the original cost of acquisition; (b) the book value of the asset (if it has been recorded); and (c) an estimate of the investment that would be needed to attain a replica of the right in question (in terms of generating net profits).

The cost of “recreating” the value of an intellectual property asset may be estimated by calculating the costs that would need to be incurred under the various appropriate headings, such as researchers’ salaries, overheads and advertising. With regard to works protected by copyright, in general it will be impossible to recreate a particular asset, given the unique nature of the works protected. In some cases (e.g. computer programs and architectural plans), however, it might be possible to produce substitutes that are functionally equivalent to existing assets.

The cost-based approach may be based on an estimate of the historic cost, that is, on what has been invested in developing an intellectual property asset. In the case of a computer program or

a design, for example, especially if a formal R&D project existed, it should be possible to calculate the costs corresponding to staff, inputs, prototypes, external services, administrative overheads, etc. Such costs must be calculated at constant prices, taking into account the retail price index in the relevant years or a similar index.

It should be borne in mind that in a cost-based approach, “cost” is not equivalent to “value”. In fact, the cost tells us little about the profits that may actually be obtained from an asset. The cost of developing a new brand (to replace an existing one) may be higher or lower, depending on many different factors, than the profits that it may generate. That cost, when the enterprise is not just targeting the domestic market, may include legal investigations, testing with potential consumers and research on language, style and colour, not to mention the costs of launching and advertising the product.

The cost-based method, although relatively simple to apply, does not take into account limitations such as possible future trends in the market and profitability, the possible useful life of the asset to be replaced and the risk involved in the activity in question.

### **Contribution to profits**

Another approach to assessing the economic value of intellectual property is based on the calculation of the contribution made by various forms of intellectual property to a firm’s profits (Smith and Parr, 1994).

Intellectual property rights may be divided into “active” and “passive” rights. The former are those that generate a price differential (“premium price”) for the firm, and those that make it possible to reduce production costs (e.g. process inventions) and increase profits over and above normal profit levels in the industry in question. The “passive” IPRs are those that do not make a direct contribution to the increase in profits.

One of the general methods proposed to measure the contribution that intellectual property makes to the profits of a firm consists in breaking down its assets into four elements: monetary assets (net working capital); tangible assets (buildings, machinery, etc.); intangible assets (skills and qualifications of the workforce, distribution networks, customers, contractual relations, etc.); and intellectual property (patents, copyright, trademarks, etc.). The method is based on the calculation of the weighted average cost of capital, defined as the minimum weighted rate of return that should be generated for each element so as to satisfy the expectations of investors. The application of this method depends on access to the firm’s economic and financial data. The economic benefits are assessed free of interest payments, so as to reflect exclusively the profits gained from the firm’s commercial operations.

For the purposes of calculating the economic contribution of each element, in particular the contribution of intellectual property, a rate of return is assigned to each of the assets mentioned above. That means allocating a value to each kind of asset, taking as a basis the book (accountancy) value and calculating the “excess” profits defined as the residual capital flow value obtained over and above that attributable to the normal returns in the type of business in question.

Obviously, various difficulties arise in the application of this method. Firstly, in most cases firms market a wide range of products and services that are affected in various ways by IPRs. Secondly, it is not easy to determine what the profit is and, therefore, the rate of “normal” return in any particular industry. Thirdly, it is also not easy to estimate the asset value of the intangible assets and the intellectual property as a basis for calculating the rate of return.

#### 4. Public policy issues

IPRs apply to a broad range of activities, with very different implications on economic growth and social and technological development. The impact of a particular IPR depends, amongst others, on the type of goods and services that it produces and trades, and on the characteristics of its national innovation system. The likely impact of an expanded and strengthened IPR regime includes impact on investment, local innovation transfer of technology, conservation and use of biodiversity, foreign trade and public health. The following will outline the potential impacts of IPRs on numerous public policy aspects.

##### Investment

The impact of IPRs on investment, particularly FDI, has been extensively addressed by the literature (Correa, 1995; Maskus, 2000 and 2005), but no conclusive evidence is available. While some have argued that stronger IPRs will foster FDI, it seems clear that the impact of changes in IPRs on investment flows will be heavily dependent on a number of other factors (such as market size, growth prospects, resource endowment, legal security and political environment) which, in many cases, have an overriding impact on investment decisions.

*Despite extensive work in literature, there is no conclusive evidence on the impact of IPRs on investment.*

Moreover, to the extent that all WTO member countries are bound by the TRIPS Agreement, the differences among various national IPRs systems will be considerably reduced and the existence of IPR protection is not likely to constitute a country-specific advantage.

Hence, the possible impact of IPRs on the flow of investments should be assessed in light of local economic and political conditions, with regard in particular to the industrial structure and the areas where the availability or reinforcement of IPRs may have a positive or negative effect. The adoption of higher standards of IPRs may not create incentives for investment if other factors are not present. In some situations, the expansion or reinforcement of IPRs may lead to de-investment or lower investment prospects in industrial capabilities.

Stronger protection may allow title holders to safely supply local markets through imports, without the need to undertake local production. Under secure IPRs, technology owners may prefer to promote the diffusion of their innovations through trade rather than through the transfer of technology or the establishment of subsidiaries in a foreign country. In fact, it was the expansion of trade that ultimately explained the reform of the intellectual property system sought by developed countries through the TRIPS Agreement.<sup>11</sup>

Changes in investment flows may also alter in some cases the industrial structure in the country, for instance, by increasing the levels of concentration. This may, in turn, lead to a reduction of competition.

##### Investment: policy issues

Will the introduction/strengthening of IPRs stimulate new FDI? In which sectors? What kind of investment can be expected? (acquisition of existing firms/establishment of new industrial plants/development of distribution systems)

Will expected FDI generate new industrial capacity? What will IPRs' impact be on imports/exports and royalty and profit remittances?

<sup>11</sup>See the United States' position in GATT, in *Patent & Licensing*. 17 (6): 11.

Will strengthened IPRs encourage new local investment?

How will IPRs affect the industrial structure of the country (changes in the relative importance of different sectors)?

Will they increase or reduce competition within particular sectors?

### **Local innovation**

The extent to which higher standards of IPRs will promote local innovation will be dependent, inter alia, on the characteristics of each individual country's "national innovation system".<sup>12</sup>

IPR systems have been very weakly linked to the innovative process taking place in developing countries, which mainly relies on traditional/indigenous knowledge and/or on the adaptation of existing technologies and their improvement through "minor" innovations: as reflected by world patent statistics, developing countries only originate a minor part of all patent applications. The patent system is related, by definition, to technological developments that are novel and result from an "inventive activity". The disciplines relating to "undisclosed information" and utility models may, in contrast, be of greater relevance for the protection of innovations developed on the shop floor and in engineering departments.

***In countries relying mainly on traditional knowledge and on the adaptation of existing technology, the linkages between IPRs and innovative processes are weak.***

The mismatch between the type of innovations prevailing in developing countries and the main modalities of IPRs may be addressed through the adoption of some specific forms of protection. For instance, innovations developed by local/indigenous communities may be subject to sui generis regimes. The TRIPS Agreement would not be applicable in this case, since it only contains obligations related to the categories of IPRs specifically addressed therein (see below).

In the area of agriculture, an important policy issue is the extent to which the protection of plant varieties (as required by the TRIPS Agreement) may hinder or foster local innovation. While some countries have opted to follow the UPOV (International Union for the Protection of New Varieties of Plants) model, new approaches may also be developed in the form of sui generis systems.

While some evidence exists about R&D conducted by foreign firms in developing countries (e.g. India), such activities are generally very limited in those countries and explained by very specific reasons. It is unlikely that an increase in the levels of IPR protection will encourage foreign firms to expand their R&D activities in developing countries, unless other conditions (availability of highly qualified personnel, good and inexpensive research infrastructure, etc.) are met. Moreover, as noted above, once most countries have adopted the TRIPS standards, IPRs will play a less significant role as a differential factor in relation to investment decisions by foreign firms.

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<sup>12</sup> On the concept of "national innovation system" see Lundvall, ed. (1992).



**Local innovation: policy issues**

Will changes in IPRs encourage the expansion or establishment of new local R&D capabilities?

What forms of IPR protection would be the best suited to foster domestic innovation? Should new forms of protection be introduced?

Will changes in IPRs stimulate the localization of R&D activities by foreign companies in the country?

**Transfer of technology**

Technology transfer has been, and will continue to be, one of the main mechanisms through which developing countries can advance in their industrialization processes. The evidence on the implications of the levels of IPRs on transfer of technology is as limited and elusive as in the case of FDI.

It is arguable that adequate IPR protection constitutes a precondition for innovators to license their technology. It is unclear, however, whether the introduction of such protection would increase the flows of technology under contractual arrangements, since IPR holders may prefer the direct exploitation of the intangibles through exports or foreign subsidiaries.

***Evidence on the implications of IPRs on transfer of technology is elusive.***

Arguments on the relevance of adequate intellectual property protection in connection with transfer of technology are particularly strong where high, easily imitable technology is at stake, such as in the case of biotechnology and computer software. It is also possible to argue that in cases where “tacit”, non-codified knowledge is essential to put a technology into operation, the transfer is more likely to take place if it is bundled with the authorization to use patents and other IPRs. If the protection of such rights and of trade secrets in the potential borrowing country is weak, technology owners are unlikely to enter into transfer of technology contracts.

Changes in intellectual property legislation may also affect the bargaining position of potential contracting parties and can make access to technology more problematic. Stronger IPRs may, in particular, imply higher costs in terms of royalties and other payments, which may in turn reduce the resources available for local R&D and make it more difficult for borrowing firms to compete in the international market.

Often, licensing agreements include a number of restrictive conditions, such as grant-back provisions and tying clauses. The adoption (or reinforcement) of appropriate measures to control abusive practices in licensing agreements (in line with part II, section 8 of the TRIPs Agreement: “Control of anticompetitive practices in contractual licenses”) is another important policy issue for consideration.

**Transfer of technology: policy issues**

Will the strengthening of IPRs encourage the transfer of foreign technology?

To what extent will stronger IPRs affect the bargaining position of IPR holders and potential technology recipients? How will they influence the level of royalty payments?

How can possible abuses by IPR holders in licensing agreements be controlled?

## Conservation and use of biodiversity

Developing countries are rich in genetic resources; they possess most of the biodiversity available in the world and are the source of materials of great value for agriculture and industry (e.g. medicinal plants). Traditional farmers, for instance, have improved plant varieties and preserved biodiversity for centuries. They have provided gene pools crucial for major food crops and other plants. Traditional medicine serves the health needs of a vast majority of people in developing countries, where access to “modern” health care services and medicine is limited by economic and cultural factors. It also plays an important role in developed countries’ markets (World Health Organization (WHO), 2000: vi).

An important policy issue is the extent to which patents should be recognized for inventions consisting of or based on biological materials. As mentioned below, the TRIPS Agreement obliges member countries to protect micro-organisms but allows for certain exceptions, particularly for plants and animals (article 27.3.b).

Countries with scarce local research capabilities and those prioritizing access to medicines and their affordability may opt to impose limitations on the patentability of substances and the associated traditional knowledge. Countries that deem the patentability of such substances to be contrary to basic cultural and ethical values<sup>13</sup> may similarly seek to limit it. It has been argued that excluding patents on biological materials and associated knowledge could discourage domestic investment in research activities. The extent of any such disincentives, however, would depend on the local capacity to undertake such research in the first place. In addition, the benefits that could eventually accrue to those able to acquire patents may be more than offset by the additional costs incurred by consumers.

***Patents have been granted, amongst others, on ayahuasca, kava, barbasco, endod, quinoa and turmeric.***

A major concern in many developing countries has been how to ensure the sharing of the benefits obtained from the commercial exploitation of biological materials and associated knowledge, as provided for by the Convention on Biological Diversity (article 15).

The misappropriation by foreign companies and researchers, notably under patents, of genetic resources found in developing countries, (as illustrated by the cases of patents granted on ayahuasca, kava, barbasco, endod, quinoa and turmeric, among others) raises another important policy issue. Some governments and non-governmental organizations have counteracted this form of “biopiracy” by challenging (in some cases successfully) the validity of such patents or by promoting the development of databases on traditional knowledge in order to pre-empt its patentability. The compulsory disclosure of the origin of biological materials in any IPR application has also been proposed.

The development of a possible sui generis regime for the protection of traditional knowledge, including farmers’ varieties, is an important policy issue in many countries. However, despite numerous proposals, little progress has been made so far in this matter at the national and international levels.

Finally, consideration should be given to the possible impact of the adoption of patents and plant breeders’ rights on biodiversity. Several studies have suggested that such regimes may contribute to a reduction of biodiversity, particularly by the replacement of farmers’ varieties by commercial, uniform varieties.

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<sup>13</sup> See e.g. the proposal for review of article 27.3.b of the TRIPS Agreement submitted by Kenya on behalf of the African countries (WT/GC/W/302 of 6 August 1999).

**Conservation and use of biodiversity: policy issues**

In view of the availability of biological resources and the local infrastructure for R&D, what kind of protection should be granted to biotechnological inventions? Should patent laws provide for a broad or narrow protection of biotechnological inventions?

What measures should be adopted in order to ensure disclosure of the origin of materials and benefit sharing in case of commercial exploitation?

How can the misappropriation of local genetic resources/biological materials be prevented?

Is there a need for developing a regime of protection for traditional knowledge?

What may be the impact of IPRs on biodiversity? In particular, will the adoption of IPRs on plants promote the substitution of farmers' varieties by commercial, uniform varieties, thus leading to a reduction in plant biodiversity?

**Foreign trade**

It is not easy to determine the impact of different types of IPRs on trade flows. However, available evidence indicates that stronger patent rights in foreign markets have had a significant market expansion effect for firms in OECD (Organization for Economic Cooperation and Development) countries, leading to an increase in their exports to countries where the levels of protection were enhanced. Strengthened patent laws, in particular, have led to a considerable increase in imports in developing countries, especially in the areas of equipment, machinery and food products in the case of large developing countries (Maskus, 2000: 116).<sup>14</sup> However, the strengthening of IPRs regarding seeds did not seem to induce more agricultural trade (Yang and Woo, 2006).

More generally, the availability and enforceability of IPRs in many cases facilitate the supply of markets by foreign title holders through exports, thus leading to a deterioration of the balance of trade in the country of importation. This is notably the case when processes of market liberalization and tariff reduction have taken place. The impact of enhanced levels of IPRs on trade should therefore be carefully examined, taking into account the possible effects on local producers and consumers.

Since IPRs are essentially territorial in nature, increasing the domestic levels of protection does not necessarily improve export opportunities for local firms, except in cases where the latter require the importation of inputs for which IPR protection is a relevant consideration.

**Foreign trade: policy issues**

Will the strengthening of IPRs lead to an increase in imports? What will be the impact on local producers and consumers?

Will the strengthening of IPRs promote exports? If so, in which sectors?

<sup>14</sup> For the case of Latin America, for instance, it was found that the potential diffusion of technology via increased international trade of technological goods generated by strengthened IPRs in Latin America was only relevant to the most relatively industrialized economies (Blyde, 2006: 10).

## Public health

Though patents are not the sole factor that determines the extent of access to medicines,<sup>15</sup> they are an important element in any public health policy,<sup>16</sup> particularly in relation to access to medicines by the poor. Patent protection, by its very nature, leads to prices for drugs higher than those that would have prevailed if generic competition were allowed.<sup>17</sup>

***The “Bolar” exception allows for e.g. the testing of a generic drug before the expiration of the relevant patent and can be a useful tool for enhancing the availability of generic medicines.***

While recognizing patent protection for pharmaceuticals, countries may adopt measures to enhance or accelerate competition, such as the “Bolar” exception (which permits generic producers to initiate procedures for the approval of a pharmaceutical product before the expiration of the respective patent) and compulsory licenses grounded, inter alia, on public health interests or sanitary emergencies.

WTO members’ right to adopt policies necessary to protect public health was expressly recognized in the Doha Declaration on the TRIPS Agreement and the Public Health (November 2001).<sup>18</sup>

Another important policy area is the determination of the standards for the patentability of pharmaceutical products and processes. Often patents on minor modifications or new versions of existing products<sup>19</sup> are granted, thus artificially extending the term of protection beyond the original patent term. Attention should also be paid to the issue of patentability of “new uses” of known medicines, accepted in some jurisdictions under a fiction of novelty.

***Countries granting compulsory licenses for getting access to cheaper drugs include Brazil, Ghana, Indonesia, Malaysia, Mozambique, Thailand and Zimbabwe.***

Finally, it is generally recognized that the extension of patent protection for pharmaceuticals does not automatically lead to greater investment by major pharmaceutical firms in drugs needed to address the diseases of the poor, such as tuberculosis and malaria.

After the adoption of the TRIPS Agreement, the United States has actively sought the establishment of FTAs where the protection of IPRs for pharmaceuticals is substantially increased, via the extension of the patent term to compensate for delays in patent examination or marketing approval of a medicine, the granting of exclusive rights with regard to test data and the “linkage” between drug registration and patent protection. These “TRIPS-plus” provisions have raised considerable concerns from a public health perspective, as they are likely to reduce access to medicines (Correa, 2006).

Interestingly one of the most recent United States FTAs (United States–Peru) no longer contains some of the most stringent and controversial provisions. When aiming to obtain Congressional approval for the draft deal, the United States Trade Representative had to agree (with Congress)

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<sup>15</sup> The lack or weakness of health care infrastructure to conduct testing, store and distribute medications, as well as to monitor patient compliance with treatments, are among the factors that may influence access to and the use of medicines, particularly in the case of HIV/AIDS medication. See International Intellectual Property Institute (IPI) (2000: 51).

<sup>16</sup> See Correa (2000a).

<sup>17</sup> Although the majority of the WHO-listed “essential drugs” are off-patent, since expensive drugs are not included in the list. However, many drugs needed to fight diseases prevalent in developing countries (such as HIV/AIDS infection) are patented.

<sup>18</sup> See WT/MIN(01)/DEC/W/2, 14 November 2001, available at

[http://www.wto.org/English/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

<sup>19</sup> E.g. polymorphs, isomers, combinations and formulations.

on certain modifications – several of which effectively represent a lowering of the IPR protection standard. These new baselines – different from what was originally envisaged by United States negotiators – were subsequently integrated into the United States–Peru Agreement. This is an important precedent, possibly showing, amongst other things, changes in the United States’ priorities and the importance of lobbying efforts (including e.g. by members of the United States Congress and civil society groups). It was suggested that this would set a new baseline and possibly generate a new series of requests for the revision of previous agreements.<sup>20</sup>

#### **Public health: policy issues**

What is the likely impact of introducing/strengthening patents on the pricing and access to drugs? How will this affect the implementation of public health policies?

How will introducing/strengthening patents affect the local pharmaceutical industry?

What measures can be adopted in order to promote generic competition?

Are more drugs for neglected diseases being developed?

How may TRIPS-plus provisions in FTAs affect public health, particularly access to drugs?

#### **Human rights**

Various international forums and academia are paying growing attention to the relationship between IPRs and human rights (Yu, 2007). The implementation of the TRIPS Agreement in developing countries in particular has raised concerns about the realization of the human rights to food, health and education, as recognized in the International Covenant of Economic, Social and Cultural Rights.

Moreover, from a human rights point of view the effects of the TRIPS Agreement are of concern as regards traditional knowledge, food safety, health, the environment, the development of peoples, patentable material and access to culture, science and education (Seuba, forthcoming).

***Human rights potentially affected by IPRs include the human rights to food, health and education.***

The United Nations Sub-Commission on the Promotion and Protection of Human Rights has examined the tensions between the application of the TRIPS Agreement and the exercise of economic, social and cultural rights, and has urged the WTO to fully consider states’ obligations emerging from international human rights instruments.<sup>21</sup> These tensions should be addressed by using as much as possible the flexibilities permitted by the TRIPS Agreement, such as parallel imports, compulsory licensing and government use of patents, and by avoiding TRIPS-plus standards (see below).

<sup>20</sup> Vivas Eugui D, Main changes in the IP chapter of the US–Peru FTA, mimeo, on file with the author. For a detailed description, see also, Roffe *et al.* (2008a). See also Roffe *et al.* (2008b).

<sup>21</sup> Sub-Commission on the Protection and Promotion of Human Rights. *Intellectual property rights and human rights*. E/CN.4/Sub.2/RES/2000/7, para 8.



## Chapter IV. The TRIPS Agreement – A Brief Overview

The following offers a brief introduction into cross-cutting and IPR-specific provisions that are contained in the TRIPS Agreement.

*The TRIPS Agreement is, by its coverage, the most comprehensive international instrument on IPRs.*

### *1. Cross-cutting provisions*

#### **Coverage, minimum standards, enforcement**

The TRIPS Agreement is, by its coverage, the most comprehensive international instrument on IPRs, dealing with all types of IPRs: copyright and related rights, trademarks, geographical indications, industrial designs, patents, integrated circuits and undisclosed information. The sole areas not covered are “breeders’ rights” (only incidentally referred to) and utility models (or “petty patents”). Notably, the agreement also does not cover the protection of encrypted program-carrying satellite signals, which is explicitly dealt with, for instance, in article 1707 of the North American Free Trade Agreement.

*Utility models and industrial designs are distinguished by the “functional aspect”: utility models are concerned with the way in which a particular configuration of an article works; industrial designs are only concerned with the aesthetic character of an article.*

The agreement provides for minimum standards of protection of IPRs. WTO members cannot, in the specific areas and issues covered by the agreement, confer a lower protection than is established therein. At the same time, members are protected against demands by other members to confer a higher protection: no member can be obliged to provide more extensive protection than established in the agreement (article 1.1).

The agreement sets forth substantive standards relating to the availability of rights, as well as procedural rules relating to the enforcement of such rights. This means that the TRIPS Agreement not only stipulates, for instance, the (minimum) exclusive rights that a patent or trademark owner must enjoy, but also specifies the administrative and judicial procedures that should be available to him in order to effectively use the conferred rights vis-à-vis third parties.

*The incorporation of enforcement rules is a major difference compared to previous international IPR conventions, which only or mainly dealt with substantive standards.*

The agreement includes detailed provisions in its part III on judicial and administrative procedures and other measures related to the enforcement of IPRs. They include, inter alia, provisions on evidence, injunctions, damages, provisional measures and criminal penalties, as well as specific rules to combat counterfeit trademark or pirated copyright goods at the border. Detailed obligations relating to procedures aimed at suspending the circulation of infringing goods by custom authorities are established.

#### **Relationship with other IPR conventions**

Several international conventions had been negotiated and adopted before the TRIPS Agreement, on various categories of IPRs. The negotiation of the TRIPS Agreement took into consideration and supplemented, with additional obligations, some of those conventions.

### **Box 2. Key IPR conventions prior to TRIPS**

Key IPR obligations adopted prior to the TRIPS Agreement include, amongst others, the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (the Rome Convention) (1961), the Paris Convention for the Protection of Industrial Property (1967), the Berne Convention for the Protection of Literary and Artistic Works (1971) and the Washington Treaty on Intellectual Property in respect of Integrated Circuits (1989).

The obligations set forth by these four conventions became binding (with some exceptions) for all members, even those that have not ratified them, except in the case of the Rome Convention which only continues to be binding on states that have ratified it. Moreover, members are bound by the provisions of the Washington Treaty, as amended by the agreement, despite the fact that the treaty never entered into force.

As a result, the TRIPS Agreement is not to be viewed as a completely new and separate convention, but rather as an integrative instrument that provides “convention-plus” protection to IPRs. Sometimes, however, TRIPS grants “convention-minus” protection, e.g. in the case of moral rights provided for by the Berne Convention.

### **Implementation**

The method of implementing the TRIPS Agreement’s provisions can be freely determined by its members within their “own legal system and practice” (article 1.1.). There are considerable differences between national legal systems, particularly between those based on Anglo-American law and those that follow the approach of continental European law. These differences are noticeable, for instance, in the field of copyright and neighbouring rights, trademarks and trade secrets protection.

### ***Members are free to determine their methods of implementing the TRIPS Agreement.***

The agreement does not constitute a uniform law. It leaves considerable freedom in many areas to legislate at the national level. Although the agreement contributes to harmonizing, to a considerable extent, the substantive (and some procedural) rules on IPRs in accordance with standards essentially comparable to those prevailing in the most advanced countries, varying degrees of legislative freedom remain at the national level to adapt IPR laws to national conditions and objectives, as discussed below.

It is critical for developing countries to exploit, to the fullest possible extent, the flexibilities that the TRIPS Agreement allows in designing their IPR systems. Those flexibilities allow countries to, inter alia, define the mode of protection for industrial designs and geographical indications, provide exceptions to the exclusive rights, allow parallel imports, grant compulsory licensing and limit data protection to cases of unfair competition. The use of such flexibilities is of particular relevance in those areas where the realization of human rights may be affected, such as in cases where IPRs may restrain access to medicines or educational materials.

### **Objectives and principles**

The main stated goal of the agreement is “to reduce distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become a barrier to legitimate trade” (preamble).



Though it is recognized that IPRs are “private rights”, the underlying public policy objectives of national systems for the protection of intellectual property, including “developmental and technological objectives” are also recognized (preamble). More specifically, articles 7 and 8 of the text provide a framework for the interpretation and implementation of the agreement.

***Three key concepts in interpreting the TRIPS Agreement include the concepts of “mutual advantage”, “social and economic welfare” and “balance of rights and obligations”.***

According to article 7, “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 the balance of rights and obligations.”

The concepts of “mutual advantage”, “social and economic welfare” and “balance of rights and obligations” mean that the recognition and enforcement of IPRs are subject to higher social values and, in particular, that a balance needs to be found between the exclusive rights conferred to innovators and the interest of society in the diffusion and further innovation of existing technology.

Article 8 is also an important provision for framing national legislation that responds to particular public interests and for preventing or remedying abuses of IPRs. Article 8.1 states that “members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement”. In addition, “appropriate measures”, provided that they are consistent with the provisions of the agreement, may be applied “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” (article 8.2).

Industrialized countries have extensively applied antitrust laws in order to balance the public and private interests involved in the use of IPRs. The implementation of the TRIPS Agreement in developing countries may require the adoption or revision of competition laws so as to ensure the control of abusive practices relating to the acquisition or use of IPRs.

### **National treatment**

Each member shall accord to the nationals of other member states treatment no less favourable than that it accords to its own nationals, subject to the exceptions already provided in the international conventions referred to above (the Paris, Berne and Rome Conventions and the Washington Treaty).

### **Most favoured nation**

If the protection conferred to the nationals of a member is more favourable than those granted to the nationals of other members, such higher protection must be immediately and unconditionally extended to the nationals of the other members, by virtue of the most favoured nation (MFN) clause (article 4).

***Any new regional trade agreement with intellectual property rights would be subject to the TRIPS MFN clause.***

One of the permitted exceptions to the MFN clause relates to international agreements made before the entry into force of the WTO Agreement, and notified to the Council of TRIPS, provided that they “do not constitute an arbitrary or unjustifiable discrimination against nationals of other

members” (article 4.d). Any new regional or subregional agreement on IPRs would be subject to the MFN clause.

### **Box 3. IPRs and regionalism**

A large number of international conventions on IPRs were adopted before the TRIPS Agreement, and two additional conventions have been signed after its adoption.<sup>22</sup> Notwithstanding the number and coverage of international conventions on IPRs, a growing number of bilateral and regional agreements on trade and investment also contain specific provisions on IPRs. The latter contain TRIPS-plus provisions, that is, higher standards of protection than those required under TRIPS (Mayne, 2005).

The United States engaged in negotiations of trade agreements that included detailed chapters on IPRs with the Andean countries, Australia, Bahrain, Central American countries (the Central American Free Trade Agreement, including the Dominican Republic), Chile, Jordan, Laos, Malaysia, Morocco, Oman, Panama, the Republic of Korea, Singapore, the Southern African Customs Union, Thailand, United Arab Emirates and Viet Nam. Most of these negotiations ended up in agreements ratified or in the process of ratification by the United States Congress. It also attempted the establishment a Free Trade Area of the Americas with a significant number of TRIPS-plus provisions. Between 1986 and 1998, the United States signed bilateral agreements on intellectual property including TRIPS-plus provisions with Albania, Armenia, Azerbaijan, Cambodia, China, Czechoslovakia, Jamaica, Latvia, Lithuania, Mongolia, Nicaragua, Peru, Philippines, Poland, Republic of Korea, Romania, Russian Federation, Sri Lanka, Taiwan (China), Tajikistan, Thailand and Trinidad and Tobago.

The European Union and the European Free Trade Association have also entered into trade agreements that include TRIPS-plus provisions with a number with developing countries (Santa-Cruz, 2007).

The implications of the adoption of TRIPS-plus standards in regional or bilateral agreements should be carefully assessed. In the area of patents and health, they have included the extension of patent terms, exclusivity on data necessary for the approval of pharmaceutical and agrochemical products, and linkage between drug registration and patents, among others. WHO has recommended that “since the public health impact of TRIPS requirements have yet to be fully assessed ... developing countries be cautious about enacting legislation that is more stringent than the TRIPS requirements” (WHO, 2001: 4).

It should also be noted, as discussed below, that by virtue of the MFN clause, only international agreements on IPRs made before the entry into force of the WTO Agreement and notified to the Council of TRIPS may provide for a differential treatment to the members of a bilateral or regional agreement, to the extent that they “do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members” (article 4.d). Any concession given in new bilateral or regional agreements on IPRs should be automatically and unconditionally extended to the other WTO members.

### **Exhaustion of rights**

Article 6 of the agreement permits any member to admit parallel imports irrespective of the type of applicable IPRs. The concept behind this article is that the title holder “exhausts” his rights after the sale of a protected product, whereby he obtained remuneration for the IPR content of the sold product.

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<sup>22</sup> The WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty (1996).

***Parallel imports take place when a protected product is imported into a country without the authorization of the IPR title holder, provided that the product was put on the market in first country in a legitimate manner.***

The application of this principle may permit the legitimate acquisition of goods in a foreign country at lower prices than those charged domestically for the same goods, thus benefiting users and consumers.

### **Equality of treatment**

Unlike other components of the Uruguay Round Final Act, the TRIPS Agreement does not provide for special and differential treatment in favour of developing and least developed countries (LDCs). The special needs of LDCs has only been taken into account in relation to measures to promote the transfer of technology (article 66.2), technical assistance and transitional periods (article 65).

### **Transfer of technology and technical assistance**

According to article 66.2, developed member countries are obliged to provide incentives under their legislation to enterprises and institutions in their territories for the purpose of promoting and encouraging the transfer of technology to LDCs “in order to enable them to create a sound and viable technological base”.

At its September 1998 meeting, the Council for TRIPS agreed to put on the agenda the question of the review of the implementation of article 66.2 and to circulate a question on the matter in an informal document of the Council. On 19 February 2003, the Council adopted a decision on the implementation of article 66.2, which establishes mechanisms for “ensuring the monitoring and full implementation of the obligations in Article 66.2”, including the obligation to “submit annually reports on actions taken or planned in pursuance of their commitments” under that article and their review by the Council at its end of year meeting each year. The reports submitted by developed countries suggest that they tend to consider “incentives” for the transfer of technology under article 66.2 in overly broad terms, including activities as diverse as trade and investment promotion, training of intellectual property and custom officials, funding provided to multilateral organizations such as the World Bank, granting general incentives to their own enterprises, building capacity to ensure pest surveillance and management in phytosanitary matters, assistance in developing legislation, scientific cooperation and governance issues (Correa, 2007).

The issue of transfer of technology to LDCs was also addressed in paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, which reaffirmed “the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2”.

The supply of technical and financial cooperation for the implementation of the TRIPS Agreement in developing and least developed countries is mentioned in article 67 of the agreement, but no specific obligations or operative mechanisms are provided for. The provision of the assistance is upon request and subject to “mutually agreed terms and conditions”.

Such cooperation shall include assistance in the preparation of laws and regulations on the protection of IPRs as well as on the prevention of their abuse, the establishment or reinforcement of domestic offices, including the training of personnel. The Council for TRIPS has on many occasions reviewed information on assistance provided to developing and least developed countries, including by intergovernmental organizations.

## **Transitional arrangements**

All WTO members were allowed one year after the date of entry into force of the WTO Agreement (1 January 1995) to implement the obligations relating to intellectual property protection (article 65.1). Developing countries and countries in transition were granted an additional period of four years, except for obligations concerning national and MFN treatment, which became applicable after the expiry of the aforementioned one-year period (article 65.2).

LDCs were permitted, in view of their special needs and requirements – “their economic, financial and administrative constraints and their need for flexibility to create a viable technological base” (article 66.1) – up to 10 years from the general date of application, 1 January 1996.

For many developing countries (e.g. Cuba, Dominican Republic, Egypt, Honduras) the transitional period of article 65.2 was insufficient to undertake the difficult and costly tasks related to the modernization of the administrative infrastructure (intellectual property offices and institutions, the judicial and customs system), the drafting of new laws with substantive and procedural provisions for the protection of IPRs, and for strengthening institutions and creating a culture for the protection of such rights (WT/GC/W/209).

In view of the possible impact of the implementation of the TRIPS Agreement on access to medicines, the Doha Declaration on TRIPS and Public Health provided that LDC members shall not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 (patents) and 7 (undisclosed information) of part II of the TRIPS Agreement or to enforce rights provided for under these sections until 1 January 2016, without prejudice to the LDC members’ right to seek other extensions of the transition periods as provided for in article 66.1 of the TRIPS Agreement (paragraph 7) .

### **Box 4. Flexibilities and pharmaceutical products: decisions for LDCs**

In implementing paragraph 7 of the Doha Declaration, the Council for TRIPS adopted on 27 June 2001 a decision on the “Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products” (IP/C/25, 1 July 2002). The General Council also adopted on 8 July 2002 a Decision on “Least-Developed Country Members – Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products” (WT/L/478, 12 July 2002), which clarified that LDC members are not obliged to grant exclusive marketing rights (EMRs) in accordance with article 70.9 of the TRIPS Agreement. If the granting of EMRs were required, the concession made by the Doha Declaration to LDCs would have been of very limited practical value, since access to generic pharmaceutical products could have been effectively blocked under EMRs for at least five years.

While LDC members were allowed to further delay the implementation of the TRIPS obligations relating to pharmaceutical products, they remained bound to apply all other provisions of the agreement as of 1 January 2006. Shortly before this deadline, LDCs jointly requested an extension of that period to the Council for TRIPS, which on 29 November 2005 agreed to extend the transitional period until 1 July 2013, or until such a date on which they cease to be an LDC member, whichever date is earlier. The decision established a “freezing clause” – similar to that contained in article 65.5 of the TRIPS Agreement – which obliges LDC members not to reduce the level of compatibility of their legislation with the TRIPS Agreement during the extended transitional period. This limitation, which was not present in the TRIPS Agreement, does not prevent LDC members from reducing the level of IPR protection, but only to do so in case the resulting protection would be lower than that required by the agreement. The limitation does not apply to pharmaceutical products.

In addition to the general transitional period referred to above, a further period of five years was contemplated for developing countries that were bound to introduce product patent protection in areas of technology not already protected in their territory on the general date of application of the agreement for that country (article 65.4). This provision was of particular importance in the area of pharmaceutical products, which was excluded from patent protection in more than 50 countries at the beginning of the Uruguay Round.

The application of these transitional periods did not require any specific declaration or reservation by the concerned country: they were automatically applicable. It would be extremely important for acceding countries to take these transitional periods into account during the negotiations for accession, in order to receive treatment equivalent to other developing countries. It should be noted, however, that some developing countries that acceded to WTO after the conclusion of the Uruguay Round were refused the possibility of applying transitional periods for the implementation of their obligations under TRIPS.

### **Dispute settlement**

Unlike previous international conventions on IPRs, under the TRIPS Agreement non-compliance with the obligations stipulated in the agreement may lead to action, including trade sanctions, by other member states (but not by affected private parties).

However, if a WTO member does not observe certain minimum standards, no other member can unilaterally apply trade sanctions against the former. Any complaint should be brought to and settled according to the multilateral procedures established by the Dispute Settlement Understanding.<sup>23</sup>

At the same time, the adoption of TRIPS means that any controversy relating to compliance with the agreement's minimum standards should be resolved under such a multilateral procedure. The adoption by another member of unilateral trade sanctions would be incompatible with the multilateral rules.

### **Monitoring and review**

In addition, the implementation of the TRIPS Agreement is subject to supervision within the WTO system. A specific body, the Council for TRIPS, is in charge of monitoring members' compliance with the agreement's obligations. This Council also offers members the opportunity of consulting on matters related to TRIPS and shall assist, upon request, in dispute settlement.

According to article 71.1, the Council for TRIPS shall review the implementation of this agreement after the expiration of the transitional period referred to in paragraph 2 of article 65. The council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter.

The council may also undertake reviews in light of any relevant new developments that might warrant modification or amendment of the agreement. Amendments merely serving the purpose of adjusting to higher levels of protection of IPRs achieved, and in force, in other multilateral agreements and accepted under those agreements by all members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS (article 71.2).

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<sup>23</sup> See above the TRIPS-related cases settled under the Dispute Settlement Understanding.

So far, only one amendment to the TRIPS Agreement has been proposed for ratification in accordance with the WTO rules. It is based on the WTO decision of 30 August 2003,<sup>24</sup> which, pursuant to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, established a mechanism for the use of compulsory licenses in exporting and importing countries when in the latter there is no or insufficient manufacturing capacity to supply needed pharmaceutical products. The amendment, if approved, would introduce a new article 31bis into the agreement that reproduces the decision. The mechanism for the grant of compulsory licenses is subject to a number of conditions that make the system difficult to operate. Only one country (Rwanda) has so far notified its interest in using the system.

## **2. IPR-specific provisions**

The TRIPS Agreement contains numerous obligations for each specific IPR it covers: copyright and related rights, trademarks, geographical indications, industrial designs, patents, integrated circuits and undisclosed information. The following provides a brief overview of the key provisions.

### **Copyright and related rights**

In the area of copyright and related rights, the TRIPS Agreement explicitly stipulates the protection of software as a literary creation and provides – for the first time in an international agreement – rental rights for phonograms, films and computer programs. It also makes mandatory the protection of data compilations under copyright. The agreement provides for a minimum term of protection for works (other than works of applied art or photographic works) not belonging to natural persons: 50 years from publication or from creation (if publication was not made within 50 years from the making of the work).

It is worth noting that the TRIPS Agreement does not require the adoption of specific measures regarding the protection of digitized copyright works, such as the so-called “technological protection measures”, which, if too broadly defined, may affect access to non-protected works and limit the fair use of protected works (Correa, 2002a).

#### **Box 5. Core copyright industries**

The core group of “copyright industries” include newspapers and magazines, publishing of books and related industries, radio and television, cable television, discs and tapes, plays, advertising, computer programs (software) and data processing. It also includes manufacturing, business practices, architecture and design, distribution (transport of goods, bookshops, record stores and other forms of wholesale or retail distribution of products protected by copyright), and copyright-related industries (production and technical assistance involving equipment used solely with copyright-protected material, for example, computers, radio and television equipment, and other listening or recording equipment).

*Source:* OMPI-Universidade Estadual de Campinas (2002: 11).

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<sup>24</sup> See [http://www.wto.org/English/tratop\\_e/trips\\_e/implement\\_para6\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/implement_para6_e.htm).

### **Main provisions on copyright and related rights**

- Protection of works covered by the Berne Convention, excluding moral rights, with respect to the expression and not the ideas, procedures, methods of operation or mathematical concepts as such;
- Protection of computer programs as literary works and of compilations of data;
- Recognition of rental rights, at least for phonograms, computer programs and for cinematographic works (except if rental has not led to widespread copying that impairs the reproduction right);
- Exceptions to exclusive rights must be limited to special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder;
- Recognition of 50 years minimum term for works (other than photographic or applied art works) owned by juridical persons, and for performers and phonogram producers;
- Recognition of rights of performers, producers of phonograms and broadcasting organizations (article 14).

In the area of “related rights” (corresponding to what European law defines as “neighbouring rights”), the agreement did not include significant new standards, except for the extension of the term of protection for performers and producers of phonograms to 50 years (20 years were granted under the Rome Convention).

Enforcement rules are also to be considerably strengthened in the copyright field, particularly due to the obligation to establish criminal procedures and penalties against copyright piracy on a commercial scale (article 61).

### **Trademarks**

The protection of trademarks has been reinforced by a comprehensive definition of signs that can constitute trademarks and by the specification of a minimum permissible period of non-use, which can be justified by “valid reasons based on the existence of obstacles” (article 19). Goods and services trademarks are put on the same footing.

The TRIPS Agreement supplements the Paris Convention with regard to “well-known” trademarks, which must be given protection even if they became known on the basis of publicity and not of an effective use in a country. The agreement allows members to keep existing differences between the Anglo-American and Continental legal systems with regard to the use of a trademark as a means of acquisition of rights, as admitted by the former.

### **Main provisions on trademarks**

- Definition of protectable signs, which should be capable of distinguishing the goods or services of one undertaking from those of other undertakings.<sup>25</sup> Service marks shall receive a protection equivalent to marks for goods;
- Registrability, but not filing of an application, can be dependent on use;
- Definition of exclusive rights conferred with respect to identical or similar goods and services;
- Protection of well-known trademarks for goods and services, including if knowledge thereof is acquired through their promotion;
- Exceptions to exclusive rights must be limited and take into account the legitimate interest of the trademark owner and of third parties;
- The minimum term of protection is seven years, renewable without limitation;
- Requirements of use are to be limited both in terms of the minimum period of non-use and the admissibility of reasons for non-use;
- Special requirements for use are limited, as well as conditions on licensing and assignment of trademarks. A trademark can be assigned without the transfer of the business to which it belongs;
- Measures to combat trade in counterfeiting products should be available at the border.

Trademark owners may also significantly benefit from new measures against counterfeiting, particularly those that should be taken at the border (article 51).

### **Geographical indications**

Geographical indications that meet certain conditions are considered by the agreement as a particular kind of IPRs. The agreement obliges member countries to protect those indications that identify a good as originating in a certain territory, “where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin” (article 22.1). With this definition, the TRIPS Agreement only requires protection of “qualified” geographical indications, such as “appellations of origin” where, as stated, a relationship between certain characteristics of the products and the place of their origin can be established.

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<sup>25</sup> Members may require that signs be visually perceptible. Hence, they are not obliged to protect audible and olfactory signs.



### **Main provisions on geographical indications**

- Geographical indications are indications that identify a good as originating in the territory of a member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the goods is essentially attributable to its geographical origin;
- Legal means shall be provided to prevent use of an indication in a manner that misleads the public or when it constitutes unfair competition, and to invalidate a trademark if the public is misled as to the true place of origin;
- Additional protection is conferred to geographical indications for wines and spirits, including ways of protecting homonymous indications;
- Negotiations shall be undertaken to establish a multilateral system of notification and registration, aiming at increasing the protection of indications for wines and spirits;
- Exceptions to the required protection may be based on prior and continuous use of an indication, prior application or registration in good faith of a trademark, or on the customary use of the indication;
- Obligations only relate to geographical indications that are protected in their country of origin.

A special, higher protection is recognized for geographical indications related to wines and spirits. This means that, with regard to wines and spirits, protection must be provided even where there is no threat of the public being misled as to the true origin of the product or where the use does not constitute an act of unfair competition. However, indications that have become a term “customary in the common language” (article 24.6) in a member can be excluded from protection. Members can also permit the use of indications of another member if it was continuously used for at least 10 years preceding 15 April 1994 or in good faith preceding that date.

### **Industrial designs**

Industrial designs that are independently created are to be protected for at least 10 years under the TRIPS Agreement, whenever they are “new or original” (article 25). Notwithstanding that this is one of the IPR areas where differences between national laws are the highest, the agreement includes very few elements of harmonization.

### **Main provisions on industrial designs**

- Protection should be conferred to designs that are new or original;
- Requirements for the protection of textile designs should not impair the opportunity to seek and obtain such protection;
- Exclusive rights can be exercised against acts for commercial purposes, including importation;
- Ten years is the minimum term of protection.

Designs essentially dictated by technical or functional considerations are not required to be protected under the agreement. Member countries may, at their discretion, develop legislation on functional designs, such as utility models.

## Patents

An important chapter of the agreement relates to patents. It includes, inter alia, standards relating to patentability and its exceptions, compulsory licenses and the duration of protection (at least 20 years from the date of filing of the application).

Patents are to be granted and the conferred rights to be exercised without discrimination as to the place of invention or the field of technology, or on the basis of whether the protected product is locally produced or imported. This provision has been interpreted as prohibiting the establishment of “working obligations” on the patentee, including compulsory licenses for lack of or insufficient working. However, the plain wording of the text does allow the interpretation that compulsory licenses can be granted in cases of non-working of the patent, since the products referred to in article 27.1 are infringing products and not those produced or imported by the patent owner.

For biotechnological inventions and as a reflection of the complexity and still unresolved differences on the issue,<sup>26</sup> article 27.3.b (which was to be reviewed in 1999)<sup>27</sup> allows for a possible exception to the patentability of plants and animals, but plant varieties must be protected by patents, an “effective sui generis regime” or a combination of both.<sup>28</sup>

### Main provisions on patents

- Patents shall be granted for any invention, whether products and processes, provided it is new, involves an inventive step and is capable of industrial application;
- Patents shall be granted in all fields of technology. No discrimination is allowed with respect to the place of the invention, or based on whether the products are locally produced or imported;
- Member countries can exclude from patentability diagnostic, therapeutic and surgical methods for treatment of humans or animals, as well as plants and animals and essentially biological processes for the production thereof;
- Exclusive rights conferred in the case of product and process patents are defined, subject in the case of imports to the principle of exhaustion (article 6);
- Inventions shall be disclosed in a manner that is sufficiently clear and complete for a person skilled in the art to carry out the invention. The indication of the best mode of carrying out the invention, as well as information concerning corresponding patent applications and grants, may be required;
- Limited exceptions to the exclusive rights can be defined by national laws (article 30);
- Conditions for granting other uses without the authorization of the patent holder (compulsory licenses) are set forth and member countries can determine the grounds to allow such uses;
- Revocation/forfeiture is subject to judicial review;

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<sup>26</sup> Unlike the United States and Japan, in Europe and many developing countries patents for plant varieties and animal races are not admitted.

<sup>27</sup> Such a review has not taken place, as discussed below.

<sup>28</sup> See below a further analysis on this subject.

- The term of protection shall be at least twenty years from the date of filing of an application;
- Reversal of the burden of proof in civil proceedings relating to infringement of process patents is to be established in certain cases.

The TRIPS Agreement specifies the contents of the exclusive rights to be conferred under a patent, including the protection of a product directly made with a patented process, and the right to produce, sell and import the protected product. Article 6 allows member countries to adopt the principle of international exhaustion of rights and, therefore, to admit parallel imports.

The reversal of burden of proof is stipulated for civil procedures relating to process patents in order to strengthen a patentee's position in cases of infringement, leaving each member the option to apply this principle to all existing or only to "new" products.

***WTO members' right to determine the grounds for granting compulsory licenses was specifically confirmed by the Doha Declaration on TRIPS and Public Health.***

Members may establish exceptions to the exclusive rights, in accordance with article 30, in order to allow, for instance, experimentation on a patented invention (including for commercial purposes) and use of an invention to require the approval of a generic medicine to be sold after the expiry of a patent. This latter exception (generally called "Bolar exception") is particularly important to ensure the early introduction of generic competition that may bring medicine prices down.

Additionally, a detailed provision (article 31) recognized members' rights to permit "other use without authorization of the right holder", i.e. to grant compulsory licenses or permit the non-commercial use by the government of patented inventions under the specified conditions. Compulsory licenses would be non-exclusive and terminate when the circumstances that originated their grant ceased to exist. The provision of compulsory licenses and government use is one of the most important "flexibilities" in the TRIPS Agreement. The United States has extensively resorted to such licenses and government use to address, in particular, anti-competitive practices by patent owners (Reichman and Hazendahl, 2002). Italy,<sup>29</sup> as well as a number of developing countries, has recently granted compulsory licenses or authorized government use of patents covering pharmaceutical products, notably antiretrovirals (see table 2).

<sup>29</sup> See decision by the Italian Competition Authority A364 Merck—*Principi Attivi in Boll.* 11/2007 available at [www.agcm.it](http://www.agcm.it), confirmed by the Italian Regional Administrative Tribunal (TAR) of Lazio (TAR Lazio 7 March 2006, no. 1713).

**Table 2. Compulsory licences and government use in developing countries**

Country, date	Type of authorization	Products	Cost reduction	Remuneration to the patent owner
Zimbabwe May 2002	Based on a declaration of emergency, it empowers the minister to authorize the use of patented inventions by any government department or third party, for the service of the state.	Antiretrovirals	From \$197–\$237 per year to \$180	n.a.
Malaysia November 2003	It authorizes the local distributing agent for an Indian manufacturer to import from India, for the purpose of supplying public hospitals for two years.	Antiretrovirals	From \$315 to \$58 per month	4 per cent value of stocks actually delivered
Mozambique April 2004	Compulsory licence to enable local manufacturing	Antiretroviral fixed dose combination		2 per cent total turnover
Zambia September 2004	Compulsory licence for local manufacturing	Antiretrovirals		2.5 per cent total turnover
Indonesia 2004	It authorizes the minister to appoint a pharmaceutical factory as the patent exploiter for and on behalf of the government.	Nevirapine and lamivudine	Fixed dose combination produced for \$38 per month	0.5 per cent net sales
Ghana October 2005	Government use	Antiretrovirals	From \$495 to \$235 per year	n.a.
Thailand November 2006  January 2007	Government use	Efavirenz  Plavix Kaletra	From \$41 to \$22 per month	0.5 per cent sales value
Brazil May 2007	Public interest	Efavirenz (600 mg)	From \$1.59 to \$0.45 per dose (a savings of \$30 million in 2007)	n.a.

Source: elaborated on the basis of Oh (2006) and Kohr (2007).

No specification is made in the TRIPS Agreement as to the grounds on which such licenses can be granted, although particular reference is made to the cases of national emergency or extreme urgency, dependency of patents, licenses for governmental non-commercial use and licenses to remedy anti-competitive practices. National laws can, however, provide for the granting of such licenses for other reasons, such as public health or public interests at large. The text of the agreement is also open with respect to the rights that can be exercised by the compulsory licensee, including production or importation.

### Integrated circuits

The layout designs (topographies) of integrated circuits shall be protected according to the provisions of the Washington Treaty of 1989. The TRIPS Agreement, however, excludes some of

the provisions of the treaty (notably with respect to compulsory licenses), and supplements it with respect to bona fide acts involving infringing integrated circuits or industrial articles containing them. The minimum term of protection is 10 years.

#### **Layout designs of integrated circuits**

- The layout designs (topographies) of integrated circuits shall be protected according to the provisions of the Washington Treaty of 1989, except those specifically excluded by the agreement (e.g. provisions on compulsory licenses);
- Protection shall extend to layout designs as such and to the industrial articles that incorporate them;
- Bona fide purchases of products involving infringing layout designs shall be liable to pay compensation to the rights holder after notification;
- The term of protection shall be a minimum of ten years.

#### **Undisclosed information**

The TRIPS Agreement is the first multilateral agreement on “trade secrets”. Negotiations in this area reflected substantial differences between the Anglo-American and the continental European law traditions. The agreement followed the latter’s approach: trade secrets are deemed protectable under the discipline of unfair competition, as established in article 6bis of the Paris Convention. No “proprietary” or exclusive rights are conferred on the possessor.

#### **Main provisions on undisclosed information**

- Undisclosed information is to be protected against unfair commercial practices, if the information is secret, has commercial value and is subject to steps to keep it secret;
- Secret data submitted for the approval of new chemical entities as pharmaceutical and agrochemical products should be protected against unfair commercial use and disclosure by governments.

In order to be protectable, the information shall be secret, possess a commercial value and be subject to reasonable steps by the possessor to keep it secret. In addition, obligations are provided for in the agreement in relation to test results and other data submitted to governments in order to obtain approval of pharmaceutical or agrochemical products. Protection of these data applies when they are the result of a significant effort, and only against unfair commercial use by third parties and disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Test data protection has been a particularly controversial issue. In the United States, Europe and Japan for example, the data submitted for the registration of pharmaceutical and agrochemical products are subject to sui generis systems of protection, based on a temporary right to the exclusive use of such data by the first applicant (generally the company that developed a new

product). In such a system, generic manufacturers cannot rely on the data submitted by the first applicant for the purpose of registering a similar product for commercial use.<sup>30</sup>

In other countries, national authorities rely on data submitted by the first applicant<sup>31</sup> to process and approve third parties' subsequent applications for a similar product, subject to evidence that its physico-chemical attributes are equivalent to those of the first applicant's product. This approach emphasizes that the registration of products should not erect barriers to otherwise legitimate competition.

The issue of data protection has become especially relevant in countries that until recently did not provide patent protection for pharmaceuticals and that applied the transitional period allowed by the TRIPS Agreement until 1 January 2005. In these countries, there is a large pool of pharmaceutical products in the public domain that are subject to patent protection in other countries. Exclusive rights over data could, if provided, become a substitute for patent protection on such products.

Article 39.3 requires countries to protect test data against "unfair commercial use". Protection is hence to be conferred against dishonest commercial practices. Practices expressly required or permitted by the law (such as abbreviated or summary procedures of marketing approval) may not be deemed dishonest. Granting marketing approval to a second entrant, based on the similarity with a previously approved product, is not a proscribed "use" under article 39.3.

Test data must be protected under the discipline of unfair competition, as established in the Paris Convention for the Protection of Industrial Property (article 10bis) and the TRIPS Agreement (article 39.1). Under this discipline no exclusive rights are granted, only the right to take legal action against whoever has obtained a commercial advantage by means of a dishonest practice (Correa, 2002b). Despite the fact that a large number of WTO members do not provide for exclusive rights over data, there has been no request of a WTO panel to rule on the meaning of article 39.3.

### **Restrictive business practices in contractual licenses**

Section 8 (part I) of the TRIPS establishes certain conditions for the control by member states of anti-competitive practices in contractual licenses relating to IPRs. Practices that may be prevented are those that "constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market" (article 40.1). Practices are to be assessed case by case.

The application of these conditions will imply that restrictive business practices in such arrangements can only be condemned under a "competition test", thereby excluding other criteria such as the "development test" proposed during the – unsuccessful – negotiation of a Code of Conduct on Transfer of Technology in the 1980s (Roffe, 1985).

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<sup>30</sup> The conferred exclusivity, however, theoretically does not prevent generic firms from developing their own data in order to obtain marketing approval of a product (provided that it is off-patent). However, the cost of developing such data is normally unaffordable for firms in developing countries and the repetition of tests to duplicate information raise important ethical issues.

<sup>31</sup> In some cases, national authorities do not request the relevant test data and just rely on the approval granted in a foreign country.

## Chapter V. The Continuous Evolution of the TRIPS Agreement

As in the case of other WTO agreements, the legal framework established by the TRIPS Agreement is not cast in stone. Instead, it is constantly evolving, including through negotiations, members' work in the TRIPS Council under the "built-in agenda" or WTO dispute settlement. The following quickly sketches key issues related to the latter two points.

### *1. Implementation, review and built-in agenda*

The TRIPS Agreement, as adopted, included a "built-in agenda" relating to geographical indications, "non-violation" cases and the protection of biotechnological inventions. Little progress has been made so far on these issues, as reviewed below.

### **Geographical indications**

Article 23.4 of the TRIPS Agreement obliged members to undertake negotiations on the establishment of a multilateral system of notification and registration of geographical indications for wines. Different proposals have been made on the subject. The European Communities proposed an international registration of geographical indications according to which registered indications would be automatically protected in the participating members, subject to a procedure for dealing with oppositions from each member who considers that a geographical indication is not eligible for protection in its territory. On the other hand, United States and Japan envisage the development of an international database of geographical indications to which members would be expected to refer in the operation of their national systems. Both approaches have support from some other members (Otten, 1999: 7). In addition, several countries have proposed extending the enhanced protection now available to wines and spirits to other products, such as agricultural products and handicrafts.

### **Box 6. TRIPS and the July 2008 Ministerial Meeting**

Select TRIPS issues also played a role in the context of the WTO's July 2008 Mini-Ministerial. More specifically, discussions intensified on the three TRIPS issues of (i) the multilateral system of geographical indications (notification and registration) for wines and spirits, (ii) extension of stronger geographical indication protection for all products, and (iii) the disclosure requirement, including the relationship between TRIPS and the CBD. (The latter two are also "implementation" issues). In spring 2008, a large group of (more than 100) developed and developing countries called for "parallelism" among the three issues (which used to be on separate tracks), submitted a "draft modalities text" detailing key parameters for negotiating legal texts and suggested that intellectual property issues be included in the "single undertaking". This was further pursued in the mini-ministerial, where proponents called for the initiation of negotiations for the geographical indication extension, and for an inclusion in the TRIPS Agreement of a mandatory requirement for the disclosure of the origin of biological resources and/or associated traditional knowledge in patent applications. However, little progress was made and with differences persisting across countries (including as to whether these issues form part of a single undertaking and how to ensure parallelism), efforts focused on procedural issues that could help forge an agreement on these issues in the future. TRIPS issues have important poverty-, development- and Millennium Development Goal-related implications, including through their impact on local communities (e.g. protection of and benefit sharing for biological resources and traditional knowledge), farmers (e.g. protection of geographical indications for agricultural products) and the environment/sustainable development.

See Abbott (2008).

Proposals relating to the expansion of the products covered by an additional protection have been supported by a number of developing countries, such as Cuba, Dominican Republic,

Egypt, Honduras, India, Indonesia, Nicaragua and Pakistan (WT/GC/W/208), the African Group (WT/GC/W/302) and the Bolivarian Republic of Venezuela (WT/GC/W/282).<sup>32</sup>

### **Non-violation**

Article 64.1 of the TRIPS Agreement provides for a non-violation nullification or impairment (non-violation) remedy under the agreement. Paragraph 2 of article 64 stipulates that the non-violation remedy “shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement”. The purpose of this moratorium was to enable the Council for TRIPS to examine the scope and modalities for non-violation complaints in the context of TRIPS and make recommendations to the Ministerial Conference (article 64.3). A decision was to have been taken – by consensus – by the end of 1999 on whether to extend this period or to determine the disciplines to be applied.

Some countries have indicated the need for an extension of this transitional period. For the Bolivarian Republic of Venezuela, for instance, the moratorium should be extended given the fact that the Council for TRIPS has not been able to define either the scope or the modalities for non-violation complaints, as required by article 64.3. Moreover, “the history of the GATT and the WTO has produced very few precedents relating to proceedings of this type which would enable them to be conducted safely in terms of law. At the same time, we consider that there is a total lack of experience concerning how inter-state non-violation complaints could be applied to intellectual property rights, which are essentially private in nature” (WT/GC/W/282).

The African Group has suggested an “indefinite” moratorium for the application of article 64 (WT/GC/W/302). Canada has proposed<sup>33</sup> extending the moratorium until the work by the Council of TRIPS, as mandated under article 64.3, is completed. Canada argued that:

there has been no substantive discussion on scope and modalities by the Council for TRIPS as required under paragraph 3 of Article 64. ... The non-violation remedy was developed in a context wholly different from TRIPS as a means of ensuring market access. In Canada’s view, transplanting this remedy into the TRIPS environment is not suitable in the context of [intellectual property] and will introduce uncertainty into the Agreement, constraining Members’ abilities to introduce new and perhaps vital measures such as those related to social, economic development, health and environmental objectives. (WT/GC/W/256)

Despite the fact that the issue of “non-violation” has been discussed at the various WTO Ministerial Conferences, it remains unsettled. The great majority of members favour the non-application of this concept in the TRIPS context.

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<sup>32</sup> See also the communication from Turkey to the WTO General Council WT/GC/W/249 (Agreement on TRIPS, Extension of the Additional Protection for Geographical Indications to Other Products), 13 July 1999; and the communication from Bulgaria, Czech Republic, Egypt, Iceland, India, Kenya, Liechtenstein, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey to the Council of TRIPS (IP/C/W/201/Rev.1, 2 October 2000).

<sup>33</sup> See also the submission by the CEFTA (Central European Free Trade Agreement) countries and Latvia (WT/GC/W/275).



## Biological inventions

Article 27.3.b was the only provision in the TRIPS Agreement subject to an early review. So far, there has been no agreement in the Council for TRIPS on the meaning of “review”. Developed countries have held that it is a “review of implementation” that is called for, while for developing countries a “review” should open the possibility of revising the provision itself. The aim of some developed countries, if a revision takes place, would be to eliminate the exception for plants and animals, and to establish that plant varieties should be protected in accordance with the UPOV Convention as revised in 1991. For some developing countries, in contrast, it would be important to maintain the exception for plants and animals, as well as the flexibility to develop *sui generis* regimes on plant varieties that are suited to the seed supply systems of the countries concerned.

In paragraph 19 of the Doha Ministerial Declaration,<sup>34</sup> the trade ministers instructed the Council for TRIPS to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD. Although the Council for TRIPS undertook such an examination, no outcome has been achieved. Developing countries have repeatedly voiced their concerns about biopiracy and the potential inconsistencies between the system of appropriation under the TRIPS Agreement and the principles of the CBD. They have proposed the establishment – through an amendment to article 29 of the agreement – of a legally binding obligation to disclose the source of biological materials claimed in patent applications (Sarnoff and Correa, 2006).

### 2. Dispute settlement and case law

Since very little jurisprudence exists so far in WTO on the interpretation of the TRIPS Agreement, an important task is to define the scope and extent of existing obligations under the standard method of treaty interpretation. In interpreting the TRIPS Agreement in the cases so far brought to dispute settlement in WTO, the panels and the Appellate Body have extensively relied on previous GATT and WTO jurisprudence, and applied the customary rules of interpretation as contained in articles 31 and 32 of the Vienna Convention on the Law of Treaties.

#### Box 7. The Vienna Convention as an interpretative tool

According to article 31(1) of the Vienna Convention, “a treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” The convention also admits as an element for interpretation the “subsequent practice” by the parties to a treaty,<sup>35</sup> as well as certain “Supplementary Means of Interpretation”. Article 32 of the convention provides that “recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of Article 31, or to determine the meaning when the interpretation according to Article 31: (a) leaves the meaning ambiguous or obscure; or (b) leads to a result which is manifestly absurd or unreasonable.”<sup>36</sup>

A corollary of these rules of interpretation, addressed in several GATT/WTO cases,<sup>37</sup> is the concept of “effective interpretation” (“l’effet utile”), which requires that a treaty be interpreted

<sup>34</sup> WTO document WT/MIN(01)/DEC/1, available at [www.wto.org](http://www.wto.org).

<sup>35</sup> The Appellate Body ruled in *Japan – Alcoholic Beverages* that “the essence of subsequent practice in interpreting a treaty has been recognized as a ‘concordant, common and consistent’ sequence of acts ... which is sufficient to establish a discernable pattern implying the agreement of the parties regarding its interpretation.”

<sup>36</sup> The negotiating history may include the history of the conventions that are specifically referred to by the TRIPS Agreement, such as the Paris Convention and the Berne Convention, and not only the negotiating history of the TRIPS Agreement as such.

<sup>37</sup> See e.g., WT/DS121/AB/R, para. 88. See also Mengozzi (1999: 26).

to give meaning and effect to all the terms of the treaty. Accordingly, whenever more than one interpretation is possible, preference should be given to the interpretation that will give full meaning and effect to other provisions of the treaty.

The Doha Declaration on the TRIPS Agreement and Public Health provides guidance for the interpretation of key provisions of the TRIPS Agreement, such as article 6 (exhaustion of rights) and article 31 (compulsory licenses) and, more generally, for the application of the agreement to situations raising public health considerations.

So far, there have been 25 complaints under the WTO Dispute Settlement Understanding partly or entirely directly related to the TRIPS Agreement. However, only nine reached the stage where a panel was appointed to determine a violation. While WTO panel and Appellate Body rulings cannot add or diminish existing obligations, they can nevertheless offer important guidance regarding their interpretation. The following sketches select key disputes where the TRIPS Agreement played a role.

In the United States-India and EU-India cases,<sup>38</sup> the complaining parties argued that India had failed to provide a mechanism for implementing the “mailbox” to be established in accordance with article 70.8 of the TRIPS Agreement. India was found to have failed to comply with its obligations under that article, since there was no legal basis – procedurally or substantively – for the grant of exclusive marketing rights when a product that is the subject of a patent application under article 70.8 became eligible for protection under article 70.9 of the TRIPS Agreement. In order to comply with article 70.9 of the Agreement, the President of India promulgated on 31 December 1994 an ordinance (the Patents (Amendment) Ordinance 1994) so as to provide a means for the filing and handling of patent applications for pharmaceutical and agricultural chemical products, and for granting of the exclusive marketing rights. The ordinance was issued on the basis of the President of India’s constitutional powers to legislate when the Parliament is not operative but, lacking Parliament’s confirmation, it lapsed on 26 March 1995. The “exclusive marketing rights” were later implemented by the Patents (Amendment) Act 1999.

In the United States-Canada case,<sup>39</sup> the United States challenged section 45 of Canada’s Patent Act. It claimed that the patent protection term of 17 years (counted from the date of grant) accorded to patent applications filed before 1 October 1989 often ended before 20 years from the date of filing. The United States argued that pursuant to articles 33 and 70.2 of the TRIPS Agreement, Canada was obligated to make available a term of protection that did not end before 20 years from the date of filing to all inventions that enjoyed patent protection on 1 January 1996, including those protected by the old Patents Act. Inventions enjoying protection under that act were covered by article 70.2 of the TRIPS Agreement (protection of “subject matter” existing on the date of application of the TRIPS Agreement). The United States prevailed: the Canadian law was found inconsistent with the agreement.

The TRIPS Agreement was incidentally invoked in the Indonesia-Autos case, in relation to the protection of trademarks. The panel, however, found that the United States had not demonstrated that Indonesia was in breach of its TRIPS obligations.<sup>40</sup>

The European Commission (EC)-Canada case<sup>41</sup> addressed the TRIPS consistency of sections 55(2)(1) and (2) of the Canadian Patent Act, as revised in 1993, regarding the “early working”, “regulatory review” or Bolar exception. This exception permits the use of a patented invention, without the consent of the patent holder, for testing required for the submission of data to obtain marketing approval for pharmaceutical products. The request for a panel was submitted in

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<sup>38</sup> See WT/DS50 and WT/DS79/R.

<sup>39</sup> See WT/DS170/R.

<sup>40</sup> See WT/DS 54/R, WT/DS 55/R, WT/DS 59/R, WT/DS 64/R.

<sup>41</sup> See WT/DS114/R.

November 1998 by the EC and its member States. In March 2000, the panel concluded that Canada was not in violation of the TRIPS Agreement. However, Canada was found to be acting inconsistently with TRIPS in terms of the permitted practice of manufacturing and stockpiling pharmaceutical products during the six months immediately prior to the expiry of the 20-year patent term. The panel report was not appealed.

Upon a complaint by the European Communities, a panel found that section 110(5)(b) of United States copyright law – relating to the enjoyment of certain works by customers in business premises – was inconsistent with article 13 of the TRIPS Agreement.<sup>42</sup>

In *United States – Section 211 Omnibus Appropriations Act of 1998*, several issues regarding the protection of trade names and trademarks were addressed.<sup>43</sup> The applicability of the Paris Convention for the Protection of Industrial Property to such matters was confirmed.

Two cases against the European Communities involved a complaint by the United States<sup>44</sup> that covered a broad list of violations under TRIPS and GATT 1994 relating to national treatment and MFN treatment of agricultural products and foodstuffs, violations of the exclusive rights granted to trademark owners, and lack of adequate enforcement procedures. Australia<sup>45</sup> made a list of complaints similar to the United States, in addition to other violations under the Agreement on Technical Barriers to Trade (Gad, forthcoming).

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<sup>42</sup> See WT/DS160/R.

<sup>43</sup> See WT/DS/176.

<sup>44</sup> *EC – Trademarks and GIs (US)*, Request for the Establishment of a Panel by the United States, WT/DS174/20 (19 August 2003).

<sup>45</sup> *EC – Trademarks and GIs (Australia)*, Request for the Establishment of a Panel by Australia, WT/DS290/18 (19 August 2003).



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## **Annex I**

### **Relevant Web Pages**

<http://www.bilaterals.org/>

[www.ciel.org](http://www.ciel.org)

[www.ictsd.org](http://www.ictsd.org)

<http://www.ip-watch.org>

[www.iprcommission.org](http://www.iprcommission.org)

[www.iprsonline.org](http://www.iprsonline.org)

[www.oxfam.org.uk](http://www.oxfam.org.uk)

[www.southcentre.org](http://www.southcentre.org)

[www.twinside.org.sg](http://www.twinside.org.sg)

[www.unctad.org](http://www.unctad.org)

<http://www.who.int/intellectualproperty/en/>

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