

**INTEGRATING PUBLIC HEALTH
CONCERNS INTO PATENT LEGISLATION
IN
DEVELOPING COUNTRIES**

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THE SOUTH CENTRE

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FOREWORD

The developing countries today face the complex challenge of implementing various international agreements that were negotiated during the Uruguay Round. In the process, they are becoming aware of the many far-reaching implications for their development, economies and societies inherent in some of these agreements.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is a case in point. Its implementation is emerging as a major concern for all developing countries.

The present document was prepared with the intention of assisting the developing countries in their efforts to adapt their laws to the standards set by TRIPs in relation to pharmaceutical products and processes, in the context of a general concern that such legislative reform can have a major impact on people's access to drugs and on public health policies in the South. In particular, the document aims to show that various options exist for developing countries in formulating their national legislation in conformity with the relevant provisions of TRIPs.

The importance of policy-oriented and technical analyses of this kind for developing countries is evident. They provide essential, practical tools to assist developing countries in promoting their national and global development objectives.

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Any views expressed are the views of the author and do not necessarily reflect the views of the Rockefeller Foundation or of the World Health Organization. The author is solely responsible for this final text.

This document has been edited by Robert Weissman.

GLOSSARY*

- ◆ **Best mode:** The best way known by the inventor at the time of filing a patent application for carrying out or practicing the invention.
- ◆ **Claim:** One or more statements in a patent or application that precisely define the specific features of the invention for which patent protection is granted or sought.
- ◆ **Compulsory license:** The authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general interest (absence of working, public health, anticompetitive practices, emergency, national defense).
- ◆ **Disclosure:** A description or revelation of an invention made by the inventor. It also applies to acts of divulgation, including those made by third parties, that may destroy the novelty of an invention.
- ◆ **Doctrine of equivalents:** A conceptual framework to determine whether a violation exists when there is no literal infringement of patent claims.
- ◆ **Essential drugs:** Drugs selected for their efficacy and safety to meet the priority health needs in a given country or region. The essential drugs concept has been the basis of WHO's drug strategy since 1975. The criteria for incorporating a drug in the WHO list of essential drugs also includes price considerations.

* This Glossary is partially based on Lechter, 1995; Vaver, 1999; Velásquez and Boulet, 1999. It focuses on terminology relating to the patent field, though some terms have a broader use.

- ◆ **Exhaustion of intellectual property rights:** Doctrine according to which a patent holder "exhausts" his/her rights

after the first legitimate sale of the patented product in a country, region or on the international market. It provides a legal justification for the admission of parallel imports.

- ◆ **Generic drug:** A pharmaceutical product which is not protected by a patent in force, and which is commercialized under a non-proprietary name or a brand name.
- ◆ **Infringement:** The unauthorized making, using, or selling of a product or process that uses an invention protected by a patent. The determination of an infringement allows the right-holder to recover civil remedies against the infringer. Some infringements are also criminal offences.
- ◆ **Intellectual property:** A category of public law that generally includes copyrights, patents, trademarks, geographical indications, industrial designs, utility models, plant breeder's rights, integrated circuits rights and trade-secrets. A *sui generis* regime for data bases has also been established in some countries.
- ◆ **License (voluntary):** Authorization given by a right-holder (licensor) to someone (licensee) to exercise acts that only the licensor can legally do.
- ◆ **Novelty:** Requirement of patentability. It exists when an invention was not made publicly available (generally anywhere in the world) before the date of application of the patent.
- ◆ **Obviousness/inventive step:** Requirement of patentability. It is generally met when the invention is not obvious to a person normally skilled in the relevant field of technology.
- ◆ **Parallel import:** The importation, without the authorization of the owner of an intellectual property right, of a protected product marketed abroad by the patentee or by an authorized party.
- ◆ **Patent:** A title granted to protect an invention, generally for a twenty-year period.

- ◆ **Patentee:** The owner or holder of a patent.
- ◆ **Patent application:** A legal petition that describes an invention and specifies the claims.
- ◆ **Patent Co-operation Treaty:** A 1978 agreement administered by the World Intellectual Property Organization (WIPO) under which inventors can file international applications in a member country and, after a search of prior art or preliminary examination, have them forwarded to other member countries for independent determination of patentability.
- ◆ **Prior art:** All of the pertinent and applicable knowledge in the public domain at the time a patent application is filed.
- ◆ **Priority right:** The right to acquire an intellectual property right where competing applications are filed, based on the priority in the date of application.
- ◆ **Right-holder/title-holder:** Terms used to indicate anyone with a proprietary interest in an intellectual property right.
- ◆ **Sui generis:** A term meaning a specialized regime of intellectual property rights, separate from copyright, patents and other chapters of intellectual property rights.
- ◆ **Working:** The use of an invention in a commercial context, such as manufacturing of a patented product, use of a patented process and commercialization of a protected product. In some cases, also the importation of a patented product.

I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) requires all WTO Member countries to adapt their laws to the minimum standards set out in the Agreement, within established transitional periods. Conforming with the Agreement by recognizing or strengthening the protection of pharmaceutical products and processes by intellectual property rights (IPRs) has posed a special challenge for developing countries. The way in which the required legislative reform is made may have a significant impact on public health policies, and particularly on the population's access to drugs.

This document presents options for the design and implementation of public-health-sensitive patent policies in developing countries. It examines approaches to selected issues in patent law that may help to strike a balance between the public and private interests involved in the protection of health-related inventions, including those of States, patients, and of the suppliers of health-related goods and services. This document has been prepared as part of an initiative aimed at exploring health-related aspects of intellectual property rights that may further the needs of the poor and excluded in developing countries. It is primarily addressed to policy makers and others concerned in the field of public health in developing countries.

I.1 Context

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The basic premises of this work are that, within the limits imposed by international obligations, notably the TRIPs Agreement¹ of the World Trade Organization, developing country patent laws should be: a) designed to serve the interests of all groups in the society, and b) responsive to health policy objectives and, in particular, to the needs of the poor.

There is broad recognition of the role that patents and IPRs can play in stimulating health-related research and development (R&D), particularly in the more advanced countries. Patents are considered particularly important given the high costs and risks of R&D and the fact that this R&D may lead to inventions of potential use to all countries². There is also recognition that the level of protection conferred on inventions may influence foreign investment, technology transfer and research (especially joint research programs and research to address local needs)³. Patents work by providing government-sanctioned, limited-term monopolies as an incentive and reward for useful inventions.

But there are price and competition costs to IPRs. In the health sector, where denial of affordable access to treatment or pharmaceuticals can have life-or-death consequences, the conditions, including price, that determine access to medicines are critical matters, especially for the low-income segments of the population. While recognizing that IPRs are not the only relevant factor, it seems clear that the way in which IPRs are established and enforced may have a significant impact on access to medicines; any IPR system must therefore strike a balance

¹ For a general analysis of the TRIPs Agreement and of the timing for its implementation under the specified transitional periods, see UNCTAD, 1996; Correa and Yusuf, 1998; Velasquez and Boulet, 1999; Correa, 2000.

² On the little attention paid, however, in pharmaceutical R&D to the specific needs of developing countries, see e.g., Beaglehole and Bonita, 1997, p. 220; Sachs, 1999; Chowdhury, 1995.

³ The theoretical work and empirical evidence on such influence are, however, controversial and inconclusive. See, e.g., United Nations, 1993; Maskus, 1998.

between creating incentives for innovation and consumers' interest in the availability and access to the protected goods.

The TRIPs Agreement has introduced a new and important international framework for IPRs -- which in turn has important implications for the health sector⁴. The TRIPs Agreement sets out detailed obligations in respect of the protection of inventions⁵, including:

- to recognize patents for inventions in all fields of technology, with limited exceptions;
- not to discriminate with respect to the availability or enjoyment of patent rights;
- to grant patent rights for at least twenty years from the date of application;
- to limit the scope of exceptions to patent rights and to grant compulsory licenses only under certain conditions;
- to effectively enforce patent rights.

The TRIPs Agreement, however, does not establish a uniform international law nor even uniform legal requirements. WTO member countries are obliged to comply with the minimum standards of the TRIPs Agreement. But they also have considerable room to develop their own patent and other intellectual property laws in response to the characteristics of their legal systems and developmental needs. In implementing the TRIPs provisions, WTO Member countries may legitimately adopt regulations that ensure a balance between the minimum standards of IPR protection and the public good. Moreover, they can adopt measures which are conducive to social and economic welfare (Article 7 of the TRIPs Agreement), such as those necessary to protect public health, nutrition and the public interest in sectors of

⁴ See, e.g., Bale, 1991; Velasquez and Boulet, 1999.

⁵ See, e.g., Sandri, 1996; Correa and Yusuf, 1998.

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vital importance for their socio-economic and technological development. Countries can also adopt measures to prevent the abuse of intellectual property rights (Article 8.1 and 8.2 of the TRIPs Agreement).

It should be borne in mind that in the case of the countries that are bound to introduce patent protection for pharmaceuticals as a result of the TRIPs Agreement, patents will only be available for products for which a patent application was filed after 1 January, 1995. This means that other products (including those already applied for or patented in other countries, or commercialized before that date) will remain in the public domain, unless the national law admits (as in the case of Brazil) the retroactive protection of the so-called “pipeline” products.

Given diverse national objectives, it is not surprising that different countries’ patent systems diverge, in some cases significantly. There is no single “patent system”. Moreover, the solutions adopted in particular countries have changed over time⁶. In the future, they may evolve further in order to better respond to equity considerations⁷ and to the nature of innovation in “cumulative systems technologies”⁸.

Countries treat specific patent issues -- including eligibility requirements, scope of protection, exceptions to exclusive rights and compulsory licenses -- in quite different ways. In developing their own IPR rules, policy and law makers in developing countries must recognize that, even within the general framework of international treaties, there is considerable room for devising and

⁶ Thus, many developed countries applied in early phases of their development legal solutions (such as the non-patentability of pharmaceutical products) more recently adopted by developing countries. For an analysis of the evolution of the patent system, see, e.g., Penrose, 1974; Bercovitz, 1990; Goldstein, 1993.

⁷ See, e.g., Thurow, 1997; Sachs, 1999.

⁸ See, e.g., Merges and Nelson, 1996.

implementing their own solutions on particular matters. Countries will be most successful in meeting their own needs if they are able to draw on the varied experience of national systems worldwide, which means that a good knowledge of comparative law is valuable⁹.

Some countries -- particularly developed countries -- have opted for legal systems that confer strong patents rights. They have done so in order to protect revenue streams from their already established technological base and to promote investment in technological innovation. There is considerable debate in such countries, however, on the level and scope of protection which are optimal to foster innovation without unduly restricting the free circulation of ideas and stifling competition¹⁰. A growing concern is voiced in some countries¹¹ on the shortcomings of the examination process and the proliferation of low quality patents (see Section IV). Moreover, the economics of patent law is still an uncertain area, for which a robust theoretical framework and empirical evidence are lacking.

Less technologically advanced countries may logically prefer to promote the transfer of technologies needed for development, and to preserve and enhance competition in order to secure access to goods, services and technologies on the most favourable market terms. Even in the countries which advocate and practice the strongest protection for IPRs, national laws provide for checks and balances to protect against the possible abuse of the powers

⁹ See, e.g., Oddi, 1996.

¹⁰ See, e.g., Scherer, 1981; Merges and Nelson, 1996; Thurow, 1997.

¹¹ See, e.g., Gleick (2000), who argues that “the patent system is in crisis...The (US) patent office has grown entangled in philosophical confusion of its own making; it has become a ferocious generator of litigation; and many technologists believe that it has begun to choke the very innovation it was meant to nourish”, p. 44.

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conferred by intellectual property protection (the provision for compulsory licenses is one such example)¹².

In designing a national patent system, policy makers should consider cross-cutting issues, such as the protection of the environment¹³ and public health, the promotion of competition¹⁴ and technology transfer¹⁵, the protection of consumers and the support of small local inventors, while respecting inventors' rights to obtain a reward for contributions made to technical progress.

In addition, careful consideration should be given to other regulatory measures affecting public health, such as those relating to the approval and registration of medicines, in order to develop a consistent legal framework that enhances access to required medicines.

The protection of public health is one of the most pressing issues in developing countries. A large part of the world population still lacks access to essential drugs; in the poorest parts of Africa, for instance, over 50 per cent of the population lack that access¹⁶. An estimated 1.5 billion people are not expected to survive to the age of 60, and more than 880 million people lack access to health care¹⁷. Of the more than 33 million HIV-positive people in the world, 95 per cent live in developing countries, and most of them

¹² See, e.g., Gutterman, 1997; Anderson and Gallini (Ed.), 1998.

¹³ See, e.g., the proposals for amendment of the TRIPs Agreement by the government of India, submitted to the WTO Committee on Trade and the Environment (WTO/CTE/1, 12 November, 1996).

¹⁴ See, e.g., Reichman, 1994 and 1997.

¹⁵ See, e.g., Correa, 1999c.

¹⁶ See, e.g., WHO, 1998. It should be noted that the great majority of "essential drugs" as identified, for instance, by WHO, are "off-patent" and the access thereto will not be affected by the implementation of new patent policies. The discussion in this paper refers only to drugs which are or may be protected in the future by patents or other IPRs.

¹⁷ See, e.g., UNDP, 1999.

cannot afford the necessary drugs¹⁸. To deal with this dramatic situation, an integrated approach to the deeply inter-related issues of national health policy, pharmaceutical policy and patent policy is required. None of these policies can be framed or implemented in isolation.

I.2 A Public Health Perspective

This document deals with patent issues from the perspective of *public health*. It focuses on issues relating to *access* to medicines. It therefore concentrates on provisions and mechanisms in patent laws that may increase the *affordability* of medicines (including diagnostics, preventive and curative medicines) rather than those more relevant to the development of new drugs or the production of pharmaceuticals, though the three issues are often interlinked.

The purpose of this monograph, however, is not to provide *specific* provisions for health-related inventions, but to suggest more *general* principles and rules that could be instrumental in developing a health-sensitive national patent system.

One reason for this approach is that developing a public health-sensitive patent system requires consideration of many key general aspects (such as the criteria for patentability). A second reason is that article 27.1 of the TRIPs Agreement bans any discrimination, in either the recognition or exercise of patent rights, based on the field of technology. This means that both negative discrimination (e.g., reducing the rights available to pharmaceutical patent holders) and positive discrimination (broadening such rights) may be deemed TRIPs-inconsistent. In the latter case, broadening rights available to holders of pharmaceutical patents could be deemed inconsistent because it could discriminate against patent owners in *other* fields of technology¹⁹. However, differential

¹⁸ See, e.g., UNAIDS, 1998.

¹⁹ Thus, a panel was requested by Canada against the European Union in the framework of the WTO dispute settlement mechanism, on the grounds

treatment does not necessarily mean discriminatory treatment because different technologies might require different treatment.

A health-sensitive approach could aim to address short-term emergencies that could justify several sorts of temporary measures (for instance, for the supply of medicines in cases of epidemics or catastrophe), or be devised as part of an integrated medium or long-term patent policy and strategy. In the latter case, attention should be given to the diversity among developing countries, and to the possibility that countries with greater capacity may want stronger patent rights than those with less. Such countries may wish, for instance, to develop a patent system that fosters cooperation with firms from more advanced countries.

In some instances, a country may -- within the limits permitted by its international obligations -- opt for different levels of protection in different areas of intellectual property depending on its respective competitive position and the expected role of national and foreign investors and technology suppliers. It may, for instance, be possible to emphasize protection in the area of information technologies through high levels of copyright protection for computer programs and databases, while recognizing more moderate levels of protection in areas where local industrial and technological capabilities are low and unlikely to be significantly improved through high standards of protection.

I.3 Scope

This document focuses on issues in patent law most relevant from a public-health perspective. The intention is not, however, to ignore

that pharmaceutical patents can get in Europe an additional term of protection, which is excluded for other fields of technology (except agrochemicals). This request, however, has not been pursued so far.

or downplay the relevance of issues that are not specifically addressed here, such as:

- procedures followed by patent offices and for the enforcement of rights;
- the interface between patent and competition law;
- issues relating to the use of trademarks in relation to medicines;
- the protection of test data submitted for the approval of medicines for commercialization²⁰.

A number of issues considered in this document may need to be addressed in implementing regulations and guidelines for patent offices, as well as in patent laws. Training of personnel in charge of patent law and regulation application is also an essential component of a patent policy. Developing a cadre of skilled personnel is particularly important, for instance, for applying patentability requirements, which depends on case-by-case evaluations.

The legal options presented in this document are intended to provide elements for national legislation which are compatible with the TRIPs Agreement. Though this Agreement may be reviewed²¹, the model options presented here are based on its existing provisions.

The way in which such options are implemented should be consistent with the level of development of each country and, in particular, with its research and manufacturing capabilities in the pharmaceutical sector. Understandably, the options followed by a

²⁰ See, however, a brief consideration of this issue in Section X on “Compulsory licensing”.

²¹ Several developing countries have submitted proposals to review the TRIPs Agreement. See, e.g., Correa, 2000.

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large developing country with significant capabilities in that sector may differ from those preferred by a small economy which is totally or substantially dependent on foreign supplies of pharmaceuticals. Likewise, patent laws may evolve as a country develops. It should be borne in mind, however, that problems of access to drugs caused by poverty and low income are common to most developing countries.

The document provides a brief discussion of the main issues to be considered with respect to the patentability of health-related products and processes. For each item, there is an explanation of the concept, the treatment found in comparative law and the implications of the TRIPs Agreement. For each of the various issues, this document presents key principles and options for the development of provisions in national patent laws. These principles aim to provide the basic concept on which more detailed provisions could be fashioned, after careful deliberation and consideration of the characteristics of each national legal system and patent law.

II. PATENTABLE SUBJECT MATTER

II.1 Products

When the Uruguay Round of trade negotiations was launched, more than fifty countries (including some developed countries) did not confer patent protection on pharmaceuticals²². While some regarded this absence of protection as necessary to promote access to drugs at competitive prices²³, others criticized it as jeopardizing innovation and unfairly depriving inventors of the benefits generated by their contributions.

The TRIPs Agreement obliges all WTO Members to recognize patents in all fields of technology (Article 27.1)²⁴. When fully in force, this obligation will have eliminated the varying patent policy approaches that previously existed.

Literally interpreted, Article 27.1 does not permit the exclusion from patentability of medicines in general or, arguably, of specific groups thereof. Under this interpretation, WTO Members could not exclude from patentability even the “essential medicines” listed by the World Health Organization (WHO)²⁵.

²² See, e.g., UNCTAD, 1996.

²³ The specific implications of the patent system and, particularly, of the introduction of product patents in developing countries in the pharmaceutical field has been extensively discussed. See, e.g., Nogues, 1990; Redwood, 1994; Rozek, 1993; Subramanian, 1995; UNCTAD, 1996.

²⁴ According to article 27.1, “patents shall be available for any inventions, whether products or processes, in all fields of technology”. See e.g. Straus, 1996.

²⁵ Currently Decision 344 of the Andean Group provides for such exception. Venezuela has submitted a proposal to review the TRIPs

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There are two exceptions in the TRIPs Agreement under which pharmaceuticals might conceivably be excluded from patentability, but neither appear sufficient to justify such an exclusion, except in limited circumstances.

The first is *ordre public*, one of the recognized grounds for exceptions from patentability under TRIPs Article 27.2. There is no universally accepted notion of *ordre public*²⁶, leaving member countries some flexibility to define which situations are covered, depending upon their own social and cultural values. Article 27.2 itself indicates that the concept is not limited to “security” reasons; it also relates to the protection of “human, animal or plant life or health” and may be applied to inventions that may lead to “serious prejudice to the environment”.

Article 27.2 indicates that non-patentability on grounds of *ordre public* is permissible if necessary to prevent commercial exploitation. In other words, it may not be possible to declare the

Agreement in a possible future WTO Round in order to specifically allow for that exclusion (see document WT/GC/W/282, 6 August, 1999). However, it has been noted that most of the drugs in the WHO list of Essential Medicines are off-patent, and that the list does not include high priced drugs. Given the methodology applied for establishing that list, the non-patentability of such drugs may not be a significant issue for developing countries. See MSF, HAI and CPT, 1999.

²⁶ For instance, under the Guidelines for Examination of the European Patent Office “ordre public” is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour (Part C, chapter IV, 3.1). Traditionally, “ordre public” in United States law referred to an invention that was “frivolous or injurious to the well-being, good policy, or sound morals of a society.” *Lowell v. Lewis*, 15 (a. 1018 No. 8568) (C.D. Mass. 1817), quoted in Chisum and Jacobs, 1992, p. 2.5. In the United States, “the trend is to restrict this subjective public policy approach to utility” (*Idem*).

non-patentability of a certain subject matter while permitting at the same time its distribution or sale²⁷.

However, the situation might be different if developing countries all over the world (or their regional organizations) collectively decided to prohibit or suspend the patentability of certain pharmaceutical products on grounds of *ordre public*. Such a decision could produce a new “state practice” that WTO panels would have to take into account. If the grounds of such a decision were sufficiently compelling to warrant at least a temporary expansion of the *ordre public* exception beyond its traditional moorings, it could also conceivably warrant an exception to the “non commercial exploitation” rule contained in Article 27.2, if such products were distributed on a not-for-profit basis. These matters are inherently speculative and to some extent contingent upon the still-to-be-determined meaning of the safeguard provisions set out in the TRIPs Agreement (See Articles 7 and 8).

A second exception which might authorize exclusion of pharmaceuticals from patentability is Article 8.1 of the TRIPs Agreement, which explicitly recognizes the right of WTO Members to adopt policies in accordance with public health concerns. However, the adopted policies are subject to a test of “necessity” and of consistency with other obligations under the TRIPs Agreement.

The “consistency” requirement may permit patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from ordinary or everyday health and nutrition measures. Emergency cases could trigger the application of a different test of “inconsistency” (as provided for under Article 8.1) or qualify as a situation not “conducive to social and economic welfare” (as provided for under Article 7). In such a case, a suspension or exclusion from patentability might be linked to and justified by a specific

²⁷ See, e.g., Correa and Yusuf, 1998, p, 193. For a different opinion, see, e.g., Leskien and Flitner, 1997.

emergency. Once the emergency subsides, the TRIPs requirement of patentability could be restored.

A key consideration is clearly the purpose for which any subject matter exclusion were to be adopted. If, for example, the same objective could be obtained by imposing permissible compulsory licenses under Article 31, an exclusion of patentability could be seen as merely an attempt to circumvent the pre-conditions of Article 31. If, instead, local situations posed such unusual problems as to merit a public interest exception, these problems might also justify overriding or limiting other articles, such as Article 31, in favour of some non-permanent exclusion of subject matter, if that exclusion was necessary to solving the problem.

An issue that may merit further exploration is whether an exception to patentability may be justified under the general GATT exception to trade disciplines, when the exception is necessary to protect public health (Article XX(b))²⁸. This article recognizes the importance of sovereign nations being able to promote domestic health interests, even if contrary to their general obligations under the WTO agreements²⁹. However, to date, Article XX(b) has been interpreted and applied rather narrowly in GATT/WTO case law³⁰, and it is doubtful whether GATT Article XX(b) would apply in the TRIPs context. In the view of a panel, the TRIPs Agreement has a relatively self-contained, *sui generis* status within the WTO, even though “it is an integral part of the WTO system, which itself

²⁸ “Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:...

(b)necessary to protect human, animal or plant life or health;...”

²⁹ See, e.g., Jackson, 1999, p. 233.

³⁰ See, e.g., Petersman, 1998; Trebilcock and House, 1999, p. 135-165.

builds upon the experience of over nearly half a century”³¹ under the GATT.

In sum, under the current TRIPs Agreement, a straightforward exclusion from patentability of pharmaceuticals -- even the category of essential medicines -- does not seem to be a viable option. The admissibility of exceptions based on *ordre public* will depend on the interpretation of both Article 27.2 and Articles 7 and 8, but does not seem a promising basis for exclusion from patentability³². Exclusions to meet specific public health emergencies, especially if limited in time, might be justifiable if they are a necessary part of an overall strategy for addressing the emergency.

II.2 Substances Existing in Nature

Some pharmaceutical products are based on, or consist of, biological materials. These include compounds extracted from plants and algae as well as human proteins³³ obtained by extraction

³¹ See the Panel Report on USA vs. India – Patent Protection for Agricultural and Chemical Products, WT/DS50/R, adopted on 16 January 1998, para 7.19.

³² It should also be noted that in many cases it may be difficult or impossible to anticipate *ordre public* considerations at the time of examination of an application, since such considerations may arise after the patent is granted (or the product is commercialized). In these cases, the granting of a compulsory license would be a logical option. See Section X.

³³ For instance, a patent claim relating to a protein isolated from nature reads as follows: “*Homogeneous erythropoietin characterized by a molecular weight of about 34,000 dalton on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least 160,000 IU per absorbance unit at 280 nanometers*” (US patent No. 4,677,195). This claim was deemed invalid by a U.S court as overly broad and indefinite. See Silbey, 1994, p. 17.

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or through genetic engineering techniques (e.g., interferon, erythropoietin, growth hormone). Plants, in particular, are an indispensable source of medicines³⁴.

Whether biological materials are patentable depends in significant part on whether they are characterized as “inventions” (and therefore patentable) or “discoveries” (not patentable). Different patent law traditions treat this question differently.

If the philosophy underpinning patent law is that broad protection can foster inventive activity, then biological materials exceptions may seem unnecessary, or even counterproductive. Moreover, some developing countries may worry that excluding substances found in nature from patentability could conceivably hinder investment in some local activities, including activities that might otherwise lead to patents on products derived from traditional knowledge or specific local skills or know-how. The extent of any such disincentive, however, would depend on local industrial capabilities and on the existence of laws providing alternative forms of protection, including utility model laws or proposed laws to protect non-secret know-how³⁵.

Countries with scarce local research capabilities and countries prioritizing medicine affordability and access may prefer a different approach, choosing to seek limitations on the patentability of substances existing in nature. Countries which deem patentability of such substances as contrary to basic cultural and ethical values³⁶ may similarly seek to limit biological materials' patentability. The ability to do so will be limited, however, by the provisions of the TRIPs Agreement which requires the patentability of microorganisms and of non-biological and

³⁴ See, e.g., Lambert, Srivastava and Viemeyer, 1997, p. 1.

³⁵ See, e.g., Reichman, 1997.

³⁶ 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 August 6, 1999).

microbiological processes for the production of plants and animals (Article 27.3.b).

National laws vary considerably in characterizing biological materials as inventions or discoveries. In some jurisdictions (e.g., the United States) an isolated or purified form of a natural product, including genes,³⁷ is patentable³⁸. The European Directive on Biotechnological Inventions (No. 96/9/EC of March 11, 1996)³⁹ adopts a similar approach. The Directive, essentially declaratory of long standing law throughout much of Europe, establishes that “biological material” and substances isolated from nature (such as new antibiotics) will be considered patentable⁴⁰.

BOX 1
PATENTING OF GENES

In many jurisdictions, gene patenting has become common practice. Claims often include natural DNA sequences without limitations.⁴¹ The only condition on these patents is that genetic materials must be claimed in a non-naturally-occurring form, that is, as an isolated or

³⁷ For instance, claim 2 of a U.S. patent obtained by Amgen reads: “A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin”.

³⁸ See, e.g., Bent et al, 1991, p, 123; Grubb, 1999, p. 213. The extent of patentability of biological materials in the USA has not been addressed yet, however, by the Supreme Court.

³⁹ “Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature” (article 3.2).

⁴⁰ See, e.g., Grubb, 1999, p. 213. See also Sena (1999, p. 736-738) who suggests the use of compulsory licenses to remedy the possible negative effects on subsequent research that may result from the extension of patentability to simply isolated materials.

purified molecule. In the United States, for example, the doctrine of *Re Deuel* (1995) has paved the way for the patenting of DNA even when encoding known proteins on the grounds that -- due to the degeneracy of the genetic code -- their structure could not have been

(continued)

predicted.^{b)} However, the principle set out in *re Duel* does not apply in Europe. Gene sequences which code for a known protein are generally now regarded as *prima facie* obvious, although such was not the case in the earliest days of molecular biology.

Some developing countries, in contrast, have explicitly excluded the patentability of existing biological materials, unless they are genetically altered.^{c)} This stance may exclude certain biotechnology-based products from the patent domain, though patents may still be granted for the process used to obtain the biotechnology-based product.

In Canada, the Federal Court of Appeal (in a case relating to a new hybrid soybean variety) rejected the claim that hybrid plants were a “manufacture or composition” (and hence patentable). The court held that since the hybrids were not “produced from raw materials” or “a combination of two or more substances united by chemical or mechanical means”^{d)}, they were not patentable. Since that decision, the Canadian Patent Office has denied patents for higher life forms like plants and animals. For instance, the patentability of the Harvard University “oncomouse” was rejected in 1995 and the denial upheld by a court in 1998 (still pending final decision).

^{a)} *Patenting may relate to genomic DNA, a natural substance, or cDNA, that is, a DNA copy of mRNA that does not exist as such in nature. The US Court of Appeals for the Federal Circuit has affirmed the validity of claims to full length DNA or genomic DNA molecules in the pharmaceutical field. See, e.g., Ducor, 1998.*

^{b)} *See, e.g., Baldock, 1999, p. 21.*

^{c)} *Thus, the Mexican law (1991/1994) excludes the patentability of all genetic materials. The Argentine patent law (1995) and the Andean Group Decision 344 (1993), do not allow, in principle, the patentability*

of materials existing in nature. The Brazilian patent law (1996), stipulates that no patents shall be granted with respect to living beings or “biological materials found in nature”, even if isolated, including the “genome or germplasm” of any living being.

^{d)} PioneerHi-Bred Ltd. v. Canada (Commissioner of Patents), 1989, 1 S.C.R. 1623. See e.g., Vaver, 1997.

The TRIPs Agreement does not define what an “invention” is; it only specifies the requirements that an invention should meet in order to be patentable. This leaves Member countries considerable freedom to determine what should be deemed an invention, and to exclude from patentability any substance which exists in nature⁴¹. In particular, DNA molecules may be regarded as building blocks of nature, which should be free for use by the scientific community and for any productive application.

II.2.1 Options - Substances Existing in Nature

If national legislation aims to provide no specific restriction on the patentability of substances existing in nature -- as is currently the case in the USA and Europe -- there is no need for a special provision on the matter. If, on the other hand, a country wants to avoid providing patents for substances as found in nature, a provision excluding the patentability of mere “discoveries” may suffice (Option 1). If a more explicit and restrictive approach is preferred, national laws may provide for specific exclusion (Option 2).

Discoveries and Substances Existing in Nature Model Options

⁴¹ The Agreement obliges Member States to protect “microorganisms” but nothing in the Agreement can be interpreted as requiring the patentability of microorganisms found in nature and not “invented”, for instance, by alteration through genetic engineering.

1. Discoveries shall not be regarded as inventions.
2. A substance found in nature, including DNA, even if purified or isolated, shall not be regarded as an invention.

Under Option 1, a substance which existed in nature but which has not yet been identified in its characteristics and in its utility may become patentable, depending on the interpretation given to the concept of “discovery”. Option 2 would exclude such a possibility. Under Option 2, patentability would require making changes in the structure of the material. In the case of genetic materials, in particular, patentability would require modification of their genetic structure in a manner that leads to a new and inventive product.

Neither of these Options would prevent an interested party from patenting the processes employed to isolate, purify or produce a biological material, if the process met the patentability requirements.

Countries should recognize that choosing among the options presented here will determine key aspects of their biotechnology legislative policy.

II.3 Uses

Pharmaceutical patents rarely relate to new chemical entities, that is, active ingredients that represent a fresh contribution to the stock of products available for medicinal use. A great number of pharmaceutical patents protect processes of manufacture, formulations, systems of delivery, and new *uses* of a known product⁴².

⁴² See, e.g., Zaveri, 1998, p. 71.

A “use” claim may be either a *product* claim or a *process* claim, depending on the context. In Europe, *first medical indications* have been dealt with as a product claim, whereas the *second medical indication* as a process claim.

II.3.1 First indication

An important patent issue in the health sector arises when a new therapeutic use is found for a known product which had no previous pharmaceutical use. Because patents protect inventions but not discoveries, the discovery of a new purpose for a product cannot render a known product patentable under general principles of patent law⁴³. Therefore, the patentability of the *product as such* would be rejected.

Some jurisdictions, however, have adopted special rules for the protection of the *first indication* of a known product, expanding the scope of protection beyond its ordinary boundaries. In Europe, for example, a legal fiction allows the patentability of a known product for such an indication⁴⁴. Under article 54(5) of the European Patent Convention, the identification of the first medical indication of a known product may suffice to get a patent on the product⁴⁵. The United States, by contrast, has adopted a more

⁴³ Unless in connection with the new purpose the product is forced to be present in an amended new form. See, e.g., Hansen and Hirsch, 1997, p. 104.

⁴⁴ See, e.g., Stieger, 1982.

⁴⁵ The Technical Board of Appeal of the EPO has ruled that such claims should be deemed as covering all therapeutic uses of the product as in the case of claims on a pharmaceutical composition. Infringement of such claims would only take place when the product is commercialized for direct therapeutic use, and not in bulk (Grubb, 1999, p. 218). The approach of granting patents for first medical indication of a known product may be deemed discriminatory vis-à-vis other sectors, although it may be justified as a limitation to the exclusion of the patentability of

restrictive approach, confining patents on uses to a particular “method-of-use.” Such method-of-use patents do not encompass protection of the product as such⁴⁶.

Under the TRIPs Agreement, countries are free to expand patent protection beyond the general principles of patent law, but they are under no obligation to do so. WTO Member countries are thus free to decide whether or not to allow the patentability of products for *first indication*.

Countries concerned about “bio-piracy” may wish to exclude the patentability of the use of known products in order to prevent the appropriation under patent rights of biological products.

II.3.2 Second indication

In some cases, a new use is discovered for a product that already has pharmaceutical use⁴⁷. Many national laws treat the new use as *process* patent claims of one of two kinds: “use” claims (such as “the use of X as an antihistaminic”) or claims on one or more actual process steps (e.g. “a method of preventing...”) ⁴⁸. The patenting of use inventions depends on whether the purpose of the use is novel and non-obvious. Method inventions may be judged independently of the purpose. Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods⁴⁹.

therapeutic methods. See sub-Section II.4 on “Methods for Treatment and Diagnostics”.

⁴⁶ See, e.g., Merges, 1992, p. 489.

⁴⁷ This was the case, for instance, of nimodipine, a known cardiovascular agent for which an application to cerebral disorders was found.

⁴⁸ See, e.g., Grubb, 1999, p. 208.

⁴⁹ See, e.g., Hansen and Hirsch, 1997, p. 120.

Patent applications on the second medical indication of a known product are usually written as instructions to the physician on how to employ a certain composition to treat a particular disease. Such applications are accepted in some countries. The European Patent Office began granting such applications, when framed under the “Swiss formula,” in 1984⁵⁰.

However, countries may deem non-patentable an “invention” consisting of the second use of a substance because it fails to satisfy various traditional patent requirements:

- it is a “discovery”;
- it does not meet the requirement of industrial applicability;
- it is equivalent to a method of therapeutic treatment (when such methods are deemed non-patentable)⁵¹; and
- the “Swiss formula” suffers from “the logical objection that it lacks novelty, since it claims the use of the compound for preparation of a medicament, and normally the medicament itself will be the same as that already used for the first pharmaceutical indication”⁵².

Many patent laws recently adopted in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether their protection for processes covers “uses” and “methods of use.”

As in the case of the first indication, nothing in the TRIPs Agreement obliges countries to introduce additional protection for the second indication. While the TRIPs Agreement obliges Member States to protect *products* and *processes* (Articles 27.1

⁵⁰ “Use of X for the manufacture of a medicine to treat Y”.

⁵¹ See the following sub-Section.

⁵² See, e.g., Grubb, 1999, p. 221.

and 28), it does not specifically refer to the protection of new uses, thus leaving Member countries free to choose whether or not to protect them. In principle, a country that broadly excludes methods of medical treatment could also broadly exclude new therapeutic uses for old products. There are, however, limits to this approach, and consistency would be required in defining excludable therapeutic methods in all cases. The impact of any such exclusions on local needs and industry should also be taken into account.

II.3.3 Options - Uses

Option 1 would exclude the patentability of an invention consisting solely of the method of use or use of a known product, even when it is the first identified use. This solution has both advantages and disadvantages.

On the one hand, this solution may help to prevent so-called “bio-piracy”-- that is, the appropriation of substances found in nature for which a new medical use is identified (often on the basis of available traditional knowledge). It should be noted, however, that due to the territoriality of the patent system and the independence of patents granted in different countries, such prohibition would not prevent a third country from granting a patent on a natural substance, unless its own national legislation or an international agreement forbids it.

Uses of Known Products Model Options

1. The new use or method of use of a known product shall not be patentable.
2. The identification of a new use for a known product does

not render the product patentable.

3. When a new use for a known product has been identified, a patent may be obtained for such product as specifically applied to such use.
4. Patents shall not be granted in respect of the method of use or use for therapeutic purposes of a known pharmaceutical product.

On the other hand, it can be argued that developing countries could benefit from the patentability of new uses either because the identification of new uses may be more affordable than the development of new active ingredients, or because new uses could be directed at specific local diseases or maladies. If these considerations prevail, no exclusion should be provided for, although the law could specify that no use claim will qualify if the characteristic or advantage is inherent in the existing use of the product or process.

Option 2 would explicitly prevent the patentability of the product for which a new use was identified. This provision may be included in order to avoid any ambiguity on this issue, though it may not be strictly necessary. In the absence of any provision on the matter, the application of the general requirements of patentability would normally lead to the non-patentability of the product as such⁵³.

Under Option 2, however, the patentability of pharmaceutical uses would be admitted for the first indication with respect to the method of use or use, but excluding the protection of the product.

⁵³ As indicated above, in the case of Europe, such patentability is based on a legal fiction and on an express provision allowing for it.

A further, less restrictive alternative, would be to admit use-bound product claims (Option 3)⁵⁴. Under this Option, a product would be claimed in relation to a specific use, and not in absolute terms⁵⁵.

Finally, Option 4 addresses the issue of the “second indication” of a pharmaceutical product. If Option 1 were adopted, it may not be needed to also state Option 4, since the latter may be deemed a particular case of the former. Moreover, if the patentability of methods of therapeutical treatment were excluded, Option 4 may not be necessary. Nevertheless, it may be advisable to include Option 4 in order to avoid any possible ambiguity or misinterpretation.

II.4 Methods for Treatment and Diagnostics

Developing countries could consider the exclusion from patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals⁵⁶. Most countries do not grant patents on such methods due to ethical reasons or to difficulties with actually enforcing those patents. In addition, a method that is applied to the human body is not considered industrially applicable and, hence, does not comply with one of the key patentability requirements of most patent laws. However, in the United States, patent practice increasingly favours the patenting of medical

⁵⁴ For instance, “a composition containing N for pressure control”.

⁵⁵ See, e.g., Stieger, 1982, p. 157.

⁵⁶ For instance, patent US 4,188,395 claimed “a method combating circulatory diseases in warm blooded animals in need of such treatment orally or parenterally which comprises administering to the animals an amount effective for combating circulatory diseases relating to heart action and blood pressure an active compound according to claim 1 either alone or in admixture with a diluent or in the form of a medicament”.

methods if they satisfy the definition of process and the other conditions of eligibility⁵⁷.

Article 27.3.a of the TRIPs Agreement explicitly allows Members not to grant patents for methods for therapeutic and surgical treatment and for diagnostics⁵⁸.

II.4.1 Options - Methods

A typical exclusion from patentability, as contained in many laws in force, may contain the following:

**Diagnostic, Therapeutical and Surgical Methods
Model Option**

Patents shall not be granted in respect of diagnostic, therapeutic and surgical methods for the treatment of humans and animals.

It should be noted that, even in the absence of specific provisions excluding the patentability of the referred methods, they may be deemed non eligible for protection due to the lack of industrial applicability, one of the essential requirements for patentability (see Section IV.3 below).

⁵⁷ A bill enacted in 1996 (amending US patent law, 35 USC 287.c) determined, however, that the use of patented surgical procedures is protected from infringement suits. See, e.g., Grubb, 1999, p. 220.

⁵⁸ Including when they apply to animals.

If the patentability of such methods were, however, admitted by national laws, its implications for the supply of health services should be assessed. Diagnostic, therapeutic and surgical patents, even if rarely granted, may negatively affect low-income patients' access to required treatments, particularly in new areas such as gene-therapy⁵⁹.

In any case, the non-patentability of methods would not affect the patentability of equipments and substances necessary to execute them⁶⁰.

II.5 Traditional Medicines

Traditional medicine -- medicine based on the use of natural products and the knowledge held in indigenous and local communities -- is of great importance in the health-care systems of many developing countries. It has been estimated that around 7,500 plant species are utilized in indigenous medicine, many of which (such as indigo) have multiple uses⁶¹. There are two major obstacles to affording patent protection to traditional medicine. First, the novelty requirement will generally impede the patentability of such products. Second, policy choices made to increase access to medicines -- including a limitative approach towards the patentability of naturally occurring products and uses

⁵⁹ Though the gene therapy methods may not be patentable as such (if the suggested exclusion is provided for) the vectors and constructs that may be used could be patentable, as well as *ex vivo* process steps not involving the administration of the transformed cells to the patient (Grubb, 1999, p. 244).

⁶⁰ In cases where the protection of such equipments and/or substances could lead to a *de facto* monopolization of the non-patented method, governments may have recourse to compulsory licenses, See Section X below.

⁶¹ See, e.g., Shankar, 1996, p. 170.

of existing products, as well as strict patentability requirements (see section 4, below) -- may lead to the exclusion of protection for most traditional medicinal products.

Moreover, national patent protection of traditional medicine will not address “biopiracy” concerns. Since the granting of patents is dependent on each *national* law, the non-patentability in one country does not mean that traditional knowledge could not be patented in another country without the authorization of the communities that developed or possessed that knowledge. In these cases it may be necessary to request the nullification of the patent, if wrongly granted, in the foreign country⁶².

Many proposals have been made to protect traditional knowledge (including of medicinal use) through a *sui generis* regime. This is the case, for instance, of proposals relating to “tribal”, “communal” or “community intellectual rights”⁶³, and “traditional resource rights”, among others⁶⁴. The establishment of such a regime would not conflict with the TRIPs Agreement, to the extent that the scope of intellectual property protection would be enlarged rather than restricted. Moreover, if a special regime were established, it would be outside the scope of the TRIPs Agreement, which only applies to the categories of intellectual property rights specified in its article 2.

Other approaches, outside of the intellectual property sphere, may also serve to *promote* the use of traditional knowledge for preventive and curative health care, or to block unauthorized appropriation by foreign countries. Act No. 8423 (1997) of the Philippines, for example, aims “to accelerate the development of traditional and alternative health care” by

⁶² An example of this was the action initiated by the government of India in relation to a patent on *turmeric* granted in the U.S., which was finally revoked.

⁶³ See, e.g., Berhan and Egziabher, 1996, p. 38.

⁶⁴ See, e.g., Posey and Dutfield, 1996.

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improving the manufacture, quality control and marketing of traditional health care materials (Section 3.d)⁶⁵. Peru passed a law in July 1999 which bans the non value-added export of some botanical species with known healing properties, which had become the target of massive extraction by foreign laboratories. The law covers the two best-known medicinal plants in Peru's indigenous pharmacopoeia: 'cat's claw' and 'maca'; and legislators are considering expanding the norm to cover other products ('yacun' and 'para-para').

⁶⁵ There is no intention to discuss the different suggestions for the protection of traditional knowledge, or to propose the adoption of any of them. The purpose is only to indicate the need to consider this issue at the national level.

III. SCOPE OF CLAIMS

Patent claims define the rights of the inventor. The scope of patent claims determines the extent of the inventor's monopoly protection, and is thus an important issue to be considered when designing and applying national patent laws. This issue is particularly relevant to health-related inventions, due to the prevailing practices of patenting in this area (see Section V below). Recently, scholars have warned that overly broad patents in the field of biotechnology could remove important research tools from the public domain and block whole areas for further research⁶⁶. The broad protection sometimes conferred in the case of inventions related to pharmaceuticals has also been questioned⁶⁷.

Patent claims essentially consist of a one-sentence definition of the invention where the technical contribution made by the inventor should be unambiguously spelled out. The scope of patent protection and, therefore, the room left for independent research and third party competition, is determined by the wording used in claims. Issues such as *how* a product is described and the *coverage* of the patent are of particular importance. The following discussion illustrates some of the possible forms and coverage of *product* patent claims.

A chemical product can generally be described in *structural* terms, by specifying, for instance, its chemical composition. This type of description offers the safest way of delineating the scope of protection.

Some countries accept, under certain conditions, *functional* claims whereby the invention is described in terms of what it **does**

⁶⁶ See, e.g., White, 1998/1999.

⁶⁷ See, e.g., Zaveri, 1998; Keayla, 1999.

rather than what it **is**. Such claims can allow extremely broad coverage, since they confer exclusive rights on any means that is appropriate to achieve the claimed functions, i.e. all ways of solving a problem are protected.

Another form of claims are the so called *product-by-process* claim⁶⁸, where a product is characterized by the process by which it is obtained and not by its elements and structure. These claims are in particular relevant for biological products that cannot be described in terms of their structure or composition (for instance, in cases in which a macromolecule is secreted by a micro-organism). These are accepted by the European Patent Office only if the products themselves are new and inventive, and therefore, patentable⁶⁹.

Use-bound claims protect the use rather than the product. An infringement of a use-bound claim can only occur when a product is prepared or sold for the specific use claimed in the patent.

In terms of coverage, claims can be more or less precise and focused. A claim may refer to a well-defined compound of therapeutic value. Often, however, in the chemical and pharmaceutical field, patent claims are drafted in a manner that covers hundreds if not thousands of compounds. This is the result, for instance, of describing a family of chemical compounds by showing the common structural nucleus of all members with a variable substituent⁷⁰.

⁶⁸ These claims may read, for instance, “compounds X when prepared by a process as Y”. In the USA the concept of “means-plus-function” claims is used to describe claims in which the invention is expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof.

⁶⁹ See, e.g., Cook, Doyle and Jabbari, 1991, p. 73 and 76.

⁷⁰ In the case of process patents, many possible variants may result from broad numeric parameters describing a reaction temperature.

National laws, including those of developed countries, deal with these issues in very different ways. Functional claims have generally been admitted in the United States, though broad functional language that may impede further research and development has been condemned⁷¹. The European Patent Office (EPO), on the other hand, accepts functional claims only when there is no other means to describe the invention in a more precise manner. “Product-by-process” claims are generally admitted by the EPO and some European countries only if it is impossible to define a product by its structural features⁷², and if the obtainable product as such is new and inventive. Under “product-by-process” claims, protection is generally only extended to a product *obtained* with the claimed process; hence, the same product if obtained by another process would not infringe on an existing claim⁷³.

Acceptance of non-structural and broad coverage claims expands the domain under the control of patent owners. Broad claims may have a negative impact on research and unduly block competition. They are also likely to lead to a great number of legal conflicts, ultimately increasing the costs for companies and consumers. Narrowing the scope of patents through strict claim description and coverage requirements creates more room for innovation and competition. From a health policy perspective, an appropriate balance needs to be found.

The TRIPs Agreement is absolutely silent on these matters. Nothing in the TRIPs Agreement obliges Members to admit functional or other types of claims as described above. Provided

⁷¹ See e.g., Sears and Hahn, 1999, p. 70.

⁷² See, for instance, the decision of the Board of Appeals of the European Patent Office T0150/82 (07.02.84).

⁷³ This limitation in the scope of protection may be overcome if it is interpreted that any product *obtainable* with the process is protected, a solution that, however, has been refused by many patent offices (Grubb, 1999, p. 203).

that there is no discrimination based on the field of technology, the TRIPs Agreement provides Members full freedom to determine the form and limits of allowable claims. Any WTO Member may require that, wherever possible, a product invention be precisely defined in terms of its specific composition or structure⁷⁴, particularly in the field of chemical substances, in order to avoid excessively broad claims and ensure the practicability of the invention. This requirement may be particularly useful in fostering the role of patent documents as a source of information and to facilitate the negotiation of contractual licenses and the actual use of patented inventions.

Regulations for implementing patent law may also contain specific instructions for claims corresponding to different fields of technology, such as chemicals, digital and mechanical inventions, in order to take into account the characteristics of each field.

III.1 Options - Scope of Claims

Several elements may be included in national laws to deal with the issue of the scope of claims. If a country wishes to ensure that the scope of protection is defined as precisely as possible, on the basis of structurally defined claims, it may follow Option 1.

Option 1 would not allow for claims defined solely on the basis of the function that an invention performs, nor the definition of a product through the process for obtaining it.

If, however, a country wished to establish a broader scope of patenting, option 2 would be preferable, since it would permit the granting of patents even if claims are defined in non-structural

⁷⁴ This was, for instance, the practice followed by Japan till the revision of its patent law in 1994.

terms and also “product-by-process claims” but, in this latter case, only in relation to the product that is “obtained” (not “obtainable”) with the process.

**Scope of Claims
Model Options**

1. The claims of a patent shall define the invention for which protection is sought in terms of its purpose, constitution and effects. A claim which only recites the operation and effects of an invention shall not be accepted. A product claim shall not be admitted if the product is not sufficiently defined as such.
2. Product-by-process claims shall be accepted only when a structural description of the invention is not possible. The protection shall be limited in these cases to the product obtained with the claimed process.

It also may be possible to combine the first part of Option 1 with Option 2, or consider other alternatives.

Policy makers should recognize that, while health-related inventions may require special attention, the rules adopted will apply to all fields of technology, and that the personnel of the Patent Office should be well trained in order to adequately apply the provisions on this matter.

IV. PATENTABILITY REQUIREMENTS

To qualify for a patent, an inventor must show that his or her invention is novel, manifests an “inventive step” (i.e., that the invention was nonobvious) and is industrially applicable.

The manner in which these criteria are defined and applied is a crucial determinant of the pool of knowledge that is taken out of the public domain. This issue is acutely important for pharmaceuticals. The registration of a large number of patents on pharmaceutical compositions, therapeutic uses, polymorphs, processes and/or forms of administration relating to an active ingredient often permits the owner company to create a high barrier against competition. If aggressively enforced through “strategic”⁷⁵, or even “sham,” litigation practices⁷⁶ as a tool to discourage competition by local companies, those (secondary) patents may extend the market power conferred by the original patent⁷⁷. Such abuses may be particularly severe in developing countries where there is a lack of or limited tradition in controlling such practices under antitrust regulations.

It is hard to undo the granting of overly broad patents and secondary patents. Once a patent has been granted, it is presumed valid. Challenging parties bear the burden of proving that the patent was wrongly issued. Consumers, especially in developing countries,

⁷⁵ See, e.g., Barton, 1995.

⁷⁶ The doctrine on “sham” litigation applies when a lawsuit is baseless and there is an intent to use it as a tool for monopolization (Federal Trade Commission Staff, 1996).

⁷⁷ See, for instance, the US Supreme Court decision in *Walker Process Equipment Inc. vs. Food Machinery & Chemical Corp.* (1965) and subsequent case law on antitrust liability when there is an attempt to enforce invalid patents. See, e.g., Chandra, 1999.

rarely have the resources to challenge overly broad patents, though they bear the cost in higher prices and decreased access to patented goods.

Strong inter-firm competition in the pharmaceutical industry has led to numerous challenges of pharmaceutical patents by affected competitors⁷⁸. But smaller, generic firms in developing countries often do not have the resources to undertake such costly litigation. Moreover, the wave of mergers and acquisitions that has taken place in the 1990s has dramatically reduced the number of major players and accentuated the oligopolistic structure of the industry. This trend increases the importance of administering the patent system to protect competitors and the public from restrictions derived from patents granted on the basis of insufficiently precise patentability criteria.

The flexibility or strictness in the application of the patentability criteria may vary across countries and over time. The correct interpretation and application of the patentability criteria are crucial for balancing public and private interests, and also to help avoid excesses that undermine the credibility of the patent system.

The eligibility standards for novelty and inventive step determine the extent to which free competition prevails⁷⁹. Technologically advanced countries that invest a substantial portion of their GNP in research and development may understandably favour permissive novelty standards and low standards of inventive step. However, even these policies are increasingly controversial given the importance of incremental innovation in some sectors and

⁷⁸ For an analysis of the vast litigation involving pharmaceutical patents, see e.g., Cook, Doyle and Jabbari, 1991; Wegner, 1994; Hansen and Hirsh, 1997, and Grubb, 1999.

⁷⁹ See, e.g., Reichman, 1994, p. 2432, 2448-2453.

the growing number of patents that protect trivial developments⁸⁰. On this issue, it has been shown that a higher innovative step requirement can increase the value of patents, because patents issued under this rule are stronger and less vulnerable to challenge by competitors. In some industries, this effect outweighs any effect of having less patents⁸¹.

Less technologically advanced countries may prefer to set higher standards of novelty and inventive step in order to preserve and enhance competition without violating minimum international standards. In so doing, they would simply follow in the footsteps of many of today's advanced countries which adopted similar policies when they were themselves developing countries.

Policy makers should recognize that there may be subtle relationships between novelty and inventive step. For example, in traditional U.S. patent law (especially before the creation of the Federal Circuit Court of Appeals in 1982), the non-obviousness standard was so high that courts took a relatively soft and permissive attitude to novelty. Today, when the non-obviousness bar is set very low, this permissive tradition may be anti-competitive and harmful to follow-on innovation by not filtering out patent requests that do not sufficiently depart from prior art.

⁸⁰See, e.g., Scherer, 1981, p. 112, recommending more rigorous eligibility standards in order to avoid the protection of trivial developments. For some examples of trivial patents granted in the United States, see Feinberg, 1994. See also *Patnews* (Internet Patent News Services) of 14.12.99 and other issues, in relation to software and "business" patents, such as an application filed on Aug. 26, 1996, on a method for trading securities between individuals; an application filed in September 1997 (granted in November 1999) on a method of automatically accessing web page information; another one filed on June 1998 on a "Jesus doll for teaching children". Several patent applications have also been reported in Japan in relation to the "cooking of curry" (e.g. JP7289214) and pizza and its cooking process (such as JP8116934). See also Gleick, 2000.

⁸¹ See, e.g., Hunt, 1999.

Developing countries should also note that high standards of novelty/inventive step can work against local innovators who cannot themselves meet these standards. One way to address this problem is to adopt a *sui generis* law that deals with “minor” inventions that fail to meet the patent standard of novelty or inventive step. Examples from the European tradition include *sui generis* industrial design laws (that protect appearance designs) and utility model laws that can protect “minor” inventions generally. However, recent studies also propose that developing countries should adopt laws to protect unpatentable know-how on the basis of non-exclusive rights. These laws could stimulate follow-on innovation in exchange for compensation without any strong exclusionary right⁸².

IV.1 Novelty

The patent system was conceived to reward the inventor for contributions to the pool of existing knowledge. The criteria used to define what is new are key determinants of the scope of possible limitations to the free access and use of technical knowledge and products in the public domain. The stricter the novelty and other requirements, the smaller the number of applications that will lead to a patent grant.

The test of novelty considers how much distance separates one claimed invention from prior art. It applies before the existence of inventive step is considered (see Section IV.2, below).

The novelty requirement in modern patent laws is generally based on an assessment of the prior art on a *universal* basis, that is, anywhere in the world. Generally, novelty is destroyed by

⁸² See, e.g., Reichman 1994, p. 2504-2558 and 1997, p. 58-75.

previous written publication, prior use or other form of public communication of the invention.

Within this framework, the legal definition and application of the novelty requirement significantly differs among countries. In some jurisdictions a flexible standard is applied, thus permitting the granting of a great number of patents. For instance, in the United States, disclosure that has taken place outside the United States is only destructive of novelty when made in a written form⁸³.

National legislation and practice differ on numerous other important questions:

- The United States, for instance, requires complete disclosure in a *single* publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications.
- In some cases, disclosure may not have been made *expressis verbis* in a prior writing, but may be implicit therein. If a “photographic” approach to novelty (i.e. only based on explicitly disclosed information) is applied, equivalents to an invention implicitly disclosed in the prior art may not be sufficient to deny patentability. The result, in these instances, can be the patenting of pieces of existing knowledge (prior art). This result can be avoided by following the European patent office’s practice of considering implicit teachings to be disclosed and part of prior art⁸⁴.
- Another aspect left to national legislation is to establish whether novelty would only be destroyed when the

⁸³ This may permit the patenting in that country of knowledge, including of indigenous communities, used but not published in written form outside United States. See, e.g., Correa, 1999a.

⁸⁴ See, e.g., Hansen and Hirsch, 1997, p. 96.

anticipation *enabled* the execution of the invention, or whether a mere disclosure of the prior art would be sufficient -- for instance, where a compound was made and tested even if a clear description of its properties or a method of making it were not available⁸⁵.

IV.1.1 Options - Novelty

In accordance with the generally accepted concept of novelty, developing countries could incorporate a novelty requirement that encompasses any written or oral disclosure, including through use anywhere in the world⁸⁶. A rule of this type may help to avoid the patenting of knowledge or materials developed by and diffused within local or indigenous communities.

Given the non-discrimination principle contained in article 27.1 of the TRIPs Agreement, no specific rules on novelty for health-related inventions are recommended, but rather the application of well-defined general rules. A possible legislative text may contain the elements identified in the box.⁸⁷

**Novelty
Model Option**

- a) An invention shall be deemed to be new when it does not form part of the state of the art. The state of the art shall

⁸⁵ This was the approach adopted by the UK Patent law of 1977. See, e.g., Cook, Doyle and Jabbari, 1991, p. 79.

⁸⁶ As mentioned before, nothing would prevent national legislation from providing for a less stringent concept of novelty in other areas of IPRs, for instance, in order to protect “minor” innovations under utility models, designs or similar forms of protection.

⁸⁷ The provisions of the law should be supplemented by specific regulations and guidelines for patent offices.

comprise everything made available to the public in any country by means of a written or oral description, by use or in any other way.

(continued)

- b) The state of the art , as defined in paragraph 1, shall include knowledge developed by or in possession of a local or indigenous community.
- c) The state of the art shall also comprise unpublished patent applications filed at the national Patent Office, where such applications are subsequently published.

The language proposed in paragraph a) of the model option, which is based on article 54 of the European Patent Convention, should prevent the patenting of local or indigenous knowledge. Paragraph b) would do this explicitly. Given the territorial nature of patent laws, such knowledge would not be patentable in the country/ies where the proposed concept of novelty is adopted, but it would not prevent patentability in other countries. In order to remedy this situation, an international standard should be adopted, for instance, as part of a possible review of the TRIPs Agreement.

Developing countries may want to accompany this exclusion with special laws that do protect such knowledge outside the patent system under a *sui generis* regime⁸⁸, or that promote the conservation and use of such knowledge, particularly traditional medicinal knowledge.

⁸⁸ See, e.g., Posey and Dutfield, 1996. See also the “African model legislation for the recognition and protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources”, prepared by the Organization of African Unity (1999).

Paragraph c) considers that inventions described in other applications, which were published on or after the date of application for a patent, shall also constitute an anticipation for the purposes of novelty. This is the solution adopted by the European Patent Convention (article 54.3).

IV.2 Inventive Step

Even if novel, an invention is not patentable if its technical teaching would or could have been discovered in due course by a person with average skills in the respective field. In United States practice, for example, courts applying the nonobviousness standard (the U.S., equivalent to inventive step) undertake a three-step factual inquiry, examining:

- (1) the scope and content of the prior art to which the invention pertains;
- (2) the differences between the prior art and the claims at issue;
- (3) the level of ordinary skill in the pertinent art.

Courts then make a final determination of nonobviousness by deciding whether a person of ordinary skill could bridge the differences between the prior art and the claims at issue given the relevant prior art⁸⁹. Though sometimes difficult to apply, the inventive step or nonobviousness requirement is critical to prevent the granting of patents on trivial developments.

⁸⁹ See, e.g., *Dratler*, 1999, §2.03[3].

The inventive step is often evaluated by considering the “unexpected” or “surprising” effect of the claimed invention. U.S. courts, however, currently reject this approach and stress that patentable inventions may result from either painstaking research, slow trial and error, or serendipity⁹⁰.

Many countries’ case law holds that there is no inventive step whenever it would be obvious -- for a person with average skills -- to test new matter with a significant likelihood of success. In the United States, the existence of an inventive step in relation to chemical compounds has been judged by taking into account the structural similarity between the claimed and the prior art compounds, the prior art suggestion or motivation to make the new compound, and the obviousness of the method of making the claimed compound⁹¹.

As in the case of novelty, national laws may be more or less stringent in evaluating inventive step or “non-obviousness”. Moreover, in any domestic legal system, courts may elevate or relax the inventive step standard at different intervals in response to either prevailing attitudes towards competition, the perception of a need to protect new technologies (such as computer programmes and biotechnological inventions), or the availability (or lack thereof) of alternative forms of protection in unfair competition laws, utility model laws, or the like.

In establishing the existence of inventive step, it is generally necessary to consider not only the knowledge derived from a single prior document, but also the combined knowledge of existing literature, patent documents and other prior art. However, current U.S. practice disfavors such an approach and holds that “the subject matter of a claim is not rendered obvious by prior art unless

⁹⁰ *Ibid.*

⁹¹ However, as mentioned before, *in re Deuel* (1995) these criteria were relaxed. The patenting of gene sequences has been allowed despite that the sequencing of genes has become a standard technique.

there is some specific suggestion or teaching in the prior art that points the way to it”⁹².

In the chemical and pharmaceutical field, there is often a close structural relationship between a compound which is claimed as new and inventive, and known compounds, such as salts of acids, bases, isomers, and homologues. In these cases it may be often deemed *obvious to try* the new compound, thus leading to its non-patentability. The EPO, for instance, has taken the view that the fact that certain advantages were predictable made it obvious to prepare a new compound⁹³. In the United States, by contrast, the presence of a predictable advantage is not deemed sufficient to exclude patentability⁹⁴.

The TRIPs Agreement is not specific with respect to the issue of inventive step. Article 27.1 establishes that patents shall be granted to protect inventions which “involve an inventive step” and, in a footnote, it allows Member countries to interpret “inventive step” as synonymous with “non-obvious”.

There is no agreement to harmonize the standard of inventive step/nonobviousness in practice. This suggests that developing countries may be well advised to consult and coordinate on this issue, possibly through their regional organizations.

IV.2.1 Options - Inventive Step

A possible option for developing countries is to define and apply strict criteria for inventive step, in order to avoid the granting of patents that may unduly block competition in health-related products and processes. Such strict criteria may prevent the protection of locally developed “minor” innovations. But these

⁹² See, e.g., Dratler, *op.cit.*

⁹³ Technical Board of Appeal, T 154/82, IPD 7031.

⁹⁴ See, e.g., Grubb, 1999, p. 195-196.

innovations may be covered by utility models (or other forms of *sui generis* protection for know-how to provide compensatory rewards without exclusive property rights), rather than by diluting the inventive step requirement.

However, inventive step criteria cannot be so strict as to undermine the duty to grant patents in all fields of technology under Article 27.1 of the TRIPs Agreement. Coordination among the patent offices of developing countries could help to establish sound State practices and to avoid disputes.

The inventive step may be incorporated in national law as presented in model option.

**Inventive Step
Model Option**

- a) Patents shall not be granted in respect of a product or processes which is obvious to a person skilled in the art.
- b) In particular, an invention shall be deemed obvious when the prior art provides motivation to try the invention, or when the method of making a claimed product is disclosed in or rendered obvious by a single piece or any combination of pieces of prior art.

A national law may only include a general provision, as contained in paragraph a). This is what most laws in force do. However, it may be possible to clarify the general rule through wording as presented in paragraph b), which specifies cases in which the existence of inventive step would be denied. This additional paragraph may help to avoid the patenting of obvious-to-try

inventions and other trivial developments, and in particular, of products which are obtainable through obvious methods.

IV.3 Industrial Applicability

The third criterion for patentability relates to the industrial applicability of the invention. Patent law around the world aims to protect technical solutions to a given problem, not abstract knowledge. The application of this criterion to health-related inventions is particularly important *vis-a-vis* inventions consisting of *uses* of a product since uses of health-related inventions may be considered as methods of treatment of the human body, not industrially applicable, and therefore not patentable.

BOX 2

INDUSTRIAL APPLICABILITY IN COMPARATIVE LAW

Countries differ in their treatment of industrial applicability. Under US law, certain developments that do not lead to an industrial product may be patented: an invention only needs to be operable and capable of satisfying some function of benefit to humanity (“useful”^a). This usefulness concept is broader than the “industrial applicability” concept required in Europe and other countries. The U.S. rule permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a technical effect^b, as illustrated by the large number of patents granted in the United States on “methods of doing business”^c.

The application of the industrial applicability requirement is often complex in the chemical, pharmaceutical, and biotechnology industries, where there are particular problems relating to the acceptable degree of speculative information. Thus, in the USA mere speculation about chemical homologues would be insufficient, while *in vitro* testing in animal tumour models of products intended for human use may be deemed sufficient^{d)}.

^{a)} See, e.g., *Chisum and Jacobs*, 1992, p. 2-50.

^{b)} See, e.g., *Bainbridge*, 1992, p. 270-272.

^{c)} See, e.g. "The growing flood of 'Wall Street' patents", in *Patnews (Internet Patent New Services)* of 29.9.99.

^{d)} See, e.g., *Dratler*, §2.03[2]

The TRIPs Agreement does not define the concept of industrial applicability⁹⁵ and, therefore, leaves countries with considerable flexibility.

IV.3.1 Options - Industrial Applicability

In order to avoid the proliferation of patents that may unduly jeopardize innovation and competition in the health sector and, particularly, to avoid the patenting of mere methods of therapeutic treatment (if so desired), patent laws may provide for as precise a concept of industrial applicability as possible, as presented in model option:

**Industrial Applicability
Model Option**

⁹⁵ It allows a Member country to consider that "capable of industrial application" is synonymous with "useful".

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Patents shall be granted in respect of inventions capable of being manufactured or otherwise industrially used.

This formulation follows the approach applied in European and many other countries, based on the industrial applicability of the invention, rather than on the broader concept of “usefulness” applied in the United States.

V. SPECIAL CASES IN PHARMACEUTICALS

Several issues relating to the application of patentability requirements may be specific to health-related inventions. WTO Member countries retain a considerable degree of flexibility in addressing most of them. These issues may be appropriately treated in implementing regulations and/or guidelines for the patent office, rather than in the law itself.

Developing countries, particularly those implementing for the first time the patenting of product pharmaceutical inventions, should carefully craft policy in these areas to ensure that patents are granted to real contributions to the prior art and to avoid granting to trivial inventions patents that impede competition. Poor drafting or administration of patent laws may also permit abusive practices that illegitimately extend patent protection beyond the 20-year term.

V.1 Selection Patents

A “selection patent” is a patent under which a single element or a small segment within a large known group is “selected” and independently claimed, based on a particular feature not mentioned in the large group⁹⁶. If the large group of elements is already

⁹⁶ A “selection invention” may take place, for instance, when a range of products characterized as having N carbon atoms has been patented, and, later on, a patent on a specific range (e.g. C1-C4) is claimed. Substantial differences exist in the treatment of these patents, including between the European Patent Office (EPO) and some national offices in Europe.

patented⁹⁷, the patent owner may use the selection patent to extend the term of protection beyond the expiration of the original patent, at least for the selected subset. While accepted in some jurisdictions when the selected elements possess a surprising advantage, selection patents have been denied when the supposed advantage is a property shared by all or nearly all of the large group. Germany has refused selection inventions by holding that disclosure of even a large group of elements is fully equivalent, for the purposes of inventive step, to the disclosure of each compound within the group⁹⁸.

An important policy issue is, therefore, to decide whether and under which conditions selection patents should be admitted. The TRIPs Agreement leaves broad discretion to national laws and practices in this area.

V.2 Prior Public Availability

Where a product has already been available to the public, the composition or inner structure of the product can be deemed to belong to the state of the art even if not published, since the product could have been analyzed and reproduced by a skilled person⁹⁹. This approach is also compatible with the TRIPs Agreement.

⁹⁷ Often broad (“generic”) patent claims are admitted, covering a large number (sometimes thousands) of possible compounds.

⁹⁸ See, e.g., Grubb, 1999, p. 197-199.

⁹⁹ See, for instance, the decision of the EPO in G 1/92 of 18.12.92, OJ 1993, p. 277.

V.3 Polymorphism

Some therapeutically active ingredients present polymorphic forms, that is, they may crystallize in diverse forms, which may have different properties that are more or less significant in terms of their therapeutic use. Independent patent applications on such forms¹⁰⁰ have become frequent. Such forms can be deemed within the prior art -- and therefore non-patentable -- if they were inevitably obtained following the process of the basic patent on the active ingredient or were covered by a previous product patent.

Some companies have sought to use patentability of polymorphs as a means to extend the monopoly protection of a known active ingredient. For instance, SmithKline applied for a patent on a polymorph of cimetidine approximately five years after the original patent was granted. That patent, however, was nullified in the UK and other countries on the grounds that the polymorph was inevitably obtained by applying the process already claimed in the original patent¹⁰¹. Another example is the case of ranetidine. The patentee obtained in the United States a patent for a polymorph expiring in 2002 as opposed to 1995 for the main patent¹⁰².

The TRIPs Agreement also leaves ample freedom to Member countries to deal with this issue in their patent office administration. Patent offices should be aware of the possible

¹⁰⁰ For instance, "Form II olanzapine polymorph having a typical x-ray powder diffraction pattern as represented by the following interplanar spacings...(WO 96/30375).

¹⁰¹ See, e.g., Cook, Doyle and Jabbari, 1991, p. 89; Hansen and Hirsch, 1997, p. 113.

¹⁰² See, e.g. Cook, Doyle and Jabbari, 1991, p. 90; Grubb, 1999, p. 205.

unjustified extension of the term of protection arising from the successive patenting of the active ingredient and its polymorphs.

V.4 Analogy processes

Some countries have permitted patenting of non-novel processes (sometimes called “*analogy processes*”) if the resulting chemical is novel and displays unexpected properties.

The United States has held “analogy process” claims to be unpatentable unless they are inventive in themselves¹⁰³, but has carved out an exception for biotechnology. The products and processes of biotechnology have posed hard problems for applying the inventive step standard, since many biotechnology “inventions” repeat previously invented processes in slightly different contexts. This problem led to a statutory amendment of U.S. law in 1995, which lowered the nonobviousness standard by deeming a biotech process claim nonobvious if it involves new and nonobvious starting materials or produces a new and nonobvious result¹⁰⁴. While this solution, targeted only to biotechnology, may be deemed discriminatory -- and hence inconsistent with article 27.1 of the TRIPs Agreement -- it has been extended by case law to other fields of technology¹⁰⁵.

While the protection of “analogy processes” has been accepted in many jurisdictions as a logical means of protecting new developments, no country is obliged under the TRIPs Agreement to follow this approach of expanding the realm of patentable subject matter.

¹⁰³ See, e.g., Grubb, 1999, p. 206.

¹⁰⁴ See, e.g., Dratler, §2.03[3].

¹⁰⁵ See, e.g., Grubb, 1999, p. 207.

V.5 Compositions

Claims are sometimes directed to a pharmaceutical composition, that is, to a formulated product containing an active ingredient and appropriate additives¹⁰⁶. For instance, patents have been granted separately with regard to the injectable and oral forms of ofloxacin, a drug of relevance to the treatment of HIV patients. There is also a patent for the eye topical use¹⁰⁷. Another example is a patent on a formulation form of “ddl” (another drug of importance to HIV patients) granted in Thailand, which may deter the entry of a generic version of the product in that country.

Compositions may refer to combinations of previously known products. For instance, patents on the combination of the following formulations were granted in the USA: Aspirin 325 mg. + Carisoprodol 200 mg. + Codeine Phosphate 16 mg. with the expiry date 13/08/2002¹⁰⁸.

If composition claims are accepted subsequent to a patent on the relevant active ingredient, the patent owner may be able to artificially extend the term of protection granted under the basic patent¹⁰⁹. Unless the composition (which often consists of the simple mixture of components) includes additives that generate a truly new and inventive product, a pharmaceutical composition

¹⁰⁶ For instance, patent US 4,188,395 contains the following claims on compositions:

“A pharmaceutical composition containing as an active ingredient an effective amount for combating circulatory diseases relating to heart action and blood pressure of a compound according to claim 1 in admixture with a solid or liquefied gaseous diluent or in admixture with a liquid diluent other than a solvent of a molecular weight less than 200 except in the presence of a surface-active agent”.

¹⁰⁷ Chirac, 1999, p. 24.

¹⁰⁸ Source: Keayla, 1999, p. 18

¹⁰⁹ See, e.g. Cook, Boyle and Jabbari, 1991, p. 91.

should generally be deemed anticipated by the effective ingredient that it contains, and not patentable.

Another means to address the problem is to limit the scope of composition claims so that composition claims holders cannot prevent commercialization of other compositions containing the same active ingredient or of the active ingredient in bulk, after the basic patent has expired.

V.6 Optical Isomers

A special case takes place when a compound is an optically active enantiomer¹¹⁰ of a compound previously known only in racemic form. While some patent offices, such as EPO, have ruled that such enantiomers may be deemed novel, the existence of inventive step has been denied, since it is obvious that in such types of molecules optically active forms can exist and it is routine to test whether one or the other enantiomers in isolation is more active than the mixture of both (“racemic mixture”). Today, it is generally accepted that one optical isomer will typically have much higher activity than the other, so that superior activity for at least one of the isomers as compared to the racemate is to be expected¹¹¹.

¹¹⁰ Enantiomers are chemical compounds which behave in relation to one another as an image does to its mirror image. In organic chemistry, enantiomers occur for example in compounds which comprise a carbon atom with four different substituents. See, e.g., Hansen and Hirsch, 1997, p. 113. It is estimated that over a quarter of known pharmaceuticals present that property. See, e.g., Cook, Doyle and Jabbari, 1991, p. 84.

¹¹¹ See, e.g., Grubb, 1999, p. 199-200; Hansen and Hirsch, 1997, p. 113-118.

V.7 Active Metabolites

In some cases, patents may be accumulated on a compound and on the active metabolite that produces the desired effect in the body. For instance, in the case of terfenadine, which had been sold for many years in the United Kingdom as an antihistamine, the patent holder obtained a further patent on the active metabolite and attempted to block competition in the market of terfenadine, after the patent for the latter had expired. This was deemed to be an unacceptable attempt to extend patent protection¹¹².

V.8 Prodrugs

When metabolized in the body, inactive compounds can produce a therapeutically active ingredient, called “prodrug”. Countries must determine whether the patent on the compound covers the prodrug, and the extent to which claims relating to certain compounds should also be allowed to include their prodrugs¹¹³.

¹¹² See, e.g., Grubb, 1999, p. 212-213.

¹¹³ In the UK, for instance, it was held that sales of hetacillin, an acetone adduct of ampicillin which was immediately hydrolyzed in the body to ampicillin, infringed the ampicillin patent, because it was “ampicillin in disguise” (Grubb, 1999, p. 211).

VI. DISCLOSURE

Patents grant temporary monopolies to inventors in exchange for public disclosure of the invention. The full disclosure of the invention is a basic principle of patent law. Access to the information on the invention is one of the traditional justifications for the granting of temporary exclusivity to the inventor. Though relevant to health-related inventions, the problem of assuring adequate disclosure is of a general nature.

In order to perform its informative function, invention disclosures should at minimum be such that the invention can be understood and executed by an expert with average skills in the discipline concerned. This test should be applied at the national level, i.e. the description should be sufficient to teach the invention to a local expert¹¹⁴.

The law should require that the disclosure be sufficient so that a person of ordinary skill could reproduce the invention. A strict rule would require patent applicants to provide sufficient information to enable the reproduction of each embodiment of the invention for which they seek patent protection. If several embodiments are claimed, an “enablement” requirement would mandate disclosure of each embodiment¹¹⁵. This approach would prevent excessively broad claims covering embodiments of the invention that have not been described by the applicant in a form that allows their reproduction by a third party.

¹¹⁴ See, e.g., UNCTAD, 1996, p. 33.

¹¹⁵ However, some patent offices, such as the European Patent Office, accept that, in order to be valid, the disclosure need not include specific instructions as to how all possible variants within the claim definition can be obtained. See, e.g., Cook, Doyle and Jabbari, 1991, p. 80.

Another possible approach, applied by some patent offices, is to permit more generalized claims for those inventions constituting a substantial *technical contribution*. Thus, “pioneer” inventions -- those that open a whole new technical field -- may be entitled more generality in their claims than mere “follow-up” inventions -- those that only constitute improvements or “minor” innovations.

Article 29 of the TRIPs Agreement covers disclosure obligations. According to this article, Members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing or at the priority date of the application. This standard only requires the applicant to submit the best mode known at the date of the application or priority. This information rarely includes the actual know-how for the execution of the invention, since production has seldom started at that date.

One important issue -- not addressed by the TRIPs Agreement -- relates to the disclosure of inventions relating to microorganisms, since access to the relevant knowledge is only possible through access to the biological material itself. Such access may be made available to third parties with the publication of the patent application (as provided under European law)¹¹⁶. However, in order to protect the legitimate interests of the applicant, this access is for experimental purposes only¹¹⁷.

It is important to ensure that the scope of protection for biological material patents corresponds to the material actually deposited. If there is no correspondence between the description

¹¹⁶ In the case of the United States, access to a deposited sample is possible after granting of the patent.

¹¹⁷ The Budapest Treaty (1977) has created a system for the international recognition of the deposit of microorganisms, that facilitates the tasks of patent offices and provides adequate guarantees to the applicants/patent holders.

and the deposited material, the patent (or claim) may be deemed void.

Finally, national laws may require that biological material patent applicants inform the country of origin of the biological material, and to demonstrate that he/she has complied with the relevant rules with regard to access to the material. This requirement¹¹⁸ will help to ensure that the provisions of the Convention on Biological Diversity and of related national implementing legislation are complied with.

VI.1 Options - Disclosure

A possible provision in national laws may include the elements indicated in model option in the next page.

The three first paragraphs of the proposed language contain the general rules, while the three remaining paragraphs relate to the specific case of biological inventions.

The implications of the concept contained in the third paragraph need to be carefully considered. Its purpose is to ensure that patents are granted in inventions that can be actually executed in practice, and that do not contain purely speculative statements. For instance, when an application includes a group or family of elements, the granting of the patent should not be based on the possibility of executing some of those elements. Under the proposed Option, the claims would be limited to what is really enabled by the invention.

¹¹⁸ An obligation of this type was incorporated in the draft of the European Union Directive relating to patents on biotechnology, as recommended by the European Parliament in July 1997. Though it was removed from the finally approved text, Recital 27 of the Directive mentions an obligation to provide information as to geographical origin of biological material where this is known, without prejudice to patent validity.

**Disclosure
Model Option**

- a) The invention shall be disclosed in a manner sufficiently clear and complete for the invention to be carried out by a person possessing ordinary skill in the art to which the invention pertains.
- b) The applicant shall disclose the best mode known, at the date of the application or priority ^{a)}, for the execution of the invention.
- c) The description shall enable the execution of all embodiments of the invention.
- d) In the case of inventions related to microorganisms, the applicant shall deposit a culture thereof not later than the date of filing of the application. After the publication of the application, any interested party shall have access to a sample of the deposited culture, subject to the obligation by said party to use said sample for experimental purposes only until such time as the patent application is refused or withdrawn, or up to the date of granting of the patent.^{b)}
- e) In the case where the description is supplemented by the deposit of a microorganism, the scope of the claim shall be determined on the basis of the material deposited.
- f) The applicant shall disclose the place wherefrom any claimed biological material was obtained and, where appropriate, shall demonstrate compliance with the access and export regulations applicable in the country from which that material was obtained.

^{a)} *The priority date means the date on which the first application was made, in accordance with the terms of the Paris Convention.*

^{b)} *For the experimental use of an invention after the granting of a patent, see subsection VII.1 below.*

The last paragraph makes it clear that the obligation to demonstrate prior informed consent would only apply in cases where there are access (or equivalent) regulations in force in the country from which the material was obtained. The inclusion of this requirement may be important to avoid cases of “bio-piracy” and to provide a basis for the sharing of benefits with the supplier of the material, when appropriate.

VII. EXCEPTIONS TO EXCLUSIVE RIGHTS

All national patent laws contain exceptions to the exclusive rights granted by a patent, with the content and scope of those exceptions varying widely. Some exceptions are particularly relevant for the health area.

All of the exceptions considered below are recognized in some fashion in many developed countries. Outright exceptions to the exclusive rights of a patent (which operate without the need of a specific authorization by a court or administrator, and in favour of any third party) may be extremely important in fostering innovation, promoting the diffusion of technologies, or facilitating access at the lowest possible prices to health-related goods.

Article 30 of the TRIPs Agreement treats the exceptions issue only in general terms¹¹⁹ and leaves WTO Member states with considerable freedom to define the nature and extent of exceptions to the exclusive rights of patent owners. Comparative law reveals different types of exceptions that may be provided for within the scope of Article 30. However, national practice is not a blank cheque, and any particular exception may be challenged before WTO tribunals.

Conversely, the boundaries of Article 30 may be affected by new state practice which may result from the wholesale adoption of certain practices by many developing countries or their regional organizations. Such a strategy would not save any given practice

¹¹⁹ Exceptions to exclusive patent rights must meet three conditions: they should be limited, not unreasonably conflict with the normal exploitation of the patent, and not unreasonably prejudice the legitimate interests of the patent owner. These conditions are to be applied taking into account the legitimate interests of third parties.

that constituted a clear violation of the TRIPs Agreement, but it might produce a differential approach in any judicial review where the violation was not clear.

VII.1 Experimental Use

A basic objective of the patent law is to promote innovation. Overly broad patent rights may harm innovation, however¹²⁰. One mechanism to address this problem is through a patent exception relating to research and experimentation, permitting use of the invention without compensation to the owner for such purposes. An experimental use exception may foster technological progress based on “inventing around” or improving a protected invention, as well as permit evaluation of an invention in order to request a license, or for other legitimate purposes, such as to test whether the patent is valid¹²¹.

While the experimentation exception is rather narrow in the United States¹²², many countries (notably in Europe) explicitly authorize experimentation on an invention without the consent of the patent owner, for scientific as well as commercial purposes¹²³.

An experimental use exception, including one for certain commercial purposes, seem to fall clearly within the category of admitted exceptions under Article 30 of the TRIPs Agreement. However, actual application of such an exception that leads to rival products not significantly different from the patented product may be deemed an infringement under the “doctrine of equivalents” in some countries’ national case law (see section 9 below).

¹²⁰ See, e.g., Mazzoleni and Nelson, 1998.

¹²¹ See, e.g., Eisenberg, 1989; Gilat, 1995.

¹²² See, e.g., Wegner, 1994, p. 267

¹²³ See, e.g., Cornish, 1998, p. 736.

VII.1.1 Options - Experimental Use

A provision on this matter may be drafted in more or less broad terms, depending on the general policy adopted and on the expected implications of such exception on foreign investment, transfers of advanced technology, and local research and development.

Experimental Use Model Options

1. The effects of the patent shall not extend to any acts done for experimental purposes relating to the subject-matter of the patented invention^{a)}.
2. The patent shall not prevent experimental use of the invention by third parties for scientific purposes or for commercial purposes that do not unreasonably conflict with a normal exploitation of the patent and that do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of such third parties.

^{a)} Based on article 27(b) of the European Community Patent Convention.

Option 1 presents an exception defined on the basis of the *purpose* of certain acts. In evaluating specific acts, consideration

should be given to their nature and scope. Thus, generally, acts involving the experimentation *on* rather than *with* the invention would be admissible. Such acts may include limited manufacturing, to the extent necessary for experimentation, but not the sale of the obtained products.

Option 1, as drafted, clearly includes experimentation for commercial purposes. In order to avoid any doubt about this, specific wording may be added (e.g. “Such acts include those done for commercial purposes”).

Option 2 reproduces the wording of the TRIPs Agreement in order to make it clear that the exception would be subject to the conditions set out in article 30 of the Agreement.

Whatever the formulation, it is advisable that the national law explicitly provide for a well-defined experimental exception.

VII.2 Early Working

Another exception specifically applicable to pharmaceutical patents¹²⁴ relates to using an invention without the patentee’s authorization for the purpose of obtaining approval of a generic product before the patent expiration date. This procedure may permit the marketing of a generic version promptly after the patent expires. Since generic competition generally lowers prices¹²⁵, this

¹²⁴ It may also apply to agrochemical products and other products the commercialization of which is subject to prior administrative approval.

¹²⁵ See, e.g. WHO, 1988, p. 31.

exception -- known in the United States as the “Bolar” exception¹²⁶ -- promotes the affordability of off-patent medicines.

The availability of generics either under a brand name (“branded generics”) or a generic name (“commodity generics”) would lead to increased competition in the pharmaceutical market, and to correspondingly lower prices for the consumers and improved affordability of drugs¹²⁷.

BOX 3
THE “BOLAR EXCEPTION”

The “Bolar” (early working) exception was first introduced in the United States by the U.S. Drug Price Competition and Patent Term Restoration Act (1984), and has been explicitly adopted by Canada, Australia, Israel, Argentina and Thailand. In many European countries it has been recognized by case law based on the experimental use exception^{a)}.

The Supreme Court of Japan has also ruled (on April 16, 1999) on the validity of experiments made before the date of expiration of the patent for the purpose of an authorization petition for selling after such date. The Court argued that “it is one of the basic principles of the patent system to allow anyone to exploit freely a new technology after the expiry of the patent term, thereby generating a benefit to society”. Given the need to undertake clinical trials in order to obtain approval for commercialization of a generic product, the Court found that manufacturing the patented product for that purpose was not an infringement of the patent, since otherwise “third parties would not be in a position to exploit freely the patented invention for a

¹²⁶ It is so named “Bolar” after a case judged by US courts in *Roche Products Inc. vs. Bolar Pharmaceutical Co.*(733 F. 2d. 858, Fed. Cir., cert. denied 469 US 856, 1984). See also, e.g., Coggio and Cerrito, 1998.

¹²⁷ See, e.g. WHO, 1988, p. 31.

certain period of time even after the patent had expired. This, in turn, would contradict the basic principles of the patent system”.

^{a)} *Ono Pharmaceuticals Co. Ltd. V. Kyoto Pharmaceutical Co. Ltd., Case No. Heisei 10 (Ju) 153, 1998.*

Some countries (e.g. the United States, Israel) have adopted the “early working” exception while simultaneously extending pharmaceutical patent terms, but the law in other countries need not include this linkage.

Given that commercialization of the generic product does not take place until after the expiration of the patent, the early working exception can be regarded as fully compatible with article 30 the TRIPs Agreement.

In the case of Canada, the law established a “Bolar”-type exception that not only allowed tests with the invention, but also production and stockpiling of the product for release immediately after the expiration of the patent (Section 55(2)(2) of the Patent Act 1993). The European Union requested a panel against Canada under the WTO dispute settlement mechanism in connection with this exception. The panel decision confirmed that an early working exception is *consistent* with the TRIPs Agreement, even in the absence of an extended period of protection for the patent. However, the panel considered that the right to manufacture and stockpile before the expiration of the patent was not consistent with the said Agreement (see WT/DS114/R, 17 March, 2.000).

The World Health Organization and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have supported the establishment of an “early working” exception in national laws “for the rapid production of generic products in order to promote competition and contain drug expenditure”¹²⁸.

¹²⁸ WHO, 1999, p. 2; UNAIDS, 1999, p.2.

VII.2.1 Options - Early Working

The “early working” exception, as noted above, may in some cases be considered as part of the experimental use exception. However, given the importance of this issue, and the uncertainty surrounding judicial interpretation, it seems advisable to include a specific provision on the matter. It may include the following:

**Early Working
Model Option**

The patent shall have no effect with respect to any acts, including testing, using, making or selling the invention, solely for purposes reasonably related to the development and submission of information required under any law of ... (country) or of another country that regulates the manufacture, construction, use or sale of any product.

The proposed wording includes, among the possible non-infringing acts, the limited manufacturing of the patented product in order to undertake the tests required by the health authorities. This option would not allow for production and stockpiling before the expiration of the patent.

VII.3 Parallel Imports

Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner. For example, a company may buy a patented machine sold in Germany and then resell it in Canada -- where the same patent is in force -- without the patent holder's permission.

The underlying concept for allowing parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, he or she has no right to control the use or resale of goods put on the market with his/her consent or in otherwise authorized form. In other words, the inventor's rights have been "exhausted"¹²⁹.

Parallel imports, where allowed, cover legitimate products, not counterfeited products¹³⁰. In some instances, however, parallel imports have been admitted (on a regional scale) even when originating in a country where the product was not protected¹³¹.

In economic terms, the acceptance of parallel imports may prevent market segmentation and price discrimination by title-holders on a regional or international scale. In other words, parallel imports allow consumers effectively to shop on the world market

¹²⁹ The doctrine of "exhaustion of rights" may be applied at the national level (rights are deemed exhausted domestically and the commercialization in foreign countries is not deemed to have exhausted the patentee's rights), at the regional level, as in the case of the European Community (exhaustion is deemed to have occurred if commercialization took place in a country member of a regional agreement), or at the international level. The presentation made in the text refers to this latter case.

¹³⁰ Abundant literature and considerable case-law (particularly in the European Community) exists on the doctrine of exhaustion and parallel imports. See, e.g., Abott, 1998.

¹³¹ See the decisions of the European Court of Justice *in re Merck v. Stephar*, *Merck v. Primecrown*, and *Beecham v. Europharm*.

for the lowest price for a patented good¹³². Parallel imports may be of particular importance in the health sector, since the pharmaceutical industry generally sets prices differently throughout the world for the same medicines. Importation of a (patented) medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the product, without preventing the patent owner from receiving the remuneration for the patented invention in the country where the product was first sold.

On the negative side, states must evaluate the argument that there is an economic risk that the doctrine of exhaustion may discourage price discrimination favouring the developing countries. It has been argued that were parallel imports to be admitted generally, companies would tend to charge a single price worldwide, leading to an increase in the (supposedly lower) price that may otherwise be charged in low-income countries¹³³. The pharmaceutical industry is reportedly concerned with the possible leaks across markets that could reduce its profit margins and thereby its ability to recoup R&D investments. There are further questions concerning parallel importing from markets where pharmaceuticals prices are regulated. For these and other reasons, states need carefully to monitor the actual implementation of their exhaustion policy.

BOX 4
REGULATIONS ON PARALLEL IMPORTS

¹³² In some countries, laws have established regulations providing for exclusive licensing agreements for the importation and distribution of goods. This kind of regulation restricts competition and may practically impede parallel importation.

¹³³ However, prices levels are generally established in different countries according to the consumers' ability to pay. Hence, the setting of a single world price may be not be economically viable.

Parallel imports have been admitted in many developed and developing countries, on a regional or international scale, for all or some areas of IPRs. For instance, in the European Communities (EC) the European Court of Justice has applied the doctrine of *regional* exhaustion of rights to the entire EC and to different types of IPRs, in order to prevent market segmentation^{a)}. Once a patented product has been sold in an

(continued)

EC country, it can be resold in any other member country without infringing on the IPR holder's rights.

Some countries recognize the international exhaustion of patent rights (and thus permit parallel imports) in case law^{b)}, while others expressly establish exhaustion principles in national patent law. The Andean Group "Common Regime on Industrial Property", as contained in Decision 344 of 1993, states that the patent owner cannot exercise exclusive rights in the case of "importation of the patented product that has been marketed in any country with the consent of the owner, a licensee or any other authorized person" (article 34. d)^{c)}.

^{a)} In the case of the United Kingdom, however, the principle of international exhaustion has been admitted in some cases. See, e.g., *Whybrow*, 1997 and *Carboni*, 1999, on the "Davidoff" case. The European Court of Justice has accepted parallel imports even in cases where the product was not protected by a patent in the exporting country (*Merck & Co. vs. Primecrown Ltd.*, December 1996).

^{b)} In Japan, for instance The High Court of Tokyo held in the case *Jap Auto Products Kabushiki Kaisha & Anor vs. BBS Kraftfahrzeug Technik A.G* (1994) that the parallel imports of auto parts purchased in Germany did not violate patents granted to BBS in Japan. In the *Aluminium Wheels* case, the Japanese Supreme Court affirmed, in July 1997, that Article 4bis of the Paris Convention ("Independence of patents for the same invention in different countries") did not apply and that the issue of parallel imports was a matter of national policy of

each country. For a review on current State practices in this area, see, e.g., Abbott, 1998; NERA, 1998.

^{c)} Similarly, the Argentine Patent Law No. 24.481 of 1995 provides that the rights conferred by a patent shall have no effect against “any person who...imports or in any way deals in the product patented or obtained by the patented process once the said product has been lawfully placed on the market in any country; placing on the market shall be considered lawful if it conforms to Section 4 of Part III of the TRIPs Agreement” (Article 36.c).

In the case of South Africa, the Medicines’ Act has authorized the Minister to prescribe “conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public”. The Minister, “in particular may ... determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent” (Article 15C.a)¹³⁴.

The TRIPs Agreement permits parallel imports. Parallel importing is one of the measures that Member countries may take to protect public health under Article 8.1 of the TRIPs Agreement. More specifically, article 6 of the TRIPs Agreement establishes that each Member country has the freedom to incorporate the principle of international exhaustion of rights -- the underlying justification for parallel imports -- in its national legislation¹³⁵. If

¹³⁴ As indicated by this text, the parallel import exception in South Africa is not general as in other countries mentioned above, but limited to medicines, and it is subject to the prior decision of the Ministry of Health. Despite these limitations, the South African law was challenged on this point by 42 pharmaceutical firms (which have recently suspended, however, their judicial action against the law) and it was included in the Special 301 “Watch list”. However, the US Trade Representative announced, on December 1, 1999, the removal of South Africa from that list. For more details on this case, see Bond, 1999.

¹³⁵ According to an UNCTAD study, “Member countries also have the option (under Article 6 of the TRIPs Agreement) to adopt a worldwide exhaustion doctrine that could build upon the experience of economic

done, in order to avoid a possible discrimination complaint under article 27.1 and benefit all sectors of the economy, parallel importing should be permitted for patented goods in all fields of technology, and not only for health-related inventions.

Because Article 6 gives complete freedom on the matter to Member countries, parallel importing rules cannot be challenged at the World Trade Organization as a violation of the TRIPs Agreement, although the authority of a dispute settlement panel to adjudicate the indirect impact of exhaustion on other rights and obligations remains uncertain.

Although Article 6 appears to give Member countries very broad leeway to implement parallel importation policies, the doctrine of international exhaustion as applied to patents remains controversial with respect to both legal and economic aspects. Some influential authorities contend that overuse of the exhaustion doctrine would conflict with the exclusive right of importation conferred by Article 28(a) and with the thrust of Article 27(1), which forbids discrimination “as to . . . whether products are imported or locally produced.” It has also been argued that an international exhaustion of rights conflicts with the principle of territoriality and independence of patent rights established by the Paris Convention¹³⁶.

Other authorities counter that Article 28 is subject to Article 6 and therefore cannot be subject to dispute settlement procedures at the WTO.¹³⁷ Footnote 6 to TRIPs Article 28.1(a) states that “this right [of importing], like all other rights conferred under this Agreement in respect to the use, sale, importation or other

integration schemes of industrialized countries” (UNCTAD, 1996, p. 34). Similarly, a document published by the World Health Organization, after review by the WTO, includes among the possible TRIPs-compatible exceptions “parallel importation of the protected product” (Velasquez and Boulet, 1999, p. 33).

¹³⁶ See, e.g., Tsuda and Sakuma, 1996, p. 10.

¹³⁷ See, e.g., Bronckers, 1998; Verma, 1998.

distribution of goods, is subject to the provisions of Article 6'. The footnote to article 51 ("...there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder...") also supports this position.

General GATT principles also seem to support the permissibility of parallel imports. Under the GATT 1947, Member countries must treat imported products in a manner not less favourable than the like products of national origin (Article III.4), while Members cannot impose restrictions "other than duties, taxes or other charges" (Article XI(1))¹³⁸.

Further, widespread resort to the doctrine of international exhaustion by developing countries could acquire some weight as state practice, helping to resolve any legal uncertainty in this area.

The World Health Organization has explicitly supported the use of parallel imports to advance the principle "of preferential pricing in poor countries". WHO has stated that "in cases where drug prices are higher in poor countries than in richer ones, recourse to parallel imports in low-income countries in order to reduce prices might be appropriate, while preventing parallel exports to industrialized countries"¹³⁹.

¹³⁸ An interpretation of these provisions is not only that parallel imports are legitimate, but that the GATT *requires* WTO Members not to forbid such imports. See, e.g., Verma, 1998. The possible application of Article XX.d of GATT (which allows for exceptions when necessary to secure compliance, *inter alia*, with "the protection of patents, trademarks and copyrights") needs also to be considered in this context.

¹³⁹ WHO, 1999, p. 2. It should be noted that the prevention of parallel trade is an issue that needs to be addressed by the importing and not the exporting country. Thus, the acceptance of parallel importation in a given developing country would not prevent any other country, including industrialized countries, from treating parallel imports differently, to the extent that such treatment is GATT-consistent.

Finally, it is important to emphasize that the issue of parallel imports is completely distinct from the issue of counterfeit pharmaceutical products. Parallel imports, by definition, relate to products which have been legitimately put on the market, not to imitations of original products. Parallel imports would be subject, in principle, to the same import and other regulations applicable to any imported medicine.

VII.3.1 Options - Parallel Imports

National laws may contain a provision relating to parallel imports on an international scale, as follows:

Parallel Imports Model Options

1. A patent shall have no effect in relation to a product which has been put on the market in any country by the patent holder or with his consent.
2. A patent shall have no effect in relation to a product which has been put on the market in any country by the patent holder, with his consent or in other legitimate manner.
3. A patent shall have no effect in relation to a product which has been put on the market in any country by the patent holder or by an authorized party.

Option 1 provides for an exception relating to parallel imports originating in any country, subject to the condition that the product was marketed in such country by the patent owner or with his consent.

Option 2 broadens the exception, as it would also allow parallel imports in cases where the product was marketed in a foreign country in a legitimate manner, even without the authorization of the patent owner, such as where the product was

not protected¹⁴⁰ in the exporting country, or where it was sold under a compulsory license. This Option may be more vulnerable to challenge in the WTO than Option 1.

A possible compromise between these two Options would be to limit the cases in which parallel imports without the consent of the patent owner are permitted, by requiring that the sale in the exporting country be made by an authorized party (Option 3). The authorization may be given by the patent owner or by a State authority under a compulsory license.

VII.4 Individual Prescriptions

Patent laws commonly exclude from the effects of the patent rights, medicines prepared for an individual case in a pharmacy or by a medical professional¹⁴¹. This exclusion, though not specifically provided for, may be deemed permitted under article 30 of the TRIPs Agreement.

VII.4.1 Options - Individual Prescriptions

An exception relating to prescriptions for individual cases may be formulated as follows:

¹⁴⁰ With the implementation of the TRIPs Agreement, pharmaceutical product patents will be recognized in all countries which are Members of the WTO. Therefore, the situation of lack of protection will become exceptional. It may still occur in cases where the inventor company decides not to apply for a patent in a given country, or where an application has been refused and, therefore, the respective product remains in the public domain.

¹⁴¹ From a public health perspective, however, the proliferation of individual prescriptions may be risky, to the extent that there are no quality assurance mechanisms to protect the consumers.

**Individual Prescriptions
Model Option**

The patent shall have no effect in relation to acts consisting of the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription and in relation to acts concerning the medicine so prepared.

Several conditions need to be met in order for this exception to apply. They relate to the purpose of the medical preparation, the person that does it, and the existence of a medical prescription. These conditions considerably limit the scope of the exception, and exclude the possibility of its use to cover other commercial uses of a patented medicine.

VIII. EXAMINATION AND OBSERVATION PROCEDURES

Patent offices in developing countries are likely to receive a large and growing number of applications claiming protection for pharmaceutical processes, second uses of known products and formulation of products already in the market. Many of these applications will not satisfy the patentability requirements, but there is a real danger of many developing countries improperly granting patents in such cases. Most developing country patent offices lack the capacity to conduct a thorough technical examination of applications for patents. They may be further encumbered by laws and regulations that do not establish patentability criteria with sufficient specificity. Moreover, in some countries, patents are granted *without* prior examination. Though patents so granted can be revoked, the burden of proof lies with the third parties that challenge the patent's validity.

Developing countries may ease the examination burden by accessing foreign applications and grants (including the reports of foreign patent offices) corresponding to a national application¹⁴². The TRIPs Agreement expressly allows Member countries to request such information (article 29.2). But local examiners should not rely uncritically on evaluations made in industrialized countries, especially because many of the latter will apply different patentability criteria.

Many countries have established and actively use an opposition or observation system to patent applications in order to curtail the granting of improper patents. Such systems provide for the right of a third party to file an opposition to the grant of a

¹⁴² The application of Chapter I of the Patent Co-operation Treaty administered by WIPO may also be considered in order to improve the examination made at the national level.

patent or to submit observations on the patentability of the invention, after publication of the application¹⁴³ and before granting¹⁴⁴.

Alternatively, the law may establish the possibility of challenging a patent before the patent office, at any time or¹⁴⁵ within a certain period after the date of the grant¹⁴⁶. This approach enables third parties to challenge patents without initiating more costly judicial procedures.

Opposition procedure may help prevent the granting of improper patents in the health-related sector and other fields of technology, while also strengthening finally granted patents.

VIII.1 Options - Third Parties Opposition

Possible texts to deal with this issue may include the following options:

¹⁴³ Such a system requires the publication of the application before granting, which is the current practice in most countries. The United States has recently adopted this rule (Public Law No. 106-113, of 29.11.99), but only for inventors who filed abroad before applying in the United States.

¹⁴⁴ This procedure is currently provided for in some laws, such as in Argentina and in Decision 344 of the Andean Group countries.

¹⁴⁵ In the USA, for instance, the patent holder can request the re-examination of a patent by the Patent Office, before or during an infringement lawsuit, in order to determine whether prior art newly called to its attention invalidates one or more of the patent claims (33 USC 302).

¹⁴⁶ A post-grant opposition procedure may be followed before the European Patent Office. "An opposition to an European patent may be filed within nine months from the publication of the grant" (article 99, European Patent Convention).

**Third Parties Opposition
Model Options**

1. Any interested person shall have the right to file observations on an application, within ... days from the publication of the application, if such person deems that the invention does not meet any of the patentability requirements or that the application does not comply with other provisions of the law. In examining the application, the Patent Office shall take into consideration the reasons alleged by the third party.
2. After the granting of a patent, any interested person may apply for an order before the Patent Office to revoke the patent on any of the grounds upon which the grant of the patent could have been refused.

Where observations or an application for revocation are made under this section, the Patent Office shall notify the applicant or the patentee, and shall give him an opportunity to be heard before deciding the case.

Option 1 stipulates an *ex-ante* system of opposition. Under this system, the observations by third parties would be submitted after publication of the application and before granting of the patent. It is important in this case to make it clear that the examiner is obliged to take into consideration the observations made, either to admit or disregard them.

Option 2 provides for the revocation of a granted patent on the basis of administrative procedures. This would save challenging parties the cost of initiating a judicial procedure and in most cases speed resolution of challenges. Timing is crucial in resolving patent challenges, since the patents are presumed valid until revoked.

IX. CLAIMS INTERPRETATION

Establishing the boundaries of protected inventions determines the actual scope of the rights conferred by a patent¹⁴⁷, and is particularly important for some health-related inventions. It is a matter of national legislation to define when products or processes that are not *literally* described in a claim may be deemed “equivalent” and therefore considered as infringing on the patent rights.

There are different approaches to deal with this issue¹⁴⁸. Under one approach, equivalence may be found if the allegedly infringing variant of a process or product performs substantially the same function in substantially the same way to obtain the same result. Another approach relies not on a functional analysis, but on an objective comparison of the elements that constitute the variant and the invention, and particularly on the extent to which the variant introduced by the potential infringer may be deemed obvious¹⁴⁹ by the skilled person in the light of the claimed invention. This latter approach may permit an adequate protection of the inventor’s interests, while leaving more room for third parties’ innovations in the field covered by the patent .

¹⁴⁷ See e.g., Takenaka, 1995.

¹⁴⁸ See, e.g., Franzosi, 1996; Schuster, 1996; Anzalone, 1996. An example of the application of the doctrine of equivalents is provided by a case decided by the Osaka High Court on May 9, 1996. Sumitomo (Japan) had argued that it had independently developed a different form of t-PA, which had been previously patented by Genentech (USA). Sumitomo’s t-PA differed from Genentech’s in relation to the 245th position of the aminoacids sequence. This difference was regarded by the Court as insufficient to avoid infringement since, despite that difference, Sumitomo’s product was equivalent to Genentech’s t-PA.

¹⁴⁹ The date at which the equivalence is considered may be the filing date of the application or the date of infringement.

BOX 5
EQUIVALENCE TEST IN THE UNITED KINGDOM

The United Kingdom employs a three-part equivalence test, established by Hoffman J. in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181: “If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim (“a variant”) was nevertheless within the language as properly interpreted, the court should ask itself the following three questions:

- (1) Does the variant have a material effect upon the way the invention worked? If yes, the variant is outside the claim. If no
- (2) Would this (i.e. that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -
- (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.”

There is no rule in the TRIPs Agreement determining how narrow or broad the “doctrine of equivalence” should be, leaving this issue to national legislation.

In general, less technologically advanced countries may be expected to favour a narrow doctrine of equivalents, which is more pro-competitive and stimulates applications by those who work around patented inventions. In developed countries, such as in the United States, there are also open questions about the desirable scope of that doctrine; many think that a narrow doctrine of equivalents is required to promote innovation¹⁵⁰. Country preferences relating to the doctrine of equivalents may also depend on a country's pharmaceutical, chemical, and biotechnology development and manufacturing capacity, and on the availability of alternative forms of protection for local innovation.

IX.1 Options - Claims

A provision on this issue may be based on the following option:

**Claims interpretation
Model Option**

- a) The scope of protection of a patent shall be determined on the basis of the statements of the patent claim(s). Protection shall not encompass subject matter that is disclosed but not claimed in the patent.
- b) An element outside the wording of a claim may be deemed covered by a claim if, for a person skilled in the art it was obvious, at the time of the application, that said element could achieve the same result as that achieved

(continued)

¹⁵⁰ See, e.g., Merges, 1992, p. 705.

by the element expressed in the claim, unless such person would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention.

- c) The simple fact that an equivalent effect may be achieved shall not be deemed as evidence of infringement.

The proposed text defines, first, the limits of the granted protection. Any matter merely disclosed in the patent document but not specifically claimed would not be covered¹⁵¹. Second, it defines when equivalence is deemed to exist, based on an examination of the obviousness of a variant to the invention, at the time of the application. Following some case law, it is also suggested that the doctrine of equivalence would not apply when strict compliance with the wording of the claims was intended by the patentee.

Third, the proposed text clarifies that the existence of an equivalent effect does not lead to a presumption of infringement. A finding of infringement would be triggered instead by a showing of equivalence with regard to the elements of the invention.

It should be noted that the time at which the obviousness of the variants is judged may lead to different results. The later variants are compared to inventions, the more likely they will appear obvious and therefore be judged an infringement of patented inventions. Variants compared to inventions at the date of

¹⁵¹ This limitation has been expressly adopted by a Federal Court in the United States in *Maxwell vs. J. Baker Inc.* (1996).

the application (as done in some jurisdictions), are less likely to be considered “equivalent” than those considered at the time of invention.

X. COMPULSORY LICENSING

Compulsory licensing enables a government to license to a company, government agency or other party the right to use a patent without the title holder's consent. A compulsory license must be granted by a competent authority to a designated person, who should generally compensate the title-holder through payment of a remuneration. Compulsory licenses do not deny patent holders the right to act against non-licensed parties.

X.1 Grounds for Granting Compulsory Licenses

The provision of compulsory licenses is a crucial element in a health-sensitive patent law. Such licenses may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention. The use of such licenses, however, has been generally opposed by the research-based pharmaceutical industry¹⁵², on the grounds that they discourage investment and R&D¹⁵³.

Most countries, including developed countries, make available some forms of compulsory licenses¹⁵⁴. Such licenses are one of the mechanisms that States can use in order to promote competition and access to drugs. While it is advisable that national laws provide for a compulsory licensing system (as further

¹⁵² See, e.g., Bond, 1999.

¹⁵³ On the impact of compulsory licenses on R&D in the USA, see Scherer, 1999.

¹⁵⁴ See e.g., Correa and Bergel, 1996; Correa, 1999b.

elaborated below), it should be borne in mind that such a system is not intended to, and can not fix problems arising from the defective granting of patents, for instance, when the novelty or inventive steps were not actually met. It is, hence, of critical importance to ensure that the patentability criteria are rigorously defined and applied in the pre-grant process (see Sections 4 and 5 above).

Compulsory licenses are generally available for lack or insufficiency of working¹⁵⁵, to remedy anti-competitive practices, for cases of emergency, governmental or “crown” use, and for other public interest grounds. Most developed countries provide for use of compulsory licenses. Many developing countries that have recently revised their patent laws have also defined a more or less comprehensive list of reasons for the granting of such licenses.

The World Health Organization has recommended the use of compulsory licenses where there is “abuse of patent rights or a national emergency” in order to ensure that drug prices are consistent with local purchasing power. UNAIDS has also recommended the use of such licenses, as provided under the TRIPs Agreement, “such as in countries where HIV/AIDS constitutes a national emergency”¹⁵⁶.

¹⁵⁵ “Working” of a patent was originally understood as the execution of the invention in the country of registration (see, e.g., Penrose, 1974). The current trend in some countries is to admit that working may take place through importation. Article 27.1 of the TRIPs Agreement has been interpreted by some (notably the research-based pharmaceutical industry) as excluding the possibility of requiring the local execution of the invention. See, however, Brazilian patent law (1996) which established such obligation unless not economically viable (article 68.1).

¹⁵⁶ UNAIDS, 1999, p. 2.

BOX 6
COMPULSORY LICENSES IN THE USA, CANADA,
FRANCE, ISRAEL AND BRAZIL

Although U.S. patent law does not provide for compulsory licenses, compulsory licenses are allowed under special legislation^{a)} and under the antitrust law. The United States is probably the country with the richest experience in the granting of compulsory licenses to remedy anti-competitive practices and for governmental use, including national security. More than one hundred such licenses have been granted (Scherer, 1998), both for present and future patents. Licensees have generally been required to pay a reasonable royalty, determined on the basis of the “willing-buyer, willing-seller” formulation (Finnegan, 1977, p. 140), but in some cases the compulsory licenses have been conferred royalty free^{b)}. In some cases, moreover, the patentee was required to make the results of its research readily available to other industry members^{c)}, or to transfer the know-how.

Antitrust authorities in the United States have recently ordered compulsory licenses in the *Ciba-Geigy and Sandoz merger* (1997) in relation to cytokine products^{d)}, and as a condition for approval of Dow Chemical’s acquisition of shares in Rugby-Darby Group Companies. In the Dow acquisition, the Federal Trade Commission required Dow to license to a potential entrant intangible dicyclomine assets, including all formulations, patents, trade secrets, technology, know-how, specifications, designs, drawings, processes, quality control data, research materials, technical information, management information systems, software, the Drug Master File, all information relating to the United States Food and Drug Administration Approvals that are not part of the acquired company’s physical facilities or other tangible assets.

Some countries have provided compulsory licenses for specific products, such as pharmaceuticals and food. Canada

(continued)

first introduced compulsory licensing for medicines in 1923. As a result of the adoption of the TRIPs Agreement and its membership of NAFTA, Canada abrogated this system in 1993 (retroactive to December 1991) -- under which numerous compulsory licenses had been granted and a sizeable generic pharmaceutical industry had developed.

Compulsory licenses specifically related to medicines have been provided in other countries as well. For instance, French law authorizes compulsory licenses when medicines are “only available to the public in insufficient quantity or quality or at abnormally high prices”. In Israel, a license can be granted, if it is necessary to assure the public of a reasonable quantity of a product capable of being used as a medicament, to manufacture a medicament or a patented process for manufacturing a medicament (section 120(a)(1) and (2))^{e)}.

Some laws refer, more generally, to public health. For instance, Brazilian Decree 3201/99 established that in cases of national emergency or public interest, declared by the Federal Executive Authorities, a temporary *ex officio* non-exclusive compulsory license can be granted if necessary. Public interest is defined to include public health protection, satisfying nutritional requirements, protection of the environment and other areas of fundamental importance to the technological or social and economic development of Brazil.

^{a)} *US Clean Air Act 1988 (42 USC Sec. 7608) and Atomic Energy Act 1988 (42 USC Sec. 2183).*

^{b)} *For instance, in FTC v. Xerox Corporation (see Goldstein, 1977, p. 124).*

^{c)} *Hartford-Empire case (see, e.g., Finnegan, 1977, p. 139).*

^{d)} *The FTC specified that the royalties could be no greater than three per cent of the net sales price.*

e) In the United States, a bill to provide for compulsory licensing of certain patented inventions relating to health has been submitted to the 106th Congress (HR 2927, September 23, 1999).

Despite the provisions for compulsory licenses in many national laws, relatively few compulsory licenses have actually been granted¹⁵⁷. But commentators generally agree that the mere authority to grant compulsory licenses itself promotes some degree of competition, and that the impact of the compulsory licensing mechanism therefore cannot be measured on the basis of the number of licenses granted. Ladas (1975) has noted that “The practical value of the existence of compulsory license provisions in the Patent Law is that the threat of it usually induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished.”¹⁵⁸

The TRIPs Agreement specifically allows Member States to grant compulsory licenses on grounds to be determined by each Member country (Article 31). The TRIPs Agreement specifies some grounds for the granting of compulsory licenses but does not restrict the possible grounds to those actually cited. In contrast, the Agreement is quite specific with respect to the *conditions* to be met should a compulsory license be granted. These conditions include: the requirement -- in certain cases -- that a license be voluntarily requested before being granted on compulsory terms, non-exclusivity, and an adequate remuneration to the patent holder.

A health-sensitive patent law may specifically provide for several grounds for compulsory licenses, notably:

¹⁵⁷ The largest number of compulsory licenses has probably been granted in Canada, under the 1969 law amendment that authorized automatic licenses on pharmaceuticals, and in the USA, under antitrust laws.

¹⁵⁸ Ladas (1975, p.427). Beier (1999) has recently presented a similar view in a comprehensive study on the matter Compulsory licenses “through their mere existence as well as through the apprehension of compulsory license proceedings are liable to increase the willingness of a patent owner to grant a voluntary license” (Beier, 1999, p. 260).

- *refusal to deal*: when the patent holder refuses to grant a voluntary license which was requested on reasonable commercial terms¹⁵⁹ and, for instance, the availability of a product is negatively affected or the development of a commercial activity jeopardized;
- *emergency*: such as when urgent public health needs exist as a result of a natural catastrophe, war or epidemics¹⁶⁰;
- *anticompetitive practices*: for instance, to correct excessive prices and other abusive practices;
- *governmental use*¹⁶¹: such as to provide health care to the poor;
- *lack or insufficiency of working* of an invention needed for health care or nutrition;
- *public interest*: broadly defined to cover other situations where the public interest is involved.

The TRIPs Agreement provides special rules for compulsory licenses granted to government agencies or contractors. Countries' national legislation may eliminate a patent owner's right to seek an injunction to bar the government or a government contractor from using its patent, allowing the patent owner only the right to seek compensation (Article 31(h)). This is, in fact, the practice in the USA, where the government may use patents without a license,

¹⁵⁹ This ground is contemplated, for instance, in the UK patent law (article 48.3d) and in China's patent law (article 51).

¹⁶⁰ The situation of some African countries in relation to AIDS may be deemed, for instance, a public health emergency.

¹⁶¹ This type of licenses is grounded, in some jurisdictions, on the concept of the eminent domain vested in the State.

and the patent owner's sole remedy is to seek compensation under 28 USC 1498¹⁶².

Some public health-concerned organizations have urged countries to grant compulsory licenses for the "essential drugs" listed by the World Health Organization (WHO). Such a policy may be of limited importance, however. Although new important therapeutic developments (e.g. for AIDS) may be patented and on the essential drugs list, most of the drugs on the list are off patent. Moreover, high-priced drugs (such as those useful to treat AIDSs) are currently excluded from the list -- and these are the medicines for which compulsory licensing may be most valuable.

A national law provision subjecting "essential drugs" (either as listed by WHO or otherwise defined by a national government) to compulsory licenses would not contradict the obligation to consider each application for a compulsory license on its individual merits (Article 31 (a)). Such a provision would specify one of the grounds for granting such licenses, but they could remain subject to case-by-case evaluation. Compulsory licenses for essential drugs would not relate to a full "field of technology" but to a limited number of inventions which are of utmost importance for public health, and thus may be deemed as not violating Article 27.1 prohibition on discrimination among fields of technology. Moreover, Article 8.2 specifically authorizes measures necessary to protect public health. Measures necessary to protect public health are also accorded an exception to GATT rules. Article XX(b) of GATT 1947 specifically permits Members to adopt measures, necessary to protect public health, which violate their general obligations under the GATT.

¹⁶² The US Executive Order 12889 regarding the implementation of NAFTA. Sec. 6, formally waives the requirement in NAFTA 1709.10.b to seek advance authorization from the patent owner on "reasonable commercial terms and conditions," if use of a patent is by or for the government. The government or its contractors are required to notify patent owners of the use, if there are reasonable grounds to know an invention is covered by a valid patent, but the government can proceed with use directly without seeking a license.

The process by which compulsory licenses are granted will influence the space enjoyed by a WTO Member to grant compulsory licenses for health-related products. Countries will be in the strongest position to issue compulsory licenses if they establish the existence of health emergencies through public hearings and undertake serious negotiations with industry before issuing compulsory licenses. Action by many developing countries, or by their regional groups, dealing with common emergencies could also reinforce the legitimacy of compulsory licenses. Such measures are *not* necessary, however.

Countries should examine the potential negative impact of compulsory licensing, as with other measures limiting patentees' rights. The consequences include the possibility of discouraging foreign investment, transfer of technology, and research, including research into local diseases. Although it has been argued that there may be some risk that compulsory licensing will lead to the marketing of inferior products (since they will be manufactured without the patentee's co-operation), the production and commercialization of medicines are in all countries subject to prior approval and State controls.

The conditions for the application of compulsory licenses are of particular importance. Procedures which are too burdensome may effectively discourage the use of the system and deprive compulsory licensing of its potential value as a pro-competitive tool. Particularly important implementation issues are considered below.

X.2 Imports/Exports

The TRIPs Agreement does not restrict the possibility that a compulsory license be executed by means of the importation of the

patented product¹⁶³. This may, in fact, be the only viable means to execute a compulsory license in cases where the size of the local market does not justify local manufacturing, or where there is a need to promptly address an emergency situation. In a post-TRIPs scenario, however, in which most countries in the world will grant patent protection for pharmaceuticals, it will become increasingly difficult for a compulsory licensee to get independent sources of supply for a patented pharmaceutical. The patent holder may (for instance, through contractual prohibitions to export imposed on its licensees and distributors), effectively block the possibility of obtaining such products through imports. This will, in practice, significantly diminish the effectiveness of compulsory licenses as a tool to facilitate access to drugs.

The compulsory licensee may import from a compulsory licensee in another country. In this case, the imported product would have been legitimately commercialized in the exporting country. Such importation may be deemed as legal parallel importation, since the patent owner would have obtained remuneration in the exporting country and exhausted his/her rights there¹⁶⁴. If this interpretation were held, there would be in fact no need to get a compulsory license to import.

A further question would be, however, whether a compulsory licensee would be authorized to export. The TRIPs Agreement stipulates that a compulsory license must be “predominantly” for the supply of the domestic market (Article

¹⁶³ The importation of the product was a key element in the Canadian compulsory system mentioned above, as revised in 1969 (McFertridge, 1998, p. 83). If the compulsory licensee imported legitimate products (sold in a foreign country by the patent holder or with his consent), its acts could be covered under an exception for parallel imports.

¹⁶⁴ The admissibility of this interpretation may, however, be challenged in the WTO on the basis that a compulsory license does not imply the “consent” of the patent owner, as required in some jurisdictions, to consider that his/her rights have been exhausted.

31.f). Hence, exports are possible, though they should probably not constitute the main activity of the licensee with regard to the licensed product. The Article 31.f limitation, however, may not apply when a compulsory license has been granted to remedy anticompetitive conduct (Article 31.k). This exception corresponds to the practice followed in the United States in cases of compulsory licenses granted under antitrust legislation¹⁶⁵.

Whatever the approach taken, it is clear that successful compulsory licensing requires that adequate alternative sources of supply be secured, either through local manufacturing (which may not be feasible for small countries) or importation.

X.3 Registration

The value of the compulsory licensing system may be undermined if a licensee faces obstacles to registering (gaining approval to market) the protected product. Such obstacles may originate from an expansive interpretation of article 39.3 of the TRIPs Agreement, as reportedly promoted in developing countries by the US government.

Article 39.3 of the TRIPs Agreement obliges countries to protect confidential data¹⁶⁶ submitted for the registration of *new*

¹⁶⁵ See e.g., “*U.S. vs. Western Elec. Co. Inc.*”, Civ. No. 17-49, 1956 Trade Cases (CCH) 168, 246, Sx (E) (3) (D.N.J. 1956); “*U.S. vs. International Bus. Mach. Corp.*”, Civ. No. 72-344, 1956 Trade Cases (CCH) 68, 245, SxI (q) (4) (S.D.N.Y. 1956); “*U.S. vs. Imperial Chem. Indus. Ltd.*”, 100 F. Supp. 504 (S.D.N.Y. 1952) (Final judgement).

¹⁶⁶ These data generally consist of the results of tests made with a new product in order to prove its efficacy and lack of negative effects. They do not involve any inventive step, and are protected under the TRIPs Agreement in recognition of the investment made for their production, rather than on their value as “intellectual” assets.

chemical entities, only if their generation involved a “considerable effort”. Article 39.3, however, does not create **exclusive** rights on such data. The only protection arguably conferred under the Agreement is against “dishonest” commercial practices in the framework of unfair competition law¹⁶⁷.

Some countries provide exclusive data protection, but these are not mandated by the TRIPs Agreement. In Europe, the first applicant may obtain exclusivity for the use of test data for six or ten years from the date of authorization¹⁶⁸, while under NAFTA, a minimum five years period of exclusivity is recognized (article 1711.6).

It is important to note that article 39.3 of the TRIPs Agreement does not apply to pharmaceutical products which are not new, and that it only obliges to protect test data relating to “chemical entities”, thus apparently excluding polymorphs, compositions, delivery systems or uses, even if new. In addition, once data on a new drug have been submitted, national health authorities may approve subsequent applications of generic products on the basis of similarity¹⁶⁹, since such authorities will not have to examine or rely on confidential information¹⁷⁰.

Some developing countries have been under pressure to adopt standards of protection on confidential data beyond those required by the TRIPs Agreement. The adoption of such standards may lead to a restriction of legitimate generic competition for

¹⁶⁷ See, e.g. Dessemontet, in Correa and Yusuf, 1998, p. 258

¹⁶⁸ Directive 65/65, as amended by Directive 87/21.

¹⁶⁹ On the concept of “similarity” under European law, see the decision by the Court of Justice of the European Communities of 3.12.98 (Case – 386/96).

¹⁷⁰ This reasoning has been applied by the Supreme Court of Canada in *Bayer Inc., The Attorney General of Canada and the Minister of Health, Apotex Inc. and Novopharm Ltd.*, of 19.5.99., to admit the registration of a “similar” product even *before* the expiration of the five years exclusivity period in force in that country.

products which are already in the public domain, particularly if exclusive rights were recognized. This issue, therefore, requires careful examination in the context of a policy aimed at increasing access to medicines.

X.3.1 Options - Compulsory Licenses

Based on the previous analysis, a provision on compulsory licenses may contain some of the following elements:

Grounds and conditions for compulsory licenses Model Option

- a) Non-exclusive compulsory licenses shall be granted in any of the following cases:
 - (i) when the patentee has refused to grant a voluntary license under reasonable commercial terms and conditions, and the working or efficient working of any other patented invention which makes a substantial technical contribution is prevented, or the establishment or development of commercial or industrial activities are unfairly prejudiced;
 - (ii) in cases of declared national emergency;
 - (iii) when required for reasons of public health, such as to ensure the availability to the population of essential drugs, or when required in the public interest, including for security reasons;
 - (iv) to remedy anticompetitive practices;
 - (v) when required by the government or a public entity to provide to the population goods and services for

health care or other public purposes, on a non-profit basis;

- (vi) when the patent fails to be worked or is insufficiently worked in the country, and working is necessary for health care or to promote a sector of vital interest for socioeconomic development;

(vii) to use a patent which cannot be exploited without infringing another patent, provided that the former patent covers an invention that involves an important technical advance of considerable economic significance, and the owner of the latter patent is entitled to a cross license on reasonable terms.

- b) A compulsory license can be conferred to import or to locally produce the patented product or a product directly made with a patented process.
- c) The license shall be granted for the remaining lifetime of the patent, unless a shorter term is justified in the public interest.
- d) Except in the cases mentioned in b), e) and f) above, a compulsory license shall be granted if the requesting party has made efforts to obtain authorization from the patent holder on reasonable commercial terms and conditions, and such efforts have not been successful within 150 days from the request. In situations of national emergency or other circumstances of extreme emergency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.

- e) A compulsory license shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use.
- f) The use of a compulsory license shall be predominantly for the supply of the domestic market, except in cases of paragraph e) above.

(continued)

- g) The remuneration for a compulsory license shall be determined as a percentage of net sales, taking into account the value of the license in the relevant domestic market and the average royalty rates usually paid in the sector or branch to which the invention belongs. The remuneration can be reduced or excluded when the license is granted to remedy anticompetitive practices.
- h) The patent office shall have the authority to review, upon motivated request, the continued existence of the circumstances that led to the granting of a license, and may admit or refuse a request to terminate the license. The eventual termination shall be subject to the adequate protection of the legitimate interests of the persons authorized to use the invention, particularly when the licensee has made serious preparations or commenced to execute the invention.
- i) The patentee shall have the right to request from a competent higher authority the review of any decision relating to the legal validity of a compulsory license or to the remuneration determined by the national authority. An application for review shall not suspend the effects of a granted license.

The wording of paragraph a(1) is based on the UK Patent Law (article 48(A (1))(b)). In some countries (Argentina, China) a compulsory license can be granted when it is proven that the patent holder has refused to give a voluntary license on reasonable commercial terms within a specified period.

It should be noted that the granting of a compulsory license under the reasons indicated in a(vii), requires a definition of “worked in the country”, an issue that national law should address bearing in mind that Article 31 of the TRIPs Agreement does not explicitly prevent a country from requiring local production. However, Article 27.1 of the TRIPs Agreement is ambiguous and some have interpreted it as requiring “worked in the country” to be defined as “made available in the country” including through imports, rather than as “manufactured in country.”. Also the reference to health care in a(3), a(vi) and a(vii) might be deemed as constituting impermissible discrimination between fields of technology; however, “public health” cannot be considered as a “field of technology” but rather as a problem area (such as education or safety) that may be served with technologies originating in different fields.

Compulsory licenses may legitimately be granted for the importation, as well as the manufacture, of a protected product. Importation will be crucial for developing countries with limited technological or financial capabilities to undertake manufacturing of the protected product and to address emergency or anticompetitive situations, in which rapid action is necessary.

The duration of a compulsory license is an important issue. If the term is too short, there may be no incentive for a third party to request or accept a license. General practice is for compulsory licenses to be granted for the remaining term of the patent. This is the solution proposed above, with an exception when justified by reasons of public interest.

Determination of the remuneration to be paid to the patent holder is a key issue. The respective royalty rates may be established on the basis of the rates generally applicable in the respective sector¹⁷¹. Another possible method may be to define a “reasonable” royalty as that which a third party would pay for a voluntary license. This method, introduced by US law in 1922, has been extensively applied in US case law relating to the infringement of patent rights¹⁷². In the case of compulsory licenses for U.S. governmental use, however, the remuneration may be based on what the owner has lost, not on what the licensee has gained¹⁷³.

The practice in Canada (while a system of compulsory licenses was in force), was to require royalty rates of 4% of the sales price of the medicines under the license¹⁷⁴. In India, the applicable policy guidelines normally limit royalty payments to a maximum of 4% of net sales, while royalties of up to 8% have also been reported¹⁷⁵.

In order to determine compensation, authorities may require the patent holder to disclose product-specific R&D investments, revenues and other relevant economic data, while ensuring adequate protection of any confidential commercial data. They may also take into account the domestic market share in the total world market for the licensed product, in order to determine what proportion of actual R&D costs the country should fairly bear. In

¹⁷¹ See, e.g., article 43 of the Argentine patent law (1995).

¹⁷² See, e.g. Chisum, 1992, para. 20.02.2. In the area of copyright, the U.S. Court of Appeals for the District of Columbia has recently held that “reasonable” royalty rates under Section 801(b) of the Copyright Act does not mean “market rates”, but a rate determined according to statutory criteria (*Recording Industry Association of America v. Librarian of Congress*, D.C. Cir. No. 98-1263, 21-5-99).

¹⁷³ See, e.g., the U.S. decision in *Leesona*, 599F 2nd. at 969.

¹⁷⁴ See, e.g., McFertridge, 1998, p. 83

¹⁷⁵ See Graber, 1999, 3.

commercial practice, royalty rates usually range from 0,5% to 10% of the (net) sales of the licensed product, depending on the market volume and turnover of the specific product¹⁷⁶, and on the stage of the technology in the life cycle, among other factors¹⁷⁷.

It should be noted, finally, that the review of a decision granting a compulsory license may be made by an administrative or judicial body, and that the patentee's rights to such review may be limited -- in accordance with the TRIPs Agreement -- to the legal validity of the license and to the accorded remuneration.

¹⁷⁶ Niess, 1999, p. 16-17.

¹⁷⁷ Kumar and Bhat, 1999, p. 21.

XI. FINAL REMARKS

This document discusses possible elements to be considered in patent laws in order to develop a health-sensitive approach that facilitates access to drugs, especially by the poor.

The main premises considered in the preparation of this document have been the following:

- The granting and exercise of patent rights should be consistent with the basic goals and interests of the society, particularly promotion and protection of public health.
- There is no single patent system. While recognizing its international obligations, each country should shape its patent law according to its socio-economic needs and objectives, including in relation to public health.
- Although the TRIPs Agreement imposes various constraints, it leaves considerable room for countries to design their national laws to address public health concerns.
- Developing patent rules to improve access to medicines, particularly by the poor, is an important public health objective.
- The improvement of access to medicines requires a pro-competitive approach in several aspects of patent legislation.

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- Such an approach should aim, as a priority objective, to ensure that patents are granted on developments that constitute true technical contributions, and that patent rights are not unduly used to block innovation and legitimate competition by generic products. In other words, a pro-competitive, public health-sensitive patent law should be primarily based on a proper application of the patentability requirements, supplemented by a set of exceptional measures (such as exceptions to patentability and compulsory licenses).
- Patent laws should contain appropriate mechanisms to correct excesses in the exercise of patent rights.
- A health-sensitive legal regime should allow governments to act efficiently in cases of emergency, including epidemic crises.









Implementing a public health approach to patent policy requires not only appropriate legislation, but personnel -- in parliaments, patent offices, public health ministries, the private sector and the courts -- equipped to handle patent legislation design and implementation.

While all the issues presented in this document are important for the design of a public-health sensitive patent law, priority should be given to those relating to the patentable subject matter and the treatment of the specific cases concerning pharmaceuticals (Sections 2, 4 and 5), to the crafting of exceptions to patents rights, especially for experimentation and early working (Section 7), and to the development of a sound compulsory licensing system (Section 10). A national law that dealt appropriately with these issues would constitute an important step forward.

Public health goals can be significantly advanced through North-South co-operation, involving both the public and private sectors, through official assistance, licensing of technology, joint










ventures and other modalities. The climate, scope and effectiveness of such co-operation, however, may be significantly enhanced if developed countries abandoned the use of unilateral actions for obtaining the protection of commercial interests of their patent holders in developing countries. International co-operation in this area should recognize the fundamental right of any person to have access to basic health care, and the corresponding obligation of governments to protect and promote public health.

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