
بسم الله الرحمن الرحيم

INTELLECTUAL PROPERTY RIGHTS: AN INTRODUCTION FOR SCIENTISTS AND TECHNOLOGISTS

by
Mohamed B. E. Fayez
Fellow, Islamic World Academy of Sciences

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PO Box 830036 Zahran
Amman 11183 – Jordan.

Telephones: *+ 962 6 55 22 104*
+ 962 6 55 23 385
Fax: *+ 962 6 55 11 803*

Email: secretariat@ias-worldwide.org
ias@go.com.jo

http://www.ias-worldwide.org

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PREFACE

The Organisation of the Islamic Conference (OIC) was founded in 1969, as an international political body. In 1981, it launched three initiatives to promote culture, trade and science and technology among its member states. Science and Technology or (S&T) was assigned to a Ministerial Committee on Scientific and Technological Co-operation (COMSTECH), based in Islamabad, Pakistan.

The OIC Summit of 1984 approved the founding of an international academy of sciences to perform as advisor to OIC countries on science matters, thus the Islamic World Academy of Sciences (IAS) came into being as an independent, non-political, non-profit-making advisor body of OIC-Member countries.

Often the IAS publishes books or monographs that address topics of interest to science and technology community throughout OIC-Member countries.

One the eminent Fellows of the Islamic Academy of Sciences, and immediate past-president of the Egyptian Academy of Sciences volunteered to prepare this specialised yet lucid document on a rather complex and topical issue; namely Intellectual Property Rights.

This subject has been high on the mind of many within the science community of the OIC, and was discussed extensively at the April 2005 meeting of the Network of Academies of Sciences in Islamic Countries (NASIC), held in Islamabad (Pakistan), where the IAS and the Egyptian Academy of Sciences decided to publish a booklet on the subject under the title. "Intellectual Property Rights: An Introduction for Scientists and Technologists.

A note of thanks is due to the staff of Prof. Fayez in Cairo as well as IAS staff here in Amman for diligently and accurately getting the manuscript type-set and edited.

Moneef R. Zou'bi
Director General, IAS

Abdel Salam Majali
President, IAS

ABBREVIATIONS

DSU	Dispute Settlement Understanding
EMRs	Exclusive Marketing Rights
EU	European Union
IP	Intellectual Property
IPRs	Intellectual Property Rights
MFN	Most Favoured Nation
MNCs	Multi-National Corporations
NICs	Newly Industrialized Countries
OECD	Organization for Economic Cooperation and Development
R and D	Research and Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WTO	World Trade Organization

1 INTRODUCTION

The prime objective of the present study, addressing specifically scientists and technologists, is to acquaint these professionals with the essentials of intellectual property rights (IPRs) that can help them in their daily practices. These essentials embrace information on the rights and obligations that must, as required by law, be observed. They also include information on the flexibilities that allow some freedom in the interpretation and implementation of the law provisions, thereby balancing somewhat the higher standards imposed by the new world IPRs order. In essence, the message is that moderation is a pertinent virtue and a prudent attitude and course of action that can be safely adopted.

Acquaintance with and implementation of IPRs should in fact be viewed within the broader framework of national technology and industrial development policy, as well as a matter that directly affects market competition and consumer protection. As such, one could readily see the relevance of the IP issues to the daily operations of scientists including R and D practitioners.

It needs to be clarified at the outset that the present study has the distinct tendency of assuring that IPRs need not be seen as a realm or an exclusive privilege of the 'North' and therefore be feared or apprehended in the 'South.' In fact a deliberate effort is made to point to the existing opportunities for developing countries to fine-tune their IPRs regimes according to their development requirements. It will also be noted that there is a deliberate tendency to quote the IPRs-relevant aspects of pharmaceuticals in the discussion more than any other science-technology-industry area. This is because experience has shown that the pharmaceutical field is probably the most sensitive to IPRs restrictive-or-permissive legal provisions of all fields, and has aroused controversies bilaterally and multilaterally that we continue to live with.

2 CATEGORIES OF INTELLECTUAL PROPERTY

2.1 Intellectual property

In broad terms, and in a rather simplistic approach, intellectual property can be seen to embrace two main categories, namely industrial property and copyright. The present study is chiefly concerned with the first category. While it may be difficult to draw sharp and definitive lines between the two categories, it is commonly agreed that copyright relates to expressions of literary and artistic works of authorship.

Facts of contemporary life developments have introduced new areas of intellectual property and dictated a change in common understandings. However, it remains generally accepted that industrial property relates to the domains of industry and business and, therefore, embraces science and technology-based creations, chiefly inventions that are applied in industry and agriculture. Additionally, the areas of trade and industrial secrets, industrial designs, trade marks and trade names, integrated circuit topographies, and perhaps also geographical indications, are included in the category of industrial property since they affect tangible products and services that are circulated in the channels of commerce.

2.2 Copyright

Copyright is traditionally the means for protection of works of culture, including visual art among several art forms. These now, however, came to include computer programs as well as technical drawings and science and technology textbooks. Artistic textile and carpet designs and similar works are borderline cases since they are protectable either through copyright law or as industrial designs. Included in this category also are “related or neighbouring rights”

which embrace the rights of producers, performers and broadcasters of phonograms and similar artistic works.

By a *de facto* situation, the tangible and intangible expressions of folklore and traditional knowledge are included among literary and artistic works that can be copyright-protected. This is a stand that has been and continues to be advocated and defended by many countries, including all countries of the South, with only lukewarm appreciation from countries of the North.

2.3 Other areas of IP

The present study lays special emphasis on science and technology-based areas of IP, particularly those addressing patents, undisclosed information (or industrial and trade secrets), and transfer of technology. It is deemed useful, however, to introduce the other commoner areas of IP even though very briefly.

Trademarks are signs or symbols, including logos, figures and names, registered by a manufacturer or a merchant to distinguish his goods and services, thereby excluding imitations that are likely to confuse or mislead the public.

Geographical indications are signs or expressions used to indicate that a given product or service originates in a certain country or part of a country, and that such origin is responsible for the good or distinguishing qualities of the product or service.

Industrial designs are usually intended to protect the external appearance of a product, which involves distinguishing ornamental or aesthetic aspects that are not dictated by the function of the article in question.

Layout designs (topographies) of integrated circuits allow the owner of the design to prevent the unauthorized reproduction and distribution of such designs.

3 THE INTERNATIONAL LEGAL FRAMEWORK

3.1 A historical note

There have been in existence, and quite recognizably, two distinct trends in international relations with regard to intellectual property. Historically, the earlier was prompted by the desire of those who generate new knowledge to legally protect their creations as industrial property or copyright. If this trend were to be permitted to continue as a dominant factor, grave situations of inequity would have prevailed to the detriment of all humanity's manifestations of civilization. International negotiations to allow developing societies and the lesser developed segments of any society to share in the wealth of new knowledge gave rise to a balancing trend which is now well recognized in the legal national and international instruments currently regulating IPRs and their enforcement.

The international regulations framework in the area of industrial property took a first concrete form by international negotiations that gave birth to the Paris Convention for the Protections of Industrial Property (1883). In the area of cultural and related creations, the first concrete international instrument was the Berne Convention for the Protection of Literary and Artistic works (1885). In succeeding years, several world accords emerged to address more specialized issues of intellectual property in the areas of industrial property and copyright. It was evident that for the most part such accords produced little impact on the legal setting in most countries, at least as far as the protection in other countries of the creations produced in a given country. With the advent and then progress in multilateral trade negotiations aiming at the review of the General Agreement on Tariffs and Trade (GATT) the world found a platform for introducing historical developments in the existing patterns of trade and trade-related activities and for harmonization of the relevant governing legal systems.

3.2 The birth of TRIPs

The last (Uruguay) round of the negotiations (1986-1993) converged on intellectual property issues with unprecedented emphasis and emerged with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) as a unique feature of the umbrella agreement establishing the World Trade Organization (WTO, concluded in Marrakech, April 1994). The TRIPs Agreement is based and expands on the rights and obligations stipulated in a number of earlier narrower-scope conventions and treaties. It also introduces new areas of protectable subject matter that have not previously been addressed internationally. Thus by virtue of its coverage, the Agreement is now the most comprehensive international instrument on the protection of IPRs. The areas of protectable subject matter that are now covered by the Agreement are listed in Box 1 below, which shows also the corresponding international conventions where they exist.

For the sake of completeness, it needs to be said that there are other categories of IP which have not been formally covered in the Agreement, but which can be of practical significance at least for developing countries. One of these concerns the area of utility models, which may be viewed as minor inventions, and can be included in the national patent legislation. There is also the area of new knowledge in the field of plants and plant varieties that can be generated by professional plant breeders or by simple farmers. Because of its unique character, a separate legislation is usually produced to protect such newly generated knowledge and agricultural products.

In all probability, the absence of these two categories of IP from among those covered in the TRIPs Agreement is an expression of the low interest of major industrialized countries in such titles. It is known that these countries and their powerful industrial lobbies were the chief proponents of IPRS protection and have actively promoted the TRIPs negotiations during the Uruguay Round. Unless and until international instruments are concluded which are binding to all

signatories, it may be assumed that only their respective national laws in the areas of utility models and plant varieties bind individual countries.

Box 1. Categories of IPRs as Listed in the Agreement on TRIPs

Protectable Subject Matter	Corresponding International Convention
Patents (Articles 27-34)	Paris Convention for the Protection of Industrial Property (1883, Stockholm Act 1967).
Copyright (Articles 9-13)	Berne Convention for the Protection of Literary and Artistic Works (1885, Paris Act 1971).
Neighbouring Rights (Art. 14)	International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organization, Rome, 1961.
Layout Designs of Integrated Circuits (Art. 35-38)	Treaty on IP in Respect of Integrated Circuits, Washing-ton, 1989
Trademarks (Art. 15-21)	Paris Convention (above)
Industrial Designs (Art. 25, 26)	Paris Convention (above)
Geographical Indications (Articles 22-24)	None
Undisclosed Information (Art. 39)	None
IPRs-Related Provisions in Contractual Licenses (Art. 40)	Unconcluded UNCTAD negotiations (1984).
Plant Varieties (Art. 27.3 (b)	UPOV, 1991

4 RIGHTS ASSOCIATED WITH INTELLECTUAL PROPERTY

4.1 Economic rights

It is certain that all producers of intellectual creations are conscious about the need to protect their IPRs as well as to maximize the economic gains that accrue from their creations. They may not be knowledgeable about the full scope of these gains and may not be sufficiently alert to the moral aspects of their rights. To an individual or to a corporate body, intellectual property can be an effective means for economic and business development by turning a viable idea into a marketable product or service, enhancing reputation for excellence, or protecting investment in R and D. It is, therefore, a duty of the stakeholder to identify the information that can be legally protected and the forms of intellectual property (patent, trade secret, trade mark, industrial design, etc.) that can provide the most suitable means of protection.

However, it needs to be emphasized at this juncture that the ideas themselves cannot be protected by law. Only the physical expressions, or embodiments, when suitably and adequately described - for example in a patent application, including how to use and make the product - can receive legal protection. The same applies to a set of information, which may be very valuable by itself. The intellectual property law also does not provide protection information *per se*, but only when expressed in a protectable form and where a protector is assigned. When disclosed in a valid patent document, for example, the information is law protected and the government authority assumes the responsibility of protection. When undisclosed and kept as a trade secret, the information may be protected only against unauthorized accessing. Also, in the copyright area, law does not protect the ideas or information itself, but only the form of their expression as literary or artistic works.

Generally, IPRs are exercised as exclusive rights that relate to the tangible products which embody the protected information. The right-holder, of a valid patent, for example, exercises his law-provided rights by excluding, i.e. preventing, third parties not having his consent from the manufacture of or the conduct of any commercial activities involving the protected product. There are certain TRIPs-stipulated limitations and exceptions to the exclusive rights in all fields of IP, as will be discussed later on. It is through such regulation that industry and trade are directly or indirectly impacted. Even where the protected information results in the creation of certain intangibles, the enforcement of the relevant IPRs may regulate the use of the creations and the commercialisation of the products that embody them.

4.2 Moral rights

Non-economic, or moral rights need also to be recognized and the necessary actions be taken to protect them. In the area of industrial intellectual property, the chief moral right of an inventor is to ensure that his name as the inventor appears in a patent application when it is filed and later in the patent document when it is issued. The owner of the invention (for example an employer) may be a different person. In the copyright area, the author has the right to be known as the author, and to prevent false attributions of authorship. The aim is to prevent actions that would damage the author's honour or reputation, or even introduce unauthorized alterations.

4.3 Duration

The country law invariably specifies the duration of the economic rights, which imply financial returns for the right holder, but for which minimum standards are pronounced for the respective intellectual property areas in the TRIPs Agreement. The moral rights, however, are usually treated as being endless timewise. This means

that the attribution of an invention to a certain person (the inventor) is a perpetual right, whereas the financial returns on the same invention continue to be earned for only 20 years (at minimum). The inventorship rights of Thomas Edison over the incandescent lamp persist until today and are eternal; any financial returns have long been exhausted. Likewise, the authorship of Dante Alighieri over "The Divine Comedy" is recognized until today and shall continue to be recognized forever.

5 THE PRE-EMINENCE OF TRADE CONSIDERATIONS

5.1 The need to protect IPRs

All evidence of recent history point to that many of the manifestations of globalisation have been linked in a causative relationship to the need to protect IPRs. The chief proponents, understandably the industrialized countries and their home-based multinational corporations, have had to live as a consequence with tensions in foreign relations with developing countries and their business concerns. Evidently, a central factor is the fact that the chief stakeholders in industrialized countries are the private-sector enterprises which constantly generate new technologies and for this purpose provide the largest share of R and D expenditure, and are therefore responsible for the largest amount of R and D–based innovations. The resulting products and services were the subject matter of the fiercest competition the world history has known within and among countries of the North, and the keenest drive to capture markets in countries of the South.

Another consequence has been the entry into the big race of Japan and several newly industrialized countries (NICs), initially as catch-up economies and later as aggressive competitors, particularly in technology-intensive goods and services. With the threat that they

may lose leadership in technology and manufacture, the US and OECD countries saw their difficulties as resulting from a too open scientific and technological system which enabled the new entrants to imitate and then to improve upon their original innovations. Their reaction was to use the instrumentality of IP and rights conferred thereby to acquire monopolistic positions that would impede the progress of the new entrants and delay the further catching-up based on imitative paths of industrialization. The newly found formula had predominantly the effect of drastically reducing the diffusion of knowledge (essentially technological knowledge) through the conventional channels of transfer of technology, including contractual arrangements, training, joint ventures and implementation of turnkey projects essentially in the areas of high technology.

As a corollary, the aimed-at diffusion was to be achieved essentially through trade in the knowledge-embodying products and services. The tendency was at the heart of the historical reform whereby the expansion of trade was deemed to be better served by enhancing IPRs protection at the international level. With the emergence of new technologies for the production of sophisticated goods and services, the importance of technology as a strategic asset became highlighted more than ever before. This is a direct corroboration of the earlier conclusion reached by the Economics Nobel Laureate Robert Solow that the bulk of the increase of economic output in the US was the result of technological advances. Shifts in IPRs protection took new expressions, particularly for the newer information technologies (including computer programs) and biotechnology. The scope and coverage of protection assumed new dimensions and, in the biotechnology field, even life forms came to be subject matter for protection by patenting.

5.2 Trade-induced knowledge diffusion

The wave of technological protectionism in the industrialized countries ultimately assumed the form of a targeted new world

economic order whereby the diffusion of knowledge was seen to be achievable *par excellence* through trade. The change was evolutionary in character and occurred over the span of several decades. Persistently pursued, the change, through multilateral trade negotiations, culminated at the conclusion of the Uruguay Round in the trade-related agreements reached, including the TRIPs Agreement. But, to be sure, the basic trend of the change lives on and is evidenced at the regional and also at the bilateral levels in the on-going negotiations for the setting up of free trade areas.

The change involves a distinct shift in basic concepts and modes of operationalisation. Prominent among these are several symptoms which all assure the prominence of the economic (financial) gains that accrue to the innovator (personally) over the non-commercial benefits to the society which result from the dissemination of new ideas to the public and encouraging further contributions that add to or build upon these ideas. In concrete terms, the distinct trend, with the globalisation of the market, at present time, is to reward the innovator with a *grand prix*, namely a monopolistic trade position expressed in the form of a "right to exclude" third parties, together with a law that condemns forms of "misappropriation" of the innovator's IPRs and privileges. It is as if the society is compensated for the monopoly it grants to the innovator by the market availability of the goods and services introduced by the innovator. The moral face in the change, nevertheless, is preserved by the advocacy that, in the process, creativity of authors and inventors in the R and D establishment is actually promoted.

In the meantime, one should not lose sight of the fact that the existing flexibilities and range of exceptions and exemptions, regardless of their real impact and inherent value, as provided for in the TRIPs Agreement, may and indeed should be viewed, not as escape hatches, but as a practical means for mitigating the effects of the new higher protection standards. Essentially, they should be thought of as means in any fine-tuning of the IPRs regime to suit, to

the extent possible, the local economic development needs. Even if optimally utilized, they can never be sufficient by themselves for the transformation of a typical developing country to a status reasonably close to that of a typical developed country in a manner that allows equal application of the same rules to obtain reasonably similar results. The inevitable conclusion that must be reached and held in the minds of planners and executives is that salvation can be sought effectively through the utilization of the local R and D resources while maximally benefiting from all the allowables by reading their legal provisions in the most liberal sense. As will be explained in the sequel, internationally agreed pronouncements stand in support of this conclusion.

6 SIGNIFICANCE OF THE HORIZONTAL PROVISIONS IN THE TRIPS AGREEMENT

6.1 General

It is claimed in the present context that a basic national drive, in any developing country, would advisably be to prepare a country-specific and policy-oriented document that sheds sufficient light on the horizontal provisions of the Agreement on TRIPs.

These are the eight provisions contained in the Agreement's Part I: General Provisions and Basic Principles. The objective is to provide policy makers, executives and science and technology professionals with a reading of that international legal instrument that helps in the execution of daily operations by highlighting the duties and obligations of all parties, and in indicating important directions for medium and long-term action.

It is fair to say that the obligations expressed in those provisions (Articles 1 to 8, in addition to other provisions, as will be discussed in the sequel) are to a notable extent, balanced by the opportunities they

pose. Because of their broad nature and location in the Agreement horizontally ahead of all other parts, these provisions must be seen as applicable to all areas of intellectual property (see Box 1) and in all fields of technology, including the particularly sensitive pharmaceutical field.

6.2 Standards of IPRs

The TRIPs provisions are an expression of the minimum standards that must be adhered to. It is so provided for in the very first provision in the Agreement. According to Article 1, "Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

In a way this makes sense, since the provisions already represent higher standards than those hitherto known in all previous world accords for the protection of IPRs. The provisions thus constitute a legal text that has a floor without having a ceiling, and thereby can be the object of persuasions (that can amount to naked pressures) that can go to any extent above the Agreement standards. Thus, to many countries, these standards are viewed as the upper limit that they are prepared to accept.

6.3 TRIPs-plus standards

In the pharmaceutical field - much like in the field of computer programs, and more than in any other field of technology - several types of higher-standard claims are known to have been expressed by developed countries MNCs that came to be referred to as TRIPs-plus standards. In any consideration of responses to such standards, the

national decision maker should not lose sight of the implications of the adjoining TRIPs Article 4, requiring the application of the 'most favoured nation treatment' principle; see discussion given below. In fact it is highly recommended, as a policy issue, that the government should give due consideration simultaneously to all TRIPs 'horizontal' provisions of Part 1 when dealing with any specific situation in the pharmaceutical or any other field. The question of TRIPs-plus standards and associated claims will be dealt with later in this study. It may be added that the provision in Article 1 affords also a direct defence against the TRIPs-plus claims. Moreover, it explicitly allows countries to extend the protection provided in their laws, if they so desire, to other areas not covered by the Agreement, such as traditional knowledge in possession of their indigenous communities.

6.4 Treatment accorded to nationals and non-nationals

National treatment (as per Article 3) requires non-discrimination between local nationals and the nationals of other TRIPs Member countries in the availability, acquisition, scope, maintenance and enforcement of IP rights. Thus no allowance is made for any possible country differences in the development levels or in the resource endowments. The rule of non-discrimination also applies to the treatment accorded to nationals of different Member countries (Article 4). Thus if any advantage, favour, privilege or immunity is granted to the nationals of another country, the same should be granted "immediately and unconditionally to the nationals of all other countries".

The difficulty attending the observance of this requirement (commonly known as the most-favoured-nation (MFN) treatment) lies in the fact that developing countries, more often than not, are exposed to pressures from the businesses based in the developed countries to allow TRIPs-plus privileges in some technology sectors, in particular the pharmaceutical sector. Yielding to these pressures carries the danger of violating TRIPs Article 27.1 in addition to opening the door for potentially countless demands to receive the

same MFN treatment. Response to the pressures should, therefore, be highly judicious and taken while prudently giving prominence to benefit-risk calculations.

6.5 Interpretation

It is well known that several developed countries have for a long time held that the individual provisions of the Agreement could be interpreted for their direct and specific purpose, i.e. in isolation from the overall context of the Agreement. This misguided understanding has been corrected by the clarification given in the Doha Declaration on the TRIPs Agreement and Public Health (14 November 2001) that each provision of the Agreement should in fact be read in the light of the Agreement's objectives and principles.

As a corollary, it is asserted, that all developing countries are rightfully entitled to make use of the broader interpretation of the TRIPs Articles 7 and 8 to benefit maximally from the flexibilities they afford. Suffice it here to recall the Doha Declaration's conclusion (Paragraph 4) that the Agreement "does not and should not prevent Members from taking measures to protect public health" and that it "should be interpreted in a manner supportive of WTO Members' right to protect public health and in particular, to promote access to medicines for all."

Situations, however, are likely to arise where interpretations differ, as well as making allegations of non-compliance with the obligations stipulated in the Agreement. It is wise to point out that legal action in such situations may be taken by states and not by affected private individuals or corporations. The complaint may then be brought up for consideration under the WTO multilateral procedures established by the Dispute Settlement Understanding (DSU). It is a related fact that needs to be remembered, namely that no WTO Member can apply unilaterally trade sanctions against another Member accused of not observing certain minimum standards. This clearly outlaws

unilateral retaliations as applied by the United States under Section 301 of the US Trade Act.

6.6 Seeing opportunities in the proclaimed objectives and principles

It is a painful reality that the Agreement, which is enforceable equally in all countries regardless of their levels of technological development, is laden with new and burdensome obligations that challenge the capacities and capabilities of developing countries. Because the explicit pronouncements of the Agreement address *par excellence* the Members' obligations, the opportunities need to be extracted by reading the implicit in these pronouncements. In this context and for this purpose, the TRIPs objectives and governing principles (Articles 7 and 8, respectively) must be examined and indeed utilized for their content of favourably development-impacting provisions. We will find therein a reasonable degree of balance between rights and duties while emphasizing the socio-economic and technological development aspects.

In any reading of the Agreement's objectives (Article 7) and principles (Article 8) (full texts given in Box 2), several indications for useful action, of defensive as well as of proactive nature, are evident including the following:

a. While giving due regard and respect to the rights of title holders and those who generate new knowledge in any field of IP, it is equally important to highlight and protect the rights of the users of such knowledge. It is essential to this end to alert the users to their rights and obligations, in balance, in all fields of technology, while addressing specifically the practitioners in the R and D establishment.
b. A central issue in the wording and intent of the objectives and principles is the interest of the local economy and welfare of the

local society. These are values that should never be sacrificed in any IPRs-related transactions or negotiations.

Box 2. TRIPs Agreement Articles 7 and 8

Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

c. Of paramount importance is the highlighting of public health and nutrition the protection of which, by express law and regulatory provisions and the requisite administrative measures, is a duty of government in parallel with the protection of IPRs as per the Agreement provisions. This naturally extends to medicinal agents that should be efficacious and safe and to foods that should be wholesome nutritionally. Concomitantly, the pricing of medicines and foods should be thought of in the same framework. In adverse situations and under conditions of extreme urgency, the government will have the right to resort to exceptional measures (including the issuance of compulsory licenses) to ensure the availability of the necessary medicines and foods.

d. The Agreement, in its preamble, is clear in laying the legal and moral foundation of its new rules by "recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives …" This notion is reiterated in more than one expression in Articles 7 and 8 where it is asserted that "the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology …"

e. A right and duty of societies, while protecting IPRs, is to guard against and "prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." Such abuses and practices are not uncommon in trade-related IPRs-based transactions, and invariably lead to the restraining or blocking of competition. Competition and competitive attributes being the hallmark of the new international economic order, anti-competitive practices have been condemned in more than one way in the TRIPs Agreement provisions. Corrective, even punitive measures have been stipulated to confront such situations.

7 EXISTING TRIPS FLEXIBILITIES AND EXCEPTIONS

7.1 TRIPs flexibilities

This is an extremely important area that the attentions of planners and executives should be drawn to, if only on account of the possible benefits that can be drawn therefrom. We refer to them collectively as flexibilities. They include TRIPs provisions that must be taken as explicitly stated, allowed exceptions. They also include specific understandings that are implicit in the TRIPs pronouncements. An international statement (The Doha Declaration on the TRIPs Agreement and public heals, of the fourth WTO Ministerial Conference, 9-14 November 2001, Doha, Qatar) came later to confirm the right of TRIPs Member countries to utilize those flexibilities (*cf.* Box 3).

7.2 Exceptions

The inclusion of some exceptions in the TRIPs Agreement is generally taken to represent one of the most important internal balances that alleviate somewhat the pressures resulting from the exclusive rights of the right holders. The basic premise in the patents field, for example, is that the inventor's rights, although well recognized and respected, are not boundless or absolute. They are, just like rights in civil life, subject to limitations in terms of duration, scope and effect.

The balance is achieved through a number of TRIPs provisions (discussed at various places in the present study) that address the question of exceptions directly or indirectly. We find these in Articles 7 and 8 on objectives and principles, respectively), Article 6 (on the exhaustion of IP rights), Article 28.1 (on parallel importation among other permissibles), Article 30 which straightforwardly addresses the matter of exceptions to the IP rights conferred by a patent, Article 31 (on compulsory licenses) and Article 40 (on the control of anticompetitive practices in contractual licenses).

Box 3. The Doha Declaration on the TRIPs Agreement and Public Health. Paragraphs 4 and 5.

1. We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

   In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.

2. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include:
   (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
   (b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
   (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
   (d) The effect of the provision in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The exceptions are allowed only if they are provided for in the national law and meet the following broad conditions as stipulated in TRIPs Article 30.

1. The exceptions must be limited and not open-ended or *carte blanche*. The basis of their selection must be to protect the interests of the local population (i.e. defensive) against the excesses of some patent owners particularly in the sensitive areas of health and nutrition. The tendency of some owners to take advantage of their dominant market position, that can amount to abuse of their IP rights, must be counteracted by preventive measures or remedial responses. It is highly recommended, therefore, that care be taken to include in the national laws a number of carefully selected exceptions that make use of the general provisions of TRIPs Articles 7 and 8.
2. Another requirement is that the exceptions should not unnecessarily restrain the freedom of the patent owner in the exploitation of his invention unless, of course, such exploitation conflicts with the welfare of the local society and public policy. This means that the exceptions should stand in balance with the patent owner's exclusive rights and not unjustifiably be offensive. The rule of reason needs to be applicable here in assessing the "normal exploitation" of the patent and its impact on the host society. It is important, therefore, that the selected exceptions should all be capable of being explained and defended.
3. While recognizing the legitimate interests of the patent owner, as depicted in Article 28 (on the owner's exclusive rights), the exceptions should not prejudice these interests or contrive to neutralize them. However, it needs to be remembered that the legitimate interests of the host society must also be respected, such as by making use of the acts permitted when the patent owner's IP rights have been exhausted. Attention is called here to the basic concept of exhaustion (Article 6) and to the relevant

permissible acts, as enumerated in the footnote to Article 28.1. Again, the rule of reason will be applicable in assessing the rights and duties of all parties involved, while keeping in mind that the basic interests, including in the field of health and nutrition, of the local population in a sovereign country rank highest.

4. The Agreement, in Article 30, was careful not to neglect the legitimate interests of third parties. Such third parties are usually those who are entitled to benefit from the exceptions beside or other than the patent title-holder. Many of them can enjoy their privileges, under the specific exceptions, without the prior consent of the patent owner and even without the payment of any remuneration (except where the exception is a compulsory license).

For the purpose of the present study, we enumerate below some exceptions, as examples of those applicable in the pharmaceutical field, that have been actually included or are recommended for inclusion in national legislations. They all meet the conditions set out in TRIPs Article 30 while benefiting from the flexibilities afforded under Articles 7 and 8.

1. Use of the scientific content of the subject matter of a pharmaceutical, or indeed any invention for the purposes of education and training.
2. Use at hands of scientific research workers in R and D institutions of such scientific content for the purpose of learning. Such use may have the ultimate goal of contributing new knowledge or perhaps competitive pharmaceutical or other products or processes.
3. Preparation of medical prescriptions and dispensing individual pharmaceutical formulations incorporating the protected product or ingredient.

4. Use of the protected invention in means of transportation that are temporarily present in the country.
5. Parallel importation of the protected pharmaceutical (or indeed any) product when the patent owner's IP rights have been exhausted.
6. All acts of use in private which do not involve commercial transactions or activities.
7. Use of the subject matter of the invention by third parties who initiated *bona fide* activities prior to the date of filing a patent application covering the same subject matter.
8. Use of the invention subject matter under the grounds and conditions of compulsory licensing, and in carrying out a compulsory license.
9. Use of the information disclosed in the patented invention for the purpose of testing or examining a pharmaceutical product prior to issuing marketing approval for that product.
10. Use of the patent information for the preparation of limited quantities of the protected pharmaceutical product with the object of submitting such quantities, together with the relevant test data, to the concerned health authorities as a condition for issuing a marketing approval for a generic version of the same pharmaceutical product. The purpose of this exception - known as "Bolar exception" and permitted under the legislations of the USA, Canada and several other countries - is to enable the requisite tests of the generic version to be completed during the later part of the patent life of the brand-name product, thereby enabling the generic version to be released commercially immediately after the expiration of the patent term, or as soon as possible thereafter.

The value of this last exception will be appreciated from the fact that, in most cases, the cost to the consumer of the generic drug is only a fraction of the cost of the original brand-name version. The

practice, commonly known as "springboarding", is now established as perfectly legitimate and is resorted to in many countries as one realistic means to protect the drug consumer interests. Needless to say, a condition to make use of this exception is the local availability of a capability to translate the patent-disclosed information into workable technological know-how that enables the preparation of the pharmaceutical product in question in small quantities initially and in commercial quantities later on.

7.3 The question of exhaustion

The question of exhaustion of IP right (Article 6) and the right of parallel importation, dependent thereupon, are both among the essential flexibilities of the TRIPs Agreement that have been confirmed by the Doha Declaration. The value of these flexibilities are perhaps more pronounced and needed in the pharmaceutical field than in any other technological field. This is because the effects of abuse of IP rights by the patent owner, through for example setting excessive prices for the newly patented pharmaceutical product, can be particularly painful when the products are life-savers or essential for the treatment of critical heath problems.

It is useful at this point to indicate that the question of scope of exhaustion has been controversial in some quarters. There have been advocates for its local (chiefly in the USA), regional (European Community), and international applicability. The Article 6 TRIPs-compliance, therefore, means that Member countries are free to decide (*cf.* Box 3) how the concept of exhaustion should applied within their territory. They have 3 main options:

1. Members may adopt the concept of international exhaustion of patent rights. Adoption of this concept in the national patent law would allow any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party.

2. Members may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other member state of a regional trade agreement. Thus within the European Union (EU), the doctrine of regional exhaustion has been applied by the European Court of Justice to the entire EU and to different types of intellectual property rights. Thus, once a product has been sold in an EU member state, it can be resold in any other member state. Such parallel importing prevents market segmentation within the EU, and this is considered to be central to the promotion of the common market of the EU.
3. The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patent in one country to only those put on the market by the patent owner or its authorized agents in that same country. In this case, there can be no parallel importation.

Most developing countries are in favour of the concept's international applicability. Accordingly, the right of parallel importation can be used for gaining access to any pharmaceutical product (or indeed any commercially produced product) when it is available anywhere in the world at better prices or deliverable under better sales terms and conditions. In most countries, international exhaustion of patent rights is recognized. In Japan, the courts have held that the parallel importing of patented products sold in one country into Japan does not violate the patents granted in Japan. In addition, the courts have also stated the issue of parallel imports is a matter of national policy of each country.

It needs, however, to be reiterated here that the rights attached to the exhaustion of IP rights extend - in addition to parallel importation - to the acts of using, selling, offering for sale, and distribution of the patent-protected product (Article 28.1). The making of the product,

however, remains the exclusive right of the patent owner who also has the right to assign or transfer the relevant technology under a negotiated contractual arrangement.

7.4 Compulsory licensing

7.4.1 Rights and obligations

We discuss under this title another one of the most important flexibilities and exceptions, contained in the TRIPs Agreement and covered, with confirmation, in the Doha Declaration (*cf.* Box 3). The grant of a license to use the subject matter of a patent without the authorization of the patent owner, commonly referred to as compulsory licensing, is the most important and also the most controversial among all exceptions to the exclusive rights conferred by the patent.

It is a government authority (as first party) which grants the compulsory license that enables a third party (i.e., a party other than the right holder) to use (i.e. to work and exploit) the subject matter of a patent without a voluntary authorization by the right holder (as second party). Despite the element of compulsion contained in the whole exercise, such authorization has been known for many generations as a reasonable exception that may be allowed to face certain difficult situations. It has been, and continues to be an essential ingredient of all national patent legislations, and finds concrete basis in the provisions of the Paris Convention for the Protection of Industrial Property (1883, Stockholm Act of 1967-Article 5) (Box 4).

The TRIPs Agreement, in Article 31, the longest and most elaborate (comprising 12 paragraphs) among all its 73 Articles, defines the grounds (i.e., bases and justifications) upon which a compulsory license may be granted, and the conditions which must be observed when the license is granted and implemented, thereby stipulating the rights and obligations of all the parties involved. It is, without doubt, an exceptional measure of major importance and serious character that can effectively bring about benefits and/or prevent damages. For this

reason, it is surprising that the instrumentality of compulsory licensing has been hardly used in developing countries (perhaps with the exception of India), while it was well recognized and used in the developed world. As the following discussion will show, compulsory licensing should be recognized and made use of, at least in the pharmaceutical field, but naturally in all fields of technology, as a corrective measure and a critical balancing element in the national legislations of developing countries that functions, in the least, to deter the excesses and abuses of IP rights by patent owners.

Box 4. Article 5 in the Paris Convention for the Protection of Industrial Property, 1883 (Stockholm Act, 1967) Paragraph A.

1- Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.

2- Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

3- Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.

4- A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four year from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

It is for this purpose that we now turn to a brief discussion of the grounds upon which a compulsory license may be granted. The TRIPs Agreement (in Article 31.b) clearly defines these grounds and limits them to the following:

1. Failure to obtain a voluntary license: According to this ground, perhaps the commonest worldwide, the prospective local manufacturer fails to obtain a voluntary license from the patent owner despite negotiating extensively with the latter. In the course of such negotiation reasonable commercial terms must have been offered and reasonable (sufficient) time must have elapsed. Again, because the rule of reason here is an important measure, the matter may be subject to judicial review. Clearly, the party seeking and failing to obtain a voluntary license must be in possession of all supportive evidence that the process of negotiation met unjustifiably with failure despite his best efforts.
2. National emergencies and other circumstances of extreme urgency: These clearly are times of hardship and difficulty that threaten a population's security, wellbeing and welfare. There are many examples that could be cited. The TRIPs Agreement did not elaborate on this point and left the matter to be decided by individual countries. However, one could conceive health hazards and threats as among the most important.

   In fact the Doha Declaration expressed concern for this matter in an unprecedented fashion. In addition to adopting a highly liberal stance by declaring that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted", the Declaration pointedly specified health crises as among such grounds. It stated that "each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency", and explicitly indicated that public health

crises could "represent a national emergency or other circumstances of extreme urgency".

While not eliminating other situations of similar nature or equal gravity, which are left for the different countries to assess, the Declaration was careful to include among public health crises "those relating to HIV/AIDS, tuberculosis, malaria and other epidemics". The list, clearly, is not limiting and these health problems are cited only as among the most serious ones. We know of equally serious diseases that afflict many developing and least-developed countries and prevail on epidemic scales or are only endemic, which in many situations equally warrant the issuance of compulsory licenses. The service that is most direly needed in these health crises is making available sufficient quantities of the needed therapeutic agents at affordable prices. Naturally no profit would or should be sought by any party under such circumstances.

It is to be noted that the government authority's decision, for such purposes and under such circumstances, may be taken without the need to enter into negotiation with the patent owner to obtain a voluntary license to exploit the invention subject matter. Clearly, there can exist room for regional, even worldwide collaboration to help countries, particularly least-developed countries, under such circumstances when local capacities and capabilities fall short of the needed supplies.

3. Public non-commercial use: This is one of the common grounds for granting compulsory licenses in the pharmaceutical or in any other technology field, but only on a case-by-case basis. The government authority's decision does not seek any profit or entry into any commercial activity. For this kind of compulsory licensing there is also no need to enter into any negotiation with the right holder to obtain a voluntary license, but the latter should be notified promptly about the decision to grant a compulsory license.

Mention may be made here of the medicinal agents that may specifically be targeted by such compulsory licensing. Depending on the local health problems and levels of affordability in the society, the pharmaceutical patents that may need to be worked (i.e. exploited) under a compulsory license could be those that cover drugs for the treatment of critical health conditions or acute forms of disease such as immune-deficiency, liver or kidney failure, immunity suppression, and life savers in general. The purpose of the compulsory licensing instrumentality may also be to confront unjustifiably excessive pricing of drugs or the unjustifiable failure of a patented drug manufacturer to supply the drug in sufficient quantities or with the required quality standard. We may also mention that it is the view of several countries that the drugs of the WHO Essential Drugs List should generally be subjected to compulsory licensing whenever a health need arises.

4. Facing anti-competitive practices: Resort to the compulsory licensing instrumentality is a natural government response to anti-competitive practices that must be expected in any field of technology, and more so in the pharmaceutical field. Generally, the anti-competitive practices will result from the abuse of the exclusive IP rights conferred by a patent and include practices which unreasonably restrain trade or adversely affect the international transfer of technology (TRIPs Article 8). Because they are considered as serious offences that must be faced with compulsory licensing as an appropriate corrective of remedial measure, that may even be punitive in character (TRIPs Article 31.k), the anti-competitive practices must first be subjected to judicial or administrative process to establish their anti-competitive character.

   With the further opening of the world economy and liberalization of trade, it is not unlikely that some patent title-holders, particularly in the pharmaceutical field, but without

excluding other fields of technology, will abuse the market-dominant position they enjoy in the developing countries. This could take the form of unjustifiably demanding excessive prices for their patent-protected products which they supply only through importation, or acting in a manner that obstructs or restrains the activities of competing manufacturers, etc.

In such situations, the implementation of the compulsory license may be associated with the following exceptional measures:

(a) Waiver of the requirement to attempt to first obtain a voluntary license through negotiation for a reasonable length of time;
(b) Waiver of the requirement that the authorized production under the compulsory license should predominantly target the domestic market, which implies that the exportation of a portion of the production is permissible;
(c) In determining the amount of remuneration due to the patent owner, the cost of correcting the effects of the anti-competitive practices may be taken into account (i.e., deduced);
(d) Refusal to terminate the compulsory license if and when the conditions which led to its issuance are likely to recur;
(e) As a preventive measure, to grant the compulsory license when it appears likely that the anti-competitive practices would produce damaging effects even before their symptoms become evident; it being understood, of course, that the patent owner has the right to request a judicial review of the compulsory license decision.

5. Failure to work or insufficient working of the patent: Although not explicitly listed among the grounds for granting the compulsory license (TRIPs Article 31.b), the Paris Convention for the Protection of Industrial Property considers the granting of compulsory licenses a means "to prevent the abuses which might

result from the exercise of the exclusive rights conferred by the patent" and cites failure to work (i.e., exploit) the patent as an example of such abuses (Article 5.A.2) (Box 4). However, the Convention imposes a restriction in Article 5.A.4 that requires that the compulsory license "may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of 4 years from the date of filing of the patent application or 3 years from the date of the grant of the patent, whichever period expires last …"

A reflection of this principle is to be found in the TRIPs Agreement Article 8 which recognizes that appropriate measures may be needed to prevent the abuse of IP rights by the right holder. More specifically, the same TRIPs Article expects Member countries in the formulation of their laws and regulations to adopt measures necessary to protect public health and nutrition. Among the most important of these is the local working of the patented invention. Such working, by the right holder himself or with his consent under a voluntary license awarded to a local manufacturer, must also be seen as the real reward that the local society receives in exchange for the strict protection given to the owner's invention for the full term of the patent. Local working means transfer of technology that contributes to socio-economic and technological development (TRIPs Article 8) and to the dissemination of technology to the mutual advantage of the producers and users of technological knowledge (TRIPs Article 7). It also means the creation of a new manufacturing capacity and new work opportunities in the host country.

In the view of some innovators in many fields of technology, including pharmaceuticals, their supply of the ready-made, patent-protected products by importation into a country could (or should) be regarded as working of the invention in that country; thereby eliminating the need for local production. This view finds little acceptance in many developing countries, since parallel importation

is available anyway when the patent owner's IP rights have been exhausted.

Regardless of its practical value, at least in the short term, the existence of an elaborate set of provisions on the question of compulsory licensing in the national law of the developing country will be useful as a deterrent that prevents the abuse of IP rights and the resort to harmful anti-competitive practices by title-holders. Eventually and in the longer term, the acquisition of a viable technological capability would hopefully enable the effective use of the compulsory license instrumentality, as a legitimate exception.

In may be added at this point that a variant of compulsory licensing that has been known in recent years in some developing countries is "government use order". This usually refers to a limited compulsory license issued to a local firm (appointed to act on behalf of the government) to make or import a specific product (or a combination of products) to meet an emergency health situation.

7.4.2 A case for the effective use of compulsory licensing in the health field

It is a painful reality of life that many developing and least-developed countries have insufficient or no manufacturing capacities in the pharmaceutical field. What is worse is the lack of the technological capabilities that enable the translation of the information disclosed in pharmaceutical product or process patents into workable technological information (or know-how). Such capabilities are acquired only as a result of the work expended in dedicated R and D laboratories.

The Doha Ministerial Declaration on the TRIPs Agreement and Public Health (November 2001) recognized in paragraph 6 the fact that these countries "could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement." More frankly, these countries cannot make effective use of the compulsory licensing exception through local working (i.e., field exploitation) of the patent itself. They, however, can issue a compulsory license for the

importation of the needed pharmaceutical product without the need to manufacture it locally and also without authorization of the exclusive right holder. Recognizing the difficulty, the Doha Conference Ministers in their Declaration instructed "the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

In connection with the present issue, it is necessary to point to some of the conditions associated with issuance of a compulsory license. According to the TRIPs Agreement Article 31 paragraph f, such issuance "shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use". The implications are highly limiting to both sides of the possible interaction. The effect is direct to countries that can manufacture drugs since it limits the amount they can export when the drug is made under compulsory license. And it has an indirect impact on countries unable to make medicines and therefore wanting to import generics. They would find it difficult to find countries that can supply them with drugs made under compulsory licensing.

As viewpoints on how to resolve this tangle were many and different, the matter took many months of debate within the Council on TRIPs and other forums. In fact the members were deadlocked and the original deadline of 31 December 2002 was missed. With continued and painstaking negotiation during the next year, and after considering many alternative proposals, a decision was finally reached and formally pronounced by the General Council. This is now known as the Decision of 30 August 2003. The following are excerpts from WTO Press Release that announced the Decision.

This 30 August 2003 agreement allows any member country to export pharmaceutical products made under compulsory licenses within the terms set out in the decision (text below). All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.

A separate statement by General Council chairperson is designed to provide comfort to those who feared that the decision might be abused and undermining patent protection. The statement describes members' "shared understanding" on how the decision is interpreted and implemented. It says the decision will be used in good faith in order to deal with public health problems and not for industrial or commercial policy objectives, and that issues such as preventing the medicines getting into the wrong hands are important.

A number of other countries announced separately that if they use the system it would only be for emergencies or extremely urgent situations. They are: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey and United Arab Emirates.

The decision covers patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits. It is designed to address the public health problems recognized in Paragraph 1 of the Doha Declaration on TRIPs and Public Health, which says that WTO ministers "recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics".

The decision takes the form of an interim waiver, which allows countries producing generic copies of patented products under compulsory licenses to export the products to eligible importing countries. The waiver would last until the WTO's intellectual property agreements are amended. Among other things, the amendments would most probably affect the TRIPs Article 31.f, imposing restrictions on exportation, and 31.h requiring the payment of "adequate remuneration" to the right holder in each case of patented drug compulsory licensing.

On account of its importance to both potential importers and potential manufacturers-exporters in the field of medicinal agents, it is recommended that the following WTO websites be visited:

The Doha Declaration on TRIPs and Public Health
http://www.wto.org/english/thewto-e/minist-e/min01-e/minded-trips-e.htm

The Doha Declaration explained
http: //www.wto.org/english/tratop-e/dda/e/dohaexplained-e.htm#trips

TRIPs and pharmaceutical patents
http: //www.wto.org/english/tratop-e/trips-e/pharmpatent-e.htm

It is a requirement, therefore, that countries intending or willing to use the Doha Declaration Paragraph 6 system should provide for this use in their national legislation.

In the recent Canada law enabling generic drug companies to export their drugs to developing countries, under the Doha Declaration, the guidelines for compensating the patent holders ranged from 0 to 4 per cent, in accordance with the human development index of the countries to which the exports go. For example, the compensation payable would be 2.4% in the case of exports to Brazil, 1.9% for China, 1.2% for India, 2.3% for Thailand, 1.06% for Ghana, 0.68% for Kenya, 0.61% for Nigeria and 0.29%for Malawi.

8 PROTECTION OF INVENTIONS BY PATENTING

8.1 Hypothesis

Technology, as a predominant factor in the build-up of wealth and power in today's world, can be acquired either by purchase (or transfer) from technology owners or by generation through one's own sweat and tears in the R and D establishment. In the first course, the technology and its impact may not be long-lasting but may be

necessary (even profitable) under certain conditions; in the second the opposite may hold true. In All cases, the old wisdom of the business world "make or buy" appears to be valid as related to products and the know-how for making products. The world societies have thus, since the industrial revolution and with the evolution of time, came to be differentiated in parallel with their major economy-impacting firms into three categories. The ability to innovate and develop an invention has persistently played the key role in such differentiation (Box 5).

It is a fact that the field of inventions and their protection by patents is the most important and relevant to the activities of scientists and technologists among all IP fields. There is need in any treatment of the subject to address a number of legal-technical issues that have field implications and that directly affect the nature and scope of rights and obligations of the inventor as well as of the society at large, and also have links to international law.

Box 5. Technology-Based Rating of Firms

Innovators:	Leading-edge R and D Capitalize on basic science research Breakthrough/leading products
Imitators:	Trailing-edge R and D Followers, catch-up pursuits Reverse-engineering R and D Me-too/second generation products
Laggards:	Unable to innovate or even to imitate Manufacture chiefly under license Fully dependent on outputs of innovators and imitators

8.2 Criteria of patentability

Patents, to protect inventions, are official grants issued by a government conferring on the owner specific exclusive rights to make, use, or sell the invention for at least 20 years, counted from the date of filing the application. The government authority (the patent office) examines the application to make sure that the invention meets the three basic criteria of patentability, namely novelty (or newness), inventive step (or non-obviousness), and industrial applicability (or usefulness). It is a fact that the Agreement on TRIPs - and likewise most world legislations - offers no definition of the invention. However the criteria of patentability usually suffice as a practical alternative to a formal definition of the invention, which can be a product or a process, as laid down in the TRIPs Article 27.1.

The measure of novelty can hardly be controversial for all inventions, since it is essentially *objective* in nature, i.e. relates to the hard fact of prior art of published information and earlier patent inventions worldwide. It is for this reason that workers in the universities, R and D institutions and industries who achieve results that are likely to have practical value of application, are advised to exercise restraint in the matter of disclosure of their results. Such disclosure can destroy the condition of novelty if it occurs through publication of the results in scientific journals, research theses and publicly distributed reports, or through public speeches and lectures. The disclosure can also occur by displaying the results, or their physical embodiments, in public exhibitions. It is worth noting in this regard that the laws of some countries allow for such disclosure to occur during a specific period (between 6 and 12 months, referred to as a grace period) before the date of application for a patent without destroying the condition of novelty. It is strongly recommended to explore this matter in the patent laws of the concerned countries and to ascertain whether the grace period in one country finds effect in another.

The measure of industrial applicability, considered also to be *objective* in nature, can, however, be disputed on a number of grounds. For example, in the pharmaceutical field, it would frequently be sufficient for the product to be 'potentially useful' without the inventor being obligated to submit evidence of such usefulness. This, in real life, is the case with most pharmaceutical chemical inventions where large numbers of chemical entities (several tens or hundreds in one patent application) are claimed to be new and potentially useful (or industrially applicable). While all of the chemical entities listed in the application are protected with the award of the patent, only one, if at all, proves to be medicinally useful and hence commercialisable. Industrial applicability, therefore, must refer to the invention being capable of implementation should this be required or commercially feasible.

The disputes that have arisen and the complaints that have been sounded, in this connection, mostly concern the so-called 'broad-blocking' patents. These cover large numbers of chemical entities that are protected without being actually made use of, thereby preventing other parties from utilizing them even for other fields of application. This also can represent another facet of hindrance to the freedom of competition.

The measure of inventive step (or non-obviousness) is both interesting and subject of differences of opinion. This is essentially because it is *subjective* in nature and dependent on the judgment of the person who examines the patent application. It is also the criterion of patentability where the ingenuity of the inventor is most dependent on, and related to the original R and D effort put into the invention. Because of its subjective character (in contrast to the two other measures which both are objective in character), the measure of non-obviousness has been the cause of many of the disputes over patentability. It is also the measure that appeared latest in the contemporary literature of patent legislation.

The observation of non-discrimination between patents as to the place of invention is another standard that the Agreement asserted (in Article 27.1). While it is difficult to argue against the wisdom of the provision, some criticisms have been sounded in respect of the requirement that all fields of technology should equally and indiscriminately be protected by patents. The critics had in mind, of course, food and drug products which, to them, deserve to receive less stringent patentability requirements.

Another non-discrimination requirement relates to the patented products that are manufactured locally and those that are imported (Article 27.1). The apparent wisdom here is that the patent-protected product when manufactured locally, by the patent right-holder or with his consent, must not suffer as a result of discrimination in favour of a similarly protected imported product, or *vice versa*. The issue, clearly, concerns the working of the invention patent which occurs through actual field implementation (in manufacturing) of the product or the process patent.

A conflict of positions has arisen because in some quarters concerned with chemical and pharmaceutical innovation and production in developed countries, the view is held that the mere importation into a country of the patent-protected product constitutes and satisfies the requirement of working the invention in that country. In this context, we may recall a provision (Article 5 A) (*cf*. Box 4) in the Paris Convention for the Protection of Industrial Property which considers failure to work or insufficient working as an abuse of the rights enjoyed by a patent owner that can be counteracted by the issuance of a compulsory license.

The ethics behind the working of the patent is that the society that grants the patent and enforces its protection, for the benefit of the title-holder on exclusive basis, deserves also to benefit from the field application of the invention, which, *inter alia*, results in the creation of some work opportunities for local citizens and the transfer of

commercializable, knowledge-based technology. The spillovers of these benefits are quite many.

Before leaving the present discussion on patentable subject matter, it may be useful to recall a view, which has been sounded in recent years, to the effect that the use (only the use) of a product (in most cases a pharmaceutical product) is by itself patentable. The counter argument centres around the fact that the TRIPs Agreement (Article 27.1) has specified that products and processes, not uses, are protectable by patenting. The protagonists of the latter position also call attention to the provision in Article 27.3(a), which allows the exclusion from patentability of "diagnostic, therapeutic and surgical methods for the treatment by humans and animals", and count the uses, even new uses of existing drugs, among the methods of treatment available to the medical profession. It must be clarified, however, that the materials (instruments, chemicals and diagnostic kits) that may be associated with the 'methods' are not among the subject matter that may be excluded from patentability.

It is pertinent also to indicate that in addition to the familiar criteria of patentability, an eligible invention should satisfy the following requirements, as stipulated in the country law:

1. The invention subject matter must not be contrary to morality or public order.
2. The invention subject matter must not be specifically excluded from patentability. For example, many countries exclude from patentability life forms and parts of living organisms. It is, however, mandatory under the TRIPs Agreement (Article 27.3-b) to provide patent protection to microorganisms.
3. The application must be filed with the patent office. It must be prepared according to a formal procedure, using standard forms and comprise sections as specified by the patent office. Prescribed fees must be paid to that office.

8.3 Utility models

Of practical value in the present context is to indicate the role and possible usefulness of utility models, which are minor inventions in all fields of technology. Utility models - an instrumentality mentioned in the Paris Convention but not in the TRIPs Agreement - are 'small or petty' inventions which can be granted to protect lesser achievements without applying all the stringent criteria of ordinary inventions. Usually the conditions of novelty and usefulness must be met, but not the condition of non-obviousness. They are realistically useful for the legal protection of minor inventions and have found recognition in several developing countries as well as in some developed countries, such as Japan. It seems they have practical value in the protection of R and D and technical achievements in catch-up type of endeavours.

9 THE EXCLUSIVE RIGHTS CONFERRED BY PATENTS

9.1 Hypothesis

Understandably, and out of compliance with the TRIPs provisions, all legislations must highlight the exclusive rights that are conferred by a patent on the patent owner. These are probably the most explicitly pronounced of all rights provided for in the Agreement. Because of their character and implications, the developed societies and their industries are outspoken in demanding their enforcement. A natural response in developing societies to the higher standards of IP rights now imposed by TRIPs Agreement, is to seek to identify legitimate defences that mitigate their effects. In the present context, the new standards are conspicuously illustrated by the exclusive rights conferred by a valid patent on the title-holder (Article 28).

Exclusivity does not simply or only refer to a right of the patent owner to be the sole user, or exploiter of the patent. More importantly,

it implies his right to prevent third parties, not having his consent, from a number of acts relevant to the invention subject matter. As enumerated in the Agreement Article 28.1, these acts specifically are: (a) making, (b) using, (c) offering for sale, (d) selling, or (e) importing the product if the patent protects a given product. Thus we have two distinct categories of restrictions embedded in the concept of exclusivity. One category comprises the acts of making; the other category embraces the acts of using and handling in commerce.

In the present analysis of the letter and spirit of the legal texts, it is wished *ab initio* to assert that the intention is to explore the Agreement's flexibilities that stand in balance with the strict rules. Needless to say, the duty of exposing the flexibilities and the benefits attached to them - while giving due regard to the rights of patent owners - is most earnestly required in the field of pharmaceuticals than in any other field of technology.

9.2 The acts of making

If taken literally, preventing all third parties from making the patent-protected product could be tantamount to granting the patent owner monopolistic rights for the manufacture of the product. Being detrimental to national and global economy on all scores, these rights are restrained somewhat by some exceptions that the TRIPs Agreement allows. In general terms, the exceptions are provided for in Article 30. Chief among these in the exception that authorizes the granting of compulsory licenses under a number of grounds specified in Article 31 (b). The first of such grounds in the failure of a third party to obtain a voluntary license to use (for commercial ends) the subject matter of a patent (e.g. of a pharmaceutical product) under "reasonable commercial terms and conditions" and after negotiations that take a reasonable length of time.

Clearly, the exception here has the purpose of allowing a reasonable amount of market competition, all of course to the benefit of the consumer. It is useful to draw attention to the opportunities

attached to such exception. A necessary pre-condition, of course, is the existence of sufficient manufacturing capacity and technological capability in the concerned sector which would enable an effective use of the compulsory license. In this context, attention must be given to the critical role that may be assumed by the national/regional R and D establishment.

The 'making' of a product in the pharmaceutical field within the context of normal exercise of exclusive rights has been taken to cover the -preparation of small amounts as well as the manufacture of commercial quantities. This understanding, however, has been challenged in a recent dispute that was resolved by the WTO Dispute Settlement Body. Canada, as a defendant, was determined to have the right to include in its national law a provision that allows the preparation of limited amounts of the brand-name patent-protected (pharmaceutical) product, during the term of its patent protection, for the purpose of their submission to local (health) authorities in connection with an application to obtain marketing approval of the generic version. The idea is that the commercial production and market release of the generic product (that sells for much lower price than the brand-name product) would be allowed to commence immediately after the expiration of the patent term. Similar flexibilities can, therefore, be introduced in the national legislations of other countries.

9.3 The acts of using and handling in commerce

The prevention of third parties from taking part in the commercial activities associated with a pharmaceutical, and indeed any non-pharmaceutical, product during the term of its patent protection could be in direct conflict with the concept of free trade and highly damaging to the interests of consumers. The TRIPs Agreement, though including such commercial activities among the exclusive right that can be enjoyed by a patent title-holder (Article 28.1) was careful - as a welcome flexibility - to stipulate (footnote to Article 28.1)

that all such activities (embracing: using, offering for sale, selling, importing, and other distribution of goods of patent-protected product) are subject to the concept of exhaustion of IP rights. This valuable flexibility was finally confirmed in the Doha Declaration of the Fourth WTO Ministerial Conference on TRIPs Agreement and Public Health. Accordingly, countries are now free to establish their own regimes for the exhaustion of IP rights (TRIPs Article 6) without challenge, but subject to the national treatment and MFN provisions of Articles 3 and 4, respectively.

It is reiterated that, in the utilization of the concept of exhaustion, there have existed three differently expressed positions. Some developed countries proclaimed that exhaustion could only be applied on a national (i.e. local) level, others (in the developed world) took it to be applicable only on a regional scale, whereas most if not all the developing countries tended to see exhaustion as applicable on an international level. In actual practice, a major application of the concept of exhaustion is in exercising the right to parallel-import patent-protected products (such as pharmaceuticals) form sources that can supply them at lower prices or under more favourable selling conditions. The now-recognized right to implement exhaustion on a worldwide scale enables countries to parallel-import pharmaceutical and indeed other products, quit legitimately from anywhere in the world without the patent owner having the right to object.

Needless to say, the other acts of using and of handling in commerce, such as offering from sale, selling and distribution, will all be permitted as consequences of the exhaustion of IP rights. The implications of this liberal interpretation, supported by the Doha Declaration, in the pharmaceutical and other fields are doubtlessly highly beneficial to the developing countries.

10 ISSUES ARISING FROM DISPUTES OVER PROCESS PATENTS

The pressures of exclusive rights associated with patented pharmaceutical products are somewhat reduced by the allowed exceptions as indicated above. The situation in respect of chemical and pharmaceutical process patents is fraught with restrictions of similar nature, but which can be compounded by serious litigation prospects. The patent owner's exclusive rights allow for preventing third parties not having the owner's consent from (a) the act of using the process, and from (b) the acts of commercial character (i.e. using, offering for sale, selling, distributing or importing) associated with the product obtained directly from that process.

The pinch of this restriction is felt more pronouncedly when the product resulting from the patented process is a well-known pharmaceutical agent, already commercially successful and has established therapeutic value, particularly in the treatment of serious illness. The exclusivity given to the patent owner in such situation enables him to reap the additional benefits of a product-by-process type of patent. For what we have here is indeed a 'process' patent, but it is one which if applied gives a definitive product as the direct output. So the protection, in effect, goes to the product. It could be seen as one of the variations of the so-called 'evergreening' phenomenon through which patent owners seek to obtain extended benefits (TRIPs–plus) that go beyond the Agreement-provided minimum standards.

The 'evergreening' of an invention is achieved by applying for (and obtaining) another patent, pertaining to the same subject matter (such as a new pharmaceutical product) protected by an earlier patent. The aim of the new application, filed during the last year or two of the 20-year life of the earlier patent, is to secure a new full term of protection (another 20 years) for essentially the same subject matter. The novelty requirement in the second patent resides in the

new or improved process which yields, if applied directly, the same pharmaceutical product.

A TRIPs-permitted flexibility that can be used to alleviate the pressures of this situation is, naturally, the parallel importation of the pharmaceutical product protected under the second (process) patent; it being established, of course, that the IP rights of the product patent-owner have been exhausted.

It is important in the present discussion to address the problems, even dangers that can arise from disputes over process patents in the pharmaceutical field more than in any other chemical technology field. This occurs when a firm, usually large and powerful, that holds a pharmaceutical process patent, files a civil lawsuit alleging that its patent rights have been infringed by a third party, usually a small firm which produced unlawfully (i.e. without the consent of the right-holder) an identical product. In such situation, the judicial authority (court judge) shall have the authority to order the defendant to prove that the process used to obtain the identical product is different from the patented process. On this point, TRIPs Article 34 states that "any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process".

This is a straightforward situation of reversal of the burden of proof where the plaintiff's obligations are limited to proving that "there is substantial likelihood that the identical product was made by the process" and that he "has been unable through reasonable efforts to determine the process actually used" by the defendant. Clearly, the defendant will be squeezed by such court order, for he will have to present a convincing proof to the contrary of the allegation while, at the same time, having to protect his own business and manufacturing secrets.

More importantly, the defendant very likely will have to sustain the damaging consequences of the highly expensive litigation process. Overall, the situation is one of a 'strategic litigation' as it is frequently

called, which is a formidable technique of larger firms sometimes used for fending away small firms. The latter, deterred by the threat, may opt not to enter into a possible confrontation with the powerful firms. Thus a healthy, perhaps beneficial competition may thereby be quenched.

11 INVENTION PATENT TERM

Doubtlessly, the extension of the term of patent protection to at least twenty years (TRIPs Article 33) is chief among the higher standards heralded by the TRIPs Agreement. The cost to be borne as a result by the developing countries is perhaps more pronounced in the field of pharmaceuticals than in many other fields of technology. The painful implications for countries that do not innovate or manufacture, but rather depend on the importation of pharmaceuticals, are compounded on account of the fact that the protection now extends to the pharmaceutical products themselves - whereas the protection was formerly limited to the production process. Thus any attempt to make the same product by an alternative, even better, process, i.e. by 'inventing around' will no longer be available.

The pressures created by the extended protection period will be further accentuated by yielding to the persistent demands of patent owners who, particularly in the pharmaceutical field, seek to achieve TRIPs–plus standards by further expanding the effective life of the patent. They contrive to achieve this goal by, *inter alia*, the following devices.

1. Persuasion to relinquish the transitional period altogether or to substantially reduce its duration.
2. Persuasion to institute (in the national legislation) protection periods of longer-than-20-years duration or to be willing to grant - at least on a case-by-case basis - limited extensions (usually 1-5

years) beyond the minimum of 20 years specifically for pharmaceutical products. The persuasions are more visible during negotiations to conclude free trade area accords.

3. Persuasion to accept 'evergreening' practices that aim at giving longer even renewed life to the patent/s protecting the invention subject matter. These practices include the protection of other inventions that comprise:
   (a) An improved process for making the same pharmaceutical product;
   (b) a new and more efficient process for the same purpose;
   (c) a novel pharmaceutical formulation or dosage form that incorporates the same product; or
   (d) another 'use' of the product in the treatment of a health problem not previously specified in the earlier patent/s.

The protection of any one of these inventions may be claimed by a separate patent application. The result may be a succession of patents, each one with a full term of 20 years that follow each other in a line.

It is not uncommon that such requests may be accompanied by political pressures that may involve some positive and/or some negative incentives. It has been held in some quarters, in both developing and developed countries, that the granting of such TRIPs-plus term-extension privileges may not be very damaging if a balance in sought by the provision of reasonable benefits for the local society.

Depending on the local political will and visions for technological development, such benefits may be reaped by arrangements that seek to:

(a) Work, or demand the working of, the invention locally by actual manufacture of the protected product or implementation of the protected process - this being in direct compliance with the Paris Convention Article 5(A) (*cf.* Box 4);

(b) Deepen the manufacturing operations by, for example, backward integration that involves the local production of some of the input materials (raw and intermediate chemicals) and the use, to the extent possible, local inputs;

(c) Deliberate use of state-of-the-art know-how in the manufacture, management and marketing operations;

(d) Train local professionals to master such operations and give them corresponding work opportunities;

(e) Encourage export orientations to meet the needs of foreign markets; and

(f) Establish a viable in-house R and D capability or suitable working links with the local R and D establishment to serve the objectives of the production activity.

It is wished in the present context to emphasize the role of the national R and D establishment in creating a viable complementarity between the contributions of foreign supplies of chemicals and pharmaceutical products and those of local firms. The former, in the vast majority of developing country situations, are the innovators and global suppliers who enjoy exclusive rights that border on monopolistic rights. The latter are importers of ready-made products, such as pharmaceuticals or pharmaceutical chemicals. These, however, should turn progressively and persistently into active rather than passive learners, and see in organized catch-up R and D activities the only escape hatch and means of survival in today's fiercely competitive world.

12 THE PRACTICAL SIGNIFICANCE OF THE DISCLOSURE PROVISION

12.1 The dual function of patent system

In the entire course of the technological development experienced in the industrial societies, the protection of inventions and innovations has been one of two supporting pillars of critical importance. The other pillar has been the inventor's obligation to work, i.e. implement his invention in the field of production in the country that provides patent protection. The latter obligation is explicitly stated in the Paris Convention on the Protection of Industrial Property (Article 5.A), *cf.* Box 4.

It is also useful, even essential for practical reasons, to recall the dual function of the patent system within the overall macro-economic system in any society, where several forces co-exist in balance and serve in the dynamic process of growth and advancement. For on the one hand, the patent provides a valuable incentive to inventors by guaranteeing them exclusive, near-monopolistic rights as a reward for their ingenuity that go with the protection of the invention for a fixed term (now 20 years). On the other hand, the patent provides an invaluable opportunity for the society to learn from the knowledge contained in the patent disclosure. Such knowledge should, in a healthy situation, inspire R and D workers in their pursuits of catch-up and competition with each other and with the patent title-holders themselves.

12.2 Disclosure of the invention

Disclosure of the invention, is a cardinal feature of the patent system, where two levels of operation are applicable:

(a) The patent applicant *must* "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art" (TRIPs Article 29.1); and

(b) The applicant *may* be required "to indicate the best mode for carrying out the invention known to the inventor.."

It is definitely a sovereign right of the country to ensure that, by law, the applicant for a patent must fully be in the compliance with these requirements. It is useful, even necessary to note in the present context that the language of the TRIPs Agreement is explicit in obligating the disclosure at level (a), while leaving the matter as an option at level (b), above.

Thus, clearly, the invention patent document must serve the dual purpose of an instrument for the protection of the inventor's rights, and for the dissemination (through publication) of information of potential technical, even commercial value. When this value has been finally demonstrated, by the actual commercial production and marketing of the protected product, the patent-disclosed information begins also to serve as an important stimulant to other innovators, almost challenging them, to produce competitive products and processes.

It is a fact of everyday life that, historically and until today, the disclosure of inventions has been a crucially important instrumentality for the advancement of technology and manufacturing industry. As such, disclosure must be seen as a legally binding act that involves rights and obligations, affecting both the inventor and the society, with both practical and moral obligations, all inseparably co-existing in balance. Among many fields of technology, the pharmaceutical field has known many of the best illustrations of the validity of this statement. The breakthrough R and D-based discoveries of new, biologically useful and commercially successful chemical entities have invariably been followed by an avalanche of scientific publications and patent releases that introduced structurally related products belonging to the same or similar chemical families and which range, commercially, between the mediocre and the best-seller. Many of such variants will be

recognized as barely efficacious therapeutically or even as comparable to the pioneer products. There may also emerge one or more products that prove to be medicinally and commercially more successful than the pioneer (or lead) pharmaceutical chemical.

All these results, it must be emphasized, could not have been achieved were it not for the disclosure of the relevant patents and the openness of the scientific literature. Only scientific workers in alert R and D institutions and manufacturing enterprises can benefit from such openness of the patent and scientific literature, and are thereby enabled to make their own contributions. Although these contributions may vary in their direct importance and level of market-worthiness, they have broader significance and impact that need now to be highlighted. Marginal improvements in a production process or alterations in the structure of the chemical entity in question may result, if successful, in the generation of "me-too" pharmaceuticals or, indeed, any manufactured product. More important, however, is the acquisition of a working capability for scientific and technological catch-up (mood and methodologies) in the R and D establishment. This, as all lessons of contemporary life have shown, is a condition for acquiring the higher level capability of innovation, which is true for pharmaceutical technology as for any other R and D-based technology.

12.3 Benefits of implementing the disclosure requirement

As a conclusion, a summary is given below of the benefits that can be reaped from the rational and prudent implementation of the disclosure requirement, while reducing (or preventing) the damage that may result from the abuses of the exclusive rights conferred on the title-holder by the patent.

1. The disclosure, if truly complete and clear, can be indicative of the applicant's intention whether to implement (i.e. work) the

invention locally, or to use it merely as a defensive mechanism to protect his imports.

2. The disclosure serves as a technical, in addition to a legal instrument that can be decisive in resolving disputes in situations of alleged infringement. This is because legally the protection of the invention is limited to the information that is disclosed in the patent document. Particularly important are the disputes that involve process patents in the chemical or pharmaceutical field where the defendant may be ordered by court to reveal the details of the process actually used by him to make an identical product. To do justice in resolving the dispute (which may involve a strategic litigation), the court will have to consider the details of the protected process as disclosed in the patent document against those revealed by the defendant.

3. A practical value of the disclosure, particularly in the chemical and pharmaceutical fields, becomes immediately apparent in the situations which warrant the issuance of compulsory licenses. The clarity and completeness of the disclosure will be most appreciated by the practitioners in the R and D or manufacturing facilities who are responsible for constructing the requisite know-how package.

4. Disclosure of the "best mode for carrying out the invention known to the inventor at filing date" can be a highly serviceable ingredient in the entire invention disclosure, at least for the purpose just indicated above. It is, therefore, strongly recommended that countries ensure its inclusion as a mandatory condition, not an option, in their patent laws. The importance of this best-mode disclosure requirement is not merely to ensure the reproducibility of the practical steps and operations of the process, but also hopefully to expose the critical elements of the process (such as the use of specific catalysts) that are responsible

for best yields and safest operation conditions. In a few situations, and depending on the importance of the invention subject matter, it may be useful to carry out the process as part of the examination procedure to at least ascertain its reproducibility and completeness.

5. Another use of the disclosure information is in gaining awareness about the latest trends and current orientations in the technology field as revealed by the inventions of the leading firms. These in fact are signals that could be useful in guiding future R and D activities of the local institutions (industrial firms and universities).

6. At the practical level, the information contained in patent disclosures serve practitioners in the pharmaceutical, and indeed in any other, industry and in R an D laboratories in compiling state-of-the-art knowledge about any particular product or process. The patent literature, for this purpose, becomes an invaluable complementarity to the open scientific literature. At this point, attention is called to yet another category of patents in the chemical field. Besides product and process patents, there is the possibility to gain product-by-process protection through a process patent, the application of which leads only to a definitive product.

7. Finally, the information disclosed in any patent finds its practical utility in enabling action at two levels:

   (a) After the patent term expires and the invention falls into the public domain, when the information can liberally and quite legitimately be used for commercial ends. The indispensable requirement for this purpose, naturally, is the possession of the commercially viable knowledge (industrial know-how) for the manufacture of the no-longer-protected product. The

availability of the requisite know-how can result either from buying it from foreign suppliers or from a deliberate replicative effort by the local R and D establishment to generate such knowledge.

(b) While the patent is enforced, i.e. before the expiry of the patent term, local R and D efforts will (or could) have the explicit purpose of learning from the patent-disclosed information at the level of actual experimentation. These may include efforts that aim at introducing marginal improvements in a process, or minor structural modifications in a molecular entity of importance. The result, if successful, could lead to what is now known as a "me-too" product. It can be asserted that the two pursuits, (a) and (b), are legitimate and can be initiated any time after the issuance of the patent document; it being understood of course that the making (or manufacture) of the protected product for commercial purposes is to be permitted only after the expiry of the patent term.

8. It must be remembered, for practical reasons, that according to the rule of territoriality of patents, the foreign inventions receive local protection only if they are locally patented under the domestic patent law.

13 UNDISCLOSED INFORMATION AND TRADE SECRETS

13.1 The protection of undisclosed information

The protection of undisclosed information, commonly known as trade and industrial secrets, is a new area of IP rights that the TRIPs Agreement introduced and required all Member countries to include in their respective legislations. Because of its newness, at least to most developing countries, the protection of undisclosed information and the related enforcement measures need to be considered in the light of the specific TRIPs provisions (Article 39) and the fields of trade and industry affected by the protection. The manufacturing sector is one of these fields, not only at the level of commercial transactions but, more importantly, at the level of manufacturing processes.

It is common knowledge that a patent protecting a pharmaceutical product or a chemical process discloses only the essential information (with minimal detail) which characterize the process and establish its uniqueness. All other information of practical value at the manufacturing level usually remain securely guarded industrial secrets. These include: (a) the fine details of the conditions (temperature, pressure, pH, catalysis, etc.) of the chemical process steps which lead in each step to maximal yields while using minimal quantities and least expensive input materials under the most logical handling methods and the safest operation conditions; and (b) the nature and specifications of the requisite capital equipment used in the unit processes and unit operations.

The importance in developing countries of undisclosed information, in all fields of technology, including in the pharmaceutical sector, will undoubtedly increase with the increased openness of the economy and the further deepening of the manufacturing operations. Also with the increased participation of the local R and D establishment in the formulation of industrial know-how, there will be an increased keenness to protect the new

hard-earned knowledge of commercial value, together with an understandable desire to be familiar with the lawful and unlawful approaches to learn from other parties' achievements. It is therefore essential that this familiarity be established with respect to the patent (dis-closed) information (basic TRIPs provision is to be found in Article 29) as well as the industrial secret (undisclosed) information (basic TRIPs provision is to be found in Article 39).

For the information, industrial or otherwise, to be truly secret and undisclosed and hence protectable, such information should have the qualifications set out in the TRIPs Agreement Article 39-2 (see Box 6).

Box 6. Text of TRIPS Agreement Article 39 Paragraphs 2 and 3

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:
   (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
   (b) has commercial value because it is secret; and
   (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

According to the new world regime for the protection of undisclosed information (TRIPs Article 39), the infringement of such information occurs when other parties disclose, acquire or use the information without the consent of the rightful owner in a manner contrary to honest commercial practices. The measure of the criminal offence, therefore, is its content of acts that are contrary to honest commercial practices; it being understood, of course, that the rightful owner of the undisclosed information has taken reasonable steps to protect the information and keep it secret. By contrast, it is to be concluded that the disclosure, acquisition or use of the undisclosed information by other parties will not be an infringement if it is established that no acts contrary to honest commercial practices were involved.

13.2 Examples of acts contrary to honest commercial practices

On account of the importance of the matter and sensitivity of the issue of undisclosed information, the following is a summary of the acts that may or may not be contrary to honest commercial practices:

1. Accessing the undisclosed information by physical force or unauthorized entry into a place of business belonging to the person lawfully in control of such information.
2. Accessing such information through fraudulent misrepresentation, thereby deceiving the lawful owner.
3. Accessing such information through any means of technological espionage.
4. Disclosure and use of such information in breach of contract.
5. Disclosure and use of such information by a person who obtained the information from a third person who obtained it unlawfully, after being informed that such information was obtained unlawfully.

It should be remembered that the disclosure, acquisition or use of secret (or undisclosed) information, without the consent of the rightful owner, is counted as an offence also because it constitutes an act of unfair competition as provided for in Article 10 *bis* of the Paris Convention for the Protection of Industrial Property.

13.3 Examples of acts not contrary to honest commercial practices

1. Obtaining the information from publicly available sources such as libraries and other open literature sources.
2. Obtaining the information by inspection or analysis of a commercially available product embodying the undisclosed information. This embraces all independent efforts of scientific R and D within catch-up endeavours.
3. Obtaining the information from the owner by natural or legitimate means and free-willingly.
4. Independent invention, discovery or compilation of the undisclosed information.
5. Use of the information that is generally accessible to persons who normally handle such information.

One valuable lesson should emerge from the above comparison, namely that the independent work of scientists in an academic or an R and D institution will not constitute an offence or an infringement of the trade/industrial secrets if such work leads to achieving the same or similar results. Such work, seen as the scientific part of a reverse-engineering effort, is the natural course of action that takes place daily in all catch-up R and D endeavours of manufacturing enterprises in the industrial world. The obtained results may be used optimally, in a competitive environment, in pursuing further R and D to achieve improved or higher-developed products that may replace the original product when its product-cycle has come to an end.

It is pertinent, at this juncture, to highlight the essential differences of conceptual and practical significance between industrial undisclosed

information (TRIPs Article 39) and industrial disclosed information (TRIPs Article 29). The first are never published voluntarily, whereas the second are *de facto* published in patent documents. The adjoining Table summarizes these differences (*cf.* Box 7).

Box 7. Comparison between Disclosed (Patent) Information and Undisclosed (Secret) Industrial/Trade Information

Patent (Disclosed) Information	Undisclosed Information
1. Must be disclosed in full	1. No obligation to disclose
2. Must be published	2. Owner never allows publishing
3. Disclosure is a legal condition of protection	3. Any disclosure nullifies right of protection
4. Government is responsible for protection	4. Owner himself is responsible for protection
5. Protection continues for the duration of the patent term (20 years)	5. No term for protection; owner decides when to terminate
6. Owner enjoys law-recognized exclusive right during the term	6. No specific exclusive rights are recognizable
7. Can be used by third parties only after falling into the public domain or with the consent of the rightful owner	7. Can be used by other parties at any time if independently and lawfully acquired
8. Administered by local patent office	8. No government authority is directly responsible
9. Applicable TRIPS provisions: Article 29.	9. Applicable TRIPS provisions: Article 39

13.4 Undisclosed information submitted for the marketing approval of pharmaceutical products

The TRIPs Agreement (in Article 39.3) attaches special importance to the protection of undisclosed information, comprising confidential test or other data, that are submitted to the appropriate health authorities in order to obtain an approval for marketing. The products to be marketed are pharmaceutical or agricultural chemical products, which utilize new chemical entities, and the origination of the submitted information involves a considerable effort. Because of this background and the cost and effort involved, it becomes an obligation of the receiving authority to protect such information against unfair commercial use. In order to provide the requisite protection, the contents of paragraph 3 of Article 39 should be examined in order to identify the conditions that need to be meet. Of these the following are provided for:

(a) The information should be truly undisclosed, i.e. meet the qualifications set out in paragraph 39.2.

(b) The information should be submitted when and if requested by the government hearth authority.

(c) The information should be of such nature as to serve the purpose of obtaining a marketing approval of the pharmaceutical product in question by the concerned health authority.

(d) The pharmaceutical product in question involves a new chemical entity. Whether newness in this context is absolute (as it is in the case of patentable inventions) or relative to the local health authority, is a controversial issue.

(e) That the origination of the submitted test or other data actually involves a considerable effort and expense is usually taken as a reality in view of the fact that biological testing to establish

efficacy and safety is a lengthy and costly process in the pharmaceutical field.

(f) The information, being of such character, would expectedly not involve any data on the industrial manufacturing process and, therefore, cannot be counted as industrial secret.

13.5 Unfair commercial use

Although it is not clear what constitutes unfair commercial use, it is generally agreed that it is at least the leakage of such information to third parties who might use the information in the manufacture and marketing of the same products. This view is supported by the fact that information comprises test and other data of interest only to the health authority concerned. These include data on the safety and efficacy of the pharmaceutical product, its possible side effects, indications and contraindications, dose levels and dosage forms, and the special precautions that need to be observed by the drug user. The information, additionally, includes a description of the methods to be used in the evaluation of the pharmaceutical dosage form as regards the qualitative and quantitative determination of the active chemical/s and additives, and bio-equivalence studies. Clearly, such information does not include any confidential facts or figures that concern the manufacture of the pharmaceutical chemical; the latter would more aptly be protected under a patent regime.

Another obligation of the health authority that receives the undisclosed test or other data is to protect such data against disclosure, except where necessary to protect the public. The latter exception has been interpreted by some authors as a license for the health authority to use the data in testing similar pharmaceutical products submitted by other manufacturers for marketing approval. This matter seems to be controversial and remains to be settled. It is recommended that caution be exercised in the use of such confidential test data. However, it may be recalled in the present

context that according to a USA law, known as Hatch-Waxman Act of 1984, a relief is available. A pharmaceutical generic manufacturer is permitted to refer to (and hence rely upon) the biological test data submitted by an earlier manufacturer in order to obtain marketing approval for his (same, generic) product without having to carry out again the highly expensive biological testing required to establish the efficacy and safety of his product. In exchange, it will be required that (a) the earlier manufacturer be granted a limited extension of the term of his invention patent, and that (b) the later (generic) manufacturer provide proof of bio-equivalence of his product to that of the earlier manufacturer.

13.6 Industrial know-how

Despite all provisions on patent disclosure in the TRIPs Agreement (Article 29) and national laws on the protection of IPRs, it remains an undisputable right of any manufacturer to hold some of his hard-earned and particularly sensitive information as undisclosed information or trade/industrial secrets. There is definitely no obligation on the owner of such information to disclose it in any official document. His only legal obligation - that stands to be verified - is to protect the information by his own effective means against disclosure, use or leakage to foreign hands. Only then can the owner claim damages in case he is able to establish that an unauthorized person has accessed the information by acts that are contrary to honest commercial practices.

Among the most precious information of a manufacturer is his industrial know-how. This is the confidential information which accounts for the most important part of the contents of a technology package, and for the greater amount of the price paid in any transfer-of-technology contractual arrangement. In most situations, the know-how becomes fully developed much later after patent protection is secured.

Obviously different in nature and make-up from one industry to another, the industrial know-how generally comprises any one of the following ingredients or combination thereof.

1. Compilation of the information necessary to set up a commercial facility for the production of a given product or range of products.
2. Specifications of the equipment used (including capacities and materials of construction) in unit processes and unit operations.
3. Layout drawings and designs of the equipment involved in a given production line.
4. Information on material and energy balance, and on requirements of all utilities and external services.
5. Information on the safe handling, transfer and storage of all input, intermediate and finished materials, and the equipment needed for these functions.
6. Disposal of hazardous wastes and byproducts in compliance with the local legislation on the protection of the environment.
7. Facts and figures on the optimal process working conditions and methods of control of such conditions and their monitoring during all stages.
8. Information on the special elements, including industrial secrets, that optimise the production yield and quality including, for example, the use of catalytic agents, and those that reduce hazards.
9. The characteristics of special steels, including specific alloys, used in every component of the product, and the specifications of the requisite jigs, tools and fixtures used in shaping components in the various stages of production.
10. Economics of the complete range of operations and the prospects of backward integration and deepening of the industrial processes.

Clearly, such information in whole or in part cannot be regarded as capable of being included in a patent document since they address the commercial production-related details necessary for a viable commercial operation. The compilation imparts commercial value to the invention by making it commercializable and ready to be invested in. During a transaction for the transfer of a technology, it is not uncommon that a price is set for the invention (so long as it is valid) and another price for the know-how package. More often than not the latter package outlives the patent and continues to be saleable long after the patent's term expires.

14 EFFECTS IN TRANSFER OF TECHNOLOGY AGREEMENTS

14.1 Background

Transfer of technology has always been a vital element in any country's drive for economic development through industrialization. More often than not, the transferred technology involves knowledge that relates to IPRs. The strengthening of IPRs, therefore, carries the chances of adversely affecting the conditions for access to and use of technology. If excessive, the use of IPRs can run counter to the basic TRIPs objective of "contributing to the promotion of technological innovation and to the transfer and dissemination of technology" (TRIPs Article 7). It can even be counted as a naked abuse of IPRs by right holders which unreasonably restrains efforts, such as by R and D practitioners, to improve and enrich existing pool of technological knowledge and thereby enhance competitiveness.

There is universal agreement that several types of restrictive business practices and all anti-competitive practices should be guarded against and their inclusion in transfer of technology contractual arrangements should be prevented. The TRIPs Article 40 is a special message to this effect. The basic philosophy here is that

such practices are imposed only as a result of negotiation between unequal partners and could be damaging to the international transfer and dissemination of technology. They can severely, and quite unreasonably restrain trade and reduce the chances of the recipient of technology to benefit from the transfer and even inhibit his competitive potential. It is generally agreed that, in some situations, the imposition of these practices in the clauses of transfer of technology contracts constitutes an abuse of the dominant market position enjoyed by owner of the technology.

It is, therefore, necessary to consider the use of effective legislative and/or administrative measures that prevent or control such practices and alleviate their adverse consequences. This means that the position of the recipient of the transferred technology will, in most cases, be defensive. While being aided by such legislative or administrative measures that might already be in place, an important defensive tool is the 'test of competitiveness'. This means the technology recipient should examine the terms and conditions of the transfer to find if the transaction in actual practice would indeed result in his acquisition of a competitive status in relation to other users of the technology, including the supplier himself, in the relevant market/s which the technology would supply.

As a corollary, we must conclude that the recipient could be immediately helped if a set of guidelines is available that indicates the restrictive practices and harmful clauses that the recipient should avoid their inclusion in the transfer of technology contract, and also the guarantees and useful clauses that he should contrive to include in the contract. Needless to say, the real value of the guidelines will be evident during the negotiation phase. After the conclusion of the contract and with the beginning of its implementation, the recipient will find the guidelines again helpful if the need arises to correct faulty actions and possible misinterpretations, and also to remedy any damages that may result. All through, the guidelines must explain why a certain provision should be included in or excluded

from the contractual license. Clearly, the use of these guidelines should be voluntary. They may, however, be backed by a national legislation that prohibits certain actions that are deemed categorically to be harmful to the national economy.

It is noteworthy that the TRIPs Agreement (in Article 40, *cf.* Box. 8) has cited, only as examples, certain (three) practices that may constitute an abuse of IP rights, having adverse effect on competition. Following is a list of several examples of restrictive practices that can be encountered in real life and that have been identified during some forums on the transfer of technology, such as the meetings (mid 1970's-mid 80's) that had originally aimed at the formulation of an international code of conduct on the transfer of technology (UNCTAD, Geneva).

14.2 Restrictive and anti-competitive practices

It is not difficult to discern the restrictive practices that are frequently imposed in the transfer-of-technology contracts for the manufacturing industry at large and are more often visible in those of the industry of pharmaceutical chemicals and even appear in the pharmaceutical formulation contracts. The following are the commonest restrictive practices that are generally encountered in several types of contractual licenses.

1. Imposition of exclusive grant-back provisions.
2. Preventing challenges to patent validity.
3. Imposition of clauses requiring exclusive dealing.
4. Imposing restrictions on research related to the subject matter of the technology.
5. Requiring obligations on the use of personnel.
6. Predetermination of product pricing.
7. Imposition of restrictions on product/process adaptations.
8. Requiring exclusive sales or representation arrangements.

9. Obliging the conclusion of specific tying arrangements.
10. Requiring export restrictions and limitations on geographical distribution of products.
11. Imposing restrictions on publicity, including requiring the use of the suppliers' logos, etc.
12. Payments and other obligations to continue after termination of IPRs.
13. Imposition of restrictions after expiration of the contract.
14. Requiring limitations on production volume, scope, etc.
15. Unjustifiable use of quality controls to limit the recipient's freedom in introducing product modifications.
16. Obliging recipient to use the supplier's trademark when this is not necessarily in the recipient's interest.
17. Requirement to provide equity or to participate in management.
18. Obliging recipient to source input materials from the supplier of the technology or from parties assigned by the supplier.
19. Imposing restrictions on the use of capital equipment or on the sources of their supply.
20. Requiring the payment of excessive royalties.
21. Requiring unduly long duration of the contractual license.
22. Imposing limitations on the use (and diffusion) of the technology already imported and paid for.
23. Imposing restrictions on the prospects of deepening of the technology or on the transfer of improvements achieved by the licensor.

Box 8. TRIPS Article 40, Paragraphs 1 and 2

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

14.3 Conclusion

It must be stated, in conclusion, that the guidelines recommendation offered earlier in the present discussion, if carried out, could include an elaborate treatment of each one of the practices listed above, as well as those frequently encountered in the contractual licenses of specific technologies such as pharmaceutical chemicals and pharmaceutical dosage forms, consumer electronics, capital equipment, etc. While discussing these negatively-impacting practices, alternative texts should be proposed that address guarantees and positively-impacting provisions which the prospective recipient should contrive to include in the contract. Arguments in support of the recommendations should be given as based on legal considerations (including the TRIPs provisions) and experiences of other countries.

Needless to say, a pragmatic thinking should guide the process of negotiation all through. This requires a prudent weighing of the possible effects of some provisions against the possible benefits that are sought through the contract in its entirety.

15 CONFRONTING THE MORE IMPORTANT PRESSURES POSED BY THE TRIPS AGREEMENT

15.1 A recap

All countries of the world experience the pressures, resulting from the higher standards of protection, but their weight is felt more in the developing countries. Understandably, therefore, the developing countries look forward with hope to an opportunity for introducing some changes in the Agreement provisions. An opportunity to serve this end was supposed to come in the year 2000 (TRIPs Article 71) but never came. Another opportunity, to address specifically the question of patent protection of life forms was anticipated for the year 1999 (TRIPs Article 27,3b) but also never materialized.

Developing countries will do themselves a service if they consult with each other and cooperate in building a position that calls for introducing a limited number of reasonable modifications or amendments that alleviate somewhat the existing pressures in all fields of technology, and particularly in the pharmaceutical field. As recent developments have clearly demonstrated, the more pinching, even threatening, pressures are those that are experienced at the bilateral level within broader trade negotiations.

15.2 The pressures

Generally, the pressures have been known chiefly as a result of the following forms of higher standards. The list includes those standards that have been introduced during the multi-lateral trade

negotiations (Uruguay Round) and are now contained in the Agreement on TRIPs and, therefore, considered among its minimum standards; these include.

1. Prolongation of the term of patent protection to at least 20 years.
2. Extension of patent protection to all fields of technology, including the sensitive areas of food and drug products, without any discrimination.
3. Placing no restrictions (or a ceiling) on the more extensive protection of IP rights than is required in the Agreement.
4. Patentability of pharmaceutical processes and products alike.
5. Reversal of the burden of proof in process patents, and the threat of strategic litigation.
6. Pressuring developing countries to reduce (sometimes to eliminate) the transitional period that precedes the full application of the TRIPs provisions.
7. Not giving priority to the use of pharmaceutical patented inventions among the grounds for the granting of compulsory licenses, even in situations of public health crises.
8. Non-differentiation between countries (on the basis of manufacturing capacities) and technological capabilities) as to their ability to make use of the exception of compulsory licensing, particularly in the pharmaceutical field.
9. Giving no regard to the possible absence in some countries of adequate pharmaceutical quality control when granting exclusive marketing rights (EMRs).

15.3 Counterbalancing the pressures

It must be stated at this point that some of these deficiencies, at least as they affect the pharmaceutical field, were under consideration by WTO Ministers when they met in Doha (November 2001). The Declaration of the Ministers contained some explicit pronouncements

that reduced the concerns of developing countries, such as those that address the pressures indicated above under numbers 7, 8 and 9.

There are, moreover, higher standards that are claimed bilaterally (sometimes regionally) in excess of the familiar (minimum) standards required by the Agreement. Most of the pressures requiring the higher IPR standards are associated with negotiations over the conclusion of free-trade agreements. The ultimate effect is that the space given to developing countries (by the TRIPs built-in flexibilities) is taken away by the pressures imposed during the free-trade agreement negotiations. The commoner of these usually referred to as TRIPs-plus standards, are the following:

1. Requiring the grant of market exclusivity (of at least five years) for test data (on efficacy and safety) submitted when applying for a pharmaceutical product approval, on the basis that the test data are undisclosed information. The net effect of this requirement, if implemented, is delaying the approval of the lower-priced generic drugs.
2. Claiming the patentability of uses, in addition to products and processes, in the pharmaceutical and food fields.
3. Requiring that a broad range of commercial activities be included in the exclusive rights of the patent owner
4. Narrowing the scope of application of the exhaustion exception, and hence the right of parallel importation.
5. Requiring the mere importation of pharmaceuticals and perhaps other products to be considered as sufficient for the working of the patented invention.
6. Narrowing to a minimum the forms of patent use for scientific and research purposes.
7. The practices of broad-blocking and defensive patenting.
8. Extension of the exclusive rights to include the products resulting from a patent-protected process.

9. Enforcement of all the Agreement provisions equally after the date of application.
10. Not making the disclosure of the best mode for carrying out the invention and obligation.
11. Non-differentiation in all allowed exceptions between patented pharmaceutical products, even when critically needed, and other product categories.
12. Restricting the use of compulsory license-produced pharmaceutical in the manner that prevents their export to needy markets even where health crises exist.
13. Imposing conditional restriction on the grounds for granting compulsory licenses authorizing generic manufacturers to produce low-cost versions of patented drugs.
14. Demanding patent extensions for products that are not new chemical entities by utilizing extensive "evergreening" tactics.
15. Omission of mandatory "Bolar exemption" provision, which allows generic drug companies to carry out R and D and production of limited quantities of the patent-protected products prior to the expiration of the patent term, to comply with the requirements of the regulatory authority.
16. Demanding the extension of the patent term (in the pharmaceutical field) to accent for delays in the regulatory approval process or in patent examination.
17. Demanding the expansion of patent protection to include subject matter that may be excluded (under TRIPs) from patentability, e.g. diagnostic, therapeutic and surgical methods.

16 TRIPS' CHECKS AND BALANCES

The TRIPs Agreement has built-in balances that may also be seen as flexibilities that can be made use of in order to reduce the effects of the newly introduced pressures. The following are examples of these flexibilities, the full interpretation of which is left to the concerned countries:

1. TRIPs Articles 7 (on objectives) and 8 (on principles)

Here we have clear signals of relevance to the health and nutrition fields that address chiefly governments with a message that the following actions are not inconsistent with the Agreement provisions:

Drug price control; subsidizing selected drug and food products (even if imported) for the benefit of the poor and the sensitive groups of the society; bulk importation of drug and food ingredients for the treatment of critical health and nutrition problems and their distribution; supervision of the distribution trade; playing a central role in parallel importation; remembering compulsory licensing as a legitimate exception that can be used as a deterrent and for remedying faulty situations, particularly when anti-competitive practices are committed and in national emergencies or other circumstances of extreme urgency, such as during public health crises; making use of the "Bolar exception", referred to previously, in the production of limited quantities of the generic version of a patented brand-name product.

2. TRIPs Article 6 (on the exhaustion of IP rights)

This flexibility, discussed in the present study in more than one place allows the parallel importation of the patent-protected pharmaceutical, or indeed any product from anywhere in the world quite legitimately and without the need to notify the patent right-holder or pay him any remuneration. It is a highly useful option, particularly when the prices of imported new products reach heights that are unaffordable to sizeable segments of the society.

3. TRIPs Article 29 (on the disclosure requirement)

This is another essential component of the patent system, which has profound practical value that, as discussed before, can be used in the R and D establishment to provide a valuable information source that helps in the national technological and economic catch-up effort. The disclosed information, moreover, is indispensable in carrying out a compulsory licensing function when the need arises. It is also a legal reference when situations of dispute are considered by court.

4. TRIPs Article 30 (on allowable exceptions)

A special section in the present study was devoted to a discussion of the question of exceptions that can be used without infringing the interests of the patent title-holder, but which will be useful in the course of normal life as well as in times of difficulty. These exceptions, as already asserted, need to be explicitly provided for in the national patent legislation.

5. TRIPs Article 31 (on compulsory licensing)

This instrumentality, being the major exception that the Agreement allows, is resorted to (as explained before) in situations of difficulty where a national emergency or a circumstance of extreme urgency arises. Typical of these situations are public health crises, such as epidemics, and any other health situation which in the best judgment of the government necessitates the control of prices, availability or quality of the medications needed for the people, or facing the harmful effects of anti-competitive practices of drug suppliers.

6. TRIPs Article 40 (on the control of anti-competitive practices in contractual licenses)

This, again as previously discussed, is a reference to the need to advise local businessmen and manufacturers in the pharmaceutical and any other field on the harmful restrictive practices, that may also

include anti-competitive practices, and on the guarantees and other useful provisions in the transfer-of-technology contractual arrangements. The value of this information lies in the fact that in most, if not all such arrangements several elements of IP rights and duties are involved in the transaction. The impact of this service will be appreciated during the negotiation phase and felt more tangibly during the implementation phase.

17 THE CRITICAL ROLE OF THE NATIONAL R AND D ESTABLISHMENT

The need for a research-and-development (R and D) activity in any country, even the smallest, can hardly be argued against. The viability of such activity as a basis for large-scale commercial production may, however, be questioned at least on account of the familiar 'economy of scale' test. Very much depends on the natural and human resource endowments of the country and, more importantly on the country's strategic goals. For in our contemporary world there can be no economic strategies without a science-and-technology backbone.

The industrial countries have the world's largest producers and most important innovators in all technological fields; they also are the world's biggest R and D spenders. Comparing the expenditures on R and D in the developed countries and in the developing countries leaves one with an impression of why the difference is what it is. To be added to the pains of this reality, is the fact that the world's largest manufacturing firms do spend substantial sums on R and D conducted overseas, but with negligible amounts spent on their R and D carried out in developing countries. When asked, the industrial giants of the world explain that the level of IPRs protection and the government-imposed price controls in the developing countries do not encourage higher levels of R and D expenditure.

The commonest argument advanced for explaining the inability of developing countries to innovate in the fields of manufacturing and to be global suppliers of value-added products, is that the development of new products is well outside the reach of local companies in any developing country. These companies are not strong enough in R and D and management capabilities or in terms of total sales, let alone manufacturing capabilities, to finance such endeavours. This view if taken literally or accepted can spell defeat before the battle for survival begins.

The basic message of the present reasoning is that R and D is a symptom of vitality that can bring worthwhile returns, both moral and material. Regardless of the nature of what in R and D endeavours is promising in any part of the world, the results would in all cases benefit from effective IP rights protection, even during the stages of catch-up or adaptive innovation (Box 5).

In the longer term, more ambitious R and D activities could emerge to enable innovations of a more fundamental nature. The very smallest prize that will be won is that a state of partial technological self-reliance, spirit-lifting for sure, will replace a state of technological dependence. The examples of Japan, and later of India and Brazil could be invoked to illustrate the profound role of R and D as a learning tool at the national level, particularly during the first stages of technological transformation in all technology fields that eventually lead to the attainment of levels of maturity. In all these experiences the role of reverse engineering in the transitional stages of technological development could not be ignored. An almost everyday practice in the manufacturing firms of industrialized societies, reverse engineering has always been a means to add even more value to already market-successful products. The legitimacy of the practice derives from the understanding that reverse engineering is essentially a means to learn from other manufacturers ' products, and to build thereupon and introduce the next generation products, without infringing any IPRs of an inventor.

FURTHER READING

The following are some reference works that have been consulted and used during the compilation of the present study. The reader is recommended to refer to such resources, among others, to gain greater coverage and depth with respect to any of the issues dealt with. They are not arranged in any specific order.

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