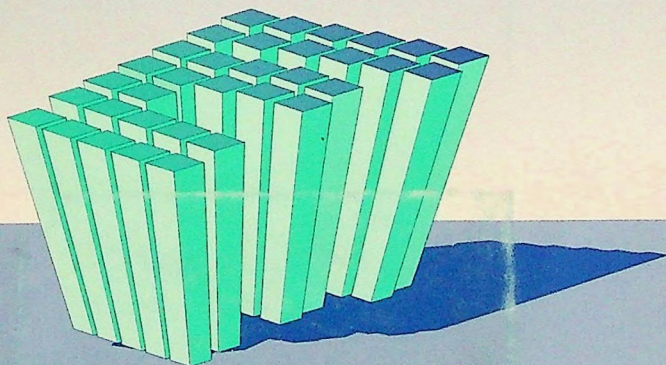


HEALTH ECONOMICS

THE URUGUAY ROUND AND DRUGS

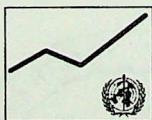


WHO TASK FORCE ON HEALTH ECONOMICS

WHO/TFHE/97.1
Distr: General
Original: English

THE URUGUAY ROUND AND DRUGS

Carlos M. Correa,
Director,
Master's Degree in Science & Technology Policy Management,
University of Buenos Aires



**WHO TASK FORCE ON
HEALTH ECONOMICS**



**WHO ACTION PROGRAMME
ON ESSENTIAL DRUGS**

February 1997



Table of Contents

Preface	v
Acknowledgements	vi
Executive Summary	vii
1. Introduction	1
2. Patents	3
3. Undisclosed information	16
4. Transitional periods	19
4.1 General grace period	19
4.2 New patentable areas	19
4.3 Protection of existing subject matter	19
4.4 Prior compulsory licences and applications	20
4.5 Pharmaceutical and agricultural chemical products	20
5. Enforcement and settlement of disputes	23
6. Implications for the development, production and marketing of drugs	24
7. Conclusions	28
References	30



Preface

"The availability and accessibility of drugs are parameters for measuring the quality of the health services and constitute social indicators of justice and equity in the distribution of a country's wealth"¹.

The strategies developed by the World Health Organization in the area of drugs focus on access to drugs for the entire population and their rational use. It is in this context that WHO is interested in the studies about possible implications of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) for innovation, development, production and distribution of drugs.

The present article was prepared by Professor Carlos Correa from the University of Buenos Aires for the international meeting on "Medicines and the new economic environment", organized in March 1995 by Professor Felix Lobo from the Carlos III University of Madrid and Dr German Velasquez from the WHO Action Programme on Essential Drugs.

I consider this article a major contribution to the understanding of the influence of the WTO Agreement on WHO policies and strategies in regard to pharmaceutical products, food safety, blood products, medical devices and others.

The WHO Task Force on Health Economics and the Action Programme on Essential Drugs are jointly publicizing Professor Correa's views as a contribution to the international studies and debates in this important area.

Dr Fernando S. Antezana
Assistant Director-General
Chairman of the WHO Task
Force on Health Economics

¹ Pharmaceutical Policy of the Andean Sub-region, WHO/DAP/93.7



Acknowledgements

The author thanks Sandra Doyle of the Action Programme on Essential Drugs for her assistance in the finalization of this document.



Executive Summary

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), which was negotiated as part of the Uruguay Round (1986-1994) may have great implications for the production of and access to drugs, especially in developing countries. The Round's Final Act signed in Marrakech in 1994, established the World Trade Organization (WTO) whose Member countries are bound to implement the principles and provisions laid down in the Agreement.

This paper comments on the possible effects of the Agreement on the development, production and marketing of drugs, as well as on access to them. In so doing, it refers to the 16 Articles (of the 73 Articles of the Agreement) which most concern the pharmaceutical sector.

Major patent provisions – The provisions on patents contain the most explicit obligations for Member countries and will have considerable impact on the drugs sector, although in varying degrees in different countries. One of the obligations is to grant both product and process patents in all fields of technology, thus eliminating the division between countries which grant patents to the pharmaceutical industry and those which do not. The Agreement also requires that Member countries establish a minimum of 20 years patent protection.

What is patentable and what is not, especially in relation to biotechnological innovation, is discussed, as is patentability in relation to a product's origin and the interrelationship between product and process patents. Exceptions to exclusive rights conferred by patents and granting of compulsory licences are both subject to certain conditions under the Agreement. The provisions on "undisclosed information" oblige to safeguard information submitted for approval of a pharmaceutical or agrochemical product, in order to protect it from unfair competition:

In connexion with the latter provision is that of "undisclosed information" which gives countries the possibility to safeguard information submitted for approval of a product in order to protect the product from what may be considered unfair competition.

Transitional periods – After the TRIPS Agreement became effective on 1 January 1996, all Member countries of WTO have had a one-year transition period within which to fulfil their obligations under the Agreement. Developing countries which join the WTO have four additional years (total of five years) and least developed countries ten additional years (total of eleven years) to comply with the provisions of the Agreement. Transitional periods are also provided for specific acts within the provisions relating *inter alia* to pharmaceuticals.

Dispute settlement – An innovation of the Uruguay Round is to be found in the way in which disputes are settled. Previously, these were subject to "positive consensus" at each stage of the dispute process. The principle now in vigour is that of "negative



consensus" which will allow each stage of the process to proceed unless there is a consensus against it.

Protection of public health – Finally, the principles embodied in Article 8 of the Agreement relating to the formulation or amendment of domestic laws and regulations, through which the Agreement must be implemented, explicitly recognize that measures necessary to protect public health may be adopted by countries, providing they are consistent with the Agreement's provisions and implemented within the time limits laid down therein.

Conclusions – Following a detailed analysis of the effects of the new intellectual property rights relating to pharmaceuticals, especially in developing countries, the study concludes that:

- (a) although protection of pharmaceutical products will be enhanced at a high standard, this will not necessarily be to the benefit of all countries,
- (b) an increase in research and development on new drugs will not take place in either developed or developing countries,
- (c) the transitional period for entry into force of the Agreement allows countries to temporarily limit the introduction of pharmaceutical patents, and
- (d) measures to be borne in mind when incorporating the provisions of the Agreement into domestic legislation are (i) compulsory licences, (ii) international exhaustion of rights, (iii) exclusion from patentability of certain substances.



1. Introduction

The agreements contained in the Final Act of the Uruguay Round will have a significant impact on the global production and marketing of goods and services. The effects will, however, vary according to the type of change introduced and the sector concerned. The production and marketing of drugs and health services may be affected at different levels and to a varying degree.

For the first time in the history of GATT, the results of the Uruguay Round include agreements on the liberalization of trade in services. The special feature of health services is, however, that they are not internationally traceable to any significant extent because of the virtually indispensable need for a physician patient relationship² and the regulations on professional practice.³

The Uruguay Round provided the framework for the negotiation of a comprehensive Agreement on intellectual property rights (Agreement on Trade Related Aspects of Intellectual Property Rights).⁴ It is this component of the Final Act of the Uruguay Round that may have the greatest implications for the production of and access to drugs, especially in developing countries.

The negotiations and the results obtained in the area of intellectual property underline the all encompassing nature of the Uruguay Round. Unlike the previous Rounds, it not only involved discussion of trade barriers at the border but also moved towards the harmonization of domestic policies ("beyond the border"), blurring the distinction between trade policy and other economic policies. In practice, the Uruguay Round has affected the series of policies which define a country's competitive environment (Tussie, 1994).

The section on patents will have the greatest effect in the drugs sector. It is the most detailed chapter and contains the most explicit obligations for Member countries. These include the obligation to grant patent protection in all fields of technology, thus eliminating the division between countries which grant patents to the pharmaceutical industry and those which do not. The pharmaceutical industry, like other industries, will have to confront a new international legal environment in which imitation will be more difficult and there will be increased opportunities to earn profits from inventions through the exercise of exclusive rights at the global level.

The TRIPs Agreement also includes for the first time in an international convention rules on restrictive practices in licensing agreements, as well as a multilateral system for protection of trade secrets that extends to information given to government authorities in order to obtain approval of pharmaceutical products. The Agreement also

² "Telemedicine" could, however, extend the supply of diagnostic services across borders or could make them available in countries or regions without the necessary infrastructure. The future of robot-assisted "telesurgery" is more questionable.

³ In some countries with a federal system, for example, physicians are not allowed to practice outside their authorized area. On the other hand, restrictions on direct foreign investment in health services do not appear to be more severe.

⁴ Hereinafter referred to as the "TRIPs Agreement".



contains provisions on trademarks, which may have implications for the pharmaceutical industry.⁵

The aim of this study is to examine the possible effects of the TRIPs Agreement on the development, production and marketing of drugs, as well as access to them. Section 2 contains a brief summary of the content of the TRIPs Agreement relevant to patents. Section 3 reviews the main provisions on "confidential information" (trade secrets). Although the Agreement deals with other areas of intellectual property, these are the most relevant to the pharmaceutical sector. Section 4 concerns transitional periods and section 5 deals with the mechanism for the settlement of disputes and enforcement. Section 6 reviews the possible implications of the Agreement for innovation, direct foreign investment and the price of drugs. The analysis focuses on the effect of the new intellectual property rules in developing countries. Finally, the last section sets out the conclusions drawn.

⁵ One of these provisions is the obligation to protect colours as a trademark, which may affect competition between products with a trademark and generic products in certain markets.



2. Patents

The TRIPs Agreement lays down minimum standards for the protection of intellectual property, including operative and procedural rules to ensure the enforcement of rights. No Member may grant protection that is less than the levels laid down nor be obliged to give more extensive protection. The Agreement must be implemented according to the domestic laws of each country; it does not directly establish rights for individuals.

The Agreement explicitly recognizes that, in formulating or amending domestic laws and regulations, Members may "adopt measures necessary to protect public health ... provided that such measures are consistent" with the Agreement's provisions (Article 8).

The question of patentability and exceptions was one of the major areas of negotiation of the TRIPs Agreement.⁶ From the beginning of the Uruguay Round, it was obvious that one of the essential aims of the industrialized countries, particularly the United States of America (USA), was to extend patentability to pharmaceutical products globally.

When the Round began, many countries did not confer protection on pharmaceutical products. Nevertheless, during the period which elapsed between the commencement of the Round in 1986 and its conclusion in 1994, this situation changed radically.

Some developing countries embarked upon economic restructuring and redefined their relations with industrialized countries, especially with regard to direct foreign investment. Changes in intellectual property were seen as components of a new framework for such relations and for attracting foreign capital.

In the majority of cases, however, changes in intellectual property law corresponded more to demands coming from outside than to endogenous motives. Many developing countries were subjected to strong pressure to amend their patent legislation exerted by the lobby of multinational pharmaceutical companies. The Government of the United States of America included intellectual property issues in its international agenda under the provisions of section 301 of the Trade and Tariffs Act (amended in 1988).⁷ Many developing countries, including Argentina, Brazil, Indonesia and Thailand, have been the subject of investigations or trade retaliations under this section.

From 1986 onwards, a new orientation in economic policy and a vigorous campaign by the USA combined to reduce substantially the number of countries which refused to grant patents in specific areas, especially in the field of pharmaceuticals. In Bolivia, Chile, China, Colombia, Ecuador, El Salvador, Indonesia, Mexico, Peru, South

⁶ The text of the section on patents has been analysed in Correa (1994). See Castado and Cerro (1994) for an overall analysis of the Agreement.

⁷ See Destler (1992) for an analysis of how this section is applied.



Korea, Taiwan, Thailand and Venezuela⁸ inter alia patent legislation was amended to this effect.

Pursuant to the TRIPs Agreement, three of the major pharmaceutical markets in developing countries (Argentina, Brazil and India) find themselves in this situation and will have to amend their patent legislation (within the time limits laid down in the Agreement).⁹

2.1 General principles

Article 27.1 of the TRIPs Agreement provides that any invention may be patented, whether for a product or a process "in all fields of technology". It adds that "patents shall be available and patent rights enjoyable without discrimination as to ... the field of technology".

This provision may be seen as one of the major concessions by developing countries in TRIPs. It puts an end to one of the most disputed issues in the history of patent law and has virtually global scope. It will not only have a direct impact on those countries which still do not allow drugs to be patented, but will also prevent any step backward in those countries which do allow such patentability, at least until the TRIPs Agreement is revised.

2.2 Non patentability: biotechnology based drugs

Article 27.2 and 27.3 both specify the exclusions from patentability which any country may establish in its domestic legislation, without being obliged to do so. Article 27.2, for example, states that:

"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Despite the seemingly general coverage of this provision, its application is subject to two restrictions.

On the one hand, exclusion from patentability may only be permitted if commercial exploitation of the prohibited invention is not allowed in the country concerned and if this nonexploitation is necessary to protect the interests mentioned previously. In other words, it would not be possible to declare that a particular object is not patentable while at the same time permitting its distribution or sale.

⁸ In the case of Bolivia, Colombia, Ecuador, Peru, and Venezuela, it should be noted that the Common Industrial Property Regime applicable to them (Decision 344 of October 1993) does not allow pharmaceutical products which appear on the World Health Organization's list of essential drugs to be patented (Article 7.c). Although this list, which is periodically revised, usually includes drugs with expired patents, it may also contain patented drugs.

⁹ This is also the case of Egypt, Pakistan, Paraguay, and Uruguay.



On the other hand, the provision prohibits other exclusions based on grounds which differ from those laid down in Article 27.2, even when these are prescribed by national law. The existence of a legal prohibition, if based on other grounds, will not be sufficient to sustain the non patentability of an invention or category of invention.

Moreover, according to Article 27.3,

"Members may also exclude from patentability:

- diagnostic therapeutic and surgical methods for the treatment of humans or animals;
- plants and animals, other than micro organisms, and essentially biological processes for the production of plants or animals other than non biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

The present economic importance of the inventions which could be excluded from protection under Article 27.3(a) is low. In the USA, only a few medical processes have been patented (it is one of the few countries which allows this) for methods that are rarely used (Berman and Lambrecht, 1991). Furthermore, patents for such methods are particularly difficult to enforce.

Correctly interpreted, the exclusion mentioned in Article 27.3(a) would not apply to any apparatus used for diagnostic or therapeutic purposes nor to "diagnostic kits", one of the main biotechnology based products on the market today.

The exclusion referred to in Article 27.3(b) reflects the significant differences which occur, even among industrialized countries, with regard to patents for plants and animals. The EEC proposals in GATT which the Article in question reflects to a certain extent were aimed at maintaining the present position of the member countries of the European Patent Convention in connection with the non patentability of animal races and plant varieties and the "essentially biological processes" for their production.

The possible exclusion of "essentially biological processes" is limited by the reference to "non biological and microbiological" processes. The concept of microbiological processes as exceptions to the exclusion is present in European legislation and in the laws of various other countries. Its aim is to restrict the exclusion from patentability to traditional methods of breeding and improvement, while keeping the obligation to protect, for example, inventions based on genetic engineering or gene transfers.

The Agreement does not specify if the replication of a substance which already exists in nature can be patented or not. This is of special importance for the biotechnology-based pharmaceutical industry in connection with products such as interferon, TPA (Tissue Plasminogen Activator) and growth hormones. The possible patentability



of products which "copy" substances already existing in nature has given rise to animated discussion and different solutions among the industrialized countries.¹⁰

Although the USA and some European countries tend to acknowledge that a substance existing in nature can be patented provided that it is isolated and in purified form, other countries consider that such cases do not involve an "invention" but simply a "discovery" and cannot therefore give rise to individual intellectual property rights.

The TRIPs Agreement allows the interpretation that such substances are not inventions, which would mean that drugs based on the replication of human proteins or other matter existing in nature would not be patentable.

Article 27.3(b) is the only provision in the TRIPs Agreement subject to an early review (four years after the Agreement enters into force). This period is even shorter than the transitional period for developing countries (Article 65). This solution shows how difficult it was to reach agreement on the biotechnology related issues. It also means that, in the short term, countries could once again be called on to extend patent protection to various categories of biotechnological innovation.

2.3 Non discrimination clause

Article 27.1 contains a non discrimination clause that refers both to the availability of patents and the enjoyment of patent rights. It was introduced into the text as a compromise during the final stages of the negotiations. The Article states that: "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

As mentioned above, this clause allows the patentability of all types of invention irrespective of the industrial sector or technological field to which they belong. It also prohibits any differentiated treatment based on the place of invention such as the one included until recently, for example, in the Canadian patent law, in connection with the granting of compulsory licences for pharmaceutical products.

In many countries, the system of granting compulsory licences could also be affected by the prohibition on discrimination according to the product's origin (locally manufactured or imported). The aim of the text's drafters was to weaken or eliminate the obligation to work the patented invention, one of the traditional foundations of the patent system. Such an obligation justified the granting of patents in developing countries as this was seen as a mechanism for the promotion of investment and the transfer of technology to developing countries (Penrose, 1974).

The weakening of the obligation to work the patent resulting from the TRIPs Agreement is undoubtedly consistent with the trend towards internationalization of production and marketing by multinational companies.¹¹ Having chosen to locate pro-

¹⁰ See the special issue of the *Revista del Mundo Industrial*, year 12, no. 24, Buenos Aires.

¹¹ See Chesnais (1994) on recent trends towards internationalization.



duction in a certain place, their strategy is to supply global markets under monopolies conferred by patents, exporting finished or semi finished products¹² rather than transferring technology or making direct foreign investment (Correa, 1989).

2.4 Rights conferred: imports

Article 28 establishes the rights that a patent should confer on its owner. It takes into account the two traditional categories of inventions: products and processes.

Patents for products confer the right to prevent third parties from "making, using, offering for sale, selling or importing for these purposes that product" without the owner's consent (Article 28.1(a)).

One important aspect of this provision is that it expressly refers to import as one of the exclusive rights of the patent owner. Nevertheless, the footnote contains a cross reference to Article 6 of the Agreement, which allows Members to provide for the exhaustion of intellectual property rights subject to national and most favoured nation treatment. Exhaustion may only apply to acts occurring within a country ("national exhaustion"), in a group of countries or a region ("regional exhaustion") or in the global market as a whole ("international exhaustion").

Recent legislative reform in a number of countries has established the principle of international exhaustion with the aim of introducing a certain degree of competition into the market. To give an example, if a patented product is sold in country A at a price of \$100 and in country B the same (legitimate) product is sold at \$80, this principle allows any interested party in country A to import the product from country B without the consent of the patent's owner.

The adoption of this principle may be of particular importance in the area of drugs in order to prevent discrimination or price abuse by the owners of patents. A point which merits further consideration is whether the principle could also be extended to cases where a product is imported from a country in which the patent owner has not been able to obtain protection (because there is no possibility of obtaining a patent, for example) or has not sought protection or protection is no longer possible because the patent has expired or for other reasons.

2.5 Rights conferred: protection of products through protection of the process

Article 28.2(b), on the other hand, provides for the extension of the protection conferred on a process to the product "obtained directly by that process". This extension, not yet recognized by many countries, together with reversal of the burden of proof mentioned below, will in many instances lead to substantial strengthening of the patent rights concerning process inventions.

This means that the granting of a process patent, even for a product already known but not patented, may result in a monopoly of the market in the product concerned.

¹² After pharmaceutical patents had been recognized in Chile, for example, it was noted that some foreign subsidiaries which formulated drugs locally were dismantled and the market was supplied directly through imports.



This would be possible if the process used to manufacture the product were totally or partly unique and irreplaceable. The extension of process protection to a product will no doubt be the cause of frequent lawsuits and threats to independent pharmaceutical companies.¹³

2.6 Exceptions to exclusive rights

Exceptions to patent rights must meet three conditions. Firstly, they must be limited, even where their scope, term or other aspects are not specified. Secondly, they must not unreasonably conflict with the normal exploitation of a patent. Thirdly, they must not unreasonably prejudice the legitimate interests of the patent owner. These three conditions have to be applied, however, taking into account "the legitimate interests of third parties".

This text obviously calls for a case by case analysis of the exceptions that may be allowed. Based on the present status of comparative patent law, the following exceptions may be deemed legitimate pursuant to Article 30:

- a) import of a product that has been put on sale by the owner of the patent or with his consent or in a country where patent protection does not exist;
- b) acts done privately and on a non commercial scale or for a non commercial purpose;
- c) use of the invention for research and experimentation or for teaching purposes;
- d) preparation of drugs for individual cases according to a prescription;
- e) use of the invention by a third party who started or carried out serious preparations before the application for the patent (or its publication);
- f) experiments carried out in order to obtain health approval before marketing a drug.

With regard to the latter, the United States Drug Price Competition and Patent Term Restoration Act permits the carrying out of tests to establish the bio equivalence of generic products before the relevant patent expires. Its purpose is to help producers of generic drugs to market their products as soon as the patent expires.

Public interest, or more explicitly public health, may be deemed to be another legitimate reason for suspending exclusive rights in accordance with the "principles" laid down in Article 8 of the Agreement

2.7 Granting of compulsory licences

The Agreement does not refer to the widely accepted notion of "non voluntary" or "compulsory" licences. It should be noted that 96 countries allow for one form or

¹³ Pfizer is presently suing a number of Latin American companies in order to prevent the sale of an unpatented product whose manufacturing process was granted a patent. One of the companies it is suing manufactures under a process licence from a Spanish company (Prescription Monitor, vol. 2, no. 1, 1995).



another of compulsory licences. Nevertheless, Article 31 on "Other Use Without Authorization of the Right Holder" contains a detailed set of conditions and limitations for the granting of such licences. In this Article, the industrialized countries have tried to limit the opportunities for use of the compulsory licence system even though its actual application has been rather limited in the past.

Grounds for granting compulsory licences

Article 31 does not interfere with domestic legislation regarding the grounds for the granting of compulsory licences. Although it mentions some specific grounds (national emergency, anti competitive practices, dependent patents, etc.), it does not limit the Members' right to apply this remedy to different situations; it only lays down the conditions to be met "where the law of a Member allows for other use".

Consequently, a compulsory licence could be granted on the following grounds *inter alia*.

Public health and nutrition or other reasons of public interest

Article 8 ("Principles") of the Agreement specifically recognizes the sovereign right of Members to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

Many countries, including some developed countries, provide for such compulsory licences in their legislation. The legal provisions are usually drafted in general terms so as to allow them to be applied flexibly. The Agreement does not prevent the granting of compulsory licences on the grounds indicated, provided that the criteria laid down in Articles 27.1 and 31 are respected.

Non voluntary licences may not be established for a special technological field *per se* (for example, foodstuffs), but only in relation to products and processes for certain purposes. A licence system could, however, include different technologies whose access and use affect health needs such as manufacturing processes and pharmaceutical products, hospital equipment and materials, diagnostic elements and other items relevant to this purpose.

National emergency and extreme urgency

These motives are specifically mentioned in Article 31(b). Basically, they could be considered as being covered by other general formulations such as "public interest". In such cases, prior negotiations with the right holder can be avoided.

Public non commercial use

In this case, a government is directly interested in using the patented invention. The Government of the USA has used such licences, for example, through NASA and in other instances of military interest. Such licences may also be used in other areas (for example, the production of drugs). In order to remain legitimate, use must be non



commercial, even though this does not exclude the possible participation of a private contractor.

Anti-competitive practices

Exclusive rights conferred by patents can lead to various forms of abuse of a dominant market position. Compulsory licences to prevent or punish anti-competitive practices have been granted in many cases in the USA on the basis of anti-trust legislation. Recent legislative reform in Latin America (Andean Group, Argentina, Chile) has expressly included these types of licence. They are also mentioned in Article 31(k) of the Agreement. For them to be applied, a judicial or administrative procedure must determine that an anti-competitive practice exists. Domestic laws can of course define the cases in which the granting of such a licence is justified. This will usually be when the price received by the patent owner is excessive or licences are granted subject to unreasonable restrictions or when other acts carried out constitute abuse.

Article 31(k) provides for the possibility that licences for anti-competitive practices shall be subject to special rules regarding remuneration to the patent owner. Thus, according to the judicial and administrative practice in the USA compulsory licences might be granted "royalty free" (Fugate, 1991).

Dependent patents

Article 31(l) contains detailed provisions on compulsory licences based on dependent patents. It defines a number of criteria for their granting: the technical and economic importance of the "second patent" (it must involve "an important technical advance of considerable economic significance"); granting of a "cross licence on reasonable terms" to the owner of the "first patent"; non assignability of the licence (except with the assignment of the "second patent"). These conditions tend to restrict the ways in which improvement patents have been used in some countries to promote access to patented technology by national companies. In this connection, the evaluation of the economic and technical importance of the second invention will be a key factor in the practical functioning of this system.

Environmental protection

One of the most pressing issues in the world today is the degradation of the environment. Important efforts are being made at the national and international levels to prevent activities that are harmful to nature and to formulate effective measures to protect the environment. In the patents sphere, the granting of compulsory licences could help to increase the use of environmentally sound technologies, as well as of technologies conceived for environmental protection. The international community made proposals in Agenda 21 to promote the use of such technologies under compulsory licences in developing countries.

Refusal of a voluntary licence

The TRIPs Agreement also authorizes the granting of a compulsory licence when the owner of a patent has refused a reasonable commercial offer, which he has been



given a reasonable amount of time to consider. The adoption of this "refusal to deal" principle may be of particular importance as a dissuasive element. A patent owner should exercise caution when refusing a voluntary licence if the law contains an effective mechanism giving an authorization to a third party who has acted within reasonable commercial parameters.

There is of course a broad margin for evaluating whether or not an application for a licence, and its refusal, are reasonable; this implies the need for detailed regulations on this type of licence, taking into account the aim of promoting dissemination of technology and avoiding monopolistic positions in the drugs sphere.

Other grounds

As mentioned above, the Agreement is not limitative as to the grounds for granting compulsory licences. In other words, domestic law can define the grounds for granting such licences, including those that are not mentioned in the TRIPs Agreement, which is only indicative in this respect.

The only sector in which there are limitations on the type of compulsory licence that may be granted is the semiconductor sector, where compulsory licences may only be granted for "public non commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive" (Article 31(c)).

Conditions for the granting of compulsory licences

The Agreement devotes particular attention to the conditions under which a compulsory licence may be granted.

- Such a licence should be granted taking into consideration "its individual merits" (Article 31(a)). This means that decisions have to be taken on each individual application and that they cannot apply in general to certain types of patents defined by their category, owner or in any other way.
- Before granting a licence, the proposed licensee should have made efforts "to obtain authorization from the right holder on reasonable commercial terms and conditions", and it is a condition that "such efforts have not been successful within a reasonable period of time" (Article 31(b)). This provision makes it mandatory to hold prior commercial negotiations with the patent owner. Nevertheless, Article 31 allows exceptions in cases of national emergency or other circumstances of extreme urgency, as well as for "public noncommercial use" or where a licence is granted to remedy anti-competitive practices.
- The scope and duration of use "shall be limited to the purpose for which it was authorized" (Article 31(c)). This clause means that a licence may be limited both in terms of scope (for example, to certain categories or types of product) and duration. Nevertheless, nothing prevents an application for a licence lasting up until the date of expiry of the patent. In fact, this practice has been generally accepted under the Paris Convention until now. For a licensee who invests in production or marketing, it will usually be essential to obtain a licence for the whole term of the patent.



Another important point is that the Agreement does not limit the purpose for which a compulsory licence may be granted. In other words, it may be granted for import as well as for local production of a patented product. In some cases (licences to remedy abuse of a dominant market position or to protect public health), import may in fact be the only way of fulfilling the purpose for which the authorization was granted. Moreover, in developing countries there will be cases in which local industry might start making up formulations under licence on the basis of imports of the active constituents whose manufacture is not viable for reasons of scale or technology.

- As prescribed in the majority of legislations, any authorization should be non-exclusive and non-assignable, except with regard to that part of the company that uses it. The non-exclusive character of a licence means that the holder may import or industrially work the invention in parallel with the licensee, by himself or by means of other voluntary licensees. It also means that more than one compulsory licence can be granted for a given patent.
- Licences should be granted "predominantly for the supply of the domestic market" (Article 31(f)). This provision (which may not be applicable to licences granted in order to remedy anti-competitive practices), if applied restrictively, may mean that it is not viable to produce locally any substances in which economies of scale play an important role.
- One important change is introduced regarding the term of licences as usually applied at present. Article 31(g) states that a compulsory licence can be terminated "if and when the circumstances which led to it cease to exist and are unlikely to recur". Consequently, the competent authorities must have the authority to review, upon motivated request, the continued existence of these circumstances. Nevertheless, termination is subject to "protection of the legitimate interests of the persons" authorized to use the invention. Without this last condition, the Article in question would have totally weakened the potential of any system for the granting of compulsory licences. Protection of the legitimate interests of the licensee should be taken to mean that the latter cannot be deprived of his right to hold a licence once he has made serious preparations to use the invention or has created production or marketing facilities. If a reasonable degree of certainty is not guaranteed, no one would be interested in applying for a licence that could be terminated at any time. Paradoxically, the licensee most affected might be precisely the one who has made the greatest contribution to remedying the situation that gave rise to the granting of the licence.
- The owner of the patent must be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization" (Article 31(h)). This provision would apply in principle to any kind of compulsory licence. For licences granted to remedy anti-competitive practices, however, the need to correct such practices "may be taken into account in determining the amount of remuneration" (Article 31(k)). Since the aim is to restore healthy competition, this provision envisages the possibility of fixing reduced remuneration in order to make it easier for third parties to apply for and



obtain a licence for this purpose. A licence free of royalties may also be granted (Mendes da Costa, 1992), as has repeatedly been done by USA's jurisprudence to remedy anti-competitive practices.¹⁴

There is still wide scope for interpretation at the national level of the criteria used to determine when remuneration is deemed to be "adequate". The provision undoubtedly establishes two elements for this interpretation: on the one hand, the adequacy of the amount must be determined by the circumstances of each case and, on the other, it is necessary to take into account as a decisive but not unique factor "the economic value of the authorization". Consequently, the circumstances of the licensee and in the country where he operates, as well as the purpose of the licence, have to be taken into account when establishing fair remuneration. A licence granted to meet public health or other needs must be subject to parameters other than those applicable when only purely commercial and industrial interests are involved. The "economic value" will differ *inter alia* depending on the size of the market to be supplied (usually the domestic market), the age of the technology, the rate of obsolescence in the sector concerned, the degree of competition from substitute products and the coverage of the patent.

The word "adequate" also needs be clarified in order to give more precise guidance to national judicial and administrative authorities. One possible interpretation is that it simply means the remuneration that the patent owner could obtain in a transaction between independent parties. This is not, however, the true meaning of the word in the original English text.¹⁵ A more appropriate interpretation would be to distinguish the value of the actual contribution made by the holder to the development of the invention, deducting any contributions by third parties, subsidies or other contributions which the patent owner may have received. The extent of amortization of research and development costs at the time of granting the licence also has to be calculated.

The patent owner must be given the possibility of having the "legal validity" of any decision relating to the granting of a licence or to the remuneration reviewed by an administrative authority at a higher level or by a judicial authority (Article 31(i) and (g)). This right does not, however, prevent a Member country from granting a licence subject to subsequent revision so any appeal against the decision granting the licence does not suspend its immediate effect. This is particularly important in cases related to public interest and the remedy of anti-competitive practices.

2.8 Term of protection

The Agreement will have a powerful harmonizing effect at the global level in respect of the term of patent rights. Article 33 establishes a minimum of twenty years from

¹⁴ One example of a "royalty free" compulsory licence is that granted by the USA Federal Trade Commission in 1990 to the French company Rhone-Poulenc for five years.

¹⁵ See Harry Small (1991) regarding the concept of "adequate remuneration". It is interesting to note that this is the only provision in the Agreement referring to "adequate" remuneration. Articles 14.4 and 70.4 use the word "equitable" remuneration instead.



the date of filing the patent application. This provision will prohibit any special period determined on the basis of the field of technology, the extent of exploitation of the invention or on any other grounds.

On the other hand, there is no obligation whatsoever to extend the term of protection beyond this minimum (as has been done, however, in the USA and Europe) for pharmaceutical patents.

2.9 Reversal of the burden of proof

Article 34 provides for reversal of the burden of proof in civil litigation involving process patents. This provision is of special importance for the pharmaceutical industry. The text's wording itself indicates the difficulties encountered in achieving a consensus on this aspect. Reversal of the burden of proof can have a negative effect on inventiveness in small scale and medium scale industries due to the risk of facing legal problems and high litigation costs.

This problem affects small companies both in developing and developed countries. It has been noted in the USA, for example, that "large firms are more likely to be able to threaten litigation and to defend against litigation. There have been at least some cases of 'strategic litigation' in which a large firm uses the threat of litigation costs to deter a start up" (Barton, 1995).

According to the first sentence of Article 34.1, it is the judge who will have the authority "to order the defendant to prove that the process to obtain an identical product is different from the patented process". This would have been a reasonable solution since it would have given the judge the opportunity to assess, in the circumstances of each case, the extent to which reversal is justified. However, the provision goes on to establish a legal presumption. It allows countries to choose between two hypotheses, but in both of them "any identical product when produced without the consent of the patent owner shall ... be deemed to have been obtained by the patented process".

The first hypothesis is that the product obtained by the patented process is "new". The Members may interpret the degree of newness required. In principle, newness means according to the usual terms of patent law, even if the product is not patentable as such. It has to be assessed at the time when the lawsuit is initiated.

According to the second hypothesis there must be "a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used." In this case, the product might not be "new", thus the scope of the provision is broader than in the first hypothesis because it applies to all products previously available. The requirement regarding "reasonable efforts" by the patent owner has to be evaluated by the judge in each particular case; if it is applied correctly, it could help to restrict any abuse by the patent owner of resort to reversal of the burden of proof.¹⁶

¹⁶ Nevertheless, the first hypothesis in Article 34.1 provides greater legal assurance and is therefore the one which would be most desirable in domestic legislation.



Finally, it should be pointed out that this provision has to be interpreted and applied in the light of Article 29. The invention of the process must be described clearly and completely since this is a condition for ensuring that any potential infringer is aware of the extent to which his acts are legitimate or not.



3. Undisclosed information

Section 7 of Part II of the TRIPs Agreement contains specific provisions on "undisclosed information". According to Article 1.2, this constitutes a category of "intellectual property" in the same way as patents, trademarks and other forms dealt with in the Agreement. Article 39.1 provides that, in order to ensure effective protection against unfair competition, Member countries shall protect undisclosed information and data submitted to governments or governmental agencies in order to obtain approval for the sale of pharmaceutical or agricultural chemical products.

There are two general considerations regarding this topic. Firstly, the Agreement subordinates "undisclosed information" to the rules on unfair competition in accordance with Article 10 bis of the Paris Convention. By adopting this approach, the Agreement clearly avoids treating undisclosed information as "property", as proposed by the USA in prior informal proposals. The conceptual framework adopted is consistent with prevailing ideas on this subject in Europe, Japan and many developing countries. The fact that "undisclosed information" is considered as a "category" of intellectual property does not mean that there is an exclusive right.

Secondly, it should be noted that the text does not utilize the words "know how" or "trade secrets". Perhaps the difficulty of achieving a common and acceptable understanding of the meaning of these words encouraged the adoption of the wording used, which does not specify the technical or commercial nature of the information but only that it is "undisclosed". Article 39 therefore applies to any commercial information, provided that it meets the requirements laid down in Article 39.2.

Article 39.2 specifies the conditions required for information to be considered as "undisclosed: it must be secret, have a commercial value and be subject to reasonable steps, under the circumstances in each particular case, to keep it secret. The conditions laid down are essentially based on the relevant legislation enacted in many States in the USA. The footnote to this Article defines practices which "at least" have to be considered "contrary to honest commercial practice", thereby limiting the possibility of divergent interpretations. The practices mentioned include those which may result from contractual or like relations (breach of contract, breach of confidence and inducement to breach), as well as the acquisition of undisclosed information by third parties who knew or were grossly negligent in failing to know that such practices were involved in the acquisition.

Although Article 39.1 refers to "undisclosed information" and other "data submitted" to governments as two separate aspects, it seems clear that in the latter case the information must also be "undisclosed" in order to be included within the terms of the Agreement. The scope of Article 39.3 is sectoral: it only protects information submitted as a condition for approving the marketing of pharmaceutical or agricultural chemical products "which utilize new chemical entities". This means, first of all, that information that is already in the public domain (for example, because it has been published in scientific reviews) and is submitted in order to obtain marketing



approval does not fall under this section. Secondly, as mentioned above in connection with reversal of the burden of proof, in such cases a "new" entity can be taken to mean an entity not included in the state of the art.

In the light of the foregoing analysis, the scope of the obligation laid down in Article 39.3 is limited by the type of novelty of the products concerned and the purpose of the submission of data (only for marketing approval). Furthermore, these provisions state that, in order to seek protection, "considerable effort" must have been made to create the information. Unlike the wording of Article 70.4, which refers to "significant investments", the expression used in the former case is much broader. A reasonable explanation would be that the "effort" made must not only be significant in economic terms but also from a technical and scientific point of view, essentially meaning experimental activities.

The protection envisaged has two purposes. One is to try to halt "unfair commercial use" of the information protected. This means that it would be possible to prevent a third person, for example, from using the results of tests submitted by another company as a basis for making a separate application to obtain marketing approval if these data were obtained using unfair trade practices. The third person concerned could obviously draw up the data and information independently or obtain them from other sources.

The duplication of tests (which often implies the suffering of animals) in order to obtain results that are already known would of course be questionable from the cost social benefit standpoint. This provision would not, however, prevent governments using information submitted by one company in order to assess information submitted by other companies, as is permitted, for example, in the case of approval for the marketing of generic drugs under the United States Drug Price Competition and Patent Term Restoration Act (1984).

In addition, protection against the disclosure of confidential information has to be ensured. Since any disclosure by third parties is already covered in Article 39.2, the obligation not to reveal data contained in Article 39.3 appears to be directed at government authorities. Two exceptions to this obligation are envisaged:

- where the disclosure is necessary to protect the public; and
- where steps have been taken to ensure that the information will not be used in a way that is commercially unfair. Subject to these exceptions, disclosure would be allowed, for example, to enable the holder of a compulsory licence to obtain marketing approval, especially when the purpose of the licence is to remedy anti-competitive practices or to meet public health requirements.

It should be noted that the original position adopted by the developing countries in the TRIPs negotiations was to reject any form of protection of know how in the text of the Agreement. At the other extreme, some industrialized countries made proposals aimed at establishing a minimum period of protection (five years) to safeguard tests and data submitted for marketing approval. The text of the Agreement as adopted



represents a compromise which gives ample opportunity for implementation at the national level. Nevertheless, it is undoubtedly a complex matter and for many countries it involves new obligations that do not only affect the private sector but also government bodies responsible for approving drugs.



4. Transitional periods

4.1 General grace period

All members of the World Trade Organization will have one year after the date of entry into force of the Agreement in which to fulfil the obligations on the protection of intellectual property (Article 65.1). Developing countries will have an additional period of four years, except for obligations concerning national treatment and most favoured nation treatment, which will become applicable after the expiry of the aforementioned one year period (Article 65.2). Least developed country Members have an additional period of ten years, which can be extended upon "duly motivated request" (Article 66.1)

4.2 New patentable areas

In addition to the general transitional period for developing countries mentioned in the previous paragraph, there is a further period of five years for countries that are obliged to extend product patent protection to areas of technology not so protected on the general date of application of the Agreement for that particular country (Article 65.4). This clause will apply to countries that only grant process patent protection or no protection at all in the pharmaceuticals sector. These provisions will only apply to countries which, on the aforementioned date of entry into force of the Agreement, do not confer product patent protection (see Article 65.5).

4.3 Protection of existing subject matter

The possible retroactive recognition of patent rights was a considerable source of dispute during the TRIPs negotiations. The Agreement adopted a negative approach to such recognition, eliminating "pipeline" type solutions as proposed by the USA. Articles 70.1 and 70.3 state that the Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for a Member (Article 70.1) and does not oblige a Member to restore protection to subject matter which on that date has fallen into the public domain. This means that Members are not obliged to confer protection on inventions that have become public (whether through private acts, publication by foreign patent offices or in any other way) before that date.

Article 70.4 confirms the application of the Agreement for the future; it allows special treatment for acts which involved significant investment before the Agreement was ratified by the Member. In such cases, the Member must provide for "equitable remuneration" to the right holder, but it may exclude or limit the applicability of other expedients (for example, interruption of use or sale of a protected product). There can be little doubt that national authorities will have to interpret the meaning of "significant investment" and "equitable remuneration", which in any event will



be subject to judicial review (Article 41.4). It is obvious that the significance of investment will have to be defined according to factors such as the size of the company in question, the type of product and the production facilities needed, as well as the cost of installation or utilization of the product entitled to protection. In order to determine "equitable remuneration", consideration will have to be given inter alia to the extent of development of the technology, the amount of the research and development costs written off and any subsidies granted to the patent owner in order to carry out the research which resulted in the technology protected.

4.4 Prior compulsory licences and application

Compulsory licences granted by a government before the date on which the Agreement "became known" do not need to respect the provisions of Article 31. The same applies to compulsory licences in a specific field of technology and which would be regarded as discriminatory under Article 27.1 (see Article 70.6). The use of an ill defined point in time (the moment at which the Agreement "became known") is confusing. This provision has apparently been adopted in order to accelerate the abolition of "automatic" licences for drugs in Canadian legislation, which allowed the growth of a large generic drugs industry in Canada.

According to Article 70.7, if a patent application is awaiting approval at the time the Agreement enters into force in a Member country, it will be possible to amend the application to claim "any enhanced protection provided under the provisions of this Agreement" (Article 70.7). Such an amendment may not, however, include "new matter". The major issue here is whether an application for a process patent may be changed into an application for a product patent. Since the distinction between a manufacturing process and a product is clearly defined, the change would imply the inclusion of new matter not included in the original claim. The answer should therefore be in the negative. On the other hand, the applicant may, for example, apply for protection for twenty years (Article 33) if the term of the patent previously applied for is less.

4.5 Pharmaceutical and agricultural chemical products

The importance of patent protection for pharmaceutical and agricultural chemical products is underlined by special transitional provisions which establish rights not granted to patent owners in other fields of technology. This special treatment is in the following form.

Firstly, applications for pharmaceutical and agricultural chemical products must be filed in a Member country (according to Article 70.8) as from the date of entry into force of the Agreement. However, the patents will only be granted after the Agreement has become binding for the Member in question and (although the relevant provision does not explicitly mention this) after the expiry of the transitional periods set out in Article 65. The time elapsing between the application and the granting of the patent may therefore be considerable. Nevertheless, Article 70.8 manages to



preserve the novelty of the application through a legal artifice based on determination of its novelty (and other patentability criteria) as though it had been evaluated on the date of filing the application in the Member country (or the date of priority if available and claimed) and not on the date when it was in fact evaluated. Patents granted in this way will last for the remainder of the term of the patent, calculated from the date of filing and not the twenty year period established in Article 33.

Secondly, irrespective of the fact that the aforementioned transitional periods extend the possibilities for non patentability in developing countries for a total period of ten years after the date of entry into force of the Agreement, Article 70.9 limits this overall period for pharmaceutical and agricultural chemical products. It establishes the right to obtain "exclusive marketing rights" for these products before a patent has been granted. These rights which appear to be inspired by the "certificates" granted in EEC countries in order to extend the term of pharmaceutical patents¹⁷ can be obtained provided that the following criteria are met:

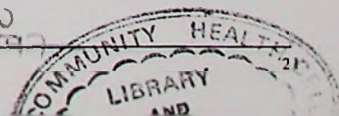
- a patent application has been filed in a Member country after the entry into force of the Agreement;
- an application has been filed in another Member country after the entry into force of the Agreement and a patent has been granted;
- marketing approval for the protected product has been obtained in the other Member country concerned;
- marketing approval has been obtained in the Member country referred to in subparagraph (a).

If these requirements are met, the Member concerned must grant these "exclusive marketing rights" for a period of five years after marketing approval has been obtained in that particular country. These rights will be terminated, however, if (a) the corresponding patent is eventually granted, or (b) the patent application is rejected in the country concerned.

The Agreement does not mention the content and scope of these "exclusive marketing rights". To what extent could the holders of such rights prevent others from marketing the product concerned? What recourse would they have against infringement? Would the provisions on granting compulsory licences be applicable? What procedures would be available to third parties wishing to use the invention, for example, for experiments, tests, marketing approval, etc.? There needs to be an in depth analysis of these and other questions relating to the implications of Article 70.9.

It is nevertheless relevant to mention that penal remedies are usually reserved for procedures related to patents; the holder of such exclusive rights may only have recourse to civil proceedings. In addition, the holder of the rights may not be placed

¹⁷ See the decision of 19 December 1991 by the Council of Europe, which establishes an additional protection certificate for pharmaceutical patents that have expired.





in a better position than the owner of the patent and, consequently, the abuse of a dominant position, public health requirements or other justified grounds could be a sufficient argument to limit the exclusive rights using means like compulsory licences (or revocation in cases of abuse). Finally, exclusive marketing rights should be interpreted as not restricting production for export to third countries.

The economic impact of Article 70.9 will vary according to the time needed for the approval and registration required to obtain exclusive marketing rights for a given product. In the pharmaceuticals sector, the carrying out of clinical and pre-clinical tests in order to demonstrate the usefulness and safety of a drug, in addition to the time required for government procedures, which is quite long in the USA and other industrialized countries, often delays the introduction of new products for several years. There are, however, indications that this period is becoming shorter, particularly for biotechnology-based products.



5. Enforcement and settlement of disputes

In addition to its operative provisions, the TRIPs Agreement contains a series of procedural rules aimed at ensuring enforcement of the protection of intellectual property rights.

If a Member considers that another Member is not fulfilling its obligations under the Agreement, it can initiate the mechanism for the settlement of disputes provided for in the "Understanding on the Settlement of Disputes". The new formula for this mechanism ensures that a decision is taken relatively quickly and that any unfavourable verdict is decided upon by "negative consensus". This means that, for a decision to be rejected by a panel, there must be a consensus to do so; in other words, a decision against a particular country may be adopted because there is no consensus to reject it.

Once the dispute settlement mechanism has been exhausted, the country concerned may apply trade sanctions against the country which is deemed to be infringing. Once these proceedings have been exhausted, action such as that taken under section 301 of the aforementioned United States Act becomes legitimate, even for sectors other than those affected by non fulfilment ("cross retaliation").

Lastly, it should be borne in mind that the TRIPs Agreement lays down minimum standards and that, at the same time, no Member country can be obliged to grant "more extensive protection" than required by the Agreement (Article 1). This signifies that any unilateral action on the part of governments requiring a higher standard of protection than that required by the Agreement or the application of trade retaliations on such grounds will clearly be unlawful within the framework of GATT 1994.



6. Implications for the development, production and marketing of drugs

The negotiations on intellectual property within the GATT framework were promoted by the governments of the industrialized countries, particularly the USA, in order to respond to the demands made by their domestic industry. Federations of industrialists in the pharmaceuticals, semiconductor and audio-visual works sectors, among others, made unstinting efforts to raise standards of protection in general and, in particular, to obtain the recognition and strengthening of rights in developing countries which did not allow such protection.

As has been seen, the Uruguay Round gave industrialized countries and the aforementioned industrial federations the opportunity to lay down universal minimum standards and at the same time to legitimize the trade retaliation mechanism applied by the USA under section 301 of the Trade Act. For the pharmaceutical industry in particular, the Round afforded the opportunity to overcome the resistance of those countries which refused to allow patent protection of pharmaceutical products. At the end of the 1970s, more than 80 countries did not provide any protection or only protected pharmaceutical processes (and not products). The USA pharmaceutical industry, moreover, considered that adequate and comprehensive patent protection was only available in 16 countries (White, 1979).

The arguments put forward by developed countries in favour of the extension and strengthening of patent protection included the positive impact this would have on the rhythm of innovation in the sector, as well on the transfer of technology and direct foreign investment in developing countries. Some of these issues are discussed below.

One of the main arguments in seeking universal and effective patent protection for pharmaceutical products has been the failure of developing countries to contribute towards the cost of research and development (R & D) by innovating companies.¹⁸ This would have a negative impact on the availability of resources to continue R & D efforts by innovating companies.

Global recognition of pharmaceutical patents will undoubtedly increase the earnings of companies owning such patents in the form of royalties and profits (Nogues, 1990). It is unlikely, however, that this increase will to any significant extent be in the form of an increase in global pharmaceutical innovation.

In 1990, the developing countries' share of global production of pharmaceutical products (formulations) was 18.4 per cent (Ballance, Pogany and Forstner, 1992). A

¹⁸ Although these countries have not contributed in the form of payment of royalties, in many cases they have contributed indirectly but significantly through the surcharges paid for the import of active ingredients. In the case of Argentina, for example, annual average flows due to overinvoicing in the mid 1980s were estimated at US\$ 80 million (Bisang, 1991), an amount equivalent to the amount estimated by the Pharmaceutical Manufacturers' Association as the annual losses of USA pharmaceutical companies due to the non patentability of drugs (Nogues, 1991).



large part of this production was carried out in these countries by the same multinationals which, in general, control two thirds or more of the markets in developing countries.¹⁹ Another large segment corresponds to "generic" products, for which no patents are in force. Estimates of the market share of formulations supplied by domestic companies by replicating products of multinational companies vary greatly, between 10 per cent and one third of the total domestic market (Nogues, 1990). This means that, even if all developing countries recognize pharmaceutical patents, the impact of recognition on an increase in pharmaceutical innovation will be marginal and will with difficulty justify the economic and social costs to be borne by these countries.²⁰

In addition, according to a study of the Office of Technology Assessment (OTA, Washington), it can be assumed that on average a new drug put on sale in the USA market during the period 1981-1983 earned an amount in dollars after tax of around US\$ 36 million more than the amount involved in its R & D. According to this study, "the long term persistence in the industry as a whole of dollar earnings that are higher than the amount required to justify costs and the R & D risk is proof of the unnecessary power of price fixing for ethical pharmaceutical products" (OTA, 1993, p.3).

To summarize, it is not possible to sustain the argument that the introduction of pharmaceutical patents in developing countries which excluded them from protection is justified by the increase in R & D by companies which will benefit from increased earnings in the form of profits and royalties.

Neither can it be expected that there will be an increase in R & D in developing countries because, if the cost of R & D for a new drug is around US\$ 150-200 million, as estimated, in developing countries there is no company with a sales volume (not less than US\$ 400 million per annum) that would allow it to make such investment. Although large pharmaceutical companies have decentralized some of their activities to R & D centres in countries other than that where they have their headquarters, the transfer of such activities to developing countries is insignificant (United Nations, 1992).

A study of inventions related to drugs carried out between 1950 and 1989 in 95 countries which recognize patents for pharmaceutical products shows that 91.7 per cent of them are to be found in 16 countries, and in 64 countries there have been no inventions at all (Challu, 1991a). In other words, the existence of patent protection as can be expected will not lead to greater capacity for innovation if other conditions are not present, particularly as far as the pre-existing scientific and technologi-

¹⁹ In the cases of Brazil and Mexico, for example, foreign companies account for 80 per cent or more of the market for formulations. Argentina and India are the most important exceptions because domestic companies account for a large share of the market.

²⁰ There are no reliable figures on the losses actually suffered by pharmaceutical companies. According to a survey by the United States International Trade Commission, losses of royalties and other revenue by the pharmaceutical industry because of inadequate patent protection amounted to US\$ 232 million in 1986. The Commission admits that these estimates may be "biased and self serving" (USITC, 1988, Table 4.5, p.1). In 1987, the industry's R & D costs amounted to US\$ 5.5 billion (OTA, 1993, Table 2.2); at the very best, generalized granting of protection would have allowed these costs to be increased by 4.2 per cent, assuming that the total additional earnings were devoted to R & D.



cal infrastructure is concerned. Even in South Korea, one of the countries which has seen the most spectacular increase in R & D capacity over the past twenty years, the impact of the introduction of patents had a negative effect on the majority of Korean pharmaceutical companies (Kim, Ro and Yu, 1994).

The positive impact of the adoption of patents on direct foreign investment and the transfer of technology is equally questionable. There is, on the one hand, no conclusive proof that greater protection leads to greater flows of direct foreign investment. In the pharmaceutical sector in particular the cases of Brazil and Turkey show precisely the opposite (United Nations, 1993). There is even evidence that pharmaceutical plants have been dismantled by foreign subsidiaries after the introduction of pharmaceutical patents. It is likely that local production of formulations in developing countries will progressively be replaced by imports of finished products (or bulk products), in other words, trade in drugs will increasingly replace direct foreign investment and the granting of licences to local companies in these countries.

★ For the time being, the only likely effect of the introduction of pharmaceutical patents as a result of the amendments to patent legislation in developing countries and the changes introduced in order to comply with the TRIPs Agreement will be higher drug prices. This will happen unless effective systems of compulsory licences and international exhaustion of rights are established.

For example, Subramanian noted that the price of drugs in Malaysia, where patent protection exists, is 20 to 760 per cent higher than in India, where there is no such protection. In Malaysia, prices are fixed according to the principle of "what the market can bear" (Subramanian, 1992). The impact of the introduction of patents in India may be incalculable: even with prices that are extremely low in comparison with those in other countries, only 30 per cent of the population can afford to buy modern drugs. According to the Indian Ministry of Trade, "patents for products will increase prices for drugs between five and ten times" (Karandikar, 1994).

The information shown in the studies by Nogues (1990) and Challu (1991a and b) coincides with this scenario of increased prices. In the case of Italy, following the introduction of patents for pharmaceutical products in 1978, drug prices increased on average by more than 200 per cent (Challu, 1991b).

Finally, it has been argued that concessions by developing countries in the area of intellectual property represent the "price" for the advantages they will obtain under the Uruguay Round as a whole, particularly in respect of market access. However, the balance of the agreements²¹ on tariff reduction, agriculture and textiles shows very poor results, barely favourable, for developing countries. The reduction of tariffs on products that are mainly traded within industries and companies and among industrialized countries is much greater (from 43 to 62 per cent) than the reduction in tariffs on products which constitute the major exports of developing countries (around 20 per cent on average). The tariff structure in industrialized countries after

²¹ The analysis which follows is based on Agosin and Tussie, 1994.



the Round continues to discriminate against agriculture and textiles products.²² In addition, the possibility given to importing countries to apply safeguard measures makes even more uncertain the advantages that might be gained.

²² For example, in the USA the average overall tariff (excluding that for oil and natural gas) after the Uruguay Round will be 5.5 per cent, but will rise to 7 per cent for nontropical agricultural products and 16.9 per cent for textiles and clothing. In the European Union, the figures will be 6.9, 16.8 and 10.1 per cent respectively.



7. Conclusions

This study shows that the TRIPs Agreement contains provisions which, on the one hand, will orient amendments to patent legislation in many developing countries in the direction of broadening and reinforcing the protection of pharmaceutical products. On the other hand, the Agreement will "freeze" the level of protection at a high standard that cannot be changed until the Agreement is revised.

The adoption of the Agreement has undoubtedly involved a major concession on the part of those countries which refused to grant patents for drugs in order to avoid the effects of market monopolies derived from exclusive rights. The information available, briefly referred to in the precedent section, shows that the universalization of pharmaceutical patents will not lead to increased R & D on new drugs by large companies nor to the possibility that this will be carried out to any significant degree in developing countries. Neither will developing countries receive increased flows of direct foreign investment or transfer of technology.

Countries which, on the date the Agreement enters into force, did not confer protection still have the possibility of limiting the introduction of pharmaceutical patents under the conditions laid down in the Agreement. Even though the transitional period for pharmaceutical and agricultural chemical products is ten years for developing countries, it has been made subject to the ambiguous notion of "exclusive marketing rights" which, incorrectly interpreted, could cancel out the advantages of the transitional period. In this connection, it is important to specify the scope of such rights and distinguish them sufficiently from the rights conferred by patents.²³

The effect of introducing pharmaceutical patents will undoubtedly depend on the degree of competition existing in the therapeutic/products categories concerned and the forms of production of formulations and competition existing in each domestic market. The form in which patent rights are implemented will also have a decisive impact. This is why it is particularly important that, when incorporating the provisions of the TRIPs Agreement in domestic legislation, countries should consider the following measures *inter alia*:

- a) including in domestic legislation a series of compulsory licences to act as an effective deterrent to monopolistic practices and encourage access to licences by local companies under reasonable conditions;
- b) guaranteeing the import of products legitimately sold on the principle of international exhaustion;
- c) excluding from patentability substances which exist in nature, including biotechnology based drugs;
- d) restricting reversal of the burden of proof to process patents for new chemical entities.

²³ This is likely to be one of the first issues to be tackled by the Council for TRIPs established under the Agreement to monitor its implementation.



In incorporating the provisions of the Agreement, attention must be paid to the principles of Article 8 in order to regulate intellectual property in a manner that is compatible with the interests of public health and minimizes the economic and social costs which such changes might have for the production and marketing of drugs and access thereto.



References

- Manuel Agosin and Diana Tussie, *Developing countries and the Uruguay Round: y la nave va? An evaluation of the changed institutional balance*, FIASCO, Buenos Aires, 1994.
- R. Ballance, J. Pogany and H. Forstner, *The World's pharmaceutical industry. An international perspective on innovation, competition and policy*, E. Elgar, Vermont, 1992.
- John Barton, "Adapting the intellectual property system to new technologies", (mimeo), 13 December 1991, Stanford.
- C. Berman and N. Lambrecht, "Medical patents in the US", *Managing Intellectual Property*, no. 10, July 1991.
- Robert Bisang, "Derechos de propiedad intelectual e industria farmacéutica", *Revista Cauce*, Year 3, no. 6, 1991.
- A. Casado Cervino and R. Cerro, *El Gatt y la propiedad industrial*, Ed. Tecnos, Madrid, 1994.
- Carlos M. Correa, "Propiedad intelectual, innovación tecnologica y comercio internacional", *Revista de Comercio Exterior*, vol. 39, no. 12, Mexico City, 1989.
- Carlos M. Correa, "The GATT Agreement on Trade Related Aspects of Intellectual Property Rights: new standards for patent protection", *European Intellectual Property Review*, vol. 16, no. 8, 1994.
- François Chesnais, *La mondialisation du capital*, Syros, Paris, 1994.
- Pablo Challu, *Patentamiento de productos farmacéuticos. Consecuencias*, Ed. Mercado, Buenos Aires, 1991a.
- Pablo Challu, "Repercusiones del patentamiento monopólico en Italia", *Industrial Property Review*, year 13, no. 39, 1991b.
- I. Destler, *American Trade Policies*, Institute for International Economics and the Twentieth Century Fund, Washington/New York, 1992.
- W. Fugate, *Foreign Commerce and Antitrust Law*, vol. II, 4 Ed. Little, Brown & Co, 1991.
- S. Karandikar, *Indian drug industry after GATT*, MVRDC World Trade Centre, Bombay, 1994.
- S.C. Kim, K.K. Ro and P.I. Yu, "Intellectual property protection policy and technological capability", *Science and public policy*, vol. 21, no. 2, April 1994.
- Philip Mendes da Costa, "Patent harmonization through GATT: TRIP or trap?", *Patent World*, September 1992.



Julio Nogues, *Social costs and benefits of introducing patent protection to pharmaceutical drugs in developing countries*, Washington, D.C. (mimeo), 1990.

OTA (Office of Technology Assessment), *Pharmaceutical R & D: costs, risks and rewards*, Washington D.C., 1993.

Edith Penrose, *La economía del sistema internacional de patentes*, Siglo XXI, Mexico City, 1974.

Harry Small, "The EEC draft Directive on rental rights and other rights", *Intellectual Property in Business*, vol. 3, no. 4, July/August 1991.

Arvind Subramanian, "Putting numbers on the TRIPs Pharmaceutical Debate", *Technology Management*, (forthcoming).

Diana Tussie, "The policy harmonization debate: what can developing countries gain from multilateral negotiations?" *UNCTAD Review*, 1994.

United Nations, *World Investment Report. Transnational corporations as engines of growth*, New York, 1992.

United Nations, *Intellectual Property Rights and Foreign Direct Investments*, New York, 1993.

USITC (United States International Trade Commission), *Foreign Protection of Intellectual Property Rights and the effect on US Industry and Trade*, Washington D.C., 1988.

Eduardo White, "La industria farmacéutica internacional, la legislación comparada sobre patentes y el caso argentino", *Revista del Derecho Industrial*, year 1, no. 2, 1979.

HE-100
05143 492

