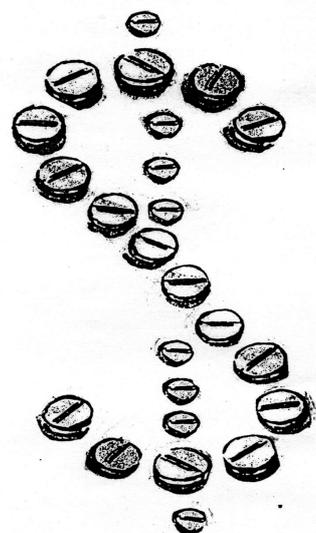


THE TRIPS AGREEMENT AND PHARMACEUTICALS



**Report of an ASEAN Workshop
on the TRIPs Agreement
and its Impact on Pharmaceuticals**

Jakarta, 2-4 May 2000



Directorate General of
Drug and Food Control



World Health
Organization

INDONESIA

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Prepared by:
Karin Timmermans and Togi Hutadjulu



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LIST OF ABBREVIATIONS AND ACRONYMS

Agreement	the TRIPs Agreement (see: TRIPs)
AIDS	Acquired Immune Deficiency Syndrome
ASEAN	Association of South-East Asian Nations
AZT	3'-azido-3'-deoxythymidine (also known as zidovudine)
BMS	Bristol-Myers Squibb
CBD	Convention on Biological Diversity
CL	compulsory license
ddI	didanosine
DNA	deoxyribonucleic acid
EPO	European Patent Office
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
GI	Genetics Institute
GM	Genetically modified
GMOs	Genetically modified organisms
GP Farmasi	Gabungan Pengusaha Farmasi (Indonesian Pharmaceutical Industry Association)
HIV	human immune deficiency virus
IFPMA	International Federation of Pharmaceutical Manufacturers
ICH	International Conference on Harmonization
IMF	International Monetary Fund
INN	international non-proprietary name
IP	intellectual property
IPR	intellectual property rights
LDC	least developed countries
MFN	most-favoured-nation
MNC	multi-national companies
MOH	Ministry of Health
NAFTA	North American Free Trade Agreement
NCE	new chemical entity
NGO(s)	non-governmental organization(s)
NIH	National Institute of Health
PTO	Patent and Trademark Office
R&D	research and development
SK-F	Smith Kline and French
SMP	safety monitoring program
TB	tuberculosis
TK	traditional knowledge
TRIPs	(Agreement on) Trade-Related Aspects of Intellectual Property rights
UK	United Kingdom
UNDP	United Nations Development Program
UNIDO	United Nations Industrial Development Organization
US	United States (of America)
USPTO	US Patent and Trademark Office
USTR	US Trade Representative
WB	World Bank
WIPO	World Intellectual Property Organization
WHO	World Health Organization
WTO	World Trade Organization

This report has been compiled by Karin Timmermans and Togi Hutadjulu.

Sections I, II, III and IV are based on the presentations and/or papers of the following resource persons:

Dr. Carlos M. Correa <i>University of Buenos Aires, Argentina</i>	Paragraph I, 2.1, 2.3, 2.5, 3.2 , 3.3, 3.4, 3.5, 3.6, 3.7, 3.9, 3.11 and 3.12
Dr. Cita Priapantja <i>IPR Society, Indonesia</i>	Paragraph 3.9
Dr. German Velasquez <i>World Health Organization</i>	Paragraph 2.2
Dr. Harvey E. Bale <i>International Federation of Pharmaceutical Manufacturers</i>	Paragraph 2.4.1
Mr. James Love <i>Consumer Project on Technology, US</i>	Paragraph 3.3, 3.4, 3.5, 3.9 and 3.10
Drs. Kai Arief Iman Selomulya <i>Indonesian Pharmaceutical Association</i>	Paragraph 2.4.2
Dr. Kumariah Balasubramaniam <i>Consumers International, Malaysia</i>	Paragraph 2.4.3
Mr. Matthew Kennedy <i>World Trade Organization</i>	Paragraph 2.1, 3.1 and 3.5
Dr. Mohan D. Nair <i>Pharmaceutical Industry Consultant, India</i>	Paragraph 4.2 and 4.3
Mr. Shakeel Bhatti <i>World Intellectual Property Organization</i>	Paragraph 2.1, 2.5 and 4.1
Ms. Yuwadee Patanawong <i>Food and Drug Administration, Thailand</i>	Paragraph 3.8
Dr. Wattana S. Janjaroen <i>Chulalongkorn University, Thailand</i>	Paragraph 2.5

Sections V and VI are based on the input from participants and delegates.

EXECUTIVE SUMMARY

Most ASEAN Countries are either members or observers of the World Trade Organization (WTO); this means they are committed to follow the rules laid down in its Agreements, or intend to make these commitments in future. One of these WTO Agreements is the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs). The TRIPs Agreement makes the granting of patents for pharmaceuticals obligatory. Since previously many developing countries allowed only for limited patent protection in this area, this represents a significant change in the pharmaceutical sector. Proponents believe this will lead to an increase in investment and in R&D, yet numerous public health experts, as well as consumer groups, have expressed concern about the impact of the TRIPs Agreement on the availability and prices of drugs. Moreover, worldwide, there is growing concern about the impact of the intellectual property rights system on innovation and on investment. A global process of rethinking is starting, in which developing countries should actively participate.

The TRIPs Agreement is not a uniform law, but a framework that sets (minimum) standards and conditions for the protection of intellectual property. These are made operational via the national intellectual property rights (IPR) legislation. Within the TRIPs framework, there is some room for manoeuvre, which can be used to design legislation which is in the best interest of the country. Measures to protect the public interest ought to be included in the national legislation, and should encompass public health aspects. In fact, TRIPs provides for a number of safeguards which may be used to protect public health and promote competition, such as compulsory licensing, and allows for exceptions which may facilitate the marketing of generic drugs ("Bolar exception"). These safeguards can be used to mitigate potential negative impacts of increased IPR protection in the pharmaceutical sector on access to drugs. However, these safeguards can only be used if they have been incorporated in the national legislation.

Safeguards such as provisions for compulsory licensing are an essential element of IPR legislation, since they signal to the patent holder that, in the case of abuse of rights and/or non-availability of the product, a third party could be allowed to use the invention. As such, they reduce the risk of misuse of the monopoly rights conferred by a patent. However, to ensure that such safeguards can be used effectively, it is important to carefully state the grounds and conditions for their use in the national legislation.

TRIPs requires that patents are granted when the typical standards for patentability, that is, novelty, inventive step and industrial applicability, are met. But the Agreement does not specify how these criteria should be defined; WTO member countries may decide how to apply these criteria. In the pharmaceutical sector, applying these criteria in a flexible way will facilitate the granting of 'secondary' patents, such as formulation patents, patents on polymorphs etc. Even if such secondary patents are relatively weak, they can be used aggressively to (threaten to) litigate, in order to stop competition. Therefore, defining the scope of patentability at the national level is an important issue.

Similarly, enforcement rules can have significant implications, since, once a patent has been granted, there is a presumption of validity. If countries have strong provisional measures under their enforcement system, these can be used to prevent competition for instance while a lawsuit is pending (which can be several years). In the absence of competition, monopolistic pricing may reduce people's access. However, if eventually a patent is found to be invalid or an enforcement rule to be unjustified, from a societal point of view it is important to consider who will reimburse the consumers, and how many people have in the meantime been denied access to essential medicines.

Outline of the report

This report aims to give an overview of the TRIPS Agreement and its possible implications on the pharmaceutical sector in developing countries; what are the issues and what are the options?

It only sketches the broad picture – in order to address these issues at national level and to draft legislation that balances the interests of producers and users of technology, cooperation among the Ministry of Health, the Ministry of Trade and the Intellectual Property Rights Office will be of utmost importance.

The first -and main- part of this report has been compiled on the basis of input from the resource persons at the workshop. It starts, in section I, with a short introduction. Thereafter, section II “general issues” provides briefly some essential background information on WTO and IPR; moreover a substantial portion is based on input from major stakeholders, since policy makers will encounter their important, differing and firm views - and will have to take them into consideration;

Section III deals with technical issues and how they translate into social and public health realities; and section IV “special issues” provides some initial reflections on how several of these concepts translate into the specific areas of traditional medicine(s) and biotechnology.

The second -smaller- part of the report lists some of the issues discussed, and contains the recommendations.

I. INTRODUCTION

Recently, international trade agreements have introduced big changes, not only in the area of trade, but, via the Agreement on Trade-Related Aspects of Intellectual Property Rights (or the TRIPs Agreement), also in the area of intellectual property. These are changes in what constitutes intellectual property and in where this is defined: important decisions are being removed from the national level to the global level. As a result, even the stakeholders are changing, and public health officials have to become involved in discussions on intellectual property rights, notably patents.

Before looking at the (technical) issues in greater detail, it is important to mention that the patent system is not without problems. In fact, developing countries have been requested to apply or expand the patent system at a moment when there is growing concern, even in developed countries, about the impact of this system on innovation and on investment. So developing countries have been requested to implement a system that has some important flaws and that is increasingly criticized:

“The relentless march of intellectual property rights needs to be stopped and questioned. Developments in the new technologies are running far ahead of the ethical, legal, regulatory and policy frameworks needed to govern their use. More understanding is needed -in every country- of the economic and social consequences of the TRIPs Agreement. Many people have started to question the relationship between knowledge ownership and innovation. Alternative approaches to innovation, based on sharing, open access and communal innovation, are flourishing, disproving the claim that innovation necessarily requires patents.”

UNDP Human Development Report 1999

“The global regime of intellectual property rights requires a new look. The United States prevailed upon the world to toughen patent codes and cut down on intellectual piracy. But now transnational corporations and rich-country institutions are patenting everything from the human genome to rainforest biodiversity. The poor will be ripped off unless some sense and equity are introduced into this runaway process.”

Jeffrey Sachs, The Economist, 14 August 1999

Developing countries should actively participate in a process of rethinking the intellectual property rights system, in terms of its impact on innovation and in terms of North-South relationship.

Furthermore, legislators in developing countries should realize that the TRIPs Agreement is not a uniform law, but that it leaves room for manoeuvre, albeit within certain limits. Countries can use this room to design legislation which is adequate and in the best interest of the country. Measures to protect public health or the public interest can be included in the national legislation. In order to do this, cooperation among the Ministry of Health, the Ministry of Trade and the Patent Office is of utmost importance.

TRIPs begins, in its very first Article, with the statement that, while countries may provide for higher levels of protection (compared to the TRIPs standards), they shall not be obligated or required to do so. Moreover, the Article continues that countries themselves shall determine how to implement the different requirements through their own domestic laws; this means that countries cannot be required to follow exactly the example of other countries - even though at times there is pressure to do so.

II. GENERAL ISSUES

2.1 Background

2.1.1 The World Trade Organization

At the end of the second World War, 23 nations signed the General Agreement on Tariffs and Trade, a treaty which aimed at progressive liberalization of international trade through rounds of negotiations. The eighth round, or Uruguay Round, lasted from 1986 to 1994 and ended with the establishment, on 1st January 1995, of the World Trade Organization (WTO), which currently has more than 130 member states. The World Trade Organization is the international organization dealing with the rules of trade between nations. At its heart are the WTO Agreements. In these Agreements, which are negotiated and signed by WTO member governments, the rules for international commerce are laid down. The WTO Agreements cover goods (the General Agreement on Tariffs and Trade or GATT), services (the General Agreement on Trade in Services or GATS) and intellectual property (the Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPs). They are lengthy and complex because they are legal documents. But a number of simple, fundamental principles underlay all of them; these are:

- *Non-discrimination.* Under the WTO Agreements, countries cannot normally discriminate between their trading partners. This is referred to as the most-favoured-nation (MFN) principle; it means that countries have to treat all foreign nations equally. However, some exceptions are allowed, for example regional free trade agreements. A second aspect of non-discrimination is "national treatment"; this means that imported and locally produced goods should be treated equally, at least after they have entered the market.
- *Transparency and predictability.* In order to stimulate free trade, the business environment should be stable and predictable. Trade rules and practices should be clear and publicly disclosed.
- *More favorable treatment for developing countries.* Opening markets can be beneficial, but also requires adjustment. The WTO Agreements allow countries to introduce changes gradually, through progressive liberalization. Developing countries, and particularly the least-developed countries, are usually given extra time (the transitional periods) to adjust to the more unfamiliar and, perhaps, difficult WTO provisions and to fulfill their obligations¹. However, at the end of their respective transitional periods, the rules and obligations under the TRIPs Agreement are the same for all countries, regardless of their level of development.

Another important aspect of WTO's work is *dispute settlement*. Trade relations often involve conflicting interests. Contracts and agreements, including those painstakingly negotiated in the WTO system, often need interpreting. When interpretations differ, disputes between countries may arise; the best way to settle these is through an

¹ In some WTO Agreements (but not TRIPs), developed countries were also given transitional periods.

agreed, standardized procedure. The WTO dispute settlement process consists of several stages. The first stage consists of consultations: the countries concerned have to agree to discuss the issue and see if they can reach agreement. If this fails, a Panel will be selected by the parties to the dispute or, failing that, appointed by the WTO Director General. The Panel will review the evidence and hear the arguments of both sides. The Panel will issue a report and its recommendations will be adopted by the Dispute Settlement Body by *negative consensus* (this means the report will be adopted unless there is a consensus in the Dispute Settlement Body -that is, among all WTO members- to reject it). Parties in the dispute have the option to appeal a Panel's report; however the Appellate Body will only re-examine the legal interpretation of WTO Agreements and rules, it will not (re)evaluate the evidence.

The country that loses, must follow the Dispute Settlement Body's recommendations. If it does not comply within a reasonable period of time, it may be required to provide compensation; otherwise, as a last resort, trade sanctions may be applied against that country.

So far, there have been about 20 WTO disputes related to the TRIPs Agreement; this represents about 10% of all WTO disputes. Taking into account the fact that TRIPs is only one of 26 Agreements, this is a fairly high percentage. Moreover, it could rise with the ending of the transitional period for developing countries; for most developing countries, the transitional period, at the end of which they have to comply with TRIPs standards, has ended in January 2000 (least developed countries have until January 2006).

2.1.2 The philosophy of Intellectual Property Rights

Intellectual property rights (IPR) deal with the creations of the human mind. The intellectual property rights system has been developed in order to try to achieve two contradictory aims:

- to promote the publication of ideas, inventions and creations, in order to make them available to others, who can then further improve them; this will nurture scientific progress or artistic inspiration;
- to provide an economic incentive for people to invent or to engage in creative efforts, by ensuring that the originator can reap financial rewards from his/her efforts.

The solution adopted was to give the inventor or creator a temporary monopoly, in exchange for making his/her idea known to society.

Different types of IPR have been developed; the most well known are patents (for inventions with industrial application) and copyrights (for artistic and literary works), which confer time-limited monopoly rights. Other elements which are included in most IPR laws are trade secrets (offering protection against unfair competition with regard to information that is not disclosed) and trademarks (focussing on 'competition on the merits' and offering protection against misleading of consumers regarding the origin of a product).

In the pharmaceutical sector, patents are the most important form of IPR protection. Patents are more difficult to obtain than other forms of IPR (an application has to be filed at, and approved by, the patent office); they are only valid when issued and in

the country where they are issued². For an invention to be patentable, it has to meet three criteria: novelty, inventiveness and industrial applicability or utility. In other words, apart from being new, an invention should not be obvious to people skilled in the art or field of technology and it should have a potential for industrial application in order to be patentable.

A patent requires the inventor to disclose his invention, in exchange for a temporary monopoly on its use. Because of this (temporary) monopoly, the inventor will be able to earn a profit in case of commercialization of the invention, either through direct exploitation, or through royalties in case a third party is given a license to use the invention. So historically, a patent was perceived to be an inexpensive way for society to encourage innovation and reward the inventor.

A patent however does not in itself guarantee profits; a patented invention will only return profits if it is successfully commercialized - that is, if society finds the invention useful. Because patents are private rights, the costs of patent application, as well as of its protection (e.g. litigation in case of infringement by an unauthorized party) are to be borne by the patentee (patent holder). Furthermore, most legal systems contain provisions for government intervention, in case the patentee misuses the monopoly rights, e.g. when the availability of the patented product falls seriously short of demand.

Patents can be granted for a product or for a (production) process. A product patent confers monopoly rights over the product, regardless of the production method. A process patent on the other hand confers rights over the process and over the products directly produced by that process. Production of the same product via a *different* production method however does not infringe a process patent and is allowed.

Box 1 Patents for pharmaceuticals in India

The difference between process and product patents can be illustrated with the example of India. The Indian Patents Act of 1970 allowed only process patents for pharmaceuticals, but did not allow product patents. This allowed Indian pharmaceutical companies to produce medicines which were patented elsewhere, provided they were able to develop an alternative production method.

2.1.3 The importance of intellectual property rights for national development.

As mentioned above, there are several types of intellectual property rights; patents, copyrights, etc. and they are very different. Their importance varies according to the sector, the type of intellectual property rights and the level of development of the country. Therefore, it is impossible to generalize; a country and sector specific analysis would be needed.

For example in the electronics and computer industries, patents are only modestly important. Although it is a very dynamic sector, the concept of a computer has largely remained the same; there are not many real inventions. Instead, existing products are

² However, it is possible by filing an international application under the Patent Cooperation Treaty, to simultaneously seek protection for an invention in each of a number of countries. Other forms of IPR, for example trademark rights and copyrights, arise automatically in some countries.

improved. In fact, in this industry, and especially in the semi-conductor sector, lead time is more important than patents: the first one to introduce a new product will have the largest market share.

However, in the pharmaceutical sector, patents are very important. In fact, the very existence of the TRIPs Agreement is due to the pressure from the big pharmaceutical companies on the US government, which in turn insisted that this issue should be on the agenda of the Uruguay Round negotiations.

There are several reasons for the importance of patents for the pharmaceutical industry:

- The costs of pharmaceutical R&D are high. While the actual amount is being disputed, it is in any case significant.
- There is a disclosure requirement, at registration,
- Usually, imitation is relatively easy; therefore the patent is important to protect the invention.
- It allows the company to make extra profits. Because of the monopoly rights the patent confers, the company can charge a higher price and earn more than would have been possible in case of free competition. Obviously, from these profits, R&D costs have to be recovered; however, the US Office of Technology Assessment has published a study³, which showed that profits in the pharmaceutical industry are considerably higher than in other industries and that the rate of return is much higher than what is needed to cover the costs.

With regard to impact on development, two aspects of development can be distinguished: economic aspects and social or human aspects. Ultimately, the latter are the most important, so intellectual property rights should be looked at from this angle. Pharmaceutical patents are a clear example: the inherent effect of patents is to increase the price, which will reduce access. Therefore, in terms of social development, the impact of pharmaceutical patents is negative. On the other hand, however, patents may have positive 'dynamic effects' so far as they foster the development of new products that benefit society.

When contemplating the importance of patents for national development, policymakers should make a profile of their country, taking into account the level of development, and, based on that, evaluate the importance of patents.

Moreover, when designing patent laws, the limited room for manoeuvre built into the TRIPs Agreement should be used, in order to make sure that the national patent law works in the interest of the country's social as well as economic development.

2.1.4 The World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) is one of the 16 specialized agencies of the UN. As of January 2000, it had 173 member states. WIPO is responsible for the promotion of protection of intellectual property rights throughout the world. Its principal activities are the progressive development of nuance in field of intellectual property, the administration of certain treaties for global protection of

³ Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, 1993.

intellectual property, and development cooperation with respect to intellectual property.

In the field of industrial property, the main objectives of WIPO's cooperation with developing countries are:

- To encourage and increase the creation of patentable inventions by developing countries nationals and thereby to enhance their technological self-reliance and their competitiveness in international markets.
- To improve the conditions for their acquisition of foreign patents and technology.
- To increase their competitiveness in international trade through better protection and more effective use of trademarks and service marks.
- To facilitate a developing country's access to technological information contained in patent documents.

WIPO can assist developing countries with the implementation of their obligations under the TRIPs Agreement. This assistance includes:

- Advising; at their request, WIPO provides legislative advice to developing countries when they are drafting laws on intellectual property;
- Awareness raising and human resources development;
- Institution building and modernization of intellectual property systems, including the provision of specially developed software;
- Publishing studies on the implications of TRIPs Agreement on developing countries.

The provision of legal technical assistance to developing countries, related to TRIPs implementation, is one of the activities under a WIPO-WTO cooperation agreement.

2.2 WHO's perspective on globalization and access to drugs

Global pharmaceutical challenges

At the beginning of the 21st century, too many people still lack access to essential drugs. WHO estimates that more than one third of world's population lacks regular access to the medicines they need. In developing countries, 10.3 million children under five years of age died last year; 8.6 million of these deaths could have been prevented if those at risk would have had access to essential drugs. Today, in 32 countries, more than half the population lacks regular access to basic, essential drugs.

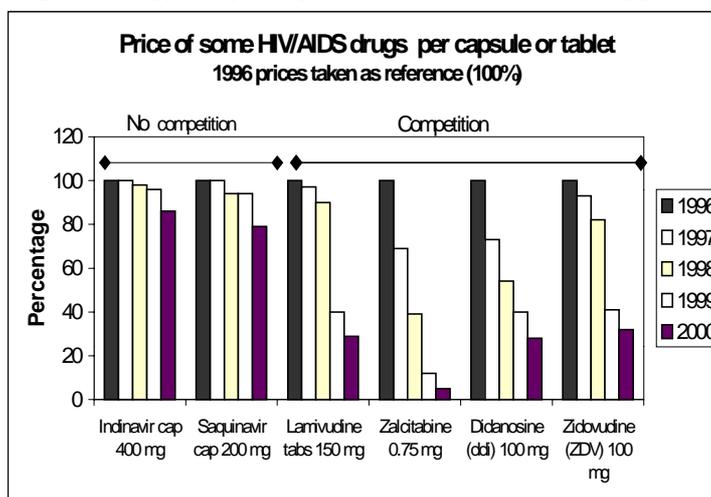
The reasons for this are multiple and complex, and include the following factors:

- Public spending for healthcare in general and for drugs in particular is insufficient, and decreasing.
- Health insurance is non-existent or has very limited coverage; most people, especially in developing countries, have to pay for drugs out-of-pocket.
- New essential drugs are costly.
- Supply systems are often unreliable and poorly managed, leading to wastage and shortages.

Ensuring access to essential drugs depends on several factors, such as rational selection of the drugs allowed on the market, affordable prices, sufficient and sustainable financing for drugs and a reliable health care and drug supply system. Price is only one of the factors in ensuring access to essential medicines; however,

especially for countries and populations with limited resources, it is an important factor. One of the most effective strategies for promoting affordable prices is to increase competition (see figure 2). Previously, many developing countries did not, or only to a limited extent, grant patents for pharmaceutical products, in order to encourage (generic) competition. The TRIPs Agreement makes the granting of patents for pharmaceutical products and process inventions obligatory, for a minimum period of 20 years. For most developing countries, these new standards represent a considerable increase in the protection granted for pharmaceuticals. They fear therefore an increase in prices of medicines, and a further reduction in their population's already limited access.

Figure 2 Effect of competition on HIV/AIDS drug prices



Adapted from: UNAIDS, B. Samb, 2000

However, the TRIPs Agreement contains a number of safeguards, which may be used to protect public health and promote competition, such as compulsory licensing and exceptions which facilitate the marketing of generic drugs ("Bolar exception"). These safeguards can be used to mitigate the potential negative impact of the TRIPs Agreement on access to drugs. However, in order to use these safeguards, countries have to incorporate them in their national legislation.

WHO policy perspective:

In the context of globalization and access to medicines, WHO insists that access to essential drugs is a human right and that medicines are not simple commodities.

WHO recognizes that patents on pharmaceuticals will stimulate R&D of new drugs, but also notices that research priorities tend to respond to (economic) demand, rather than to medical need. Therefore, WHO recommends that:

- Patents on pharmaceuticals should be managed in an impartial way, protecting the interest of the patent holder as well as safeguarding public health.
- Public investment is needed to ensure development of new drugs.
- Support should be given to any measures which will improve access to all essential drugs, including mechanisms to promote competition, such as providing comparative price information, promoting generic policies, reducing duties, taxes and mark-ups, allowing parallel imports, equity pricing⁴ of newer essential drugs and making use of the TRIPs safeguards.

⁴ Equity pricing refers to a pricing system under which the poor do not have to pay the same price as those who are better off.

2.3 The history of the TRIPs negotiations

In order to increase the understanding about the TRIPs Agreement, it is useful to briefly consider the history of its negotiation.

Before the Uruguay Round, about 50 countries did not grant patent protection for pharmaceutical products; this included a number of developed countries, such as Portugal and Spain, as well as many developing countries, for instance Brazil, India, Mexico and Egypt. TRIPs Article 27, which states that patents should be granted in *all* fields of technology without exclusion, therefore meant a significant change for the pharmaceutical industry; suddenly patenting of pharmaceutical products was made almost universal, since all WTO member states were obliged to grant it.

Industrialized countries argued that patent protection in all fields of technology, as stated now in TRIPs Article 27, would have three main effects in developing countries:

- there would be more foreign direct investment (FDI),
- it would promote the transfer of technology,
- patent protection would promote local R&D.

Developing countries were reluctant to extend patent protection to pharmaceuticals. They realized that pharmaceutical production was highly concentrated in developed countries. More importantly, innovation -the development of NCEs- was almost exclusively undertaken in industrialized countries. At that time, 96% of worldwide R&D expenditures took place in developed countries and only 4%, in all areas of science and technology, in developing countries. This is perhaps the most dramatic asymmetry in contemporary North-South relations, since it relates to the ability to create and apply new scientific and technologic knowledge.

In addition, even before the adoption of TRIPs, a number of economic studies⁵ showed that patent protection for pharmaceuticals in developing countries would lead to an increase in prices for medicines, to an increase in royalty and profit payments abroad and to a greater market penetration by foreign firms. Finally, the experience even of developed countries, such as Italy, which had recently adopted patents for pharmaceutical products, raised further doubt whether there would be any benefits (see paragraph 2.5.1).

For almost 3 years, from 1986 until May 1989, developing countries refused to negotiate an agreement on intellectual property. But finally it was not possible, politically, to avoid the discussion and the drafting of the Agreement started.

For developing countries, there were two potential benefits in negotiating the TRIPs. First, the trade-offs; the possibility that in other areas of the Uruguay Round negotiations, developing countries could obtain benefits, for instance access to markets for textiles and agricultural products. Unfortunately, for most developing countries it seems there have been less benefits than expected. Second, under the agreement there is a multilateral system for dispute settlement; the expectation was that, by having such a system, unilateral action by the US -on the basis of "Special" section 301 of their Trade Act- would cease. The US applies the 301 or super 301

⁵ For instance by the World Bank.

section in order to threaten or retaliate with trade sanctions against countries on the basis of what they consider to be 'non-compliance with adequate standards of intellectual property'. Unfortunately this expectation has not been fulfilled either; the US has continued to use section 301.

The views of Japan and the EU during the negotiations are interesting too. Their main interest was that, while an Agreement should establish a certain level of protection, it should not amount to a restriction to trade. For instance, the TRIPs position on parallel import -countries are free to decide whether or not they allow this- should be looked at from this perspective. Moreover, Japan was concerned about potential abuses of the system, since rights on intangible property may be properly used but also can be abused; in fact the US has quite a long tradition of anti-trust cases related to the abuse of IPR, which have led to the granting of a number of compulsory licenses.

All these positions and concerns are reflected to some extent in Articles 7 and 8 of the Agreement, in which the objectives and the principles of the Agreement are stated. Particularly Article 7 refers to the balance that needs to be achieved between producers and users of technology; this is an important aspect which should be taken into account when developing the national legislation in order to implement the Agreement.

2.4 Stakeholders' views

Three important stakeholders are the innovative pharmaceutical industry, the national pharmaceutical industry and the consumers. The views of representatives of these groups are presented in paragraphs 2.4.1 to 2.4.3.

2.4.1 The international innovative pharmaceutical industry's perspective (IFPMA)

The importance of intellectual property rights for pharmaceutical R&D

New medicines and access to these new medicines, which will be vital in the fight against communicable and non-communicable diseases, are dependent on strong patent and other intellectual property protection.

"The patent system secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the *fuel of interest to the fire of genius* in the discovery and production of new and useful things."

Abraham Lincoln, 1859

The patent system represents a compromise between competing short-term and long-term economic and social interests. Along with a well-functioning regulatory structure and marketing system, it allows the private pharmaceutical industry to operate and contribute to a socially driven public health sector by providing it with cost-effective new technologies.

The commercial sector discovers and develops nearly all new drugs and vaccines, but this is expensive and risky; the patent system provides the incentive necessary to investigate thousands of new compounds and to invest an average of several hundred

Table 3 Importance of patent protection for development of innovative products in various industries:

Industry	% of products which, without patent protection, would not have been	
	introduced	developed
Pharmaceuticals	65	60
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Fabricated Metal Products	12	12
Primary Metals	8	1
Electric Equipment	4	11
Instruments	1	1
Office Equipment	0	0
Motor Vehicles	0	0
Rubber	0	0
Textiles	0	0

Source: *Patents and innovation: an empirical study by Mansfield, Management Science, 1986.*

million dollars in R&D. The dependence of pharmaceutical and vaccine discovery and development on adequate and enforceable intellectual property rights is the highest among various sectors (see table 3).

Table 3 shows that the first rank is held by the pharmaceutical industry. The same author has also published studies showing that developing countries benefit from strong patent protection, especially in terms of attracting investment. In some developing countries, which have

adopted stronger patent protection in recent years, such as Korea, drug R&D has been rising. This is a fundamental change, which promises to improve the supply of effective new drugs and vaccines and to improve access to medicines for patients worldwide.

However, recently, "compulsory licensing" has been touted as a magic policy to improve access to medicines in developing countries. Compulsory licensing of a patent to a competitor, provided for in some way in most countries, is normally limited in application to extraordinary circumstances, often related to technology issues in industry mergers. Proponents of an activist compulsory licensing (CL) system see the issue in terms of consumer price benefits arising from effectively abrogating the patent's marketing exclusivity. They ignore many of the problems with this approach:

- it assumes that there is a licensee that can duplicate the originator's skills in manufacturing an equally safe and effective product;
- it assumes that governments will use this "tool" as a pro-consumer tool, leading to cheaper drugs. However, governments tend to use CL measures for industrial policy;
- most damaging, if a country adopts CL measures or if a disease area (e.g. HIV/AIDS) is subject to CL policies, fewer research funds will be allocated to that country or disease.

Finally, the protection of trademarks, also under TRIPs, helps to clean up counterfeit products from the marketplace. The effect on public health is that through the reduction of trade in unregulated counterfeit products, the quality of the drug supply is improved.

Problems of access to drugs

With regard to inadequate access to drugs, two major gaps can be identified: 1) a "discovery/development" gap between the morbidity/mortality and available remedies; and 2) an "access imbalance" between consumption of medicines in the developing and the developed world. The exposure of poorer countries to the discovery/development gap is particularly acute because of mitigating circumstances of poverty, poor infrastructure and urbanization.

In addition, there are other pharmaceuticals-related gaps that contrast the health situation in the "North-South" context:

- *The Quality/Counterfeit Medicines Gap:* Patients in developing countries are more frequently exposed to substandard products and counterfeits, due to the relatively large gap in regulatory capability and training between developed and developing countries as well as the differences in enforceability and penalties for counterfeiting activities;
- *The R&D Imbalance:* While the relative incidence of infectious diseases is higher in developing countries, until now little pharmaceutical research and development has taken place in these countries;
- *The Urban/Rural Gap:* The minority of the population living in towns receives three-quarters or more of medical services and products; this is a global phenomenon, but it bears most heavily on poorer populations in developing countries; and,
- *The Drug Production Imbalance:* With over $\frac{3}{4}$ of the world's population, developing countries produce less than $\frac{1}{10}$ of drug output; further, $\frac{2}{3}$ of the latter production is concentrated in a few developing countries, such as India, China, Egypt, Republic of Korea, Brazil. Thus, many developing countries have choices of products from just a few sources.

Improving access conditions means focusing on a wide number of factors restricting access to health care and medicines. For instance, in developing countries, funding is often insufficient to provide even the most basic healthcare services and products. Usually, people working in the informal sector cannot enter the social security health care system. These are just a few examples to illustrate existing barriers.

Cost and Price Issues

There is no price at which a 'non-invented' drug can be purchased. In the absence of a new drug, the 'price' of a treatment or cure is infinite. Innovation makes a therapeutic option available. Further, therapeutic competition among alternative drugs drives market prices lower, with post-patent conditions making the product a generic 'commodity' subject to even greater competitive pricing pressures (see figure 4).

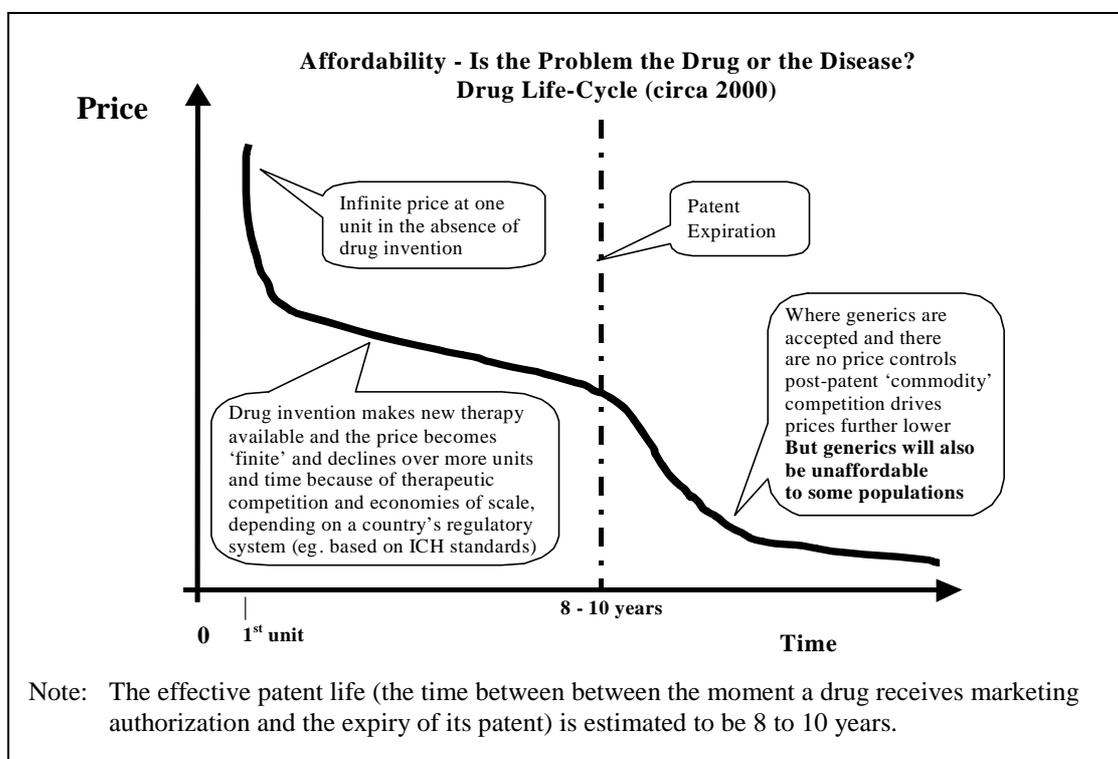
Moreover, according to the innovative pharmaceutical industry, the following issues should be considered:

- Regarding the impact of patents on price, the linkage is weak or non-existent since price levels are determined by many factors: distribution conditions and markups, price controls, inflation, taxes, measurement techniques etc. A 1995 study showed that countries with intellectual property protection did not have higher prices than countries without such protection. The Children's Vaccine Initiative noted that while patents and royalties do not raise the price of vaccines 'dramatically', "... countries which do not recognize IP.... may actually inadvertently hinder access

to vaccines... by discouraging legal vaccine technology transfer and by failing to encourage domestic vaccine research and development".⁶

- Patents do not, in fact, have an influence on access to those drugs which most of the population in developing countries actually consumes, which are primarily off-patent drugs.
- Countries without effective patent protection could produce their own versions of patented products. In fact, India already produces generic copies of patented AIDS drugs. If patents were indeed the problem, large populations within India should have easy access to these generic versions of AZT and other medications; but this is demonstrably not the case. Access is poor in some countries regardless of the status of patents.
- Patented products also face competition from off-patent products for the same conditions as well as from other therapeutic alternatives. Indeed, the time between the introduction of an innovative drug and of therapeutically similar products has lessened dramatically over time.
- Generic production is not an automatic answer to access; generic producers in developing countries may charge lower prices than the original innovator, but prices are still above levels which most people in developing countries can pay.

Figure 4 Estimated Drug Life Cycle



Source: Dr H. E. Bale

⁶ CVI, *Intellectual Property Protection: its role and benefits*, 1999.

IFPMA's recommendations

The following global actions are suggested to improve access and innovation in the areas of medicines and vaccines for the benefit of developing countries:

- 1) Encourage *public-private partnerships* for the development and distribution of medicines and vaccines where existing therapies are lacking or not getting adequately distributed.
 - Develop a global "orphan-type" incentive plan, using market exclusivity and tax incentives to encourage companies both in the North and South to perform research and develop drugs for currently neglected diseases.
 - Foster public-private vaccine partnerships to stimulate the development of new drugs and vaccines and/or to increase international financing for their distribution, such as the Medicines for Malaria Venture or the Global Alliance for Vaccines and Immunization.
- 2) Foster *local industry investment in R&D and transfer of know-how* into developing countries by accelerating the adoption of TRIPs standards for intellectual property rights; local companies must shift their activities from copying drugs to developing new drugs, which are important in the fight against priority diseases.
- 3) *Encourage local innovation by avoiding price controls*, either directly or indirectly. Price controls tend to reduce the supply of newer innovative therapies and can have a distinctly dampening effect on innovation in pharmaceuticals, a trend which has been observed in Europe as well as in Japan. Price controls are a very short-sighted policy: while they may make current medicines cheaper, in the long run they will make developing new drugs more difficult. Furthermore, as price controls often go from being "price ceilings" to "price floors", they can lead to higher prices in the medium- to long run, compared to permitting competitive pricing in the post patent period.
- 4) Stimulate the supply of affordable *quality generics* in developing countries by working to inculcate the importance of quality manufacturing procedures locally. Negative approaches, such as attempting to withdraw trademarks for medicines, should be avoided. Trademarks are a sign of the origin of a medicine, and trademark owners must therefore stand behind the quality of the product. If consumers avoid unbranded generics it is not because of trademarks, but rather because consumers lack confidence in their quality. Thus the answer is to focus on quality. To deny trademarks rights would be to soften the pressure on generic drug producers to produce high standard medicines.
- 5) Ensure the supply of needed drugs by working to *prevent parallel trade*. Parallel trade is product diversion, which may seem seductive if a country's officials believe that they will be receiving relatively low-priced imports. However, parallel traders would be buying up supplies of essential drugs in a low-price country for resale in higher-priced markets, thus diverting them from the population who needs them. When parallel trade is discussed, it is always assumed by proponents that there are only parallel imports, and that there is no diversion of key products via parallel exporters. However, if it is assumed that parallel imports can make a significant difference in lowering the price

domestically, then someone else abroad must be paying more through this diversion.

Furthermore, even for importing countries, the alleged benefits of parallel trade tend to be less than expected. The European Union's experience shows that the benefits of parallel trade accrue mainly to the parallel traders, not consumers, because the former capture most of the "rents" arising from the differences in ex-manufacturer prices across countries. In addition, parallel trade increases opportunities for counterfeit and substandard products to enter the market, creating increased health and safety risks for consumers, as well as increasing the burden on inadequately resourced regulatory staff in developing countries.

- 6) Consider creating publicly financed research centres in the region to foster medical research, pooling the scientific expertise and resources of several countries, to increase the capacity for research in diseases of regional interest. While industry does its own drug discovery and drug development research, it also has worked with public agencies, such as the National Institute of Health (NIH), to build on basic research to bring new compounds to patients. Perhaps through such a mechanism ASEAN countries and local and international industry together could develop effective treatments for malaria, TB, HIV/AIDS, cancer and depression over the next decade or so.
- 7) Join with judicial authorities, the police and industry professionals to implement anti-counterfeiting legislation. Severe penalties should be imposed.
- 8) Adopt global drug review standards to speed up the approval of new drugs. Improved access to medications can be helped through reducing unnecessary tasks and duplication in the review of drugs internationally. One major effort, conducted in partnership between the public and private sectors, is the International Conference on Harmonization (ICH); its mission is to improve the efficiency of the registration process for new pharmaceutical products, specifically in Europe, Japan and the USA.
- 9) Empower consumers to choose well. Another vital aspect of effective access to medicines relates to information about these medicines and their proper use. Patients and consumers around the world are increasingly seeking more information about medicines to empower themselves in their own medical care. The Internet, as a truly global medium, has the potential to be a positive resource, but the use of the Internet to distribute medicines can also pose dangers. In the area of globalization of information and trade, governments and international institutions need to consider appropriate policies regarding this new health care medium.

IFPMA's conclusions

The benefits of the new system of intellectual property rules far outweigh any foreseen costs. The problem of access to health care and pharmaceuticals is serious and may get worse as conditions of poverty remain and are aggravated by continuing regional warfare.

The problem of access to health care and medicines in developing countries is multifaceted. It is important that the relative significance of the various barriers is better understood, so that priority can be given to removing the most serious barriers.

2.4.2 A national pharmaceutical industry perspective (GP Farmasi, Indonesia)

"The defense of intellectual property rights today is the new frontier as were the human rights yesterday. An effective intellectual property system is indispensable to technological development which leads to economic growth and social welfare. Of the four incentives provided by a patent system, namely, to invent, to disclose, to invest and to "invent around", the incentive to invest is the most important.

A patent and other intellectual property are property and are not and cannot be monopolies (a patent does not take from the public and give to the individual; on the contrary, it takes from the individual and gives to the public) and this misconception has caused a lot of mischief. Subject matter that is viewed as too important to be protected (e.g. pharmaceuticals) is, on the contrary, too important not to be protected."

Prof. Thomas Field

Intellectual property rights are a compromise between the incentive to create knowledge and the desirability of disseminating knowledge at little or no cost. While the debate deals with positive and negative implications, there is no systematic empirical evidence for either concerns that intellectual property rights would slow innovation or for their alleged positive impact on research and development. Intellectual property rights can disadvantage developing countries in two ways, namely by increasing the knowledge gap and by shifting the bargaining power towards the producers of knowledge, most of whom reside in developed, industrial countries. Effects on distribution might be particularly strong with respect to the effects of patents on the price of medicines, due to the weak bargaining power of developing countries in negotiating prices with monopoly suppliers (World Bank '98).

The quotes above are an example of the conflicting views expressed on the topic of TRIPs and its impact on access to drugs and on the pharmaceutical industry.

National pharmaceutical industries in developing countries are concerned about trends to focus R&D efforts exclusively on problems for which lucrative markets exists, such as impotence, obesity, jet-lag and baldness, rather than on widespread, serious tropical diseases. It is also worth noting that most industrialized countries, while having a patent system in place since a long time, introduced product patents for drugs only relatively recently (see box 5); that is, after their pharmaceutical companies had attained a very high degree of development.

Box 5 Introduction of patents			
Year of introduction of pharmaceutical product patents:			
UK	1949	Japan	1976
France	1960	Sweden	1978
Germany	1968	Switzerland	1977
Italy	1978	Spain	1992

Source: World Bank, 1990.

Noting the above and other concerns, the implications of TRIPs Agreement on the national pharmaceutical industry might be:

- When markets are small, there will be no interest to invest in technology transfer.
- Several case studies indicate that there is little evidence that the introduction of TRIPs compliant standards of IPR would stimulate transfer of technology,

encourage foreign direct investment, strengthen research, development and innovation and ensure early introduction of new products.

- The introduction of new products by national industries will be delayed.
- New medicines will be more expensive.
- This may create an impression of denying people the right to new drugs.
- The gap between local and multinational companies will widen.
- There will be a shift in market share from generics to branded/originator products.

The national pharmaceutical industries therefore believe that Governments should introduce appropriate policies to alleviate possible negative implications, such as those listed above, of the introduction of TRIPs standards.

2.4.3 A consumer's perspective (Consumers International)

Access to essential drugs and affordable medical services are major consumer concerns. Currently, over two billion people do not have regular access to life-saving drugs, this, consumer organizations believe, is a crisis situation.

The multinational companies (MNCs), particularly the American industry, have been advocating that developing countries need to provide strong patent protection for pharmaceuticals (20 years) in their national legislation. During this period, the patent holder will have an exclusive monopoly for the manufacture, distribution and sales of the patented drugs. Generic manufacturers can copy them only after the patents expire. If developing countries have to wait for 20 years to manufacture new life-saving drugs, they will be waiting in vain. Modern drugs have a short lifespan. The top sellers of today will be almost extinct in about 10-15 years. Table 6 gives the US ten top prescription drugs in 1983 and traces their ranking during the following 14 years.

Table 6 *Top prescription drugs in 1983 and their ranking in 1988 (US) and 1997 (world)*

Product	1983 US sales	1988 US sales	500 prescription drugs by worldwide sales 1997 - rank
	1983 rank	1988 rank	
Tagamet (SK&F)	1	2	154
Inderal (Ayerst)	2	13	321
Dyazide (SK&F)	3	12	365
Motrin (Upjohn)	4	39	-
Aldomet (MS&D)	5	72	-
Valium (Roche)	6	25	296
Feldene (Pfizer)	7	10	153
Naprosyn (Syntex)	8	4	146
Keflex (Dista)	9	44	-
Diabinese (Pfizer)	10	98	-

Source: (1) 1983 & 1988 US ranking, *SCRIP* No. 1381, Jan 27, 1989, p. 17.

(2) 1997 Ranking: *Annual Report 500 Drugs: 500 Prescription Drugs by worldwide sales*, *Pharma Business*, July/August 1998.

Of the top ten US prescription drugs in 1983, only three were able to retain their ranking within the top ten after five years. None of them was in the top 100 in 1997,

and 4 drugs were not even in the list of the 500 top selling drugs that year. The consumer organizations, therefore, reject the position taken up by MNCs, that the TRIPs Agreement should be implemented in ways which would prevent compulsory licensing and parallel imports. Consumers reject this position because no drug at the end of 20 years will be worth manufacturing. The prices fixed indiscriminately by the MNCs (see table 7), will prevent access of the life-saving drugs to over two billion people.

A major argument put forward by multinational drug companies for strong patent protection is to have exclusive rights for a period of time so that they can earn adequate profits to cover their costs of R & D and to continue further R&D. This seems to be a justifiable argument. Therefore, we would need to know how much profits MNCs make, how much it costs to develop a new chemical entity and the amounts MNCs really spend on R&D. Unfortunately, independent data on the cost of R&D are scarce.

Table 7 Retail prices in USD of 100 tablets Zantac in 11 Asian countries

Countries	Zantac (100 x 150 mg) in US\$
Bangladesh	9
India	2
Indonesia	41
Malaysia	55
Mongolia	183
Nepal	3
Pakistan	22
Philippines	63
Sri Lanka	61
Thailand	37
Vietnam	30

Source: *Retail Drug Prices: The Law of the Jungle*, HAI News No. 100, April 1998.

To understand fully the implications of the TRIPs Agreement on access to drugs of consumers in the ASEAN region, it will be necessary to examine the pharmaceutical sector in the ASEAN countries and in the world. Comprehensive research and development to discover and develop new chemical entities require human, technological and financial resources, which, at present, are available in only 10 advanced industrial countries. The United Nations Industrial Development Organization (UNIDO) has classified 190 countries into 5 groups based on the degree of development of pharmaceutical technology and industrial production (table 8).

Table 8 A typology of world's pharmaceutical industries

Stage of development of the pharmaceutical industry in the country	Number of countries		
	Total	Industrial	Developing
Sophisticated pharmaceutical industry with significant research base:	10	10	0
Pharmaceutical industry with some innovative capabilities: *)	17	12	5
Pharmaceutical industry with capability to produce both therapeutic ingredients & finished products:	14	6	8
Pharmaceutical industry formulating finished products only (from imported therapeutic ingredients):	89	2	87
Countries and states without a pharmaceutical industry:	60	1	59

*) Each country in this group discovered and marketed at least one NCE between 1961-1996.

Adapted from: *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy* by Robert Balance, Janos Pogany & Helmet Forsteiner, UNIDO, 1992.

Empirical data on pharmaceutical production and consumption in five ASEAN countries -Indonesia, Malaysia, Philippines, Singapore and Thailand- are given in table 9.

Malaysia produces about 50 per cent of the country's requirements of pharmaceuticals. The other four ASEAN countries in table 9 are almost self-sufficient. However manufacture in all ASEAN countries is limited mainly to formulation of dosage forms from imported raw materials. The pharmaceutical industry in these countries is, therefore, totally dependent on the availability of raw materials in the world market. Before the TRIPs Agreement came into force, the national patent legislation in most developing countries did not provide patent protection for pharmaceutical products. This enabled developing countries like Argentina, China, India, Korea and Mexico to have a strong vertically integrated pharmaceutical industry. They were able to put into the world market raw materials of all essential drugs at competitive prices.

Table 9 Pharmaceutical production and consumption in five ASEAN countries

Country	Consumption per capita in US\$ (1990)	Percentage ratio of production to consumption	
		in 1975	in 1989
Indonesia	3.9	94.6	98.8
Malaysia	7.8	27.5	49.5
Philippines	7.7	98.5	89.7
Singapore	20.1	58.2	83.5
Thailand	6.6	71.7	87.6

Source: UNIDO, *op. cit.*

All these countries now have to change their national legislation on patents in accordance with TRIPs Agreement. They will have to provide 20 years patent protection for pharmaceutical products. As a result, the multinational drug companies will have the monopoly of all patent protected drugs and will not be marketing raw materials at competitive prices. The pharmaceutical industry in developing countries will therefore collapse.

The only way to avoid this and to strengthen the pharmaceutical sector in the ASEAN and other developing countries will be through compulsory licensing and parallel imports. These are allowed in the TRIPs Agreement. National legislation on patents which allows for compulsory licensing and parallel imports will enable consumers in the ASEAN countries access to affordable pharmaceuticals. This, consumers believe, is a short-term solution.

In order to arrive at a long-term solution, the short and long-term implications of the TRIPs Agreement on access to pharmaceuticals need to be critically examined and analysed. Consumers have expressed the following concerns:

- The TRIPs Agreement represents an unprecedented transfer of power over economic functioning from the heads of nation states to MNCs.
- There should be a major review of the WTO multilateral trade agreements. Subsequent reforms should incorporate as a central objective the promotion of sustained development in the Third World.

- The special problems of the least developed countries (LDCs) should receive particular attention. In 1978, according to the United Nations, there were 28 LDCs. In 1998 there were 48. The rapid decline into poverty is due to rapid liberalisation, imposed by WB/IMF structural adjustment programmes and, recently, WTO.
- Trade policy should be a powerful instrument for economic development, and this aspect must not be lost sight of by narrowly focussing on liberalisation.

Based on analysis of empirical data on the impact of the TRIPs Agreement on access to drugs and health services in developing countries, the UNDP's Human Development Report 1999 has listed the following concerns:

- Liberalisation, privatisation and tighter intellectual property rights are shaping the path for the new technologies, determining how they are used. But the privatisation and concentration of technology are going too far. Corporations define research agendas and tightly control the findings with patents, racing to lay claim to intellectual property under the rules set out in the TRIPs Agreement.
- Poor people and poor countries risk being pushed to the margin in this proprietary regime controlling the world's knowledge.
- In defining research agendas, money talks, not need. Cosmetic drugs and slow-ripening tomatoes come higher on the priority list than drought-resistant crops or a vaccine against malaria.
- Despite the risks of genetic engineering, the rush and push of commercial interests are putting profits before people.
- From new drugs to better seeds, the best of the new technologies are priced for those who can pay. For poor people, they remain far out of reach.
- Tighter property rights raise the price of technology transfer, blocking developing countries from the dynamic knowledge sectors. The TRIPs Agreement will enable multinationals to dominate the global market even more easily.
- New patent laws pay scant attention to the knowledge of indigenous people. These laws ignore cultural diversity in the way innovations are created and shared – and diversity in views on what can and should be owned, from plant varieties to human life. The result: a silent theft of centuries of knowledge from some of the poorest communities in developing countries.
- There is a need for a comprehensive review of the WTO Agreements to redress their perverse effects, undermining food security, indigenous knowledge, biosafety and access to healthcare.

The people's response has been loud and clear during the violent events in Geneva, Seattle, Davos and other places. Why have people reacted so violently? People see that power is controlled by market forces operating under faulty global governance

supported by rules, institutions and practices that have been formulated by a selected few. People ask that they be given a participatory role in decision making to ensure that people will be put at the centre of development and that the highest priority be given to goals of enhancing social development and ensuring human well-being for all throughout the world. People want a restructuring of the present global governance with a new set of rules, institutions and practices that will ensure global responsibility, so that the benefits of globalisation will be shared equally by all the people of the world and not exclusively by the 20 per cent of the people living in the richest countries.

To conclude, consumers believe it is critical to examine the TRIPs Agreement and explore the best options in interpreting and incorporating relevant provisions into national legislation. The better options will be those that will strengthen the technological, economic and commercial development of the pharmaceutical sector in developing countries, which ultimately will ensure regular access to affordable, good quality, safe and effective drugs.

Moreover, long term solutions would include a World Trade Organization that ensures both free and *fair* international trade, with a mandate extending to global competition policy with antitrust provisions and a code of conduct for multinational corporations.

2.5 Country experiences

2.5.1 Experiences with the introduction of patents for pharmaceuticals

In most developing countries, TRIPs standards became enforceable only a few months ago; therefore time is too short to have evidence about its implications. But the experience of countries which have adopted pharmaceutical patents in the past decade is relevant in this context. What happened to foreign direct investment (FDI), transfer of technology and (local) R&D? What happened to drug prices?

Latin America

Several Latin American countries, such as Chili and the Andean countries changed their patent legislation in 1990/1991; pharmaceuticals became patentable.

With regard to FDI, the experience of countries such as Chili, Colombia and other Andean countries is that after the adoption of patent protection for drugs, FDI in the pharmaceutical sector has not increased, except through the acquisition of local companies by foreign companies. But there has been no new investment. In addition, a large number of formulation plants have been closed down. So after the introduction of the patents, many foreign companies have decided not to produce (or formulate) locally any more, but to import. As a result, there was no increase in FDI and the trade deficit in this area has increased substantially due to the substitution of local production by direct import.

With regard to the transfer of technology, unfortunately, the situation is not better. As mentioned, many local companies have been acquired by foreign companies; there is

no clear increase in transfer of technology to local companies. In general, in the area of pharmaceuticals, there is little real transfer of technology. License agreements usually mean that the patent holder provides the active ingredient, not the technology for the production of the active ingredient, and the licensee is usually just formulating. Therefore it can be concluded that transfer of technology in this area was never very substantial, and has not increased.

Finally, there is no sign of any increase in pharmaceutical R&D in these countries, nor are there any clear prospects that R&D for diseases relevant to developing countries will increase in industrialized countries.

Italy

Italy has introduced patent protection for pharmaceuticals in 1978. At that time, Italy was a reasonably large producer of pharmaceutical products and an exporter with a trade surplus. A number of years after the introduction of these patents, prices for medicines in Italy had increased significantly, almost 200 %, and Italy began to be a net importer of pharmaceutical products, going from a trade surplus in pharmaceuticals to a very severe trade deficit in this area.

Thailand

The first patent law in Thailand was enacted in 1979, and excluded pharmaceuticals. It was revised in 1992; the essence of the revision was the inclusion of pharmaceutical product and process patents. A further revision, introducing petty patents and addressing the issue of parallel import, was enacted in March 1999.

A study⁷ to assess the impact of the introduction, in 1992, of patent protection for pharmaceuticals concluded that:

- technology transfer in the pharmaceutical sector has been minimal and has been limited to formulating techniques; no increase in technology transfer was seen after the enactment of the 1992 patent law;
- technology that could lead to R&D of new pharmaceutical products in Thailand is not likely to be transferred;
- since the enactment of the 1992 patent act, there has been an increased tendency to import drugs (compared to local production), indicating that foreign companies benefited more from change in patent law than local companies; the share of originator products as percentage of the total pharmaceutical market increased, on average by 4% per year;
- there has not been much foreign direct investment in the pharmaceutical sector since 1992;
- for products already on the market, the study did not reveal any price change, however, due to the selection of products (all selected drugs had competitors in the Thai market) and a variety of interfering factors, the question of the impact on drug prices is in fact not answered by the study.

⁷ WHO Collaborating Centre for Health Economics, Chulalongkorn University, Bangkok, Study of the Implications of the WTO TRIPs Agreement for the Pharmaceutical Industry in Thailand, 1999.

2.5.2 Development of TRIPs-compliant legislation in developing countries

While experience with the actual implementation of TRIPs in developing countries is limited, a number of observations can be made based on countries' preparations for becoming "TRIPs compliant":

- As mentioned earlier, TRIPs leaves substantial room for an implementation in a way which takes specific national policies and priorities into account. This flexibility is built into the TRIPs Agreement. Developing countries therefore should implement the TRIPs while truly taking into account Article 1.1 of the Agreement, which provides that members are free "to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice".
- Efforts related to the implementation of the TRIPs Agreement will not end by the end of the transitional periods, since part 3 of the TRIPs Agreement provides minimum standards for the enforcement of IPR protection. The workload and pressure on the legal system of developing countries, related to enforcement, will only begin after the end of the transitional periods.
- Implementation will reach beyond the intellectual property offices, since the enforcement rules included in TRIPs may require the revision of national laws in respect of civil, criminal and administrative procedures as well as a revision of the role of police and customs authorities. Thus, TRIPs enforcement should be part of a wider approach which comprehensively strengthens the legal and law enforcement infrastructures.

A final important observation relates to post-TRIPs era: the legal structure of TRIPs emerged from and belongs to the legal and historical traditions of developed countries. In fact TRIPs has been described as reflecting the legal culture, paradigms and interests of industrialized nations. However often IP has been equated with TRIPs and it is important to make a distinction. IP does not have to be contradictory to the policy objectives of developing countries; in fact, some believe that increased protection of intellectual property rights may enhance the achievement of those objectives. The development IP rights which are of interest to developing countries, covering their knowledge base and information resources, may make IP a more positive discipline for these countries and can present an important aspect of sustaining the effectiveness and acceptance of IP systems worldwide. Specifically, a lot of interest has been expressed on the part of developing countries for standards providing for the protection of traditional medicine and know-how and biodiversity.

III. TECHNICAL ISSUES

3.1 General overview of the TRIPs Agreement

In order to describe the provisions of the TRIPs Agreement which relate to the standards of patent protection it is useful to recall some of its basic features:

- It is an integral part of the Agreement Establishing the World Trade Organization, and therefore subject to the WTO dispute settlement system;
- It covers not only patents but all other main areas of intellectual property rights;
- It lays down not only the minimum standards of intellectual property protection, but also the procedures and remedies that should be available for effective enforcement.

The basic balance in the TRIPs Agreement

Finding a balance in the protection of intellectual property between the short-term interests in maximizing access and the long-term interests in promoting creativity and innovation is not always easy. Doing so at the international level is even more difficult than at the national level. Especially with regard to pharmaceutical patents, tension between the need to provide incentives for research and development into new drugs and the need to make existing drugs as available as possible can be acute.

The TRIPs Agreement attempts to find an appropriate balance. Its Article 7 ("objectives") recognizes that the protection of intellectual property should contribute to the promotion of technological innovation, to the transfer of technology, and to a balance of rights and obligations. The Agreement emerged from a negotiating process where the need for balance was very much to the fore. This will be illustrated below.

Patentability of pharmaceutical inventions

The main rule relating to patentability is that patents shall be available for any invention, whether a product or a process, in *all* fields of technology, provided the invention meets the standard criteria for patentability - namely, novelty, inventive step and industrial applicability. In addition, countries are required to make the grant of a patent dependent on adequate *disclosure* of the invention and they may require information on the best mode for carrying it out. Disclosure is crucial, since it makes important technical information publicly available so that others may use it for advancing technology in the area, even during the patent term, and it ensures that, after the expiry of the patent term, the invention truly falls into the public domain.

Three types of exception to the above rule on patentable subject-matter are allowed; these exceptions may be of interest from a public health perspective:

- Inventions the prevention of whose commercial exploitation is necessary to protect *ordre public* or morality, including to protect animal or plant life or health;
- Diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- Certain plant and animal inventions.

The rights conferred and the term of protection

According to TRIPs, the minimum rights that must be conferred by a patent follow closely those that were found in most patent laws, namely the right of the patent owner to prevent unauthorized persons from using the patented process and making, using, offering for sale, or importing⁸ the patented product or a product obtained directly by the patented process.

Under the TRIPs Agreement, protection must last for at least 20 years from the date of filing of the patent application. The WTO Panel in "Canada - Term of Patent Protection" recently found that this rule applied not only to new patents but also to patents in force at the end of a Member country's transition period⁹.

It should be noted that, although the issue of patent term extension to compensate for regulatory delays in the marketing of new pharmaceutical products was raised in the Uruguay Round negotiations, the TRIPs Agreement does not contain an obligation to introduce such extension.¹⁰

Limitations/exceptions to these rights

Under the TRIPs Agreement, patent rights are not absolute but can be subject to the following limitations or exceptions:

- Countries may make *limited exceptions*, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Thus, for example, many countries allow third parties to use a patented invention for research purposes where the aim is to understand more fully the invention as a basis for advancing science and technology. The Bolar provision (see par. 3.5) is another example of an exception.
- Countries may authorize the use by third parties (*compulsory licenses*) or for public non-commercial purposes (*government use*) without the authorization of the patent owner. Unlike what was sought by some countries in the negotiations, the grounds on which this can be done are not limited by the Agreement, but the Agreement contains a number of conditions that have to be met in order to safeguard the legitimate interests of the patent owner (see Article 31). Two of the main conditions are that, as a general rule, an effort must first have been made to obtain a *voluntary license* on reasonable commercial terms and that adequate remuneration shall be paid to the right holders.
- Countries have the right to take measures, consistent with TRIPs provisions, against *anti-competitive practices*. When a practice has been determined after due process of law, to be anti-competitive, the conditions for issuing compulsory licenses are more flexible. For example, the two conditions specifically referred to above (regarding voluntary license and remuneration) may be relaxed. The Agreement also provides for consultation and cooperation between Member Countries in taking actions against anti-competitive practices.

⁸ "Importing" is subject to the provisions of TRIPs Article 6; see paragraph 3.4 and annex C.

⁹ The Panel Report was circulated to WTO Members in May 2000 but is not yet adopted (Canada has since appealed).

¹⁰ The effective period of patent protection for inventions of new chemical entities is much less than the full 20 years, because part of that period will have expired before marketing approval is obtained from the public health regulatory bodies. For this reason, most of the major developed countries have introduced systems whereby a prolonged period of protection can be obtained to compensate, at least in part, for this loss of the effective period of protection.

Other policy instruments

It should be remembered that governments may use public policy measures outside the field of intellectual property to address issues of access to and prices of drugs. For example, many countries use price or reimbursement controls. The TRIPs Agreement makes it clear that WTO Members may, in formulating or amending their rules and regulations, adopt measures necessary to protect public health and nutrition, provided that such measures are consistent with the provisions of the Agreement.

Transition provisions

The TRIPs Agreement lays down some rather complicated transition provisions which give countries periods of time to adapt their legislation and practices to their TRIPs obligations; these periods differ according to the type of obligation and the stage of development of the country concerned. With regard to the protection of pharmaceutical inventions, there are two situations. The basic rule is that developing countries have until the 1st January 2000 and least developed countries until 1st January 2006 to meet their obligations.

A small number of developing countries, which did not grant patent protection for pharmaceutical products, have until 1st January 2005 to introduce such protection. However, from 1 January 1995, they have to provide a system where applications for pharmaceutical product patents can be filed (often referred to as a "mailbox" system). These applications do not have to be granted until after 1st January 2005. If found to be patentable by reference to their filing (or priority) date, a patent would have to be granted for the remainder of the patent term counted from the date of filing. In the event that a pharmaceutical product that is the subject of a "mailbox" application obtains marketing approval prior to the decision on the grant of a patent, an exclusive marketing right of up to five years will have to be granted provided that certain conditions are met.

TRIPs in context

Most developing and least developed countries already grant patent protection for pharmaceutical products. In these countries, the TRIPs Agreement will therefore not lead to fundamental changes, although a certain amount of adjustment in legislation, for example in respect of patent term and compulsory licensing, may be necessary. With respect to the fairly limited number of countries that did not provide patent protection for pharmaceutical products at the time of entry into force of the WTO Agreement, some, including Brazil and Argentina, have decided to provide such protection more quickly than is required under the TRIPs Agreement.

The TRIPs Agreement pays considerable attention to the need to find an appropriate balance between the interest of rights holders and users; this was an important theme in the negotiations. This is not only reflected in the basic underlying balance related to disclosure and providing an incentive for R&D, but also in the limitations and exceptions to rights that are permitted and in the transition provisions. Whether this balance has always been found in the right place is a question for discussion among WTO Members.

The protection of pharmaceutical inventions is one aspect of much wider negotiations, covering not only the protection of intellectual property in general in a coherent and non-discriminatory way but also further liberalization and strengthening of the multilateral trading system as a whole. While it is true that some countries put

particular emphasis on TRIPs matters in the Uruguay Round negotiations, it is also true that other countries attached great importance to other areas, for example textiles and agriculture. A strong and vibrant multilateral trading system is believed to be essential for creating conditions for economic growth and development worldwide. This, in turn, will generate the resources required to tackle health problems.

3.2 Standards for patentability

TRIPs requires that patents are granted when the typical standards for patentability, that is, novelty, inventive step and industrial applicability, are met. But the Agreement does not specify how these criteria should be defined and applied. So there is room for WTO members to decide how to apply these criteria, in a strict way or in a very flexible way.

Some countries apply these criteria in a very flexible way and, paradoxically perhaps, a good example is the US. An example is the novelty requirement. Usually, the novelty requirement means that a patent will not be granted if the invention has been disclosed anywhere in the world. This is the universal standard of novelty. Disclosure can take place through *publication* or through *use* (if an invention is used, it means the public knows it). These are the typical ways in which disclosure can destroy novelty, and therefore can destroy patentability.

But the US has standards for novelty which are lower. Under US law, novelty is destroyed if an invention has been disclosed through publication or through use in the US. But outside the US, novelty will only be destroyed if the disclosure took place via publication. Novelty is not destroyed if disclosure was done through use of an invention outside the US. This is the reason why, in the US, patents have been granted, and this has created a lot of concern in developing countries, on traditional or indigenous knowledge, plants and genetic materials used for centuries in developing countries; the Indian Neem tree is one of the well known cases.

Similarly, the way in which the inventive step requirement is applied, is very loose. This has drawn a lot of attention lately, because of a number of patents granted on so-called business systems, for instance the “one-click” method for buying books by e-commerce. This has been patented and as a result no other company can use a system for ordering a product via the internet, based on only one click.

Figure 10 Animal hat patent

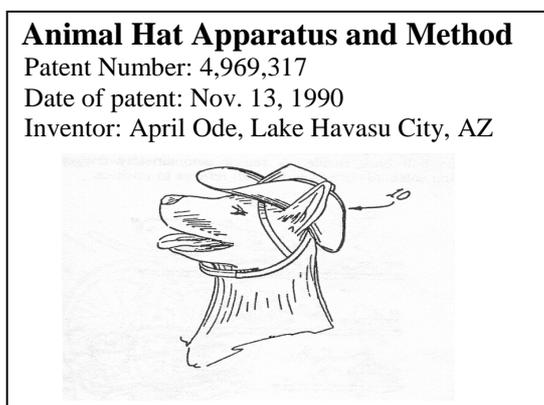


Figure 10 shows an example of a patent granted in the US in 1990, which is still in force: patent number 4,969,317 Animal Hat Apparatus and Method. There are many other examples of trivial inventions for which patents have been granted, and this has created considerable controversy. The patent in this example is not very significant, since it has little economic importance. But the same loose criteria are applied in other sectors, such as pharmaceuticals.

When thinking about patents for pharmaceuticals, implicitly one thinks about new drugs, about new chemical entities (NCEs). Each year, only a limited number (less than 100) of NCEs are being developed. Yet thousands of pharmaceutical patents are being granted, since around most NCEs, there is a large number of patents which relate to processes, dosage forms, formulations etc. This creates a very difficult situation for companies which are interested in producing a generic version.

Some concrete examples:

- *Processes*: Erythropoietin is a human protein, an important biotechnology based product. The first to sequence the gene that codifies for this protein was a US company, Amgen. But with 2-3 months time lag, another company, Genetics Institute (GI) also sequenced the gene and each claimed to be the inventor. In fact, it could be argued that the inventor was nature and that the companies just discovered it. However, in the US, a decision was taken in favor of Amgen, and as a result GI was unable to commercialize this product in the US. GI then applied for a number of process patents, not in the US, where it had lost, but in several developing countries in Latin America. So in Chili, Argentina, Mexico and some other countries, GI owns process patents related to erythropoietin, on the basis of which it has tried to stop any production and commercialization of erythropoietin. A process patent puts the burden of proof on the defendant¹¹, therefore, once the patent has been granted, it can be used aggressively to stop competition since there is an assumption of validity. Maybe the defendant can prove after 2-3 years (this is how long it usually takes) that he has the right to produce erythropoietin, because the patent was invalid or because a different process is being used, but in the meantime the defending company may already have gone out of business.
- *Uses*: Some countries are also issuing patents for new uses of a known product; e.g. the second indication for pharmaceuticals. An example is AZT. AZT was a known product but a new patent was granted for use in case of HIV infection. There was no real novelty, so it is under a fiction of novelty that such patents are granted. It is important for countries to consider whether they will grant patent protection for such new uses.
- *Polymorphs*: Polymorphs are different crystals of the same molecule. So chemically, it is the same thing. Sometimes, the originator company asks for a new patent for a different polymorph; this may lead to an extension of the patent protection. A well-known case is cimetidine. SK-F obtained a patent for cimetidine and 4 or 5 years later applied for and obtained a patent on a polymorph, with which the patent protection would effectively have been extended for 4 to 5 years. In this particular example, the second patent was challenged and eventually invalidated, but this creates situations in which companies are forced to litigate.

Due to such flexible application of patentability criteria, a growing number of patents are granted, which leads to over-protection. So while there is a role for the patent system to protect real inventions, the system should not be misused by granting patents for polymorphs, dosage forms, formulations, processes etc., which limit the scope for generic introduction and competition.

¹¹ TRIPs Article 34 requires that for process patents, the burden of proof is on the defendant .

Finally, it is important to realize that it is not relevant whether the secondary patents are strong; even if they are weak, big companies can use them aggressively against small, local or generic companies and stop competition, because litigations are cumbersome and costly. Therefore, defining the scope of patentability, including patentability of secondary inventions, is a very crucial issue.

3.3 Compulsory license

A compulsory license is an authorization which is granted by the government without the permission of the patent holder. Most countries have provisions for compulsory licenses, either under their patent law or, as in the US, through anti-trust legislation. Under the TRIPs Agreement, countries have the right to issue such licenses. While the Agreement does not limit the grounds -or reasons- for granting compulsory licenses, countries can only use those grounds which are allowed by their national legislation. The development of appropriate national legislation is therefore crucial. TRIPs further states that the conditions under which a compulsory license is granted should be regulated in accordance with the TRIPs Agreement (Article 31).

Grounds

Countries have specified many different grounds for issuing compulsory licenses; these can include public health reasons. Other grounds are for instance emergency situations, epidemics, public non-commercial use, to remedy anti-competitive practices or to protect the environment; it is entirely up to the national law to decide which are the grounds, so there is a lot of flexibility. The German law, for example, simply states that compulsory licensing is allowed 'for reasons of public interest'; a broad description that can be used in many situations. Under US law, compulsory licenses can be issued to remedy anti-competitive practices and for use by the Federal Government; both these grounds are used extensively for issuing such licenses.

Conditions

A compulsory license limits the rights of the patent holder, but does not take those rights away. TRIPs therefore specifies the conditions that need to be applied when countries want to grant a compulsory license. An important condition is that each case shall be considered individually. Also, in general, efforts should first be made to obtain a license from the patent holder (a so-called voluntary license), on reasonable terms. What is considered 'reasonable' depends on national (case) law.

The conditions mentioned in TRIPs merit careful reading, and it is important to select carefully the wording when translating TRIPs into national legislation:

- Remuneration for the patent holder shall *take into account* (not "be equal to" or "be based on") the economic value of the authorization. So if the contribution of a patent is minor, as for instance in case of a formulation patent, the royalty rate can be lower. Under US national law, compensation is based on *what the patent holder has lost*. In case of a CL to provide drugs to a population who would otherwise not be able to afford those drugs, it could be argued that the patent holder lost nothing.
- In case of public non-commercial use or government use, TRIPs does *not* require countries to provide for the right of injunction, only for payment of compensation.

Again, this is important for the actual implementation of a CL for public use. This is practiced in the US; the US Government cannot be sued for infringement of a patent, it can only be sued about the amount of compensation paid. Under US law, the same applies to contractors acting on behalf of the US Government.

- A decision to issue a CL must be subject to review, but this does not have to be a judicial review; TRIPs only requires that the review is independent, so countries may opt for an administrative review, which is less burdensome and much faster. It seems advisable for developing countries to provide for an administrative review only, to prevent patent holders from blocking the use of a CL by initiating time-consuming court procedures.
- A compulsory license shall be *predominantly* for the supply of the domestic market. A CL therefore would hardly interfere with practices of differential or tiered pricing. However, "predominantly" is not exclusively, so some export is still possible. Public interest groups advocate that export to a market where a CL has been issued, should be allowed; otherwise, countries with small markets, where local production is not viable, would not be able to use CL provisions effectively.
- If a CL is issued to remedy anticompetitive practices, many of the conditions do not apply, such as the requirement to first try to obtain a voluntary license. Also, the restriction on export no longer applies; this is important for the US, which frequently issues compulsory licenses to remedy such practices.

Main function

At times, the fact that few such licenses have been granted is used as an argument against the compulsory license system. While it is true that in some countries, e.g. UK, few compulsory licenses have been issued, other countries, such as the US, have granted a large number of compulsory licenses. But regardless of whether or not they are used frequently, provisions for compulsory licensing are needed, because they will encourage the patent owner to behave correctly. They give a sign to the patent owner that in the case of abuse of rights and/or non-availability of the product, a third party could be allowed to use the invention; this prevents malpractice and misuse of the monopoly rights. In fact, one of the most important aspects of a compulsory license system is its impact on the actual behavior of the patent owner, therefore it is a necessary element in any IPR law. However, to ensure the system can be used effectively, it is important to carefully state the grounds and conditions for its use in the national legislation; these should include its use for reasons related to public health.

3.4 Parallel import

Parallel importation refers to the importation, without authorization of the patent holder, into a country of a product from a third country, where this product has been marketed by the patent holder or in another legitimate manner. It is mainly used when the price in the third country is considerably lower than the price the patent holder charges in the country concerned. Parallel import is allowed under the TRIPs Agreement; in fact, TRIPs explicitly states that it does not address the issue of parallel import, thereby leaving countries free to determine their own policy in this respect.

At times it is being argued that allowing parallel import in developing countries will result in an increase in counterfeit and/or substandard products in the market and will therefore have a negative impact on consumers. This is speculation. However the benefits are quite clear and there is a strong economic rationale for developing countries to adopt parallel import.

A market where price discrimination is common, such as the pharmaceutical market where prices for the same product can vary considerably between countries, will fundamentally change if parallel import is allowed. The multinational pharmaceutical industry argues that parallel import will prevent preferential prices for developing countries. To the extent that developing countries do indeed benefit from preferential prices, this could be true. The drug companies' worries are understandable since, obviously, revenues would come under pressure if 'high-price markets' such as the US would start parallel importation of cheaper drugs from, for instance, Canada. If this were to happen (in fact, currently there is considerable support in the US for allowing parallel import of drugs from Canada), companies would be tempted to react by harmonizing their prices across borders. The solution however seems to be to prevent parallel importation *in industrialized countries*, instead of putting pressure on developing countries in this respect.

It is worth noting that the US legislation on IPR allows parallel importation; however, in the US, parallel import of medicines is forbidden by regulations related to Food and Drug Control.

3.5 Exceptions to the exclusive rights

TRIPs Article 30 allows for limited exceptions to the rights conferred to the patent holder. These exceptions however can be challenged and subsequently reviewed by the WTO. In the context of pharmaceuticals, the most common exception to the exclusive rights of the patent holder is often referred to as the 'Bolar provision'. A Bolar provision¹² allows interested (generic) manufacturers to start producing test-batches of a product before the patent expires, in order to collect the necessary data for submission to the registration authorities; this will reduce the delay for generic products to enter the market after the patent has expired, and thereby enhance competition. The text of the TRIPs Agreement does not specifically address this issue. However, in a recent WTO dispute, a WTO Panel¹³ ruled that a provision in Canadian law, which permits the use of patented products by generic producers for the purposes of seeking regulatory approval from the authorities for the marketing of their generic version soon after the patent expires, is allowed under TRIPs. However, the Panel also decided that manufacturing and stockpiling of patented medicines by generic producers during the six months prior to the expiry of the patent term (which was also permitted under Canadian law) is *not* allowed.

¹² The name refers to a court case in the US, "*Roche Products Inc. vs. Bolar Pharmaceutical Co.*", which dealt with this type of exception.

¹³ The WTO Panel in "*Canada - Patent Protection for Pharmaceutical Products*".

With this decision, the Panel effectively has decided that a 'Bolar type' provision is 'TRIPs compliant', provided certain conditions are met¹⁴. Moreover, there is no requirement to provide for a patent term extension of the original product, as a compensation, in order to legitimize a Bolar exception (as is done in the US).

Another useful exemption is an experimentation clause, which allows companies, universities and other research institutions to experiment with patented inventions. Such experimentation may lead to new innovations, to improvement of existing inventions or to the realization that the granting of a patent was not justified and that it should be revoked.

3.6 Enforcement

Enforcement is not discussed very much, but the rules related to enforcement can have significant implications. As mentioned before, sometimes patents may be granted without sufficient justification, they may in fact be invalid. However, once a patent has been granted, there is a presumption of validity. This may create serious problems if countries have strong provisional measures under their enforcement system, such as for instance provisions allowing the patent holder to stop potential infringements.

This can be illustrated with the example of fluconazole in Chili. Fluconazole was in the public domain, no patent was granted on the product in Chili. However one company obtained a process patent on fluconazole in Chili. In Chili, in case of a lawsuit, a patent owner can ask the judge for a provisional measure to prevent potential infringement and stop commercialization of the product. So when a local company started producing fluconazole, the patent owner, based on the process patent, started a lawsuit and asked for a provisional measure, as a result of which the local company had to stop production and commercialization. Litigations like this often take several years. In this case, after the local supply was stopped, the price for the consumer was significantly higher than before the suit was brought. Finally, after several years, the judge came to the conclusion that there was no infringement, that in fact the patented process was not applied for the production of fluconazole by the second company and this company was allowed to resume producing and selling the product. But the question now is: who will reimburse the consumers? How many people have in the meantime not been able to use the product because of the higher price?

So while it may look like a minor point, enforcement regulations may have important consequences. When preparing legislation, such practical cases should be considered. The law can contain very nice substantive rules, but if, at the level of the procedures and in particular the provisional measures, the public interest is not taken into account, unexpected problems may result.

¹⁴ Bolar provisions, like other exceptions to patent rights, must still comply with the requirements of Article 27.1. That is, they may not discriminate according to the place of invention, the field of technology or whether products are imported or locally produced.

3.7 Opposition procedures

It is also important to consider providing for opposition procedures before granting a patent. This means that before a patent is granted, society is given an opportunity to make observations about the application. So the patent office may receive contributions from other companies, from academics, from NGOs etc. before the patent is granted, *before* the problem is created. In many laws, in particular in Latin America, but also in Japan, this system was established; it is a powerful tool in order to avoid the granting of patents which otherwise, later on, may have to be invalidated, but which, in the meantime, can be used against local and/or generic companies to prevent or limit competition.

3.8 Increasing access to HIV/AIDS drugs – Thailand’s experience

The patent law

Thailand has had a patent law since 1979, however, for pharmaceuticals, this law provided for process patents only. Since 1986, the US Trade Representative (USTR) has negotiated with the Thai Government about the inclusion of pharmaceutical product patents in the law. The US pressure led, in 1992, to the amendment of the Thai patent law. The amended version included pharmaceutical product patents, increased patent protection from 15 to 20 years and provided for pipeline protection. It also established a Pharmaceutical Patent Committee, to monitor prices and supply of patented drugs. This Committee was abolished during a further revision in 1999, which also made some other modifications, such as the introduction of petty patents.

Due to the regulations for pipeline protection, in some aspects, Thailand has a “TRIPs-plus” patent law. Pipeline protection, via the safety monitoring program (SMP), grants indirect market exclusivity to pharmaceuticals which do not qualify for a patent due to lack of novelty. Designed to monitor for adverse reactions for at least 2 years, under the SMP, new drugs can be used only in hospitals, under the supervision of physicians. Based on that experience, companies have to submit a report to the Thai FDA with safety data obtained in Thailand. After release from SMP, the product can be sold outside the hospital setting and generic products can be registered (on the basis of bio-equivalence data).

Box 11 Market exclusivity in Thailand

Effective market exclusivity for drugs in Thailand will last:

- 10-15 years for patented drugs (20 years patent duration, minus 5-10 years for R&D and registration);
- 5-6 years for non-patented NCEs, under the Safety Monitoring Programme.

The current (1999) Thai patent law allows parallel import and includes a ‘bolar-type’ provision, in addition to provisions for compulsory licensing. But due to the conditions imposed by the law, it is not easy to obtain and use a compulsory license.

The law’s impact on drugs

In the period 1979 - 1992, when only process patents were granted, after 1 or 2 years, a generic version could appear. On average, about 24% of the patented drugs would have a generic on the Thai market, creating competition and thereby increasing accessibility.

Currently, it takes 5 to 15 years after the introduction of the original product for a generic version to appear (see box 11). As a result, prices of patented drugs are high; this has not only reduced access but also caused a significant increase in government expenditures for drugs. In 1997, five years after its introduction, it has been estimated that the market exclusivity of the 25 top selling products under the SMP had caused an increase in drug expenditures of about 2,000 million Baht (approximately 50 million US dollars). This figure could increase 10-fold once the full impact of the introduction of product patents would be felt (around the year 2000). Finally, the new patent legislation has affected the local industry (see paragraph 2.5.1).

Access to HIV/AIDS drugs

While limited access due to high prices is noticeable in all therapeutic classes, the situation is particularly dramatic in case of anti-retroviral drugs, a category of drugs which are important and expensive. In Thailand, more than 1 million people are HIV infected and there are more than 100,000 patients with full blown AIDS. It is estimated that less than 5% of the Thai HIV/AIDS patients can afford double antiretroviral therapy.

Access to these drugs is determined by a number of factors, including the registration status, that is, whether they are allowed on the market, and whether they are sold at an affordable price. While several antiretroviral products are registered in Thailand, only AZT and didanosine (ddI) are classified as essential drugs. Neither should be affected by product patents or SMP regulations, since they have been approved for marketing in Thailand a number of years ago (AZT in 1987; ddI in 1992), so they are not patentable (not new). Yet currently there is a problem with affordability of ddI, though not with AZT. For AZT, only a process patent was granted (since the application was filed before the 1992 law was enacted); as a result, generics are presently available at more affordable prices.

In case of ddI, the situation is different. While ddI does not have a product patent in Thailand either, its manufacturer, Bristol-Myers Squibb (BMS), has obtained a formulation patent; BMS claims that the formulation they invented significantly improves bioavailability. In fact, this claim, and therefore the validity of the patent, is questionable, since in the US, the patent application for the same formulation has twice been rejected on the basis that it was obvious to someone 'skilled in the art'. But revocation of a patent is very difficult and time consuming, and the Thai patent is effectively being used to block generic competition; as such, it reduces access to this important product.

Under pressure from domestic patient- and activist groups to make the drug affordable, and from the US to refrain from issuing a compulsory license, the Thai Government has recently allowed 'generic' production of ddI-powder, which is not covered by BMS' formulation patent. But, while being a way out in this particular case, this obviously is not a structural solution.

3.9 Undisclosed information

Undisclosed information refers to information which is secret and has commercial value because it is secret. Undisclosed information, or 'trade secrets', is protected in

the TRIPs Agreement under the framework or discipline of unfair competition. There are important differences between the protection conferred under unfair competition and the protection conferred by other forms of IPR protection, especially patents:

- A patent owner obtains exclusive rights. This means he is the only one who can use the invention, commercialize the product etc. A patent owner can prevent any other person from using that invention. Even if a third party has developed the same product/process in an independent manner, without taking the technology of the patent owner, he is not allowed to use it, since the exclusive rights conferred are absolute. This is why, in economic terms, a patent confers a monopoly right.

In the case of undisclosed information there is no exclusive right. If a third party develops the same information independently, this third party can use that information.

The philosophy is *not* to give exclusive or monopoly rights, but to provide protection against unfair competition and against dishonest commercial practices, such as industrial espionage.

Box 12 Interferon

In the pharmaceutical sector, many companies are trying to find solutions for the same problems. Competition is about coming first. An example is interferon, a human protein, developed on the basis of genetic engineering. Many companies in the US have tried to be the first to sequence the gene that codifies for interferon, in order to be able to produce it through genetic engineering. The race was won by Genentech, which obtained a patent. Once Genentech had this (product) patent, the other companies were out of this business; they were not allowed to put Interferon on the market, because the exclusive rights conferred are strong in the case of a product patent.

- TRIPs does not create property protection for undisclosed information, but just refers to its possession. This is another important difference with a patent or trademark, in respect of which the owner has 'property'.
- The value of undisclosed information does not lie in innovation or novelty -even a list of clients can be protected, though obviously this is not an invention- but in the fact that it has commercial value and in the fact that it is secret. So there should be measures to protect such information from disclosure; under TRIPs, this is an obligation.
- Unlike patents, which in general last for 20 years, in the case of undisclosed information there is no defined time limit. Undisclosed information is protected as long as it is kept undisclosed, as long as it is secret. The duration of the protection therefore depends on the *factual* situation, not on any legal provision.

Implications for drug registration data.

TRIPs Article 39.3, which refers to information required by governments to provide registration for medicines or other chemical products, should be understood in this context. The subject of this protection is test data: the data of clinical trials carried out by the originator company in order to prove safety etc. This information is not invented or created. It is obtained by applying standard protocols on a certain (*new*) chemical substance. This is acknowledged by the TRIPs Agreement itself, which makes this kind of protection conditional upon the fact that there should have been a considerable effort to develop this information. Therefore, the concept here is not the protection of creation but the protection of investment and, in fact, there is a lot of concern about the expansion of the intellectual property system into the area of investment.

Furthermore, TRIPs requires this protection only in respect of NCEs. There is no need to provide this kind of protection for a new dosage form or for a new use of a known product.

However, when there is patent protection, the exclusivity given by the patent is considerably stronger, so Article 39.3 is mainly relevant in case of a NCE for which patent protection is not recognized. In such a case, two kinds of protection should be given: protection against disclosure and protection against unfair use.

Some countries, such as the US and the EU, have decided, in their (national) legislation, to give additional protection; they have adopted the concept of *exclusivity* for test data. This means they grant TRIPs-plus protection. In the US, the originator of the information is given a 5-year exclusivity period for the use of this information. In the EU, this is 10 years. But this is not the concept of TRIPs, this is not something that other countries need to follow; in particular developing countries interested in creating a competitive environment in the pharmaceutical sector should *not* follow this example.

It is important to realize that data exclusivity can interfere with the actual use of a compulsory license. For example, after the originator has submitted the relevant data and obtained registration of a NCE (first application, first registration), what would happen to a second company which wants to register the same product, either using a compulsory license, or in case the NCE is not patented?

- In EU and US, during the data exclusivity period, the second company can not rely on the information from the first registration, so it will not be able to register the same product unless it develops its own clinical test data.
- However, the authorities already know the characteristics and effects of the product (due to the first registration), so for consideration of the second application, all the authorities need, is confirmation that the second product is indeed similar to the first product. How to prove similarity is a matter for the national legislation; some countries require bio-equivalence tests, others may have different requirements. But under TRIPs, authorities can rely on the data from a prior registration. The second company therefore can obtain registration, based on the fact that the product is already registered.

The latter solution is adopted in the law of some countries, e.g. Argentina and Canada. The Supreme Court in Canada has ruled (in 1999) that this is legitimate, under Canadian law as well as under NAFTA, because the Authority is not requesting again for undisclosed information, it is just checking whether the two products are indeed the same.

Stakeholder's views on data exclusivity

The innovative pharmaceutical industry argues that granting data exclusivity for test data is crucial, since the development of these data is expensive. Allowing other companies to rely on data developed by the innovator, instead of having to develop their own clinical data, would give them an unfair economic advantage. This, in turn, could create a disincentive for the introduction of innovative products and would discourage local R&D.

Consumer groups, such as the Trans-Atlantic Consumer Dialogue, on the other hand argue that, since data exclusivity essentially protects investment, companies seeking data exclusivity should be required to disclose the amount actually invested. This would enhance transparency and allow the establishment of a relation between the actual investment and the protection provided.

Others have proposed the development of a model for a time limited “royalty type” of payment for the use of the originator’s clinical data as a basis for registration of (branded) generics.

Options

Under TRIPs, countries have options to decide how they wish to regulate the protection of undisclosed information. They can opt for TRIPs-plus protection by granting data exclusivity, or for strictly following the TRIPs standards. In making this choice, policymakers will have to weigh the protection of the interests of originator companies against the importance of creating a competitive environment in order to increase access. From a public health perspective, the introduction of TRIPs-plus standards seems not advisable for developing countries.

3.10 Trademarks, public health and drugs

Trademark protection is usually considered to be in the interest of consumers, since it avoids confusion about the origin or manufacturer of a product. At the same time, trademarks protect companies which invest in quality, since they cannot easily have their products confused with similar products from different companies. This should provide incentives for companies to invest in the quality of their products, which ultimately benefits consumers.

Trademarks and public health

But trademark protection is not always in the interest of the consumer. An example related to public health is the case of baby food and infant formula in Guatemala. Guatemala, following WHO advice, discouraged pictures of fat, healthy babies in advertisements and on packages of infant formula. Such photos, public health experts found, incite mothers to buy infant formula even when this is unnecessary and unaffordable. Moreover, there is a considerable risk of incorrect preparation, as a result of which these products could become harmful. But one company, when told to remove the baby picture from its packages, complained that this was a violation of its trademark and, as such, against international agreements. They even involved the US government in the issue. Eventually the Supreme Court of Guatemala overturned the domestic law which -for public health reasons- banned such advertising, based on the idea that it violated an international trade agreement.

This shows that in some developing countries, courts give more deference to international trade agreements than the US courts would. Judges in US consider their country and its laws to be sovereign. Furthermore, it is not sure that the Guatemalan law indeed was conflicting with international trade agreements, but authorities were made to believe it was, and this had consequences.

In a similar case, the Canadian Government refrained from passing pro-public health legislation banning distinctive packages for cigarettes, after being warned that this

might be against the rules of international trade agreements signed by Canada and that it could lead to litigation.

So obviously, trademark protection can affect public health measures.

Trademarks and drugs

A number of issues are important with regard to trademarks and drugs:

- National requirements that the generic name (INN) is printed on the package of a medicine. Some companies claim that this undermines the economic value of their brand, and on several occasions the US government has thrown its weight behind such companies. However, national legislation in the US requires exactly the same.
- Obligations for generic prescribing (common in the public sector; sometimes also in the private sector), and
- Permissions and/or incentives for generic substitution by pharmacists; both are at times said to be violating trademark rights, even though they stimulate competition and can help to make the best use of limited health budgets.

In all these examples, there clearly is a public interest that ought to be protected.

Trade dress

Another issue in this context is the so-called 'trade dress' protection. Trade dress in the context of medicines refers to the appearance of a drug, for example the specific shape or color of the tablets. Originator companies try to prevent imitation of the trade dress of their products; they try to stop the generics from looking similar. But from a public health perspective, there are some arguments in favor of generics looking similar -though not necessarily the same- to the original product, since this would reduce confusion and therefore medication mistakes. This is especially important in situations, such as in the US, where insurance companies require frequent switches between different branded or generic versions of the same product, based on the outcomes of price negotiations.

There has been a case in which a Canadian court ruled that the public health reasons for permitting a similar look were more important than commercial interests. Even so, at the moment, the relation between patient compliance, medication errors and trade dress protection for drugs is not very clear, and would merit further study.

3.11 State practice and WTO participation

When a WTO dispute arises, obviously the parties to the dispute can present their arguments (complaint and defense) to the Panel concerned. But other WTO members can also make submissions when they have a trade interest in the case. For instance in the case of the EU complaint against Canada on the Bolar provision, a number of countries, including some developing countries such as Colombia, made submissions for the consideration of the Panel. Such active participation by developing countries in the WTO is important, since it will draw attention to their policy objectives and it will highlight possible implications from their perspective; these factors will be taken into consideration by the Panel.

Similarly, state practice is important when a decision is taken by a Panel or Appellate Body. This means that the kind of legislation countries adopt in order to implement

the Agreement will create precedents that may influence decisions by WTO Panels and the Appellate Body. If for instance all the ASEAN countries adopt provisions related to the protection of public health, this will create a kind of state practice which the Panels will need to consider. According to the Vienna Convention, one of the elements to be taken into account for the interpretation of international agreements, is the way in which countries have applied a particular treaty.

It is therefore important to consider that what is done at the national level may also have an impact in terms of interpretation of the Agreement. If countries use a very limited, strict interpretation of the TRIPs Agreement, Panels will look at TRIPs issues in the same 'narrow' way, but if countries use a broader interpretation, the Panels and Appellate Body may read the TRIPs Agreement in the same way.

3.12 TRIPs Review

The TRIPs Agreement has an in-built agenda, which means that the Agreement itself provides for its review after some period, which has already elapsed. So irrespective of the launching of another Round of Trade Negotiations, there will be negotiations in the framework of the TRIPs, which may lead to changes in the Agreement.

Article 27.3(b)

Probably the most important area of revision is the revision of Article 27.3(b), which relates to plants, animals and biotechnology. The Article -and its revision- is very important for developing countries, since it has an impact on such different issues as breeders rights, farmers rights, patenting of (human) genes and recognition of informal or indigenous systems of innovation, notably with regard to biodiversity. Most of these issues however are beyond the scope of this report and will not be addressed here.

In the context of pharmaceuticals, the most important issue relates to naturally occurring products and biotechnology. The current TRIPs text allows the interpretation that substances which already exists in nature (such as insulin, growth hormone etc.) are discoveries, not inventions, and can not be patented, even when produced via biotechnological methods¹⁵. It would seem that this is the best option for developing countries (with the possible exception of those developing countries which have biotechnological capabilities) to follow in their national legislation.

Box 13 National legislation

With regard to TRIPs Article 27.3.b, countries could consider to specify in their national legislation that the following shall not be patentable:

- plants and animals, in whole or any part thereof, including DNA, cells, seeds, varieties and species
- the human body and all its elements, in whole or in part.

Many developing and least developed countries are seeking a formal clarification and/or assurance that plants, animals, micro-organisms and parts thereof are not patentable. Some countries have granted protection to *non-naturally occurring* living

¹⁵ The biotechnological methods themselves however may be patentable.

organisms and their parts (including genes). During the review, developing countries should, at the very least, ensure that the *status quo* is maintained. This may however not be easy, since a number of developed countries would like to expand the patentability of "life".

Non-violation clause

There is however another important provision which is under review in this in-built agenda. This provision is the so-called non-violation clause. In the GATT tradition, this has been a principle, according to which a country may bring a complaint against another country even when there is no formal violation of an Agreement, when it is considered that the reasonable expectations of the first country have been frustrated.

This clause was included in the TRIPs Agreement under a moratorium, which stated that within a period of five years member countries should review in which way this non-violation clause could be applied. In this context, non-violation means that even if a country's legislation is in conformity with the TRIPs Agreement, a second country may complain that the implications of a particular clause are infringing the spirit of the TRIPs Agreement.

This is an undesirable situation, since the TRIPs rules are quite clear and, more importantly, establish *private* rights, so there seems to be no reason for TRIPs to contain a clause for non-violation complaints between governments. In fact many countries have already expressed a view like this, for instance Canada has proposed to extend the moratorium until further review is done, and some other countries have proposed to eliminate this provision.

Amendment of TRIPs

The last point related to the review of the Agreement relates to the amendment of the Agreement. Some governments have proposed that the mandated review should not just discuss the implementation of the existing rules, but also discuss the revision of the rules, because many (developing) countries are not happy with the present rules. This possibility exists. There is nothing in the WTO system that would prevent a group of countries from promoting the revision of the rules. So these Agreements are not fixed forever, they can be changed, there is a mechanism that is provided for.

For instance Venezuela submitted a proposal to the Ministerial Conference in Seattle to exclude from patentability the Essential Drugs as listed by WHO. Although it is not clear whether this proposal is a good one or not (there are different views on this, including among public health advocates, because of the very limited scope of the list and the fact that the more expensive drugs are not included), it shows there are such possibilities.

But there is a strategic discussion to be held, before any such proposal is made, on the bargaining power which developing countries have to promote and obtain a change of the TRIPs Agreement which is favorable to their interests. Furthermore, obviously, the implications for developing countries of any specific proposal should be thoroughly evaluated beforehand.

Transitional period

While not part of the built-in agenda, an important topic during the discussions related to the TRIPs review will be the issue of the extension of the transitional period for developing countries. There is no agreement on this. But the majority of the

developing countries have not yet amended their legislation in a way that fulfills the TRIPs requirements. In other words, the majority of the developing countries are today in violation of some part of the TRIPs Agreement, since their transitional period ended on 1st January 2000. But so far, few developing countries have had the time, the political support, infrastructure and the technical advise needed to implement this complex Agreement.

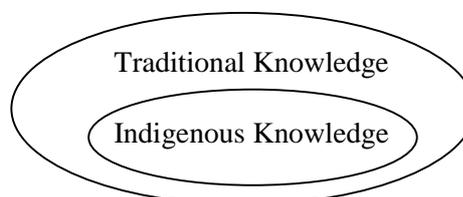
For instance in Latin America and the Caribbean, only two countries have more or less amended their legislation in order to cover all the areas in the way the TRIPs Agreement requires. Therefore, the reality is that developing countries need some additional transition period. The fact that there is no consensus to grant this, creates an undesirable, dangerous situation, because any of these countries may, anytime, be brought to a Panel and could eventually be sanctioned on the basis of non-compliance.

IV. SPECIAL ISSUES

4.1 Traditional medicinal knowledge & intellectual property rights

The rise of modern information technologies has led to an increasing awareness of the value of traditional knowledge, including in particular traditional medicine. At a time when the wealth of nations lies increasingly in the knowledge which their peoples hold, the use of intellectual property rights related to 'traditional knowledge' has become an important issue. While the debate is in its early stages, there is a lot of concern and controversy, but also considerable confusion. This is partly due to the fact that there is no common terminology, and that the concepts and expectations of different stakeholders vary.

Figure 14



So what is meant by the terms 'traditional' and 'indigenous' knowledge? Although indigenous knowledge is generally considered traditional knowledge, not all traditional knowledge is indigenous knowledge. Indigenous knowledge can be seen as a subset of traditional knowledge (TK). For example,

information passed down by traditional means amongst the Gagudju of Australia may be referred to as 'indigenous knowledge' or 'traditional knowledge'; however, the information passed down by early North American colonists through traditional means would be 'traditional knowledge' but not 'indigenous knowledge'. This distinction between 'indigenous' and 'traditional' knowledge resurfaces in a modified form in the field of traditional medicine, especially in Asian countries.

In the Asian context, the terms 'indigenous' and 'traditional' are used to differentiate knowledge according to the codification of the tradition, rather than the affiliation of the knowledge holder. A distinction is made, particularly in South Asia and China, between the *codified* systems of 'traditional medicine' and *non-codified* medicinal know-how, which includes tribal and 'indigenous medicine'. The codified knowledge systems include the Ayurvedic system of medicine, which is codified in the 54 authoritative books of the Ayurvedic System. As will be discussed below, this distinction may have implications in the intellectual property context for the relation of the subject matter to the public domain.

The following priority areas with regards to traditional medicine and intellectual property can be identified: (i) availability, scope and use of IPRs in traditional medicine; (ii) systematic documentation of traditional medicine for IP purposes; and (iii) regional and inter-regional information exchange on traditional medicine and compilation of databases thereof.

Following consultations with a wide spectrum of stakeholders, including governments, practitioners of traditional medicine, pharmaceutical industry, research institutes, non-governmental organizations (NGOs) as well as indigenous and local communities, a number of issues and concerns have been identified. These focus on

patents and trade secrets; some of the issues and concerns related to patents are summarized here.

Practitioners of traditional medicine expressed a wide range of views and needs in relation to the patent system, reflecting diverse points of view and ongoing experimentation with the patent system. These included propositions to use the existing patent system for TK protection, to develop *sui generis* protection for TK, modeled upon but different from the patent system, to exclude certain systems of traditional medicine from patentability, as well as the assessment that the patent system is entirely inadequate for the protection of traditional medicine.

A common point among these diverging views was that the interactions between traditional medicine and the patent system are growing rapidly. Stakeholders noted that these interactions encompass two developments: first, there is an increasing number of patents filed and granted over TK-based inventions. Hence the informal innovations of TK systems enter the ambit of IPR policy. Secondly, TK holders and policy makers are developing new uses for the patent system as a tool within TK-related frameworks, such as access and benefit sharing frameworks, access to affordable health care, etc.

Availability of patent protection versus disclosure in the case of traditional medicine

The availability of patent protection for traditional healers is hampered on one hand by problems related to the acquisition and exercise of rights, and on the other hand by the disclosure of patentable inventions during the documentation of traditional medicine; the publication of documented traditional medicinal knowledge is a high priority for initiatives which aim at making traditional medicine more widely available as a source of primary health care.

Depending on the knowledge holders' views regarding the grant of exclusive rights over traditional knowledge, they either seek disclosure or try to avoid it.

- Traditional healers who seek to prevent the grant of any patents over their inventions have adopted *systematic disclosure of documented traditional medicinal knowledge* as a strategy, because such disclosure destroys the novelty of the innovation and makes it unpatentable. Some organizations are therefore systematically disclosing the innovations compiled in their traditional-knowledge-databases.
- On the other hand, practitioners of traditional medicine who seek to obtain patents for traditional medicine-based inventions have developed documentation strategies which *prevent* disclosure in a sufficiently clear and complete manner. They have adopted strategies which are intended *not* to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

To resolve specific problems related to the *unintentional* disclosure of traditional knowledge, two modifications or additions to the existing system are proposed:

- an extended grace period could be provided for the patent applications of TK holders. This would exclude premature disclosure of traditional knowledge from prior art, if that disclosure was made within a specified period before the filing of an application. A practitioner or documentation project making such a premature disclosure, e.g. because they were unaware of its IP implications, would be temporarily protected against the consequences of such disclosure.

- a registration mechanism could be developed for informal innovations, similar to certain national petty patent systems, which would give registered TK holders the right of precedence in matters of filing of applications for protection of such registered traditional know-how.

Those practitioners of traditional medicine who are interested in obtaining patents often experience a number of problems, which make the formal IP system inaccessible for them. This system is based on document-intensive, highly codified structures and procedures. It presupposes the existence of written records, a condition which traditional practitioners cannot rely upon in practice, because traditions often lack written records.

The high costs of filing patent applications is the second, and biggest obstacle to the acquisition of patents by practitioners of traditional medicine. Possible measures to reduce transaction costs and make the patent system more accessible are:

- collective filing of patent applications by traditional healers' associations, in order to share transaction costs;
- financial and legal assistance to traditional healers' organizations for the filing of patent applications;
- an extended grace period for TK holders, as mentioned above, to give practitioners of traditional medicine additional time to raise funds for the fees for patent applications,
- collective management of industrial property rights, based on existing models for the collective management of copyrights.

Patents over TK-based inventions granted to non-TK holders

In recent years, public concerns have focused on patents over traditional medicine-based inventions which were obtained by non-TK holders. Even though in some cases these patents were revoked after evidence of their long standing use in traditional medical systems was produced, this so-called biopiracy has generated wide-spread concerns about the equity of the formal IP systems and the recognition of TK as prior art.

The issuing of such patents could be avoided by taking steps to include traditional medicine documentation in the searchable prior art, such as:

- Inclusion of TK newsletters, databases and registries into existing IP information systems for non-patent literature.
- Inclusion of standardized TK documentation into the regular procedures of patent-issuing authorities.
- Development of standards for the international exchange of traditional medicine documentation within existing international IP information systems for the search of prior art.
- Inclusion into the International Patent Classification of classes, subclasses etc. for traditional medicine, so that traditional medicine-based patents can be systematically searched.

Customary protection of traditional medicinal knowledge

The IP needs of TK holders are shaped by their contact with the formal IP systems as well as by the informal IP regimes that prevail in their societies and communities. Contrary to a commonly held view, exclusive rights and monopoly powers over informal innovations are not uncommon within indigenous and local communities.

Many local and indigenous communities have evolved diverse but stable societal structures which regulate the flow of traditional knowledge and innovations. Such customary or 'informal' regimes may bear remarkable similarity to formal intellectual property systems, and can be just as effective in protecting the local innovator in his or her local context.

The first type of informal regimes are *secrecy regimes*. These are independent from government regulations or community support, and depend entirely on the inventor's ability to prevent disclosure. However, in small, traditional communities it is often difficult to conceal innovations, especially when they consist of modifications of more generally known traditional techniques. Secondly, in the absence of formal protection, healers use *rituals* as part of their traditional healing methods; these often allow them to monopolize their innovations, despite disclosure of the phytochemical products or techniques used.

The impression exists that in many traditional societies such ritual and magical powers are part of informal regimes which protect traditional medicinal know-how from unauthorized use by third parties. Effectively, *ritual can function as a barrier to reverse engineering*, that is, a mechanism which prevents the use and development of technologies based on imitation. In the local context and within supportive cultural frameworks, ritual regimes can create monopolies approximating those of modern patents which confer on their

Box 15 A healer in Karnataka

An example is the case of a traditional healer in Karnataka, India. Since more than 20 years, he treats 50 to 60 patients per day and has developed a specialization in skin diseases. He uses about 40 medicinal plants for oral and external application and produces each application individually for each patient. He only applies his formulations personally and performs elaborate rituals during the treatment to obtain support from Laxmi, the goddess of wealth. His medicines are effective *only* in association with the appropriate ritual components. The intangible property consisting of the rituals associated with his practices makes the healer's personal involvement mandatory, even though the technology is fully disclosed.

owners certain exclusive rights in relation to products and processes, which constitute the subject matter of the patent: "to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, or importing for these purposes that product" or process, respectively.¹⁶

Conclusion

Systems of traditional medicine are rich and diverse sources of creativity and innovation. Practitioners of traditional medicine and other stakeholders consider such knowledge systems to be a constantly renewed source of wealth, both as an economic asset and as cultural patrimony. This is the case in both developing and developed countries.

The intellectual property issues related to traditional knowledge cut across the conventional branches of intellectual property law, such as copyright and industrial property, since in many cases practitioners of traditional medicine do not separate 'artistic' from 'useful' aspects of their know-how and intellectual creations.

¹⁶ Articles 28.1(a) and (b), TRIPs Agreement.

Numerous indigenous and local communities have protocols for protection of traditional medicine under customary law. Increasingly, we are witnessing a convergence between the formal intellectual property system, on the one hand, and 'informal' systems for protection of traditional knowledge, on the other. These systems have been integral and effective within their spheres and have, until recently, existed in virtual independence of each other. Their convergence results from two consequences of current globalization processes, namely, the growing relevance of intellectual property to an increasing number of countries and users, and the expanding recognition that traditional medicinal know how is a valuable economic and cultural asset within the global information society.

However, many legal and practical problems remain yet to be fully understood and addressed: the collective ownership/custodianship of traditional medicine; the problem of ownership and exercise of rights in traditional medicinal knowledge which exists across different countries in a region; practical means for the exercise and management of rights; mechanisms for application of customary law to protect traditional medicine; and the need for comprehensive documentation, and documentation standards, for traditional medicine.

In order to achieve better understanding and wider consensus on these issues it is necessary to address basic conceptual problems and test practical solutions to the protection of traditional medicine.

4.2 Implications of the TRIPs Agreement on Biotechnology

Like in other disciplines, for biotechnology, protection of intellectual property provides encouragement for innovations involving genetic engineering, in addition to according incentives for investments, which may lead to new products and processes. The general prerequisites for patentability, namely, novelty, inventiveness and industrial applicability (or utility) apply to biotechnology inventions as well. As a rule, though this may appear paradoxical, new biological material is patentable, if obtained through non-biological processes. Non-biological processes are defined as those where the *hand of man* had a part to play.

Article 27.3 (b) of TRIPs gives members the freedom to exclude plants, animals and "essentially biological processes" from patentability. However, it also states that micro-organisms and non-biological and micro-biological processes have to be patentable.

The wording is deliberately ambiguous, which gives countries some freedom to interpret this in their national legislation as they deem fit. This freedom of interpretation could be restricted during the mandatory review of this Article (see paragraph 3.12).

Gene Patents

An enormous amount of debate is on-going on the question of patenting genes. The problems faced on this issue are related to philosophical, theological, ethical and moral objections regarding its implications on society.

There are two major and diverse views on the question of patenting genes. The first view is that a gene or a gene sub-fragment is already existing in nature; its identification is a discovery, not an invention, and therefore it is not patentable. The second view is that the skills required to construct full-length genes and define their function and utility are not straightforward and simple and, therefore, are patentable.

The second view has been accepted by patent authorities in US, Europe and Japan; the countries where biotechnology is most developed. With the isolation of more disease-related genes, the number of sequences for which patents will be filed, will increase in coming years. However, as the processes of gene-sequencing and cloning will become standardised and will eventually become 'routine', patenting genes may become more difficult.

One of the most controversial aspects of patenting human genes or sequences is the question of ownership of the data and rights of the donor. From the investors' point of view, exclusivity gained through patenting is essential for commercial exploitation and for the development of new therapeutic and diagnostic tools. But when the rights to genetic data from people are sold (the right to one gene associated with obesity was sold for US\$ 70 million), can the person or population from where the gene originated claim a share of the royalties?

Applications for patents on genetic data from populations in developing countries should consider at least the following factors:

- informed consent for the use of those data,
- rewards for indigenous groups in case of commercial exploitation,
- the cultural diversity and political rights of indigenous population should be respected in international agreements and in patent laws.

So far, none of this has happened, and developing countries should look into these issues.

Critics aver that patenting a human gene is equivalent to patenting life, which is counter to all norms of patentability. Biotech companies argue that they are only claiming the right to use genetic information to develop diagnostics and therapies and not for owning the rights over the genes. One position therefore could be that the gene itself is not patentable, but that a diagnostic kit based on a new gene can be patented. Other issues relate to setting up standards for genetic testing and the emotional issues of predicting diseases and the impact this may have on insurance schemes, employment, etc.

Box 16 Data on Gene Patents:

- 1175 human gene sequences have been patented (between 1981 and 1995);
- Only 16% of human DNA sequence patents filed have been issued so far (due to time lag for issue);
- Patentees are industry (75%), publicly funded research agencies such as NIH, US Department of Health, Pasteur Institute, Salk Institute (15%), and Universities (10%);
- Legal interpretations differ as to whether the patent protects only the sequence disclosed or whether it covers all possible forms of the gene.

Genetically Modified Organisms

In conventional breeding, whether in animals or plants, individuals are selected with beneficial traits and crossed. Genes mix randomly, leaving the final outcome to chance. The number of traits which can be introduced in the species by this process is limited. While the objective of biotechnology remains the same, i.e. to alter the genetic make-up to improve the species, the method used accelerates the process by isolating the DNA sequence responsible for a particular trait and introducing it in the same species or -and here lies a major difference with conventional breeding- in another unrelated species.

By using this technique, biotech scientists believe that plants can be modified to resist attack by pests, thereby ensuring less use of harmful pesticides, and to tolerate broad-spectrum herbicides. They believe that genetically modified agricultural products can be superior in terms of increased production and increased quality.

Box 17 Current Status of GM Foods

Countries growing GM crops are mainly the US (21 million hectares), Argentina (5 million hectares), Canada (3 million hectares) and Australia (0.2 million hectares). A few other countries have some experimental cultivation.

Crops concerned are mainly soyabeans, maize, cotton, canola, rapeseed, and potatos.

1998 sales of GM crops were estimated to be over US\$ 2 billion, an increase of over 20-fold since '94.

Hot debates surround the Genetically Modified Organisms (GMOs). They stem from concerns over the safety of such modified products to consumers and to the environment. Some of the concerns are related to lack of enough time-tested evidence for their safety to human health and environment. Moreover, there are concerns about

possible undesirable gene transfer across different species, which could lead to creation of new resistant weeds, alter ecosystems by destroying all pests or evolve new varieties of pests and lead to a loss of biodiversity, normally ensured through nature's selection process. A final objection is related to the denial of options and choices to the consumers of the food they want to consume.

Where this does the overall balance lie in this debate? The rational approach would be to evaluate the risks through scientific experimentation and validation to the utmost satisfaction of the strictest regulatory agencies and consumers. The problems and prospects need to be evaluated in an impassionate manner by the concerned parties.

Patents on Plants and Transgenic Plants

TRIPs Article 27.3 requires countries to have some form of protection for plant varieties in place, either via patents or via a sui generis system. Therefore, countries may choose for legislating a plant varieties' protection Act. Breeders' rights to control the production, sale and distribution of propagating material (seeds or cuttings) can also be granted protection under such legislation.

Many countries, including some in the European Community, classify plant varieties as unpatentable subject matter, even when the transgenic plant would satisfy the essential pre-requisites of novelty, inventiveness and utility. However, in most countries, patents are granted for processes and genetic materials used to create transgenic plants.

Since 1985 the US Patent and Trademark Office (USPTO) has allowed the patenting of plants. Plant patents have been granted by European Patent Office (EPO) from 1989. But in 1995, EPO severely restricted the scope of Plant Genetic Systems and allowed claims only on the herbicide-resistant gene and the process used. In Japan, plant patents are allowed, however, some disputes over territorial rights are brewing between Japanese Patent Office and the Ministry of Agriculture.

Animal Patents

In 1987, in a case involving polyploid oysters, the USPTO ruled that animals could be patented. In spite of the potential of transgenic animals as useful 'factories' for therapeutic proteins at a future date, current uses of such patented animals are as experimental models for screening assays, for example the Oncomouse (used to screen compounds for anti-cancer activity). In 1988, the Harvard Oncomouse was granted a Patent by USPTO. The European Patent Office, after much debate, granted the Patent in 1992. But it is incorrect to conclude that there is universal agreement on the patentability of the Oncomouse; for instance Denmark has said 'No' to animal patents.

The debate centers on ethical and moral issues, as well as animal rights.

Conclusions

Biotechnology, particularly modern biotechnology, which is primarily based on the exploitation of the genetic engineering techniques, is in a relatively infant stage. Like in any other R&D activity, investment requirements are high and returns are never assured in terms of bankable products and processes of commercial utility. The time frame involved also could be long. Consequently, rewards for such risky investments have to be assured, and protection of intellectual property of the inventor or his sponsor is one system which will ensure returns on investments. The uncertainties inherent in biotechnological product development are common to both healthcare and agriculture-related biotechnology products and processes. There have been some successes, but the majority of companies survive of R&D funds, venture capital and sponsored projects from large corporations. Due to various concerns and ambiguities, including moral, ethical, theological and political factors, there has been no consensus on uniform standards for inventions in this area. This picture will become clearer in the coming years.

The practice of protecting one's inventions through patents requires very careful and informed inputs. Drafting, filing, prosecuting, defending and maintaining patents require special expertise, which can be acquired only through professional training and practice. The first step is to ensure that there is an organization to impart adequate patent literacy to the scientists, to create an awareness of the usefulness of the system not only as a commercial tool, but also as a source of scientific and technical information within a legal framework. Keeping abreast of the developments in the patent arena also enables scientists to read into the future technological potential of many scientific discoveries.

The next five years are crucial to developing countries, as the fruits of science and technology will become ever more important in view of their commitment to join the global community in trade, commerce and industrial development.

4.3 Biodiversity

4.3.1 Biodiversity Convention

In 1992, 170 countries met in Rio de Janeiro to discuss the details of a proposed Biodiversity treaty, the Convention on Biological Diversity (CBD). Even though the US delayed signing of the treaty, the other Members endorsed the Convention.

The CBD has enunciated its primary objectives as (1) conservation of biodiversity, (2) sustainability of biodiversity, and (3) equity in use of biodiversity.

Of these three, the most relevant to the current discussion is the issue of equity in use of biodiversity resources, particularly of developing countries.

A simple model for defining sovereign rights over genetic resources has been developed, which includes provisions for negotiating access to natural products by private organisations through an approved Material Transfer Agreement including payment terms approved by a centralised agency. The ownership of natural products as tangible property could be according to land tenure; samples gathered from public land are owned by the State, while those gathered from private or commercial land are owned by the landowner or the community. An option to transfer traditional knowledge confidentially as trade secrets for commercial research and development should be available to individuals, groups and communities against appropriate compensation.

Article 15 of the Convention on Biodiversity (CBD) deals with the Sovereign Rights of Nations over their genetic resources. These are deemed not to be the heritage of mankind, but are the properties of the countries and/or communities and are, therefore, trade-able commodities with economic value. This is in contrast to protection of Intellectual Property Rights. Patent Laws do not permit patenting of natural products under the doctrine of nature principle. Hence, to protect the biodiversity resources uniquely available to sovereign States, new legislations are required.

Very few countries have legislation with appropriate statutes to protect Biodiversity and therein lies the immediate problem of establishing legal rights to indigenous natural resources. Countries should enact Biodiversity Bills (to protect their natural treasures), the basic principles being that a foreigner or foreign organization can not take away any biological resources for research or commercial use without permission of the country of origin. Local organizations will not be allowed to transfer even research results on biological resources to any foreigner without permission. Based on models as described above, parties from the source countries and sourcing agencies could negotiate and sign material transfer agreements prior to granting permission to use genetic resources for R&D or for commercial exploitation.

The legislation should also ensure that benefits are equitably shared between conservers of the resources and users. However, even though all the signatories to the CBD have confirmed such approaches for the protection of their sovereign rights, most are yet to enact appropriate legislations in this regard.

An issue which needs to be considered in detail is a mechanism to determine a fair and equitable compensation to the owners or guardians of bio-resources. Since all natural resources cannot be profitably converted to viable commercial products, it is

difficult to assess the real value of the transferred material at the time of the transfer. The most equitable way would probably be to pay a relatively low upfront compensation, followed by an agreed royalty payment as a percentage of commercial revenue for a specific period of time.

4.3.2 Geographical indications

Yet another way of protecting a country's biodiversity assets which are uniquely endemic to certain geographical locations in the country is via the use of geographical indications. A "geographical indication" refers to the use of a place name to describe a product; such a name usually identifies both the product's geographical origin and its characteristics. Products such as Scotch Whisky, Champagne and Roquefort Cheese fall in this category.

Biological assets, which are distinguishable in terms of quality and/or traits and which are known as originating from a specific geographical region, could be protected through appropriate national legislations on geographical appellations. Coupled with trademark issues, lack of protection of geographical indications could mislead the customer. Where applicable, developing countries should bring geographical indications in their national legislation in order to protect their bio-assets.

V. ISSUES DISCUSSED IN WORKING GROUPS

After receiving input (presented in sections I to IV) from the resource persons, on the third day, participants formed smaller working groups in order to discuss the numerous important issues raised during the previous two days and to draft recommendations.

Key issues discussed include:

- ASEAN Countries, when revising their intellectual property rights legislation in order to make it TRIPs compliant, should make sure the revised legislation is in the interest of the country; participants were especially concerned that access to drugs should be ensured within the framework of TRIPs;
- Criteria of patentability; what are the current criteria, should they be revised?
- Ethical issues related to the patenting of (modified) living organisms and 'the patenting of life' in general;
- Genetic engineering, and the importance of patents in this context;
- How can traditional medicinal knowledge be protected under the intellectual property right system; is there a conflict between the development of traditional knowledge and its protection?
- The significance of WTO Panel rulings with regard to "Bolar-type" provisions, and the implications of these rulings for ASEAN Countries;
- What are the implications, if any, of TRIPs trademark provisions on generic policies, such as generic prescribing, generic substitution and requirements to have generic names (INNs) on the label?
- Current practices with regard to intellectual property rights in different ASEAN Countries and how these practices vary among the ASEAN Countries;
- In order to ensure that the public health interest is taken into account during the implementation of WTO Agreements, as well as during future multilateral trade negotiations, national Ministries of Health should liaise with other relevant government bodies; similarly, cooperation with relevant ASEAN Committees should be pursued;
- The importance of involving NGOs in discussions and future meetings on this topic, and mechanisms via which this could be done;
- Whether ASEAN Countries should work together with other developing countries; and if so, how can this be done, which mechanisms exist?

VI. RECOMMENDATIONS

Recommendations from the Delegates to the ASEAN Workshop on the TRIPS Agreement and its Impact on Pharmaceuticals Jakarta, 2-4 May 2000

The workshop recognizes the importance of access, at the national level, to affordable drugs which meet international standards of quality, efficacy and safety.

The workshop also recognizes that most ASEAN Member Countries are signatories to the WTO/TRIPS Agreement, and should therefore abide by its rules. However, it is stressed that the TRIPS Agreement allows for some flexibility, and ASEAN Countries are advised to use this flexibility to ensure that their national and developmental objectives are met and to protect public health.

The workshop also notes that compulsory licensing¹⁵, parallel import and a Bolar provision are in compliance with the TRIPS Agreement.

The workshop recommends that:

1. National governments should adopt legislation specifying patentability criteria in order to ensure the protection of real inventions and to ensure a balance of rights and obligations of the patent holders and the end-users; these criteria should be applied strictly¹⁶.
2. National governments should pass patent legislation providing for compulsory licensing and parallel import and containing a Bolar provision.
3. An ASEAN ad-hoc expert meeting on the impact of globalization and trade liberalization on the health sector should be established immediately, in order to develop:
 - model legislation, including appropriate provisions for compulsory licensing, parallel import and a Bolar provision,
 - a system to monitor the implications of the TRIPS on access to drugs in the ASEAN Countries,
 - guidelines on how to deal with disputes related to TRIPS and access to drugs,
 - a common position in relation to the implementation of the TRIPS Agreement with a view to protect public health.

The ad-hoc expert meeting should include WHO and relevant NGOs as partners.

¹⁵ TRIPS however sets some conditions, which have to be followed when issuing a compulsory license.

¹⁶ Due to a very flexible interpretation of the criteria of novelty, inventive step and industrial application, at times the patent system is being misused and is becoming an obstacle to innovation, instead of a stimulus. More strict application of the criteria for patentability may help to prevent excesses.

4. The workshop strongly recommends that ASEAN Member Countries should adopt a common and united stand against any pressures/actions against individual Member Countries in relation to measures, within the framework of TRIPS, which are meant to safeguard public health interests and/or access to drugs.
The workshop strongly recommends that ASEAN Member Countries adopt a common position in any future trade negotiations affecting the health sector, including the review of the TRIPS Agreement.
5. ASEAN Countries Representatives to the WTO should request that WTO allows the involvement of WHO in negotiations in relation to trade agreements having an impact on the health sector, including the review of the TRIPS Agreement.
6. ASEAN Member Countries should further study TRIPS provisions on trademarks in relation to public health. To this end, expert reports should be obtained:
 - from WIPO, on the status of national legislation and control measures with respect to trademark protection of health related products in WIPO member countries,
 - from WHO, on the impact and public health consequences arising out of TRIPS provisions on trademarks, the use of generic names (INN) vs. brand names, the use of the generic name on package of medicines, prescribing by generic names, generic drug substitution and trade dress protection.
7. ASEAN Member Countries should gather information on various approaches for the protection against unfair commercial use of test data of new chemical entities, and on the implications of these approaches on access to drugs.
8. The workshop notes that the TRIPS Agreement does not include specific provisions related to the protection of traditional or indigenous knowledge (systems, practices, naturally occurring plants, products), and recommends that new methodologies and instruments be developed for this purpose. These should be based on the Convention on Biological Diversity (CBD) and other International Agreements currently available¹⁷.
In this context, trade marks, trade secrets, geographical indications and plant variety protection should also be taken into consideration.
9. ASEAN Member Countries need to develop national legislation, as well as an ASEAN position on the protection of traditional/indigenous knowledge. This position should then be advocated at the international level.
10. ASEAN Countries should develop an inventory and registry of their biological resources and traditional knowledge, taking into account the intellectual property implications of such inventories and registries. There should be a network of information exchange among ASEAN Member Countries for this purpose. The workshop also recommends to further study the various aspects of intellectual property rights in relation to traditional systems of medicine and indigenous knowledge available in each country. This should be done in collaboration with various other organizations working in these areas.

¹⁷ Notably the Convention on International Trade of Endangered Species (CITES), the Declaration of Chiang Mai, the Declaration of Belem and the outcome of the WIPO meeting on intellectual property and genetic resources, Geneva, April 2000.

11. ASEAN Member Countries should develop a collective position on the sovereign rights in genetic resources and traditional knowledge, including traditional resource rights. Efforts should be made for an international agreement on such rights.
12. ASEAN Member Countries should have a collective position for the interpretation and review of TRIPS Article 27.3(b)¹⁸.
13. The patentability of micro-organisms should be confined to genetically engineered micro-organisms only. Naturally occurring and mutated or selected micro-organisms should be excluded from patentability.
14. In respect of the protection of plant varieties, a sui generis system of protection is recommended. Countries are free to adopt a sui generis and/or patent system for the protection of plant varieties.
15. A second¹⁹ ASEAN ad-hoc expert meeting should be set up to discuss in depth issues related to biotechnology, including gene, vector, process and products. Members of the expert group should include technical experts, NGOs and community representatives. The Human Development Report 1999 on the risks of genetic engineering should be taken into account while examining the options in international agreements on biotechnology.

The workgroup further recommends that:

16. ASEAN Member Countries should request WHO to provide technical assistance with regard to the implementation of TRIPS bearing in mind that public health takes precedence over commercial and trade interests.
ASEAN Member Countries should request the WTO, WIPO, UNCTAD and other relevant organizations and NGOs to provide further appropriate assistance in order to help them to be consistent with the TRIPS Agreement and its reviews.
17. The recommendations and the report of this workshop should be sent to the ASEAN Secretariat, relevant ASEAN Ministries, WTO, WHO and WIPO, so that appropriate follow-up actions can commence without delay.

¹⁸ Article 27.3(b) addresses the patentability -or the exclusion from patentability- of plants, animals, micro-organisms and biological processes.

¹⁹ A first expert group is proposed in recommendation 3.

ANNEX A

Workshop Agenda

Day I: Tuesday, 2 May 2000

Opening Ceremony

General background and overview:

- *Background on GATT and WTO* by Mr. M. Kennedy (WTO)
- *Intellectual Property Rights*
by Dr. C. Correa (University of Buenos Aires)
- *WHO's perspective on globalization and access to drugs*
by Dr. G. Velasquez (WHO)

Lunch

General overview of the TRIPS Agreement by Mr. M. Kennedy (WTO)

WIPO's role in relation to the TRIPS Agreement by Mr. S. Bhatti (WIPO)

The TRIPS Agreement with a focus on pharmaceuticals - what will change for developing countries by Dr. C. Correa (University of Buenos Aires)

Discussion (panel)

Implications of the TRIPS Agreement for pharmaceuticals:

- *Pharmaceutical Industry Perspective*
 - by Dr. H.E. Bale (IFPMA)
 - by Drs. K.A.I Selomulya (GP Farmasi)
- *Consumers Perspective*
by Dr. K. Balasubramaniam (Consumers International)

Discussion (panel)

Day II: Wednesday, 3 May 2000

Options and choices in patent legislation: compulsory licensing, parallel import and Bolar provision

by Mr. J. Love (Consumer Project on Technology)

Implications of the TRIPS Agreement on Biotechnology

by Dr. M.D. Nair (Pharmaceutical Industry Consultant)

Traditional medicinal knowledge and Intellectual Property Rights

by Mr. S. Bhatti (WIPO)

Discussion (panel)

Trade secrets:

- by Dr. C. Priapantja (Indonesian IPR Society)
- by Dr. C. Correa (University of Buenos Aires)

Trademarks and pharmaceuticals

by Mr. J. Love (Consumer Project on Technology)

Discussion (panel)

Lunch

Thailand's experience with increasing access to HIV/AIDS drugs under TRIPS

by Ms. Y. Patanawong (FDA, Thailand)

The implications of the WTO TRIPS Agreement for the pharmaceutical industry in Thailand

by Dr. W. S. Janjaroen (Chulalongkorn University, Thailand)

Options and choices in patent legislation: TRIPS compliant but not "TRIPS-plus"

by Dr. C. Correa (University of Buenos Aires)

Discussion (panel)

Day III: Thursday, 4 May 2000

Input from the ASEAN Senior Officials Meeting and the 5th ASEAN Health Ministers Meeting

Working groups to discuss and draft recommendations

- Working Group 1: Biotechnology and Traditional Medicine
- Working Group 2: Compulsory Licensing, Parallel Import and Bolar Provision
- Working Group 3: Trademarks and Trade Secrets

Lunch

Working Groups (cont.)

Presentation and discussion of draft recommendations (plenary)

Adoption of recommendations

ANNEX B

Opening Address by Dr. Achmad Sujudi, Minister of Health, Republic of Indonesia

Distinguished Experts or Facilitators from WHO/HQ, WTO, WIPO, Consumers International and other International Experts
Distinguished WHO Representative to Indonesia and ASEAN Secretariat
Distinguished Delegates of ASEAN member countries,
Distinguished guests, ladies and gentlemen

It is my pleasure to welcome you all today to this ASEAN workshop on the TRIPS Agreement and its impact on pharmaceuticals. I believe that all participants from all ASEAN countries involving various sectors namely health, trade, commerce, industry, legislation and consumers will share information and raise the awareness on these challenges posed by international trade on human health.

I extend sincere thanks to the World Health Organization and the Rockefeller Foundation, for collaborating with us in financially supporting and organizing this workshop. I would also like to thank the delegates from ASEAN member countries, UN Agencies, international NGOs and other institutions for joining and facilitating the workshop.

Ladies and gentlemen,

Globalization and trade liberalization is an inevitable condition that will enter every country in this world. The liberalization of trade in health is not extremely recognized by the people in the health sector, although many people have discussed the matter, not much action has been taken. To prepare for globalization one country cannot work alone but has to work together with other countries. For this reason, the 5th ASEAN Health Ministerial Meeting which was held last week in Yogyakarta has agreed upon the importance of strengthening the collaboration among ASEAN countries with regards to the health implication of trade liberalization and international trade agreement. I, therefore convince this ASEAN workshop will be very useful on such matter for all parties concerned, at both inter and intra ASEAN countries.

The TRIPS agreement requires patent protection to be available for any invention in any field of technology in all WTO member countries. This becomes very important, particularly it is also aimed at pharmaceuticals, which in many countries it had previously -totally or partly- been excluded from patent protection. Due to the TRIPS Agreement, however, pharmaceuticals are now subject to the globally harmonized system in all member countries.

Distinguished guests, ladies and gentlemen,

Although social benefits may arise from patent protection through the discovery of new drugs, the TRIPS standards may be a challenge to many developing and least developed countries. Studies on the TRIPS agreement indicate that the globally harmonized high standards of TRIPS patent system may have great impact on the health sector and may affect negatively in the access of drugs in the developing and the least developed countries.

The availability and accessibility of drugs at the basic health service level is an essential component of the national health policy in many countries and will remain one of the priorities in their national health policy in the future. Concerns and apprehensions on the implications of the TRIPS agreement on health sector have already been expressed at the World Health Assembly and in other international forum on health. We agree with the message from the World Health Assembly that public health interest is of paramount consideration. Although most of essential drugs have already been off-patent, the access to essential drugs, particularly for those new drugs potentially to be essential must be safe guarded in the implementation of the trade agreements. We consider that in the negotiations of multilateral trade agreements and their implementation, public health concerns must be heard and weighed appropriately.

Ladies and gentlemen,

In order to comply with the TRIPS agreement and other agreements under the WTO convention, most ASEAN countries will have to revise their national legislation related to intellectual property rights. Depending on their level of development, countries have until 2000 or 2005 to amend their legislation. In this regard, understanding on its implication on the health sector is urgently needed and the options to safeguard public health interests must be secured.

The TRIPS agreement contains complex and controversial issues. Therefore, the highest promotion of the understanding of the Agreement and of its health implications among participants is essential. Experts from around the world, who have the extensive experience on patent issues, will facilitate on the various issues of intellectual property rights, particularly related to pharmaceutical sector. The interaction among participants and experts is expected to improve the understanding on the Agreement and the capacity and knowledge to effectively deal with a number of health related issues included in the Agreement. This will assist participants to identify some options to safeguard health interests in the implementation of the Agreement and in future negotiations.

Ladies and gentlemen,

Based on guiding principle, vision and mission, policies, directions and strategies of the new framework for ASEAN cooperation in health development as well as ASEAN spirit, your valuable inputs would be able to address these challenging issues and to establish an appropriate mechanism for minimizing the negative impact and maximizing the potential gains. I wish you all success in the process, output and follow-up of this workshop. I also wish you fruitful deliberations and a pleasant stay in Jakarta.

In full hopes and with the blessing of God Almighty on us all, I hereby declare the ASEAN workshop on the TRIPS agreement and its impact on pharmaceuticals officially opened.

Thank you.

**Remarks from Dr. Suthad Setboonsarng,
Deputy Secretary General of the Association of South-East Asian Nations
(ASEAN)**

Read by Mr Yong Chanthalangsy, ASEAN Secretariat

H.E. Dr. Achmad Sujudi, the Minister of Health of Indonesia
Dr. Georg Petersen, WHO Representative to Indonesia
Distinguished guests,
Ladies and Gentlemen,

It is indeed a great pleasure for me to address the opening of the ASEAN Workshop on TRIPS Agreement and its impact on Pharmaceuticals. Allow me to congratulate Directorate General of Drug and Food Control of Indonesia for convening this meeting at this very important juncture.

Excellencies,
Ladies and Gentlemen,

The Sixth ASEAN Summit, held in December 1998 in Ha Noi, emphasized the theme: "Unity and Cooperation for an ASEAN of Peace, Stability and Equitable Development". The ASEAN Leaders declared among others: *we shall, together, make sure that our people are assured of adequate medical care and access to essential medicines; and we shall endeavor to narrow the gap in the levels of development among the Member Countries and reduce poverty and socio-economic disparities through greater sub- regional cooperation.*

The Ha Noi Plan of Action (HPA) adopted by the Sixth ASEAN Summit stated among others that *ASEAN has to ensure adequate and effective protection, including legislation, administration and enforcement, of intellectual property rights in the region based on the principles of the Most Favored Nation (MFN) treatment, national treatment and transparency as set out in the TRIPS Agreement.*

In recognizing that economic progress does not translate into gains for the poor, vulnerable and infirm nor can guarantee access to basic needs such as health care, the ASEAN heads of government, earlier at their Second Informal Summit held in December 1997, spelled out their vision a dynamic, economically integrated by 2020 which is also a socially cohesive and caring ASEAN where hunger, malnutrition, deprivation and poverty are no longer basic problems.

When the TRIPS Agreement is looked at from this perspective, one should not forget that the availability of, and accessibility to drugs at affordable prices for people is essential in ASEAN and will remain one of the priorities in ASEAN's health policy in the future. Therefore, in bringing the legislation in line with TRIPS Agreement, sufficient attention must be given to ensure the health of the people because the TRIPS Agreement may also have impact on accessibility to medicines.

ASEAN member countries are in the process of implementing the activities of the Ha Noi Plan of Action (HPA) related to intellectual property rights. One of the activities

of the HPA is to ensure that intellectual property legislation of ASEAN member countries conform to the TRIPS Agreement of the WTO through the review and introduction of TRIPS-consistent intellectual property laws.

As things stand now, ASEAN member countries which are WTO members have amended their existing and introduced new intellectual property legislation to comply with the TRIPS Agreement and those that are not members of the WTO, have prepared their intellectual property laws and regulations based on the WIPO model law. Thus, intellectual property laws, especially the patents law of most of the ASEAN member countries are and will be TRIPS compliant.

The availability of new technology in the health and pharmaceutical industries present both challenges and opportunities for the region. ASEAN has to quickly work together address these challenges and take advantage of the opportunity.

The rapid integration of the international market also requires ASEAN to work closer in international for a to safeguard its interests. Joint positions should be forged, where possible. This is important not only in the WTO but also in other for a where international standards or regulations are being established.

Distinguished guests,
Ladies and Gentlemen,

Another important issue is the need for assistance from developed countries and relevant international organizations in relation to the implementation of the TRIPS Agreement, and human resource development so that ASEAN can implement the TRIPS Agreement efficiently and have the necessary skills to negotiate with their counterparts.

Within ASEAN, the ASEAN Working Group on Intellectual Property Cooperation (WGIPC) was established in 1996 under the purview of the ASEAN Senior Economic Officials (SEOM) to implement the activities of the Program of Action and the HPA and to serve as a forum for regular consultations and to monitor regional and international developments in intellectual property.

One of the activities of the Working Group is to explore the possibility of setting up ASEAN common trademark and patent systems. As an initial step towards the eventual establishment of such systems, ASEAN member countries agreed to set up ASEAN Regional Trademark and Patent Filing Systems. The Experts Groups on Trademarks and Patents established by the WGIPC are currently working towards the finalization of the filing systems.

A Pharmaceutical Product Working Group (PWG) was also set up to address harmonization of pharmaceutical regulations among ASEAN Member Countries. The objective of the PWG is to develop harmonization scheme of pharmaceutical elimination of technical barriers to trade posed by the regulations, without compromising on drug quality, efficacy and safety.

In its work, the PWG has taken into account the current regulations in ASEAN Member Countries, activities of the WHO and the International Conference on

Harmonization (ICH). The following areas were initially identified by the PWG for harmonization under respective Ad Hoc Committees: Pharmaceuticals (Quality); Pharmacological and Toxicological Data (Safety); Clinical Data; and Administrative Data and Product Information.

Ladies and Gentlemen,

The 5th ASEAN Health Ministers' Meeting, held from 28 to 29 April 2000 in Yogyakarta, agreed upon, among other the missions: to ensure availability and accessibility of safe, affordable, efficacious and quality health related products and services to meet the needs of ASEAN; to strengthen the national and collective ASEAN capacity on the issues of health implications from globalization and trade liberalization; and to enhance the competitiveness of ASEAN health related industries taking into account the strength and diversity among ASEAN Member Countries.

Among other actions in the adopted plan of action to address the impact of globalization/trade liberalization on the health sector, the Ministries agreed to: harmonize product registration requirements and standards for health products; develop strategies to strengthen ASEAN's capacity and competitiveness on health related products (pharmaceuticals, including traditional medicine and biomedical products, including vaccines) and health services; develop a system to monitor the health of vulnerable groups in ASEAN countries; to strengthen collaboration on health research and development with a focus on pharmaceuticals, including traditional medicines and biomedical products, including vaccines; and intensify development of human resources for health in the area of globalization and trade liberalization.

May, I, finally, express my sincere thanks to the World Health Organization (WHO) for its technical assistance given to the ASEAN. The relationship between the WHO and ASEAN has been a very fruitful one thanks to the implementation of the Memorandum of Understanding between the two organizations.

Good health is the most virtuous fortune. It will not happen by itself. ASEAN has to work harder and closer to accomplish a Healthy ASEAN by 2020 where economic progress has a human face, as called for the ASEAN Vision 2020.

I wish this meeting all the success.

Thank you

**Remarks by Dr. Georg Petersen,
WHO Representative to Indonesia**

His Excellency Dr Achmad Sujudi,
His Excellency Mr Yong Chanthalangsy,
Distinguished Participants, Ladies and Gentlemen,

I am pleased to be with you here today at the start of this important workshop.

At the beginning of the 21st century, we are faced with persistent inequalities in health status, *between as well as within* countries. This is a problem affecting disadvantaged populations in developed *and* developing countries alike. It highlights a worldwide need for health policies that focus on disadvantaged populations.

As you know, availability and accessibility of drugs in health facilities is crucial to the successful implementation of the national health policies, and will remain so in future.

A country's health service cannot respond to people's needs unless it guarantees that people have access to essential drugs of assured quality. Access to drugs represents a very important measure of the quality of health services, and is one of the key indicators of equity and social justice.

Access to essential drugs is a key priority for the World Health Organization. Our longstanding aim is to help ensure equity of access to essential drugs of good quality, and to promote their rational use. This is simply part of the fundamental right to health care, and our work in WHO is built on this premise.

During the last two decades, much has been achieved in expanding access to drugs and vaccines; the number of people having access to essential drugs has nearly doubled, from 2 billion in 1977 to nearly 4 billion in 1997.

Yet, we still have a long way to go. Today, one-third of the world's population still lacks access to the drugs it needs. In the poorest parts of Africa and Asia, over 50% of the population does not have access to the most vital medicines.

Many factors determine the complex question of access; these include adequate financing, reliable supply systems and affordable prices. While all these factors need to be in place, we should avoid the pitfall of simply shifting the blame, of making a shortfall in one factor the justification for the poor performance of another.

We are all aware of the formidable challenges faced by countries in the pursuit of their health development goals. Nowadays, the health sector is facing not only its own systemic problems, but also challenges imposed by the external environment. These challenges have assumed a new, complex and bigger dimension with globalization and international trade liberalization.

In the context of trade liberalization, health concerns and apprehensions have mainly focussed on the implications of the TRIPS Agreement on the pharmaceutical sector.

In a very diverse world, the TRIPS Agreement sets *uniform, high* standards for the protection of Intellectual Property Rights, including for patenting of pharmaceuticals.

These high standards, some believe, will encourage research and the development of new medicines.

Others argue that these standards will increase prices, and thereby reduce access to drugs, especially of the poor.

Let me be clear: we need both.

New medicines are needed to combat old and re-emerging diseases, such as malaria and TB, and to deal with newer diseases such as AIDS.

But new medicines are of little help if those who need them most cannot afford them; if they widen the health gap, instead of bridging it.

We will need to find a balance between pressing public health needs, and legitimate private sector interests.

We will have to look for new solutions, and in doing so we will have to be honest and creative.

We will have to work together, as partners.

We will have to find new ways to link supply to demand *and* to need.

Together, we have to succeed where the market has failed.

For the market has failed.

In developing countries, an estimated 8 million children under 5 years old died last year. They died of diseases for which we have the cures – but their parents or their countries could not afford them. Eight million children per year – that means 21,900 children *today*.

Similarly, priority setting for research and development in the pharmaceutical market is imperfect. Research priorities may match (economic) demand, but often they do not match medical need.

We cannot stress it too much: *essential drugs are not simple commodities* like any other.

But medicines are traded. They are produced, marketed and sold across the globe – benefiting some, but failing to reach too many others. So the rules regulating this trade are crucial.

In our globalized world, the rules governing trade are laid down in a number of international agreements: the WTO Agreements. One of them is the TRIPS Agreement, which this workshop will examine in detail.

The TRIPS and other WTO Agreements provide for a number of safeguards, meant to protect the public interest and public health. We should make sure that these safeguards are fully understood and used properly.

We should study our options under those safeguards carefully, and make wise decisions, which protect health, while not hampering trade unnecessarily.

For the 191 member countries of the WHO have clearly stated, in the World Health Assembly, almost exactly one year ago, that, at the interface of health and trade, public health interests are paramount.

Ladies and gentlemen,

This is the 2nd time in 2 weeks that delegates from the ASEAN countries meet in Indonesia to discuss about globalization in relation to health. This, I think, is significant.

It shows -I hope- that health is becoming more important, or rather, that there is an increasing awareness of the link between health and development. We have known for years that poverty causes ill health, but nowadays it is becoming increasingly clear that ill health also keeps people in poverty.

Health is not a luxury, and health care is not a peripheral issue; health is part and parcel of the development process and of poverty eradication.

We in the health sector have known since a long time that diseases do not stop at borders. Recently, here in the ASEAN region we have learnt, much to our cost, that in our global village, financial and economic crises can behave like contagious diseases, spreading rapidly from one country to the next. This has taught us that, while globalization has the potential to bring many benefits, it also has potential dangers. And like in disease control, we will have to work together to minimize the risks and to maximize the benefits.

Therefore, if we want to integrate health and development, in order to improve both and to seriously reduce the problems of poverty, we will have to look beyond our borders.

Beyond our national borders, and beyond the borders of our -familiar- health sector.

I am very pleased to see that this workshop brings together people from different countries and different sectors. People concerned about health and people concerned about justice, trade and development.

I think this can be a very powerful forum for launching ideas and identifying options that will help us to move forward in our common aim to ensure that the people in this region can obtain the medicines they need, as an important step to improve health and reduce poverty.

I am therefore looking forward to the outcome of this workshop, and I wish you success with your efforts to address this important topic.

Thank you.

ANNEX C

Selected articles of the TRIPS Agreement

PART I - GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1: Nature and Scope of Obligations

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.
2.
3.

Article 6: Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

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 socio-economic 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.

PART II - STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

Section 5: Patents

Article 27: Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, 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.
2. 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.
3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) 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.

Article 28: Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:
 - (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing⁶ for these purposes that product;
 - (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.
2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

⁵ For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

⁶ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 30: Exceptions to Rights Conferred

Members may provide exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties.

Article 31: Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) The scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) Such use shall be non-exclusive;
- (e) Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) Authorization of such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

⁷ "Other use" refers to use other than that allowed under Article 30.

- (j) Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
- (l) Where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
 - (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
 - (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 34: Process Patents: Burden of Proof

1. For the purpose of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, 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:
 - (a) if the product obtained by the patented process is new;
 - (b) if there is 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.
2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.
3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Section 7: Protection Of Undisclosed Information

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 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 practices¹⁰ so long as such information:
 - (a) in 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.

¹⁰ For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes 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.

ANNEX D**List of Participants****GOVERNMENT DELEGATES:**

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