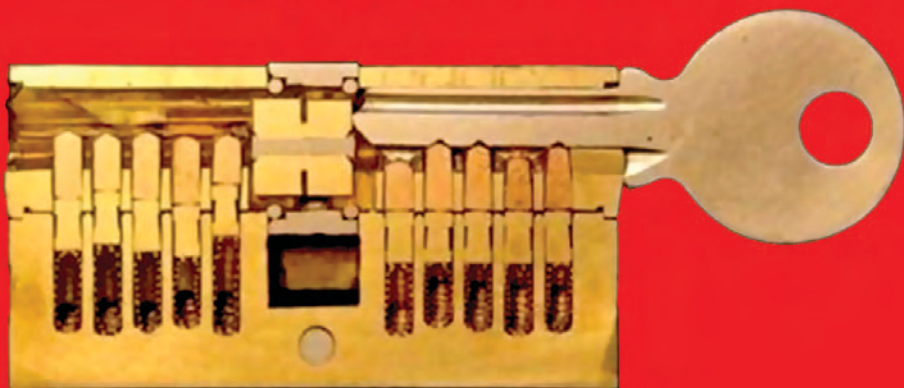


# **The WHO “Red Book”** on Access to Medicines and Intellectual Property – 20 Years Later

Germán Velásquez  
and Pascale Boulet



# **THE WHO “RED BOOK” ON ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY – 20 YEARS LATER**

**Germán Velásquez  
Pascale Boulet**



**SOUTH  
CENTRE**

***THE WHO “RED BOOK” ON ACCESS TO MEDICINES AND INTELLECTUAL  
PROPERTY – 20 YEARS LATER***

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## ABBREVIATIONS AND ACRONYMS

ACP	African, Caribbean and Pacific Group (Lomé Convention)
ASEAN	Association of South-East Asian Nations
DAP	Action Programme on Essential Drugs
DC	Developing countries
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GSP	Generalized System of Preferences
IMF	International Monetary Fund
IPR	Intellectual property right
ISO	International Standards Organization
LDC	Least-developed countries
MERCOSUR	Southern Common Market
MFA	Multifibre Arrangement (on international trade in textiles)
MFN	Most-favoured-nation
NAFTA	North American Free Trade Agreement
R&D	Research and development
TBT	Agreement on Technical Barriers to Trade
TPRM	Trade Policy Review Mechanism
TRIMs	Trade-Related Investment Measures
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
UPOV	International Union for the Protection of New Plant Varieties
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization



## PREFACE

The publication in 1998 by WHO Essential Drugs Department of the document “Globalization and Access to Drugs: implications of the WTO/TRIPS Agreement” marked a point in time in the movement to ensure access to essential medicines for all. It had been drafted to implement a 1996 World Health Assembly resolution on the “Revised Drug Strategy” that constituted the first mandate given by countries to the World Health Organization (WHO) to work on intellectual property in relation to health. But the publication, often referred to as ‘the WHO red/blue book’, ended up being much more than that. It constituted a document which marked the beginning of an international policy process to address the issue of innovation and access to essential medicines.

Before the creation of the World Trade Organization (WTO) and the TRIPS (trade-related aspects of intellectual property rights) Agreement, many developing countries did not grant patents on pharmaceutical products, others only granted patents on pharmaceutical processes and patent terms varied considerably among countries, e.g. 10 years in the Andean Community. The absence of patent protection created favourable conditions for the development of a generic industry in several countries, such as India, Brazil, China, Argentina or Egypt, similarly to what had happened in some European countries and Japan before pharmaceutical patent protection was passed into law. Therefore, lack of pharmaceutical patent protection contributed both to economic development and access to affordable medicines in countries where pharmaceutical expenses were mostly paid out-of-pocket.

The adoption of the TRIPS Agreement within the auspices of the World Trade Organization radically changed this situation by imposing all WTO Members to make 20-year patents available in all fields of technology. Medicines were now subject to the same intellectual property rules than any other industry. At the time, trade officials had little interactions with health officials leaving policy makers in the dark – unaware of the collateral impact of the harmonization of intellectual property standards created by the TRIPS Agreement.

The WHO publication, three years after the entry into force of the WTO and the TRIPS Agreement threw a stone into the water: for the first time, WHO was alerting its Member States about the potential negative consequences of a trade agreement and how best to implement it to protect access to essential medicines. The audience was significant: the document was to be sent to all Ministries of Health, translated to sixth languages.

This triggered a series of reactions, never seen before, from the pharmaceutical industry, the US Government and the World Trade Organization, reproaching WHO to step out of its role. This publication discloses how the WHO ‘red book’ was turned to the ‘blue book’: “Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement”. The strength of the reactions highlights the position of the US Government, the WTO and the pharmaceutical industry, which, at the time, were insisting on a strict interpretation of the TRIPS Agreement, in line with the US standards of intellectual property protection.

In parallel, the HIV/AIDS crisis dramatically revealed that patents were used by pharmaceutical companies not only to recoup R&D investments but also to maximize profits, independently of what people and governments can afford to pay. People living with HIV/AIDS in developing countries were dying because they could not afford the newly life-saving antiretrovirals priced between USD10,000 and USD12,000 a year. The court case brought in by the pharmaceutical industry against South Africa was a case in point: governments were pushed to implement the TRIPS Agreement as expected by patent holders without much flexibility. The ethical nature of the issue led to such a massive mobilization of many different stakeholders from patients, advocacy organizations to medical communities, academia, international procurement organizations and non-governmental organizations that the pharmaceutical industry dropped the case.

The primacy of public health over trade interest was then officially acknowledged in the 2001 WTO Doha Declaration. The Declaration, endorsed by all WTO Member States, confirmed the flexibilities enshrined in TRIPS, e.g. the right of each country to “take measures to protect public health, and, in particular, to promote access

to medicines for all”. The Declaration confirmed countries’ “right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted”. Since then, most countries have amended their patent laws to include the TRIPS flexibilities and an increasing number of countries have used them to protect access to essential medicines. However, these measures are still perceived as not favourable to business investments and are not used very often by governments despite being enshrined in national and international law. In parallel, pharmaceutical companies started to reduce their monopolistic rights through license agreements and patent pooling in the field of HIV/AIDS; however, too many countries are often excluded from agreements and pooling – left on their own to find other solutions.

Today, an increasing number of new medicines are protected by patents in the developing world and remain priced out of reach of patients and governments, as illustrated by cancer drugs or the new very effective drug against hepatitis C priced at USD1000/pill in the US. The high prices escalation of new patented medicines is already leading to unjustifiable medical access restrictions even in developed countries. Can licensing be an option for other types of public health challenges beyond HIV/AIDS and in such a way that addresses all needs? What types of incentives would be needed to foster further collaborations?

This points to another limitation of the patent system which has become obvious over the past 15 years: even though patents remain at the centre of pharmaceutical innovation, they have not been designed and cannot drive innovation in areas where profits are uncertain, such as neglected diseases. Of the 1,556 new drugs approved between 1975 and 2004, only 21 (1.3 per cent) were specifically developed for tropical diseases and tuberculosis, even though these diseases account for 11.4 per cent of the global disease burden. Public private partnerships flourished over the past 15 years to compensate for this public policy and market failure, but cannot constitute the solution to a systemic problem. The Global Strategy and Plan of Action on public health, innovation and intellectual property, still on-going under the auspices of the WHO, was adopted to design new mechanisms that drive innovations of public health importance and ensure affordable access to the resulting products.

But this 10-year process needs to be boosted. Other emerging infectious diseases, such as Ebola, and antimicrobial resistance are reminding us that the failure of the patent system to incentivize innovation is not limited to neglected populations in remote areas but is a global public health issue.

If patents remain the only incentives, research will continue to go only into diseases with high potential return on investment. Governments need to be in the driving seat of essential public health research, not pharmaceutical companies, to finance new incentives and models which also secure access down the line. If research of public health importance is financed principally through public funding, essential products can be made available at costs plus a small margin, as new models such as Drugs for Neglected Disease Initiative (DNDi) have demonstrated.

The reactions to the WHO red book shed some light on the cynicism of the debate at the time. As opportunities arise to discuss a new public-health driven medical innovation framework under the auspices of the WHO, it is hoped that countries will come to the negotiation table with the highest ambition to build a new and sustainable research environment that will benefit all.

Bernard Pécoul  
DNDi Executive Director

## **PART I**

# **GLOBALIZATION AND ACCESS TO DRUGS: IMPLICATIONS OF THE WTO/TRIPS AGREEMENT**

### **EXECUTIVE SUMMARY**

The aim of this document is to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs, and especially about the WTO agreement on intellectual property (TRIPS Agreement) that may have repercussions in the pharmaceutical field. Therefore, the paper is meant to be non-technical in nature and does not deal with all aspects of patents nor of the TRIPS Agreement, but examines the Agreement only from the perspective of public health and access to drugs. The first part gives an introduction to the international trade system from the GATT to the WTO. The second part analyses the section on patents of the TRIPS Agreement in relation to access to essential drugs.

### **The Uruguay Round and the TRIPS Agreement**

In 1994, the Uruguay Round negotiations culminated in the signature of an agreement instituting the World Trade Organization (WTO). The Organization came into being on 1 January 1995 and had 132 Members in October 1997. In deciding to become Members of WTO, States also undertake to abide by its rules. A certain number of treaties on trade in goods and services are annexed to the WTO convention and are therefore binding on all Members. Among these "multilateral" agreements, the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) will probably have the greatest impact on the pharmaceutical sector.

The TRIPS Agreement establishes minimum standards in the field of intellectual property. All Member States have to comply with these standards by modifying, where necessary, their national regulations to accord with the rules of the Agreement. The main change

with respect to pharmaceuticals, compared to the pre-existing multilateral conventions, is the obligation to grant patent protection to pharmaceutical product and process inventions.

### **The question of drug patents**

Previously, the GATT did not address the issue of the level of protection that should be accorded to intellectual property, and Member States had adopted various approaches towards drug patents. While some used to grant patents for pharmaceutical product and process inventions, some others allowed patent protection only for process inventions, thus not preventing local companies from developing different manufacturing processes for drugs that were not patent protected as a product. Other countries did not grant any form of protection for inventions in the pharmaceutical sector. Moreover, the term of protection conferred by a patent varied greatly between countries.

Under the TRIPS Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. As soon as the Agreement applies in a Member State, the patent holder should therefore have the legal means to defend against copies of patented drugs. If a country fails to bring its legislation in conformity with the TRIPS Agreement as such, it can be the subject of a complaint under the WTO dispute settlement system, and if, after an adverse ruling against it, it still fails to comply, it then may incur trade sanctions authorized by the WTO.

### **When must the Agreement's rules be applied?**

The TRIPS Agreement allows developing countries a general transition period of five years (up to 2000) to amend their patent legislation in accordance with these new rules, whereas a term of ten years (up to 2005) is available for developing countries which have not yet provided product patent protection for pharmaceuticals, in order to make that change. Least-developed countries are given 11 years, with a possible extension, to harmonize their regulations with the new international obligations. For those countries which did not provide product patent protection for pharmaceuticals already as of January 1995, the

Agreement will apply only to new drugs for which a patent application has been made after the entry into force of the WTO Agreement. These applications for pharmaceutical product patents are stored until modified national patent laws are adopted. As of the end of the transition period, the examination of the application has to begin, according to the conditions laid down by the Agreement. If the application is accepted, a patent will be granted for the remainder of the 20-year patent term counted from the date of filing the application. In case the invention obtains a marketing authorization before the entry into force of the new patent regulations, and if another Member State has already allowed such a patent protection for the same invention, the invention's owner may be given exclusive marketing rights for up to five years until the decision to grant or reject the patent application is made.

### **Public health needs and drug patents**

The Agreement requires all WTO Member States to grant patents for pharmaceutical products or process inventions for a minimum of 20 years. Although social benefits may arise from patent protection through the discovery of new drugs, the TRIPS standards derive from those of industrialized countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement.

The Agreement leaves Member States a certain amount of freedom in modifying their regulations. The terms invention and discovery are not defined in the Agreement, yet how they are defined could have important implications in the biotechnological field. The Agreement says that Member States may provide limited exceptions to the patent holder's exclusive rights in their laws. National public authorities may be allowed, within the conditions laid down in the Agreement, to issue compulsory licences against the patent owner's will when justified by the public interest. The Agreement does not prohibit parallel imports. These restore price competition for patented products by allowing the importation (without the holder's consent) of identical patented products which have been manufactured for a lower price in another country.

Member States must be aware of these possibilities when they amend their legislation. Each country's strategy in regard to globalization of drug production and distribution will have to be incorporated into its national pharmaceutical policy, a component of national health policy. It is essential that all involved in this sector should understand what is at stake and play an active part in the reforms of intellectual property regulations now under way.

Therefore, health providers and managers should keep in mind that: The TRIPS Agreement establishes minimum standards in the field of intellectual property. All WTO Members have to comply with these standards by modifying their national regulations. Public health concerns should be highly considered when implementing the TRIPS Agreement.

## INTRODUCTION

The trade agreements emerging from the \*Uruguay Round and globalization<sup>1</sup>\* are going to have a significant impact on the global market for goods and services. The production and marketing of drugs and health services could be affected to varying degrees.

The Uruguay Round served as a framework for the negotiation of a global agreement on intellectual property rights\* (Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS\*). This Agreement is the part of the Final Act of the Uruguay Round that could have the greatest repercussions on the production of and access to drugs, especially in developing countries.

In this context, the Forty-Ninth World Health Assembly in May 1996 adopted a resolution requesting the Director-General to *"report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs"*.

The Action Programme on Essential Drugs has therefore drawn up a plan of action with the following objectives:

To identify issues in the WTO Agreements relating to access to essential drugs and pharmaceutical policies, and to inform Member States about them.

To study the implications of globalization for innovation, and for the development, production, marketing and pricing of drugs, so as to identify the possible effects of the TRIPS Agreement and other trade agreements on access to essential drugs.

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<sup>1</sup> **Note:** The words marked with an asterisk\* are explained in the section "Definitions and terminology".

To inform Member States about the need to take steps to protect public health in parallel with the implementation of the new trade agreements.

This document is an initial response to the request by the World Health Assembly.

After a brief overview of the development of international trade, it gives pointers on how to read the TRIPS Agreement from the perspective of access to drugs. It also seeks to identify how much freedom is left for Member States to regulate the protection of intellectual property, and how they can enact legislation that both conforms with the Agreement and is consistent with health policy.

# **1. BRIEF HISTORICAL BACKGROUND TO THE INTERNATIONAL TRADING SYSTEM**

## **1.1 The Simultaneous Creation of the GATT, the IMF and the World Bank**

The GATT\* (General Agreement on Tariffs and Trade) came into being after the Second World War, at a time when new international organizations were being established to build an integrated world economic system. Three major issues had to be addressed for the global economy to emerge from the war and its previous disarray successfully: exchange rates, reconstruction and the organization of international trade in goods. In 1944, responding to each of these questions, the allied nations envisaged the establishment of three new international organizations.

The IMF (International Monetary Fund) and the World Bank were established by the Bretton Woods Agreements of July 1944, which were signed by 44 allied nations. The IMF was set up to manage the international monetary system. The management of exchange rates would henceforth be based on a new general principle: the fixed parity of currencies and cooperation between nations. It was implicit that States would no longer be able to freely manipulate the international exchange rate of their currency and all Member States were specifically prohibited from making competitive devaluations unjustified by their economic situation.

The World Bank, or as it was named at the time, the International Bank for Reconstruction and Development (IBRD), was initially intended to help the war-devastated European economies to finance production projects. Very soon, however, European reconstruction moved out of its sphere of competence and development financing became its main function.

In parallel with the Bretton Woods Conference, the idea of returning to an international trading system based on free trade appeared. This desire was manifested, on the one hand, in the United

Nations, by a project for an International Trade Organization, and on the other hand, by the proposal for an international conference for the multilateral reduction of barriers to international trade. The two things led respectively to the "Charter Instituting an International Trade Organization", adopted in March 1948 at the Havana Conference, and a General Agreement on Tariffs and Trade (GATT), which resulted from negotiations between 23 nations that took place from April to December 1947 in Geneva.

In practice, the International Trade Organization did not come into being in 1948 as the country that initiated the process did not ratify it. However, the agreement concluded in Geneva – resulting from the first "Round" of multilateral trade negotiations – gradually became institutionalized so that it became more than just a treaty; the GATT (also referred to as the General Agreement) went on to become, de facto, the main institutional framework for matters of international trade.

## **1.2 The Objectives, Nature and Functioning of the GATT**

### ***Objectives***

The objectives of the GATT are clearly stated: they are to conclude "*reciprocal and mutually advantageous arrangements*" with a view to reducing customs duties and other barriers to trade and eliminating all discrimination in international trade.

### ***Nature***

Since the GATT was not strictly speaking an international organization, it did not have Members but "*contracting parties*", that is, nations that adhered to the General Agreement. To become a contracting party, a State had to submit its candidature and negotiate concessions relating to customs duties and access to markets with the signatories of the General Agreement. If successful, these negotiations were concluded with a vote by the contracting parties granting this status. The GATT was thus a group of States that had different obligations and rights depending on the degree to which they had adhered to the General Agreement.

### ***Obligations of the contracting parties***

Under the terms of the treaty, each country had to concede most-favoured-nation\* treatment to all other parties. Each signatory State also granted tariff concessions to the other parties, that is, they limited the customs duties imposed on the importation of foreign goods.

Signatory States were obliged not to take certain measures that would result in obstacles to international trade. In practice, this type of obligation amounted to a code of good conduct in trade, which Member States undertook to adhere to when they joined the General Agreement. This was principally designed to prevent discrimination between national products and imported products, to regulate the use of anti-dumping measures, to prohibit quantitative restrictions to trade, and to regulate subsidies.

Depending on the specific situation and particular characteristics of each State, some exceptions to these obligations were agreed. Certain sectors, namely services, agriculture and textiles, were largely excluded from the scope of the General Agreement. Some States also enjoyed the benefit of special rules. Since the signature of the General Agreement in 1947, developing countries had frequently pointed out that the general principles of the GATT worked against them. But their grievances were not acknowledged until the first United Nations Conference on Trade and Development (UNCTAD) in 1964, when the principle of differential treatment was invoked. UNCTAD has since become a subsidiary body of the United Nations General Assembly, well known for defending the economic interests of developing countries.

### ***The "Rounds"***

As the essential objective of the GATT was to promote continuing liberalization of international trade, it was necessary to institute a procedure to enable the contracting parties to negotiate in this area. Therefore, rounds of multilateral trade negotiations (MTN) were instigated, during which the tariff concessions accorded by one party to another were generalized to all parties by means of the most-favoured-nation clause.

Overall, the earlier rounds of negotiations from 1947 to 1961 led to very substantial reductions in customs duties between the countries concerned.

The Kennedy Round, which lasted from 1964 to 1967, led to a further decrease in customs duties on a basis of a formula, and to the negotiation of an agreement on anti-dumping practices. But the contracting parties were not able to agree on the idea of a linear reduction in customs duties or on the problem of non-tariff\* barriers which also constituted barriers to trade.

It was at the Tokyo Round (1973-1979) that most of the agreements on non-tariff barriers were eventually signed: technical barriers to trade, government procurement, subsidies, customs valuation, import licences and anti-dumping practices.

### **1.3 The Uruguay Round and the Creation of the WTO: The New Global Economic Environment**

At the beginning of the 1980s, it became apparent that the General Agreement was no longer so well adapted to the realities of trade as it had been in the 1950s. The complexity and volume of world trade were now very different from what they had been 40 years earlier. As the globalization of the economy progressed, international investments saw an unprecedented growth, and trade in services – not covered by the GATT rules – began to be a major interest for more and more countries, and was closely bound up with the increase in global trade in goods.

The GATT rules were also deemed inadequate in other ways: in the agriculture sector, for example, where the loopholes in the multilateral system were widely exploited and where attempts at liberalization were essentially in vain – and in the field of textiles and clothing, where an exception to the normal GATT areas of influence had been negotiated in the form of the Multifibre Arrangement (MFA). The institutional structure of the GATT and its system for the settlement of disputes were also becoming sources of concern. All these factors were enough to convince GATT Members that a renewed effort should be made to strengthen and enlarge the multilateral system.

### ***Long and difficult negotiations***

The seeds of the Uruguay Round were sown in November 1982 at a ministerial meeting of those GATT Members involved, held in Geneva. But it took four years of effort during which an attempt was made to explore and elucidate the issues at stake and gradually work towards a consensus, before the ministers, meeting again in September 1986 at Punta Del Este (Uruguay), decided to launch the Uruguay Round. They adopted a programme of negotiations encompassing practically all the outstanding problems of trade policy, including the extension of the trading system into several new fields, in particular services and intellectual property rights. These were the most wide-ranging trade negotiations ever undertaken, and the Ministers gave themselves four years in which to complete them.

At the ministerial meeting in Brussels in December 1990, disagreement on the nature of the commitments to be made to reform trade in agricultural products led to the decision to extend the negotiations. In December 1991, a complete draft of the Final Act containing the text of the legal instruments elaborated for all the issues raised at Punta del Este, with the exception of measures relating to access to markets, was presented in Geneva. During the next two years, negotiations oscillated continually between the apparent inevitability of failure and anticipation of imminent success. Several deadlines were set and then not met. Services, access to markets, anti-dumping rules and the proposal to establish the WTO joined agricultural trade as the principal sources of conflict. The differences of opinion between the United States of America and the European Community became the critical issue on which the long desired success of the negotiations came to depend.

In the end, the Final Act embodying the results of the multilateral trade negotiations of the Uruguay Round was signed on 15 April 1994 at Marrakech, Morocco, by Ministers representing most of the 125 governments that had taken part.

Today, the WTO has 132 Member States. Twenty-nine countries<sup>1</sup> have filed applications to join, and talks are under way with the working groups that deal with accessions.

Previous rounds of negotiations had mainly been confined to discussions of how to eliminate trade barriers at the frontiers between countries, making for an optimal expansion of international trade and better use of the world's wealth. The Uruguay Round was much more ambitious, and was more oriented towards harmonization of national trade policies, particularly in regard to the protection of intellectual property, thereby enlarging the domain of international trade and the jurisdiction of the international organizations active in this field.

***The results of the Uruguay Round: strengthening and enlargement of the multilateral trade system***

**Strengthening:** with the creation of the WTO, a fully-fledged international organization with international legal status, its own governing bodies, and rights and obligations came into being.

**Enlargement:** this resulted from the introduction of new areas covered by multilateral trade agreements such as services (GATS\*) and intellectual property, as well as a more extensive application in the area of agriculture and textiles.

The result of the Uruguay Round is a framework convention, the Agreement establishing the WTO, under which come a variety of multilateral and plurilateral sectoral conventions. Signature of the WTO convention means adhering to all the multilateral conventions (multilateral agreements on trade in goods, General Agreement on Trade in Services, and Agreement on Trade-Related Aspects of Intellectual Property Rights), whereas adhesion to the plurilateral conventions is optional (aeronautics and government procurement).

A certain number of simple basic principles run through all the instruments, which together make up the multilateral trading system.

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<sup>1</sup> 32 countries in August 1998.

### ***Trade without discrimination***

In accordance with the well-known "most-favoured-nation" clause (MFN), Members are bound to grant other Members' products treatment that is no less favourable than the treatment they accord to the products of any other country. Thus, no country can accord special trade advantages to another or discriminate between other countries: all countries are on an equal footing and all share in the benefits deriving from a reduction in the obstacles to trade. Customs unions and free trade areas are the exceptions that are officially authorized (Article XXIV of the GATT of 1947). An Enabling Clause dating from 1979 provides a permanent legal basis for special and differential treatment in favour of developing countries in the area of trade in goods.

A second form of non-discrimination, which comes under the heading of "national treatment", provides that once products have entered a market, they should not be subjected to treatment less favourable than that accorded to like products of national origin.

### ***Predictable and growing access to markets***

The security and predictability of access to markets depends to a large extent on the use that is made of customs duties. While quotas are prohibited on the whole, customs duties are permitted in the WTO regime and are commonly used by governments to protect national production and to raise revenue. They are, however, subject to certain rules – for example, they must not discriminate between imports – and are to a large extent "bound". Having bound a given customs duty for a specific product, a country may no longer raise it unless compensation is negotiated with the principal suppliers of that product.

The key to the predictability of a trade system often lies in the transparency of national legislation, regulations and practices. Several of the WTO agreements contain provisions in this respect. These aim to ensure transparency at the national or multilateral levels by means of formal notifications that must be addressed to the WTO.

### ***Promoting fair competition***

The WTO is not a "free trade" institution, as it is sometimes thought to be, if only because it authorizes the imposition of customs duties and, in limited circumstances, of other forms of protection. It is more accurate

to say that it reflects a system of rules designed to ensure free competition that is open and without distortions. The rules on non-discrimination are aimed at ensuring conditions for fair competition, as are the rules on dumping and on subsidies. The GATT rules that defined the conditions in which governments could impose countervailing measures to these two forms of "unfair" competition have been expanded and are set out specifically in the WTO agreements.

### ***Encouraging development and economic reforms***

More than three-quarters of the WTO's Members are developing countries and countries in transition towards a market economy. During the eight years of the Uruguay Round – from 1986 to 1994 – more than 60 of these countries implemented programmes to liberalize trade, sometimes as part of their negotiations to join the GATT, and in some cases independently. At the same time, developing countries and the economies in transition began to play a much more active and influential role in the Uruguay Round negotiations than they did in earlier rounds of negotiations.

The provisions of the GATT of 1947 that were intended to favour developing countries remain in place in the framework of the WTO. In particular, Part IV of the GATT of 1994\* contains three articles, introduced in 1965. These encourage industrialized countries to assist developing countries "*as a matter of conscious and purposeful effort*" in their trading activities, and not to expect reciprocity for concessions accorded to developing countries that are inconsistent with their trade development and financial needs.

### ***How does the WTO differ from the GATT?***

The WTO is not simply a continuation of the GATT; it has a completely different character. The main differences are as follows:

The GATT was a series of rules, a multilateral agreement without an institutional foundation and with just an ad hoc secretariat, originating from the attempt to establish an International Trade Organization in the 1940s. The WTO is a permanent institution with its own secretariat.

The GATT was applied on a "provisional basis" even if, after more than 40 years of existence, governments came to regard it as a permanent commitment. Commitments entered into under the aegis of the WTO exist in their own right and are permanent.

The GATT rules applied to trade in goods. The WTO covers not just goods, but also trade in services and trade-related aspects of intellectual property rights.

The GATT was originally a multilateral instrument but, towards the 1980s, several new agreements of a plurilateral and hence optional nature were added to it. The agreements\* on which the WTO is founded are almost all multilateral and therefore carry with them commitments to which all Members have subscribed.

The WTO system for the settlement\* of disputes is faster and more automatic, and thus less susceptible to blockages than the former GATT system. The implementation of the decisions resulting from the WTO settlement of disputes will be better assured.

The WTO fulfils five essential tasks:

1. Administration of the new multilateral trade agreements.
2. Provision of a forum for fresh negotiations.
3. Settlement of disputes.
4. Surveillance of national trade policies.
5. Cooperation with other international bodies in drawing up of economic policies at the global level.

#### **1.4 The Protection of Intellectual Property Rights before the WTO**

Intellectual property law, and especially patent law, is primarily national law. An inventor who files a patent application in a State is asking that State to recognize his exclusive right to his invention within the territorial boundaries of that State. There is not yet a world patent issued by a World Patent Office. The World Intellectual Property Organization (WIPO\*), among its other tasks, administers the application of the

conventions within its field of competence. But each State alone is responsible for the patents it decides to grant or not to grant on its territory. Thus the monopoly conferred by a patent can only be accorded in States that recognize its existence. Before the Uruguay Round, many States did not issue patents for pharmaceuticals on their territory, which meant that the inventor had no particular right over his invention in that country, hence the proliferation of copies of patented drugs in some countries.

At the international level, the regulation and protection of intellectual property rights had previously been managed mainly by WIPO. But WIPO conventions, and in particular the Paris Convention, only impose general rules, such as the rule on national treatment which requires equivalent treatment for foreigners and nationals. Another example is the rule on the right of priority, which permits the organization of protection of a right in several countries. Moreover, these conventions on intellectual property are not binding upon the States that have not ratified them. The GATT itself did not deal with the level of intellectual property protection, although it contains some provisions of relevance in Articles III, IX and XX(d). These provisions were hardly discussed until the GATT ministerial meeting in 1982 brought up the problem of counterfeit goods\* in international trade. The pharmaceutical industry in some developed countries had complained of commercial losses due to the weakness of intellectual property rights protection in most of the newly industrializing countries (NIC).

Some countries appeared to be influenced by the perception that their competitiveness, dependent on technology and creativity, was not adequately protected worldwide by existing rules on intellectual property. The inadequacies of protection and rules related to IPR's enforcement, together with the absence of an international dispute settlement system led them to argue for the inclusion of intellectual property matters into the trade negotiations. Respect for intellectual property rights would then be made a prerequisite for the granting of the benefits anticipated in the WTO Agreement. Thus intellectual property was added to the agenda of the Uruguay Round trade negotiations.

## **2. READING THE TRIPS AGREEMENT FROM THE PERSPECTIVE OF ACCESS TO DRUGS**

### **2.1 General Presentation of the Agreement**

A comprehensive Agreement on Trade-Related Aspects of Intellectual Property Rights is annexed to the WTO convention. The objectives, set out in the introduction to the Agreement, are essentially aimed at strengthening and harmonizing certain aspects of the protection of intellectual property at the global level.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter the Agreement) covers both categories of intellectual property: literary and artistic property (copyright and neighbouring rights) and industrial property (trademarks\*, patents\*, geographical indications, industrial designs, and trade secrets).

These objectives are to be realized in two ways: firstly, the Agreement requires Member States to ensure minimum standards of protection for the various rights, leaving them the choice of how they achieve this. Secondly, WTO Members must make available procedures and remedies to permit the effective enforcement of IPRs by right holders (Part III of the Agreement, not discussed in this document). The minimum standards of protection are based on the basic provisions of the principal international conventions in force (Paris 1883 and Bern 1886, as revised) administered by WIPO, with which the TRIPS Agreement will coexist without taking their place. In all the areas it covers, the Agreement provides for the application of the principle of national treatment and of most-favoured-nation (MFN) treatment. The interests of developing countries are explicitly taken into account.

This Agreement, and particularly the section on patents, is probably the element of the Final Act of the Uruguay Round that will have the most important repercussions in the field of public health, especially for access to drugs in developing countries.

## 2.2 Fundamental Principles and Objectives of the Agreement: The Necessary Balance between Intellectual Property and Accessibility

It is generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products. In the first place this is because consumers are not in a position to judge, for example, the quality of drugs, hence the need for a monitoring and surveillance system ensured by the State. Secondly, this is because drugs play a significant social role in that they are an integral part of the realization of a fundamental human right – the right to health. That is why they are classified as essential goods, to emphasize that they have to be accessible for all people.

The concept of accessibility is very important. It means that policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices. If the objective is accessibility, then the best possible supply must be ensured. This objective coincides with the general objective of the GATT for the last 40 years – seeking to eliminate barriers to trade so that consumers have the greatest possible access to all the goods available in the world.

The general paragraphs in the TRIPS Agreement (preamble and general provisions) stress the need to promote adequate and effective protection of intellectual property rights, but to do so as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation. The preamble to the Agreement states that:

*"Members, desiring to reduce distortions and impediments to international trade, and **taking into account the need** to promote effective and adequate protection of intellectual property rights, and **to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade**;"* (authors' emphasis).

The protection of intellectual property rights should be adapted to this objective of not generating undue distortions. Protection of

intellectual property rights under the TRIPS Agreement should not lead to any discrimination in international trade.

It also states that *"Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives..."*

This means that the protection of intellectual property rights is not an end in itself but has a functional role to play in relation to the priority objectives of public policy for which these rights were created. It should be harnessed to the service of development.

Article 7 – Objectives, but also Article 8 (2), clearly indicates the subordination of the protection of intellectual property rights to public policy objectives in other areas of the State's activity, especially social and economic welfare, which depends in part on national health and social policies. This Article also stresses that the interests of all sectors involved must be taken into account. It states:

*"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 – in paragraph (1) allows national regulations to be adapted to the fundamental objectives of public policy set by governments in certain domains, provided these regulations are not contrary to the provisions of the Agreement. Public health and nutrition receive a special mention among these objectives, which amounts to express recognition of measures that might be adopted to guarantee accessibility. By virtue of this Article:

*"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."*

Paragraph (2) of this fundamental Article should also be mentioned, in so far as it once again expresses the need for a well-balanced interpretation of measures to protect intellectual property rights. These should be protected in such a way that they do not give rise to abuses detrimental to the necessary balance between national objectives and sectoral interests for which the State is the guarantor. Thus, in accordance with Article 8.2:

*"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."*

At this point, Article 1 – Nature and Scope of Obligations – is of critical importance, for it establishes that Member States are not obliged to grant greater protection than that set out in the Agreement. It also recognizes that Member States are entirely free within the framework of their own legal systems and practices as to how they implement the obligations to which they have subscribed. The Article states that:

*"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."*

These general provisions were included in the Agreement to make for a balance between the rights of patent holders and their obligations vis-à-vis society. Member States may therefore base certain particular provisions of their national regulations on these principles. They can also bring their regulations into line with the obligations of the Agreement in such a way that their national objectives for the protection of intellectual property also accord with those imposed in other sectors

of State activity which the latter deems to be necessary, provided such regulations do not contravene the Agreement.

From a social and health policy perspective, the provisions open up the possibility of establishing national regulations, taking into account the imperative of guaranteeing the best possible access to drugs.

### **2.3 Patents for Pharmaceutical Products and Processes available All Over the World**

The TRIPS Agreement requires patent protection to be available for any invention in any field of technology in all WTO Member States. This provision is essentially aimed at pharmaceutical products, for which certain developing countries, as well as developed countries, had refused to grant patents. Because of the high prices of patented drugs and the large amount of expenditure required for research and development (R&D\*) in the pharmaceutical field, some countries had chosen to imitate products patented in industrialized countries through reverse engineering\*, in order to meet their national requirements for drugs at a lower cost and to develop their technology. Other countries with no pharmaceutical industry bought these copies of patented drugs at competitive prices.

This is similar to the practice adopted by many developed countries some years ago when their own pharmaceutical industry was not yet very highly developed.

Despite the positive contribution that the patent system may bring to public health by generating incentives for innovation, it should be pointed out that the emergence of a generic\* drug sector in a number of developing countries represents a set of successful social policies that may be harder to duplicate under TRIPS.

The table below gives a detailed explanation of Article 27.

<b>Article 27.1</b> <b>Patentable subject matter</b>	<b>Comments</b>
<i>... patents shall be available for any inventions, whether products or processes,</i>	<p>Some countries only made available process patents for pharmaceutical inventions. Under TRIPS, product patents must also be available; the protection of rights on a product is much broader in scope.</p>
<i>in all fields of technology,</i>	<p>Some countries, unable to invest in R&amp;D, have been excluding pharmaceuticals from patentability so as to allow the possibility for copies of patented drugs to be produced locally or imported – from other countries which also do not respect pharmaceutical patents – without the authorization of the company that invented the drug.</p>
<i>provided that they are new, involve an inventive step and are capable of industrial application.</i>	<p>Usual definition of the conditions of patentability of an invention.</p>
<i>...patents shall be available and patent rights enjoyable without discrimination as to the place of invention the field of technology</i>	<p>No discrimination between national and foreign inventions, or between foreign inventions.</p> <p>No discrimination between types of products – pharmaceutical or other.</p>

Article 27.1 Patentable subject matter	Comments
<i>and whether products are imported or locally produced.</i>	Some countries have been issuing compulsory licences for lack of exploitation of patents. This type of obligation was intended to require foreign companies to set up on the national territory in order to exploit their patents, with resultant transfers of technology. The Agreement would here appear to allow these companies to import their patented product without having to transfer the related technology.

Henceforth, from the end of the transition periods, patent holders must be given the right and legal means to prevent imitation of a patented drug. If national regulations on patents do not provide it, or if it is not respected, the Member State in question may, pursuant to the disputes settlement process, be the subject of a complaint before the WTO Dispute Settlement Body\*.

## 2.4 Non-patentable Inventions: Biotechnology Inventions

As the general rule of the TRIPS Agreement is the patentability of any invention in any field of technology, the only exceptions authorized are those laid down by the Agreement. The Agreement authorizes certain exclusions from patentability\*, based on “*ordre public*” or morality, especially in regard to protection of human, animal or plant life, or to prevent serious damage to the environment. Members may also exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals.

But the main concern is biotechnological\* inventions. Article 27.3(b) provides that only plants, animals and essentially biological processes for the production of plants or animals may be excluded from patentability. However, the same provision states that micro-organisms, as well as micro-biological and non-biological processes are not covered and have to be patentable. But a doubt remains as to the nature of some of these biotechnological inventions, which find their origin in organisms existing in nature. Indeed, a patent can only be granted for an invention which is new, inventive and capable of industrial application, and not for a discovery. Micro-organisms only seem to be patentable on the condition that a real intellectual human contribution, which has to be new, is demonstrated.

Article 27.2 & 3 Exceptions	Comments
<i>2. Members may exclude from patentability inventions</i>	Two conditions for refusal to grant a patent:
<i>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,</i>	commercial exploitation (production, distribution, sale) of the product in question is prohibited throughout the territory in the interest of “ordre public”, morality, or the environment... by any entity whatsoever
<i>provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.</i>	the only possible justifications for excluding an invention for patentability under this provision are “ordre public” or morality, including the health and life of humans, animals or plants and the environment. Hence a legal prohibition based on other grounds is not covered by this provision.

Article 27.2 & 3 Exceptions	Comments
<p>3. <i>Members may also exclude from patentability:</i></p> <p>a) <i>diagnostic, therapeutic and surgical methods for the treatment of humans or animals;</i></p> <p>b) <i>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.</i></p>	<p>Specific exceptions allowed are essentially biological processes, plants and animals. But, patents for inventions of micro-organisms and for non-biological and micro-biological processes must be available. This means that inventions based on genetic engineering and gene transfers should be patentable whereas substances existing in nature should not.</p>

Given the development perspectives of biotechnology, this question is extremely important. Indeed it is the only one for which a review (in 1999) has been specifically planned by the Agreement. Developing countries rich in natural resources, should, in their new regulations, define the ambiguous terms *biotechnology* and *invention*, in order to benefit from these new provisions.

## 2.5 Effects of Protection: A Monopoly of Working for 20 years

Traditionally, a patent confers a monopoly for working the invention upon the patent holder. Any person imitating the invention or new manufacturing process, without the consent of the patent holder, is committing an act of infringement.

### ***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 acts of making, using, offering for sale, selling, or importing 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.*

### ***Attenuation of the monopoly through exhaustion of rights***

The exclusive right, conferred by Article 28, to import the patented product or process merits special attention on account of a footnote attached to it. This footnote states that the exclusive right to import is subject to Article 6 of the Agreement. Under that Article, the issue of exhaustion of rights cannot be addressed by the Dispute Settlement Understanding, unless it is the basis for a discrimination claim. For practical purposes, this means that countries can have the exhaustion regime they have chosen. Therefore, the Agreement does not impose any obligation on Member States on this point, which remains purely a national issue. A Member State is completely free to decide whether or not to apply the principle of the exhaustion of the patent owner's rights.

### ***What is the exhaustion of intellectual property rights?***

The issue of national exhaustion is relevant not only to importation rights but also to distribution rights. In principle, if the theory of the exhaustion of rights is not applied, the importation of a patented product (or parallel\* importation) without the authorization of its patent owner is illegal. The monopoly conferred by the patent includes not only the exclusive right to manufacture and work the patented product, but also

the exclusive right to import it, if the patent owner manufactures it, or has granted a licence to manufacture it, in another country.

The exception to this general rule of prohibition is to be found in the principle of the exhaustion of rights. According to this principle, an intellectual property right is exhausted when a patented product is first put on the market with the consent of the patent holder. From the perspective of trade liberalization, it is considered that from the moment the product is marketed, the patent holder can no longer control its subsequent circulation. By virtue of this principle, the patent thus confers a monopoly on the invention (that is, the know-how) and not on the products legitimately resulting from this invention. The patent holder retains the exclusive right to manufacture the patented product and to put it on the market, but, from that moment on, has no further right over the actual product. The patent holder thus loses his monopoly of importation and sale.

***How is the principle of the exhaustion of rights to be applied?***

The TRIPS Agreement leaves Member States free to decide whether or not to apply this principle on their territory. There is, however, one further point that must be made.

One of the fundamental rules of the TRIPS Agreement is non-discrimination between Member States. There are, by virtue of the TRIPS Agreement, three main options open to a Member State wishing to apply the principle of the exhaustion of rights:

- either an international exhaustion of the rights of the patent holder, in other words, the possibility granted to a third party to import into the territory of the relevant Member State the same patented product from any other WTO Member State in which it has been put on the market with the consent of the right holder. The Member State opting for this principle would have the widest range of supply of products with the obligation (through the MFN clause) to accept products from all Member States.
- or a regional exhaustion of the rights of the patent holder (cf. the European Union), or the possibility of importing onto the territory of that State the same patented product originating

- from any other Member State of the same regional union;
- or national exhaustion, which amounts to limiting the circulation of products covered by the IPR in one country to only those put on the market by, or with the consent of the patent owner, in the same country.

This provision of the Agreement is very important in so far as it allows the supply of the product to be increased and prices to be moderated through competition, in other words, improving accessibility through importation. Member States could improve the accessibility of products, including drugs, by establishing that the exclusive rights of the patent holder may not be claimed in cases where products marketed with that patent holder's consent in any other country are imported. No State may complain of a breach of the Agreement on this ground.

Nevertheless, although parallel importation is legal in terms of the TRIPS Agreement, questions of economic strategy arise concerning the scope of the application of the theory of the international exhaustion of intellectual property rights. In practice, while authorizing parallel importation may help to bring down prices through competition, it may also discourage patent holders from granting licences for local working, and thus run counter to some countries' technological development. Some authors therefore advocate a conditional authorization of exhaustion of intellectual property rights (Remiche, 1996). Why not anticipate the possibility of parallel importation only if, after a certain time has elapsed, the patent holder is not working the invention locally or is not meeting local demand at reasonable prices? In that case, the authorization of parallel imports would be motivated by the country's desire to industrialize and to supply the local market with sufficient drugs at affordable prices.

According to other authors, the effect of international exhaustion of rights would be for right holders to move towards a single worldwide price for their products, which they would be likely to seek to set at the price that the market can bear in the wealthier countries.

### ***Strengthening the monopoly through the patenting of processes***

Compared to pre-existing conventions, the TRIPS Agreement strengthens the rights conferred by a process patent.

- In the first place, the Agreement imposes protection of the product obtained by the patented process as though there was also a patent for the product itself.

Article 28.1(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***" (authors' emphasis).

This extension of the protection of the manufacturing process to the resulting product increases the protection conferred upon the holders of know-how. The issue has been raised as to whether, in practice, the inventor of a new manufacturing process for a product already known and not protected by a patent could be granted exclusive rights to that product under the Agreement. This would only happen if the patented process used to manufacture the product was totally or partially unique and irreplaceable.

The fundamental question that then arises is whether or not it would be possible, based on this reasoning, to obtain an exclusive right to exploitation for a drug not covered by a patent, (for example, a drug included in the WHO Model List of Essential Drugs), through a new process for the manufacture of that drug. The answer would appear to be negative, since only the product directly obtained by the new process enjoys the protection attaching to the new process. This implies that a manufacturer using the old manufacturing process could not be accused of infringement of the process patent. However, the extension of process protection to a product may lead to an increase in lawsuits, which may be a deterrent to small local companies.

It is clear that developing countries will need to monitor the interpretation and application of this provision very closely.

- Secondly, Article 34 reverses the burden of proof in certain circumstances regarding process patents in infringement proceedings.

Article 34 Process patents: burden of proof	Comments
<i>For the purposes 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,</i>	If (civil) proceedings for infringement of a process patent are initiated,
<i>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.</i>	the judge may decide to reverse the burden of proof (which in principle falls upon the plaintiff) and require the person suspected of infringement to prove that an identical product has been obtained using a manufacturing process different from the patented process.
<i>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:</i>	This is not in fact a matter left to the judge's discretion since Member States must make this reversal of the burden of proof a legal presumption, which the judge will be obliged to respect.
	Country Members must then provide for the reversal of the burden of proof in one of the following cases or both:

<b>Article 34</b> <b>Process patents: burden of proof</b>	<b>Comments</b>
<i>(a) if the product obtained by the patented process is new;</i>	1st case: only if the product made with the patented process is a new product. Therefore, Members may have to define the newness of such a product.
<i>(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.</i>	2nd case: whether or not the product (obtained by the patented process) is new, the defendant is required to prove that he has not used the patented process to obtain an identical product.

By virtue of Article 34, Member States must therefore provide for reversal of the burden of proof in their legislation. In other words, if the owner of a process patent suspects somebody of having used his patented process to obtain an identical product, it will be the person suspected of infringement who must prove his innocence. The Agreement calls upon Member States to provide for the application of this legal mechanism either when the product (obtained by the patented process) is new, or independently of the novelty of the product, in any case when the patent owner cannot determine that the patented process has not been used. It would seem that the first case, more restrictive since it only applies to new products, is the one best suited to the situation of developing countries.

Finally, the principal innovation of the TRIPS Agreement lies in the obligation imposed on all Member States to grant patents for drug manufacturing processes and for actual drugs. Since patents are a monopoly of the exploitation of an invention, the Agreement amounts to a limitation of supply and thus directly affects accessibility to products, including drugs.

### ***Extension of the duration of the monopoly***

Pursuant to Article 33, the duration of protection offered will not cease until expiry of a period of 20 years from the date the patent application is filed.

This provision may result in an increase in the duration of the patent owner's monopoly in many Member States where there is no therapeutic competition. In the pharmaceutical field, the logical consequence of this provision is that drugs will be sold at high prices, as is the case for all monopoly products, for a longer period of time, and manufacturers of generic products will have to wait longer before they can produce the drug in question and sell it at a more accessible price.

It is thus in regard to the length of protection that the Agreement will have one of its most important harmonizing effects. Unlike other provisions, which leave Member States a certain amount of room for manoeuvre, the Agreement is particularly strict and specific concerning the duration of patents.

In other words, the Agreement prohibits Member States from deciding on a special period of protection of less than 20 years depending on the field of technology, as was done by certain developing countries in the case of pharmaceutical products. The Agreement, indeed, imposes a minimum duration; but there is no provision in the Agreement that obliges Member States to issue patents for an even longer duration, as is the case in the United States and in Europe, especially for pharmaceutical products, to compensate for the length of time elapsing between the filing of a patent application and the effective marketing of the product.

## **2.6 Application of the TRIPS Agreement**

With regard to the dates of application of the TRIPS Agreement, a distinction is made between the least-developed countries and developing countries, and also between countries with or without a system of patent protection for pharmaceuticals at the time of the establishment of the WTO.

<p><b>Article 65</b> <b>Transitional arrangements</b></p>	<p><b>Comments</b></p>
<p><i>1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement</i></p>	<p>In general, industrialized countries were only obliged to start applying the provisions of TRIPS in 1996.</p>
<p><i>2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement,</i></p> <p><i>other than Articles 3, 4 and 5.</i></p>	<p>Developing countries have 4 extra years to implement the provisions of the Agreement on the different aspects of intellectual property rights, that is, until 1 January 2000.</p> <p>During this transitional period, developing countries must nevertheless comply with the obligations on national treatment and MNF treatment.</p>
<p><i>3. Any other Member which is in the process of transformation from a centrally planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.</i></p>	<p>The same period of 4 years is accorded to the former socialist republics under certain conditions.</p>

<b>Article 65</b> <b>Transitional arrangements</b>	<b>Comments</b>
<p><i>4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2,</i></p>	<p>For developing countries that did not grant product patent protection for pharmaceuticals before the signature of the WTO Agreement and have not done so by 1 January 2000,</p>
<p><i>it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.</i></p>	<p>these countries will benefit from a further period of five years – making a total of ten years – to take the necessary steps to ensure such protection.</p>
<p><i>5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.</i></p>	<p>During transitional periods, the Member States concerned may continue to apply their old regulations but must not take decisions that are even more contrary to the Agreement.</p>

### ***For industrialized countries: 1996***

In accepting to become Members of the WTO, States have committed themselves to respect the rules set out in certain agreements, including the TRIPS Agreement. In order to comply with these rules, each State is supposed to amend its legislation so that it conforms with the minimum rules laid down by the Agreement.

The industrialized countries, which mostly have a high level of protection of intellectual property already, have been allowed a period

of transition\* of one year to bring their intellectual property law completely into line with the rules of the TRIPS Agreement.

***For developing countries: 2000 or 2005***

Developing countries have a period of transition of five years in which to meet all the obligations incumbent upon them under the Agreement, with the exception of non-discrimination between nationals and foreigners (national treatment), or between different foreign nationals (MFN treatment). By the year 2000, they should have introduced into their national regulations on intellectual property the various rules of the Agreement they accepted by acceding to the WTO.

However, the Agreement grants a further derogation to developing countries that did not issue patents before they joined the WTO, for example, for pharmaceutical products. In practice, a number of developing countries only granted patents for drug manufacturing processes, or possibly no patents at all in the pharmaceutical sector. In this case, Article 65.4 gives them an extra five-year period of grace to introduce patentability of these products in their legislation, which amounts to a total transitional period of ten years for developing countries in respect of pharmaceutical products.

However, given the substantial time that elapses between the application for a patent for a new pharmaceutical product and authorization to market that product, strict application of this provision would have the consequence that new patented drugs would not be marketed in developing countries until at least 2015 (2005 + about ten years of development prior to marketing).

In order to limit this effect, the TRIPS Agreement also has special transitional provisions ("mail-box" and "exclusive marketing rights" mechanisms – see below) for cases in which a State does not grant pharmaceutical products patents as of January 1995 and therefore has a period of ten years in which to do so.

**For least-developed countries: 2006**

**Article 66**

*"1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.*

*2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."*

Under Article 66.1, least-developed countries benefit for 10 years after the general one year transition period of 1996, while a showing of hardship may qualify them for further delays. However, they are also affected by the “mailbox” and “exclusive marketing rights” transitional provisions regarding pharmaceuticals.

**2.7 During the Transitional Period**

***Establishment of a "mail-box" in 1995***

<b>Article 70.8 Protection of existing subject matter</b>	<b>Comments</b>
<i>8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural</i>	For countries that do not grant pharmaceutical patent protection as of 1 January 1995,

<p><b>Article 70.8</b> <b>Protection of existing subject matter</b></p>	<p><b>Comments</b></p>
<p><i>chemical products commensurate with its obligations under Article 27, that Member shall:</i></p> <p><i>(a) notwithstanding the provisions of Part VI,</i></p> <p><i>provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;</i></p> <p><i>(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and</i></p> <p><i>(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with</i></p>	<p>independently of the transitional periods accorded to them,</p> <p>these countries must implement as from 1 January 1995 an adequate infrastructure to receive patent applications for such inventions of pharmaceutical products.</p> <p>These applications shall be examined at the latest in 2005 for developing countries and 2006 for the least developed countries, in terms of the criteria for patentability set out in the Agreement, which shall be applied as if they were being applied on the filing (or priority) date of the application. This is a juridical artifice to preserve the novelty of the inventions made from 1995 onwards that will not receive patent protection for a maximum of some ten years.</p> <p>Such inventions will receive the protection due to them (if they meet the criteria of the Agreement for patentability) as from the date of the grant of the patent after the end of the</p>

<b>Article 70.8</b> <b>Protection of existing subject matter</b>	<b>Comments</b>
<i>Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).</i>	transition period and for the remainder of the 20 years counted from the filing date.

In summary, as from the entry into force of the WTO, on 1 January 1995, countries must have an adequate infrastructure to receive and store patent applications for new drugs. Since it takes about ten years to test a new molecule and authorize its marketing, the invention should remain pending until 2005 at least. This is also the date at which the TRIPS Agreement becomes applicable to some developing countries in regard to pharmaceuticals. Those developing countries therefore will not have to examine before 2005 pharmaceutical patent applications filed since 1995. If the application properly fulfils the necessary conditions for patentability (novelty, inventiveness, and capable of industrial application), which are to be applied on the filing date, the patent will be issued for a period of 20 years. This is done on the understanding that the period will commence on the filing date (1995 for example) and run for the remainder of the due term\* (until 2015 in the example).

### ***Possibility of exclusive marketing rights***

Furthermore, if a patent application for a pharmaceutical product filed in a developing country after 1st January 1995 (or within the priority period of the Paris Convention) under the "mail-box" clause, should obtain a marketing authorization in this country before the expiry of the transitional period, (which is before 2005), the Agreement provides for the applicant to be accorded upon request exclusive marketing rights, for a maximum duration of five years, until the patent is either granted or refused.

Two conditions are necessary for the implementation of this provision: a patent must have been granted for the same product in another Member country in response to a patent application filed only after 1st January 1995 (or within the priority period of the said

Convention), **and** a marketing authorization for this product must have been obtained in this other Member country.

These conditions have been devised to ensure that the product for which an application has been filed is indeed a genuine invention. In the pharmaceutical sector, it may then be of importance to provide the possibility of exclusive marketing rights only for new chemical entities and to ensure that the other country in which a patent has been granted has effectively examined whether the application meets the patentability requirements.

<p><b>Article 70.9</b> <b>Protection of existing subject matter</b></p>	<p><b>Comments</b></p>
<p><i>Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a)</i></p> <p><i>exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter,</i></p> <p><i>provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member</i></p>	<p>For inventions covered by "mail-box" protection,</p> <p>pending the granting of a patent, exclusive marketing rights shall be granted during the transitional period, as from the time the invention receives marketing approval. These rights will be accorded for a maximum of five years until such time as the patent is granted or rejected</p> <p>To be accorded these exclusive marketing rights, four conditions must be met:</p> <ul style="list-style-type: none"> <li>• a patent application must have been filed in Member State A after 1 January 1995;</li> <li>• an identical application must have been filed in another Member State B after the entry into force of the WTO</li> </ul>

<b>Article 70.9</b> <b>Protection of existing subject matter</b>	<b>Comments</b>
	<p>Agreement and a patent actually granted;</p> <ul style="list-style-type: none"> <li>• a marketing authorization for the patented product must have been obtained in State B;</li> <li>• a marketing authorization is also obtained in State A.</li> </ul>

### ***What happens to existing patents?***

Under the heading of “*Protection of Existing Subject Matter*”, the Agreement sets out the steps that must be taken or not by Member States at the end of the transitional periods in respect of subject matter that already exists on those dates such as patents current at the end of the relevant transitional period.

<b>Article 70</b> <b>Protection of existing subject matter</b>	<b>Comments</b>
<i>1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.</i>	The Agreement will be binding only once it applies in a country (i.e. the end of the transition periods at the latest) and therefore is not retroactive.
<i>2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected</i>	DCs in 2000, and the LDCs in 2006, must give protection, in accordance with the rules of the Agreement, to the products or processes already patented on their territory, or grant a patent for inventions already made and still fulfilling the conditions for

*in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. ...*

protection stipulated by the Agreement.

*3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain....*

Inventions falling into the public domain before 2000 and 2006 do not incur any obligation for Member States.

*6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to use without the authorization of the right holder where authorization for such use was granted by the government before that date this Agreement became known.*

Compulsory licences granted before the date the Agreement became known are not subject to the provisions of Article 31.<sup>1</sup>

*7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the*

Applications for patents pending examination on 1 January 2000 or 2006 may be reformulated to obtain better protection under the Agreement, provided the content of the application is identical in regard to the criterion of novelty.

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<sup>1</sup> It should be noted however that the wording of Article 70.6 about the "date [this] Agreement became known" is quite unusual in an international instrument and that there are no right answers until a WTO panel takes a decision.

*provisions of this Agreement.  
Such amendments shall not  
include new matter.*

For countries already granting patents for pharmaceutical products, as a result of these provisions, the patents granted before 1995 continue to be governed by the old regulations up until 2000 for developing countries and 2006 for least-developed countries (subject to TRIPS national treatment and MFN which became applicable on 1 January 1996). When the transition period expires, however, the obligations of the Agreement will also apply to patents still in force. In other words, a patent still valid on that date in the country in question should enjoy a minimum of 20 years' protection from the filing date, even if the patent was originally granted for a shorter period.

Thus, at the expiry of the transitional periods, that is, in 2000 or 2005 for developing countries, and 2006 for the least-developed countries, patents existing at that time should be **protected** by the provisions of the Agreement. In other words, a Member State is obliged, as from that date, not only to make available the substantive provisions required by the Agreement but also to ensure that procedures and remedies are available so as to permit the right holder to take action against any infringing act under the terms of the Agreement (cf. Article 28 – "*making, using, offering for sale, selling or importing*" the protected product or process).

## **2.8 How Can the Monopoly be Limited?**

The anxieties and the extent of the reactions generated by the TRIPS Agreement are related to the requirement, new for some Member States, to recognize that the owners of new know-how in the pharmaceutical field are entitled to a monopoly of 20 years. Several experts from developing and developed countries fear a substantial increase in drug prices in countries that did not grant patents in the past.

However, the TRIPS Agreement expressly provides two means of obtaining exceptions and limiting the exclusive rights conferred by the

patent on its owner. These two provisions may be used to ensure greater accessibility to essential drugs.

### ***Exceptions***

Article 30 of the Agreement allows “*exceptions to the exclusive rights*” of the patent holder. This is the situation in which a person can use the patent object with no need to ask the authorization of the holder and without being in an illegal situation. Those exceptions are national legal exceptions and therefore need to be set out in the national patent law.

By virtue of Article 30:

*"Members may provide limited 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 account of the legitimate interests of third parties."*

It appears from the reading of Article 30 that these exceptions are subject to three following conditions:

- They must be limited. The authors of the Agreement have attempted to avoid an uncontrolled proliferation of the number of exceptions.
- They must be duly justified; and
- They must not unreasonably affect the patentee's legitimate interests. The aim is to strike a balance between the interests of third parties (which are the grounds for the existence of the exception) and the interests of the patentee.

Apart from these three types of restriction, whose interpretation is within the WTO's remit, Member States are left a considerable margin of latitude for implementing the Agreement through national legislation. The Article does not spell out the different grounds on which Member States may base their exceptions, nor the precise cases that can be the subject of such exception to the monopoly. A number of exceptions

meeting the foregoing three conditions could be envisaged. Articles 7 and 8 of the Agreement, in particular, merit consideration.

### **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"* (authors' emphasis).

### **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 (authors' emphasis).*

*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"* (authors' emphasis).

Both the promotion and the transfer of technology, as well as public health or nutrition could justify derogation of the patentee's exclusive rights. Scrutiny of the exceptions existing in much national legislation gives an idea of the different possibilities (Correa, 1997):

- parallel importation of the protected product;
- acts carried out on a private basis and for non-commercial purposes;
- scientific research and experiments involving the patented invention;
- preparation of drugs by unit and on medical prescription in pharmacy dispensaries;

- a person being, in good faith, already in possession of the invention covered by the patent;
- tests carried out before the expiry of the patent to establish the bio-equivalence of a generic drug.

This last exception is at present the subject of consultations under the WTO dispute settlement system between the European Union and Canada, as Canadian legislation allows generics manufacturers to carry out experiments and tests required to obtain marketing approval, and also to manufacture and stockpile copies of patented products, before the relevant patents expire.

### ***Compulsory Licences***

Basically, the patent holder is free to exploit the protected invention or to authorize another person to exploit it. However, when reasons of general interest justify it, national public authorities may allow the exploitation of a patent by a third person without the owner's consent.

While limited possibilities of use without authorization of the right holder are permitted under Article 30, compulsory\* licences under Article 31 are another mechanism in which the patented object can be used without the permission of the rightful owner. The terms of compulsory licence are often used to denote licences granted by the judicial or administrative authorities.

French law, for example, provides that *"if required in the interest of public health"* (Article L.613-16 of the Code on Intellectual Property), patents issued for drugs may be subject to the regime of compulsory licences. The law authorizes this procedure when the patented drugs *"are only made available to the public in insufficient quantity or quality or at abnormally high prices"*.

The Paris Convention left States free to grant compulsory licences *"to prevent possible abuses"* connected with monopoly. Thus, in Article 5A.(2) of the Paris Convention, *"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from*

*the exercise of the exclusive rights conferred by the patent, for example, failure to work."*

One of the objectives of the TRIPS Agreement was precisely to limit these cases of *"utilization without the authorization of the right holder"* and to impose specific conditions on Member States.

Thus, pursuant to Article 31 of the Agreement:

- authorization of such use will be considered on its individual merits; authorization will be granted only if the proposed user has made efforts to obtain the licence on reasonable commercial terms;
- the scope and duration of the authorization must be limited;
- authorization is non-exclusive;
- the authorization is non-assignable;
- the predominant objective of the authorization must be supply of the domestic market;
- the authorization will be suspended if the circumstances that led to it cease to exist;
- the patent holder will be given adequate remuneration, taking into account the economic value of the authorization.

These are the main minimum conditions stipulated by the Agreement and Member States must fulfil them when they grant compulsory licences. These conditions must therefore be included before the end of the transition period in the new national legislation on patents. They must be respected whenever a compulsory licence is issued by the public authorities.

Apart from these conditions, Member States are left with a broad scope for action in regard to the grounds and reasons for compulsory licences (as is the case under Exceptions of Article 30). Five kinds of use without authorization of the right holder are expressly envisaged by the Agreement:

- licences for public non-commercial use by the Government;
- licences granted to third parties authorized by the Government for public non-commercial use;

- licences granted in conditions of emergency or extreme urgency;
- licences granted to remedy a practice determined after administrative or judicial process to be anti-competitive;
- licences arising from a dependent\* patent.

However, the Agreement does not state that these are the only cases authorized. Thus Member States are not limited in regard to the grounds on which they may decide to grant a licence without the authorization of the patent holder. They are in practice only limited in regard to the procedure and conditions to be followed. The Agreement refers to five types of licences but the list is not exhaustive. Achievement of the objective of accessibility, already mentioned, requires adequate exploitation of such possibilities for use without the permission of the patent holder in order to guarantee satisfactory conditions of supply. Compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices.

### ***Compulsory licence on the grounds of public health***

According to Article 8 of the Agreement, Member States may adopt the necessary measures to protect public health and nutrition (provided these measures are consistent with the provisions of the TRIPS Agreement). There are many instances of regulations that envisage compulsory licences for reasons of public health. In practice, if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy, such as a vaccine against AIDS or malaria, the national law may provide for the granting of a compulsory licence, under the conditions of Article 31.

### ***First attempt to obtain a voluntary licence***

In all cases in which the Agreement authorizes the granting of licences without the permission of the patent holder, the potential user is required, as a precondition for the granting of a compulsory licence, to have attempted unsuccessfully to obtain a voluntary licence contract, from the patent holder, on reasonable commercial conditions and after a certain period of time. The only cases in which such an attempt is not

required are cases of national emergency, other circumstances of extreme urgency, public non-commercial use and adjudicated anti-competitive practice. The logic of this procedure is that it makes for a certain balance between all the sectors involved, obviating possible abuse by patent holders while retaining a certain flexibility, which contributes to accessibility.

### ***Utilization by governments***

The concept of a licence for utilization by the government or by authorized third parties is very important for accessibility, for in both cases, countries where drugs are supplied directly by the government may then authorize such licences for these products. In case of public non-commercial use, it is not necessary to fulfil the condition that a voluntary licence must first be applied for, although the patentee must be informed.

### ***Non-exclusivity***

The Agreement states that licences granted without the authorization of the patentee may not be exclusive. This means that any interested person may apply for such a licence, which will increase the supply of products to the highest level possible under market conditions.

### ***Second patent***

Under a number of conditions, a compulsory licence may be issued where a new invention requires the use of a pre-existing patented invention for working.

### ***Licences granted on the grounds of anti-competitive practice***

It is very important to foresee actual cases of anti-competitive practice when bringing national legislation into line with the Agreement, that is, laws on the protection of competition and anti-monopoly laws. It is also extremely important to qualify these situations to ensure that the system functions as well as possible and to avoid excessively long delays, the result of which is to reduce the practical value of such mechanisms (rapid ageing of drugs). To this end, the essential elements that should figure in national regulation of anti-competitive practice must include artificial price increases and price discrimination practices. If such situations are found and proved, and this can be done quickly and objectively, it should be possible to grant a compulsory licence.

### ***Abuse of rights and local working of the invention***

The TRIPS Agreement is supposed to coexist with the conventions existing in the domain of intellectual property, and thus does not annul the provisions of the Paris Convention, but rather incorporates them into the TRIPS Agreement by reference. According to the latter, the absence of local working of patented inventions is an abuse of rights by the patent holder, and if this situation persists for more than three years, a compulsory licence may be granted. The TRIPS Agreement retains the notion that possible abuses by patent holders should be prevented. Article 8.2 authorizes Member States to take *"appropriate measures ... 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."*

It is surely possible to maintain that for developing countries with a certain level of infrastructure, local working of a patented invention does contribute, in the pharmaceutical sector, to the *"socio-economic and technological development"* of a sector of vital importance. Hence some Member States might establish in their legislation that for *"sectors of vital importance"*, if the patent holder does not manufacture the product locally and is still only importing it after three years, he or she could be required to grant a compulsory licence for local manufacture with a view to improving supply of the domestic market or price conditions.

For other countries, however, importation of pharmaceuticals may seem more appropriate; "the existence of economies of scale and well-established know-how may result in import prices that are lower than the prices that might be proposed by local industry" (Remiche, 1996).

The question of local working is rather loosely covered in the TRIPS Agreement. Article 2 of the Agreement states that certain provisions of the Paris Convention, including the possibility of compulsory licences for absence of local working, are applicable to all Members. At the same time, Article 27.1 appears to recognize the legality of import monopolies when it states that *"patent rights [shall be] enjoyable without discrimination ... as to whether products are imported or locally produced"*.

The authors of this document have tried to interpret this question, like other “sensitive” provisions, in the light of the principles and objectives of the Agreement and of existing legislation. However, it is not impossible that a Member State may submit a complaint to the WTO Dispute Settlement Body (DSB) because it considers that another State has not transposed the provisions of the Agreement correctly into its domestic legislation, as a result of erroneous interpretation. In that case, the DSB alone would be competent to decide. There are thus a number of uncertainties attaching to the TRIPS Agreement that will be clarified in the years to come.

### **3. CONCLUSIONS: ISSUES AT STAKE AND CONSTRAINTS ON ACCESS TO DRUGS**

#### **3.1 The Drug Patents Debate**

The TRIPS Agreement is one of the most controversial agreements of the Uruguay Round in terms of its objectives and consequences. This is clearly shown by many of the references listed in the bibliography (see page 47).

Some authors, in favour of the TRIPS Agreement, argue that the protection of pharmaceuticals by patents should lead to:

- an increase in the flow of technology transfer and direct foreign investment to the benefit of developing countries, so improving dissemination of know – how at the global level;
- an increase in the resources devoted to R&D by local pharmaceutical companies in developing countries, resulting in the development of new drugs more suited to their own needs (patents being regarded as a stimulant to innovation, encouraging inventors to divulge and to market their inventions);
- an improvement in the welfare of the population, resulting from a wider range of better quality products;
- the end of the "brain drain" from developing to industrialized countries caused by the absence of protection for their inventions in their countries of origin.

Other writers, less optimistic or even opposed to the Agreement, respond that:

- The prices of patented drugs and the amount of patent royalties will increase with the strengthening and prolongation of the patent holders' monopoly.
- There could be a real concentration of production in industrialized countries: multinational firms will be free to export finished or semi-finished products rather than

transferring technology or foreign investment directly to developing countries.

- The introduction and strengthening of patents for pharmaceutical products will certainly not lead to an increase in R&D investment by enterprises in developing countries, which have to contend with a lack of technical infrastructure, and financial and human resources. Likewise, the non-patentability of pharmaceutical products existing prior to the TRIPS Agreement gave developing countries the opportunity to progress and to acquire basic technology through reverse engineering before being able to invest in R&D.
- The replacement or adaptation of existing infrastructures set up for the development of imitations of patented products will involve considerable costs.
- The implementation of the Agreement will involve substantial administrative costs.

It is at present very difficult to assess the impact of the TRIPS Agreement in developing countries: the market structure, the situation of the local pharmaceutical industry, the balance of payments, consumer habits, the legal environment, the country's pharmaceutical policy are all factors that make each State a special case, particularly in its perception of the effects of globalization.

There are, however, a number of points that should be mentioned.

- Intellectual property rights were included in the agenda of the Uruguay Round on the **initiative of industrialized countries**, following pressure from a variety of economic groups. A number of factors prompted this initiative: firstly, certain countries still refused to sign the Paris Convention, and there was no legal mechanism to constrain States to comply with its provisions. At the same time, freedom of trade and globalization were facilitating imitation of branded\* products, resulting in significant financial losses for multinational companies. Finally, in the pharmaceutical sector in particular, the strengthening of intellectual property rights would make it possible to contain the growing competition from the generic

drugs industry (through more sustained investment in R&D as a result of patents).

- The previous rounds of GATT negotiations had been confined to discussion of ways to eliminate trade barriers at national frontiers to bring about an optimal expansion in international trade and better use of the world's resources of wealth. The Uruguay Round, much more ambitiously, set out to harmonize national trade policies, in particular in regard to the protection of intellectual property, thereby enlarging the domain of international trade and the competence of the international organizations active in that domain, and reducing the sovereign national jurisdiction of States. Because the geographical distribution of know-how is concentrated in industrialized countries, this harmonization is likely to **strengthen their existing economic superiority**, in particular by prohibiting developing countries from copying a new product by reverse engineering, and thereby developing their own technology.
- The Agreement spells out **universal standards of protection** of intellectual property, which are in practice the standards applied in industrialized countries. It also lays down some general obligations for compliance with these standards. Thus, the Agreement establishes a minimum uniform regime for intellectual property rights applicable to all Members of the WTO, irrespective of the differences in their level of development (apart from the transitional periods). This fact marks a radical break with the earlier GATT strategy of differential and more favourable treatment for developing countries adopted at the Tokyo Round.
- The TRIPS Agreement establishes, in Article 2.1, that the substantive provisions of the Paris Convention (which provides rules related to patents) shall be applicable to all WTO Members. By making this reference, the Agreement forces Member States that have not signed this convention to be bound by it, which amounts to an **express obligation to apply a treaty** without having signed it.

It is thus very clear that the Uruguay Round negotiations were largely dominated by industrialized countries and that developing countries were constrained to accept commitments sometimes running

counter to their economic and social development. According to the World Development Report for 1997, "Poor countries often lose out because the rules of the game are biased against them – particularly those relating to international trade. The Uruguay Round hardly changed the picture."<sup>1</sup>

It is therefore imperative to be aware of the possible consequences of the WTO agreements, especially the TRIPS Agreement in the area of pharmaceuticals, and to optimize the mechanisms as well as the freedom provided in the Agreement to ensure availability of drugs and fair competition.

### **3.2 Some Recommendations**

Each country's strategy in regard to globalization in the field of the production and distribution of drugs will have to be incorporated into its national pharmaceutical policy, a component of national health policy.

The new international economic and social context is likely to have an important effect on the equitable access of populations to health and to drugs, especially in developing countries. The new rules in the area of intellectual property could increase these countries' dependence still further.

The major implications concerning access to drugs are linked with the strengthening of the monopoly of working conferred by a patent on its holder. By 2005 at the latest, all developing countries will have to grant legal protection by patents to pharmaceutical products. Such a monopoly situation could lead to an increase in drug prices. That is why developing countries that are WTO Members should make the fullest use of the periods of transition they have been granted to transcribe the provisions of the TRIPS Agreement into their domestic law. Member States have an obligation to integrate into their patent legislation the minimal standards established by the TRIPS Agreement (patents for 20 years, no differential treatment between nationals and foreigners, reversal of the burden of proof), but the Agreement leaves

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<sup>1</sup> UNDP. *Human Development Report 1997*. New York & Oxford: Oxford University Press; 1997.

certain margins of freedom that can be used to limit the adverse effects on prices and access to technology.

Thus, under the exceptions to the monopoly that are authorized by the Agreement, the law should cover the possibility of authorizing parallel importation of patented drugs sold at lower prices in another country, or establish – as has been done by the Group of Andean Countries – that a drug on the WHO Model List of Essential Drugs should be the object of a compulsory licence for public health reasons, under the conditions laid down in the TRIPS Agreement.

At the same time, a certain number of "sensitive" provisions of the TRIPS Agreement, particularly the general principles concerning the protection of health, the obligation to exploit the patent locally, anti-competitive practices, and the exclusive marketing rights conferred during the periods of transition, will necessarily be subject to interpretation in their application. It would seem fundamental for developing countries to establish a joint position *vis-à-vis* these hotly debated questions, a position founded on the demand for a balance of rights, and also of the duties of patent holders *vis-à-vis* the community.

Finally, the new provisions of the TRIPS Agreement may have, to a greater or lesser extent, serious implications for the pharmaceutical sector, even if it is impossible to quantify them at present. It is essential that everyone involved in this sector should understand what is at stake and play an active part in the reforms of intellectual property regulations that are under way. National drugs policies should define strategies and guidelines today for the new regulations on patents, the new conditions for the transfer of technology, the new orientation of R&D, etc. All of these elements could have an important impact on access to drugs, one of the main objectives of national pharmaceutical policy recommended by WHO.



## **DEFINITIONS AND TERMINOLOGY<sup>1</sup>**

### **Biotechnology**

Integration of natural sciences and engineering in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services.

### **Brand name**

Name given to a drug by the manufacturer. The use of this name is reserved exclusively to its owner.

### **Compulsory licence**

This term is used when the judicial or administrative authority is allowed by law to grant a licence, without permission from the holder, on various grounds of general interest (absence of working, public health, economic development, and national defence).

### **Counterfeit goods**

Counterfeiting is a form of infringing activity. Counterfeit goods are generally defined as goods involving slavish copying of trademarks.

### **Counterfeit medicine**

According to WHO, a counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging. This definition includes intellectual property and non-intellectual property elements.

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<sup>1</sup> The terms defined in this chapter are marked with an asterisk the first time they appear in the document.

## **Dependent patent**

A patent that cannot be exploited without using another patent. When the use of compulsory licences is necessary, it is subject to certain conditions in the TRIPS Agreement:

- a) *"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;*
- b) *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*
- c) *the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."*

## **Drug Regulatory Authority**

A Drug Regulatory Authority is designated by the State to ensure compliance with regulations applicable to drugs: issuing of marketing authorizations, authorizations of dispensaries, etc.

## **Essential drugs**

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage form. The WHO Model List of essential drugs is intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.

## **Exhaustion of intellectual property rights (see parallel imports)**

This is a partial extinction of the right of the patentee – holder of the patent – consisting of the termination of certain of his prerogatives, due to exhaustion of rights. According to this theory, the patentee's right is exhausted when the product covered by it is put into circulation for the first time, if this has been done with the consent of that right holder. It follows that once the product has been put on the market, the patentee

may no longer exercise control over the subsequent circulation of that product.

## **GATS**

The General Agreement on Trade in Services constitutes one of the new domains of competence assigned to the WTO. It is compulsory for all Member States and is aimed at liberalizing trade in services. It is likely to have consequences in the field of public health in that it may provide for Member States to open their domestic market to foreign suppliers of hospital and medical services.

## **GATT/WTO**

The World Trade Organization is the institutional successor to the General Agreement on Tariffs and Trade (GATT). The latter was a very particular institution: the GATT was, in fact, simply a treaty signed in 1947 by 23 nations and not an organization such as the International Monetary Fund or the World Bank, which were established at the same time. The GATT was thus a multilateral instrument whose objective was to promote and regulate the liberalization of international trade through "rounds" of trade negotiations. In 45 years, there have been eight rounds of negotiation under the auspices of the GATT. The first rounds were only concerned with sectoral reductions of customs duties. In the Kennedy Round (1964-1967) and the Tokyo Round (1973-1979), the scope of the negotiations was enlarged to include global reduction of customs duties and non-tariff measures constituting a barrier to trade (dumping, subsidies and government procurement). The last round of negotiations opened in Uruguay in 1986 and ended with the signature of the Final Act in Marrakech in 1994, establishing the new WTO. This Organization has international legal status and henceforth all matters relating to international trade will fall within its jurisdiction. The WTO agreements consist of multilateral agreements that become binding upon Member States when they join the WTO, and plurilateral agreements that are optional.

## **GATT 1947/GATT 1994**

The General Agreement on Tariffs and Trade of 1994 is one of the WTO multilateral agreements. It consists of the original text of the GATT of 1947 as revised and modified during the various rounds of negotiations, including the concessions agreed during the Uruguay Round.

### **Generic drug**

A pharmaceutical product usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or other exclusivity rights. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary or brand name.

### **Globalization**

Phenomenon arising at the end of the twentieth century characterized by worldwide interpenetration and interdependence of all sectors – economic, political, social, cultural and military. In other words, globalization, as the result of technical and economic evolution, is equivalent to a transformation of society resulting in the negation of territorial frontiers.

### **Good manufacturing practice for pharmaceutical products**

Good manufacturing practice (GMP) is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization (product licence).

### **INN (international non-proprietary name) or generic name**

Common, generic names selected by designated experts to identify new pharmaceutical substances unambiguously. The selection process is based on a procedure and guiding principles adopted by the WHA. They are recommended for worldwide use, destined to be unique and public property (non-proprietary).

## **Intellectual property**

Intellectual property rights are exclusive rights, often temporary, granted by the State for the exploitation of intellectual creations. Intellectual property rights fall into two categories: those rights relating to industrial property (invention patents, industrial designs and models, trademarks, and geographical indications) and those relating to literary and artistic property (copyright). The Agreement on Trade-Related Aspects of Intellectual Property Rights covers the main categories of intellectual property law.

## **Licence**

A contract whereby the holder of an industrial property right (patent, trademark, design or model) cedes to a third party, in whole or in part, the enjoyment of the right to its working, free of charge or in return for payment of fees or royalties.

## **Marketing authorization**

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality.

## **Most-favoured-nation (MFN)**

Article 1 of the GATT of 1947 requires Member States to comply with a general obligation to apply most-favoured-nation treatment. According to this Article, "Any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country, shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties". In other words, it is prohibited to treat products differently on account of their origin. In order to avoid any discrimination, any advantage accorded to one country must also be accorded to all other Members of the GATT.

## **Multilateral/plurilateral agreements**

The new Agreement instituting the WTO consists of multilateral trade agreements that are binding on all WTO Member States and plurilateral trade agreements whose acceptance by Members is optional.

The Multilateral Agreements include the multilateral agreements on trade in goods, the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The agreements on trade in goods comprise the GATT of 1994, the Agreement on Agriculture, the Agreement on the Application of Sanitary and Phytosanitary Measures, the Agreement on Textiles and Clothing, the Agreement on Technical Barriers to Trade, the Agreement on Trade-Related Investment Measures (TRIMs), the Anti-dumping Agreement, the Agreement on Customs Valuation, the Agreement on Pre-shipment Inspection, the Agreement on Rules of Origin, the Agreement on Import Licensing Procedures, the Agreement on Subsidies and Countervailing Measures and the Agreement on Safeguards.

The plurilateral agreements are the Agreement on Trade in Civil Aircraft and the Agreement on Government Procurement.

## **Parallel imports**

Products imported into a country without the authorization of the right holder in that country, which have been put on the market in another country by that person or with his consent. According to the theory of exhaustion of intellectual property rights, the exclusive right of the patent holder to import the protected product is exhausted, and thus ends, when the product is first launched on the market. When a State or group of States applies this principle of exhaustion of intellectual property rights within a given territory, parallel importation is authorized to all residents in the State in question. In a State that does not recognize this principle, however, only the patent holder that has been registered has the right to import the protected product.

### **Parallel patent**

This term is used when an invention is covered by more than one national patent registered by the same person in different countries.

### **Patent**

A title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes a sufficiently clear and full description of it, and claims this monopoly.

### **Patentability**

This means that a product or manufacturing process fulfils the necessary conditions for protection by a patent. There are two categories of patents: product patents and process patents.

### **"Pipeline" protection**

This type of protection was supported by the United States of America during the Uruguay Round but ultimately was not included in the TRIPS Agreement. It is a kind of retroactive protection, to the effect that pharmaceuticals already patented in other countries but not yet patented in the "pipeline" country (because its legislation did not grant patents for pharmaceuticals), nor marketed in that country, may be claimed for protection as such as soon as the Agreement comes into force. However, the TRIPS Agreement imposes protection only on inventions still meeting the criteria for patentability (notably because they have not yet been disclosed) on the date of entry into force of the Agreement.

### **Piracy**

Pirated goods are goods that violate copyright and related rights. Publishers and producers of records, films and recorded tapes are often the victims of breaches of copyright. The computer software industry is particularly affected.

## **Research & Development (R&D)**

The activity of devoting money and energy to researching a new technology in any field, and then developing the product or process obtained. In the pharmaceutical field, the costs of R&D are particularly high. The invention and development of a new drug requires considerable investment, hence the demand from the pharmaceutical industry for patents to be issued for all new inventions, with a view to recovery of the funds invested in R&D.

## **Reverse engineering**

A practice for discovering the manufacturing process of a product starting from the finished product. This practice has often been used to copy original drugs in countries that do not grant patents for pharmaceutical products.

## **Settlement of international trade disputes**

The dispute settlement mechanism allows countries to challenge the measures taken by their trading partners and obtain a ruling on the compatibility of these measures with the provisions of the WTO agreements. The "*Understanding on Rules and Procedures Governing the Settlement of Disputes*", that is part of the Agreement establishing the WTO, instituted the Dispute Settlement Body (DSB), which is competent to deal with any dispute arising in regard to any of the multilateral or plurilateral WTO agreements.

## **Tariff/non-tariff barriers to trade**

The tariff measures constituting a barrier to trade are customs duties, taxes imposed on goods entering a territory other than their territory of origin. The non-tariff measures constituting a barrier to trade are all the other regulatory or legislative measures that result in the distortion of competition in international trade. These include: commercial dumping, technical barriers to trade, government procurement, subsidies or customs valuations.

## **Technical barriers to trade (TBT)**

The Agreement on Technical Barriers to Trade is one of the multilateral agreements on trade in goods and therefore binding on all Members. It expands and spells out the TBT Agreement concluded at the Tokyo Round. It aims to ensure that technical regulations and standards, and testing and certification procedures, do not create unnecessary barriers to trade. Nevertheless, it recognizes that a country has the right to take measures, for example, to protect the health and life of humans and animals and for the preservation of plant life or protection of the environment, at the levels it deems appropriate, and that nothing can prevent it from taking the necessary measures to ensure respect for these levels of protection. Countries are thus encouraged to have recourse to international standards where they are appropriate, and in particular to the WHO standards of quality applicable to pharmaceutical, biological and food products; but they are not required to modify their levels of protection following standardization.

## **Term of protection**

This is the duration of the lifetime of a patent, in other words, the time during which the title holder to the invention may enjoy a monopoly for its exploitation. The TRIPS Agreement imposes a minimum term of 20 years for all product and process patents, measured from the date on which the patent application was filed.

## **Trademark (Article 15 of the TRIPS Agreement)**

*Any sign or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combination of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.*

## **Transition period**

In the TRIPS Agreement, certain countries are granted periods of transition, adapted to their levels of development, constituting waivers to the time limits normally stipulated for compliance with the Agreement. Whereas all WTO Members are entitled to a one-year transition period, developing countries and, subject to certain conditions, the former socialist republics are granted four extra years to bring their legislation into conformity with the Agreement. Likewise, the least-developed countries are accorded an extra ten years to start applying the provisions of the Agreement, with a possibility of extension.

## **TRIMs**

The Agreement on Trade-Related Investment Measures recognizes that certain measures may have the effect of restricting or distorting trade. It provides that no Contracting Party may apply trade-related investment measures (TRIMs) that are not compatible with Article III (national treatment) and Article XI (general elimination of quantitative restrictions) of the General Agreement. To this end, an indicative list of TRIMs agreed to be incompatible with these Articles is annexed to the Agreement. This list includes measures requiring an enterprise to buy a certain volume or a certain value of locally produced goods (provisions relating to the content of elements of local origin) or which limit the volume or value of the imports this enterprise may purchase or use to an amount linked with the volume or value of the local products it exports (prescriptions relating to the balance of trade). The Agreement provides for compulsory notification of all TRIMs that do not comply and their elimination within two years for developed countries, five years for developing countries and seven years for the least-developed countries.

## **TRIPS**

The Agreement on Trade-Related Aspects of Intellectual Property Rights covers a new field in multilateral international trade law. It was proposed that this subject should be included in the multilateral trade negotiations of the Uruguay Round in an attempt to remedy problems of international piracy and infringement of intellectual property rights. The Agreement establishes minimum standards of protection for each

category of rights. These standards should be integrated into the national legislation of all WTO Members, and should be applied in accordance with the principles of most-favoured-nation treatment and national treatment. They subsume and extend to all WTO Members the substantive obligations of the main treaties administered by WIPO, i.e. the Bern Convention for the Protection of Copyright and the Paris Convention for the Protection of Intellectual Property, with the addition of other obligations when necessary to complement the scope of these Conventions. The TRIPS Agreement, as an entity in the block of multilateral agreements, binds the obtaining and maintenance of customs benefits in the framework of WTO to respect for intellectual property rights by the State in question. It is the agreement in the Final Act of the Uruguay Round that could have the most implications for the production of and access to drugs, particularly in developing countries.

### **Unfair competition**

This is defined in the TRIPS Agreement as any act of competition contrary to honest trade practices, leaving it to the authorities in each country to define the concept of commercial honesty. More generally, it is defined as wrongful actions committed in professional practice, of a nature such as to incur the civil liability of those committing them. Such actions would be likely to attract clients or turn them away from a competitor in a wrongful manner.

### **Uruguay Round**

"Rounds" of negotiation were instituted when GATT was established. The GATT agreement itself results from the first round of negotiations, since the objective in 1947 was to get States to negotiate in the domain of international trade with a view to granting mutual trade concessions. When the GATT became institutionalized, it was decided to keep the idea of rounds of multilateral trade negotiations (MTN). Thus there have been in succession the Geneva, Annecy and Torquay Rounds, followed by the better known Dillon Round, Kennedy Round, Tokyo Round and Uruguay Round. It was the round that lasted longest (1986-1994) and also the most ambitious, being the origin of the establishment of the WTO and a string of multilateral agreements.

## **WHO Certification Scheme**

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce guarantees, through the issue of a WHO certificate, the quality of pharmaceutical products entering international commerce. It is a simple administrative procedure that enables importing countries to obtain information on whether a product has been authorized to be placed on the market in the exporting country, and assurance that the manufacturer has been found to comply with WHO standards of good manufacturing practice. This system is particularly useful for countries with limited capacity for quality control of drugs.

## **WIPO**

The World Intellectual Property Organization was set up in 1970 to manage the protection and regulation of intellectual property rights. It replaced the Union for the Protection of Intellectual Property, an association of States with permanent independent bodies established by the Paris and Bern Conventions. In 1996, WIPO had 140 Member States and was administering 18 international conventions, the most important of which are the Paris Convention on intellectual property (1883 – 114 Members), the Bern Convention on copyright (1886 – 102 Members), the Madrid Agreement on the international registration of marks (1891 – 37 Members), the Patent Cooperation Treaty (1970 – 68 Members), the Budapest Treaty on the international recognition of the deposit of micro-organisms (1977 – 26 Members) and the International Union for the Protection of New Plant Varieties (UPOV 1961 – 24 Members). Since the existing conventions in the field of intellectual property do not provide for any system of sanctions for non-compliance, it was proposed in the WTO negotiations to introduce the obligation to ensure minimal protection of intellectual property rights, and to make compliance a condition for the granting of customs concessions. The TRIPS Agreement will coexist with the earlier conventions administered by WIPO, without replacing them.

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**Language:** French.

**Address:** Association Internationale de Droit Economique (AIDE), 3 Place Montesquieu, 1348 Louvain-la Neuve, Belgium.

**Summary:** Very detailed juridical analysis of the new situation of pharmaceutical patents with the establishment of the WTO. Reviews the traditional fundamental elements of patents and describes their new function that has led to the TRIPS Agreement. Raises the problem of the inclusion of intellectual property law in the domain of multilateral trade. Analyses and discusses all the provisions of the Agreement relating to patents, and particularly the limitations of patent rights.

- Rozek RP. The consequences of pharmaceutical product patenting: a critique. *World Competition*, 1993, 16:3.

**Key words:** economic development, developing countries, patent, pharmaceutical industry.

**Language:** English.

**Address:** World Competition, P.O. Box 5134, 1211 Geneva 11, Switzerland.

**Summary:** A critique of Pablo Challu's article, published in the same journal in 1991. Three main arguments: an erroneous approach to the economic development of a state, questionable and incomplete data, and inappropriate cost analyses.

- Subramanian A. Putting some numbers on the TRIPS pharmaceutical debate. Special issue on the management of international intellectual property. *Int. J. Technology Management*, 1995, 10 (2/3):252-268.

**Key words:** patent, pharmaceutical product, market, price, retroactive legislation, compulsory licence, Argentina, India, Malaysia.

**Language:** English.

**Address:** International Journal of Technology Management, 17 Beeward Close, The Leyes, Wolverton Mill, MK12 GLJ, United Kingdom.

**Summary:** Estimation of the consequences of the introduction of patents for pharmaceutical products in terms of prices, benefits and welfare of the population in a certain number of developing countries.

- Weissman R. A long, strange TRIPS. *University of Pennsylvania Journal of International Economic Law*, 1996, 17:4.

**Key words:** developing countries, pharmaceutical industry, patent, essential drugs.

**Language:** English.

**Address:** University of Pennsylvania, Journal of International Economic Law, USA.

**Summary:** An overview of the different policy options possible in terms of patents. Background to the offensive taken by the pharmaceutical industry before and during the Uruguay Round negotiations. Analysis of the TRIPS Agreement, discussing in particular the margins of freedom the Agreement leaves to governments to elaborate a system of patents for pharmaceutical

products. Conclusions suggest the alternative for developing countries of establishing an essential drugs programme.

## Country studies

### **AFRICA**

- Yusuf AA. Intellectual property protection in the countries of Africa. Special issue on the management of international intellectual property. *Int. J. Technology Management*, 1995, 10(2/3):269-292.

**Key words:** Africa, intellectual property rights, rules of protection, Paris Convention, Berne Convention, AIPO, ARIPO, licence, transfer of technology, patent.

**Language:** English.

**Address:** International Journal of Technology Management, 17 Beeward Close, The Leyes, Wolverton Mill, MK12 GLJ, United Kingdom.

**Summary:** Presents first the status of the protection and exploitation of intellectual property rights in Africa, before considering the impact of the new international rules in the field of intellectual property.

### **ARGENTINA**

- FIEL (Fundación de Investigaciones Económicas Latinoamericanas). *Protection of intellectual property rights: the case of the pharmaceutical industry in Argentina*. Buenos Aires, 1990.

**Key words:** pharmaceutical product, patent, WIPO, Uruguay Round, developing countries, Section 301, Argentina, Brazil, India, Italy, Korea, Mexico.

**Languages:** Spanish, English.

**Address:** Fundación de Investigaciones Económicas Latinoamericanas, Esmeralda 320, Buenos Aires, Argentina.

**Summary:** Demonstration of the links that exist between intellectual property rights, pharmaceutical products and

international trade. Stakes in the protection of intellectual property rights during the Uruguay Round negotiations, and resulting from American trade policy. Analysis of the situation in Argentina: the new patent legislation and economic assessment of its application.

- Rozanski F. Nueva legislación argentina de patentes de invención. *Derechos intelectuales*, volumen 7, Editorial Astrea, May 1996.

**Key words:** patent, transitional period, duration of protection, licences, constitutional reform.

**Language:** Spanish.

**Address:** Editorial Astrea, Argentina.

**Summary:** Analysis of the evolution of the invention patent system in Argentina up to the latest legislative reform in line with the TRIPS Agreement.

- Zuccherino DR. Breve panorama de la legislación sobre patentes de invención en la República Argentina. *Revista La Información*, Junio 1995, 786, T.71, Año 66.

**Key words:** invention patent, WIPO, GATT, constitutional reform.

**Language:** Spanish.

**Address:** Revista La Información, Buenos Aires, Argentina.

**Summary:** Outlines the problem of patents in Argentina in parallel with the situation of intellectual property rights at world level.

- Zuccherino DR. Propiedad intelectual y dinámica competitiva. *Revista La Información*, Mayo 1996, 797, T.73, Año 67.

**Key words:** patent, competition, intellectual property.

**Language:** Spanish.

**Address:** Revista La Información, Buenos Aires, Argentina.

**Summary:** Examines the question of the relationship between invention patents, competition and economic development.

## **BRAZIL**

- Gosain R. Patent law reform in Brazil – an update. *Patent World*, October 1994, pp. 38-41.

**Key words:** Brazil, patent law, reform.

**Language:** English.

**Address:** Armstrong International Limited, The Courtyard, 12 Hill Street, St Helier, Jersey, JE2 4UB, United Kingdom.

**Summary:** Develops the essential points of the reform of the Brazilian law on patents, following international pressures: patent protection of micro-organisms, chemical and pharmaceutical products, pipeline protection, exhaustion of rights and regulation of compulsory licences.

- Gosain R, Sherrill HK. The effects of GATT/TRIPS on Brazil's patent legislation. *Patent World*, May 1995, pp 24-26.

**Key words:** Brazil, patent, reform.

**Language:** English

**Address:** Armstrong International Limited, The Courtyard, 12 Hill Street, St Helier, Jersey, JE2 4UB, United Kingdom.

**Summary:** An analysis of the reform of the Brazilian patent law: extension of the domain of patentability, duration of protection, compulsory licences, local working of the patent, registration of applications for patents on new materials.

- Medina I. Patentability of pharmaceuticals and the new trends in Brazilian legislation. *Patent World*, November 1990, pp 33-35.

**Key words:** Brazil, pharmaceutical product, patent.

**Language:** English.

**Address:** Armstrong International Limited, The Courtyard, 12 Hill Street, St Helier, Jersey JE2 4UB, United Kingdom.

**Summary:** Relates the history of the patentability of pharmaceutical products in Brazil from the Imperial Constitution of 1824 to the 1990s.

- Redwood H. *Brazil - the future impact of pharmaceutical patents*. Oldwicks Press Ltd, 1995.

**Key words:** Brazil, patent, pharmaceutical product, biotechnology, costs, R&D.

**Language:** English.

**Address:** Oldwicks Press Limited, 5 Links Avenue, Felixstowe, Suffolk, IP11 9HD, United Kingdom.

**Summary:** Analysis of the consequences of patent protection of pharmaceutical and biotechnology products in Brazil. More specifically, the following points are developed: the controversy in Brazil on the issue of the patentability of pharmaceutical products, the pharmaceutical industry in Brazil, a market study of patent protection of pharmaceutical products in Brazil, a study of the consequences in terms of costs and delays in the field of R&D.

## **CANADA**

- Torremans P. Compulsory licensing of pharmaceutical products in Canada. *International Review of Industrial Property and Copyright Law*, 1996, 27:3.

**Key words:** Canada, patent, pharmaceutical product, licences, generic products, NAFTA.

**Language:** English.

**Address:** IIC, VCH Verlagsgesellschaft mbH, P.O. Box 101161, D 69451 Weinheim, Germany.

**Summary:** Presents the traditional Canadian approach to patents for pharmaceutical products based on lax regulation of compulsory licences, the changes made to the legislation following signature of the TRIPS and NAFTA Agreements and the implications for the Canadian generic drugs industry.

## **EGYPT**

- Abouelenein AA. *Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the pharmaceutical industry in Egypt*. Federation of Egyptian Industry; Cairo, June 1996.

**Key words:** Egypt, patent, drug, price, pharmaceutical industry.

**Languages:** Arabic, English.

**Address:** Federation of Egyptian Industry, Cairo, Egypt.

**Summary:** A view of a member of the Board of the Association of Egyptian Industries on the effects of the TRIPS Agreement on the

country's pharmaceutical industry compared with its present state, and the economic, social and health effects likely to ensue.

- Ghorab MG. *Agreement on intellectual property and pharmaceuticals in Egypt*. Egypt, 1996.

**Key words:** Egypt, drug, patent, price, R&D, investments.

**Language:** Arabic.

**Address:** Medicinal drugs holding company (of which Mr Ghorab is the Chairman), Egypt.

**Summary:** Brief presentation of the current drug situation in Egypt followed by an outline of the solutions envisaged to take account of the TRIPS Agreement, in particular, policies on registration and pricing, support to R&D activities, and instigating strategic alliances. Analysis of the advantages accruing from patent protection for the pharmaceutical industry and the economy in Egypt.

- Shaarawi NM. *Intellectual property rights – Egypt*, Glaxo Wellcome Egypt, SAE, 1993.

**Key words:** Egypt, patent, drug prices, R&D.

**Language:** English.

**Address:** Glaxo Wellcome Egypt.

**Summary:** The view of a multinational established in Egypt on the possible consequences of the TRIPS Agreement on drug prices and the advantages resulting from it for the Egyptian pharmaceutical industry in the field of R&D.

## INDIA

- Ahuja SD. GATT and TRIPS – The impact on the Indian pharmaceutical industry. *Patent World*, September 1994, pp 28-34.

**Key words:** India, patent, pharmaceutical product.

**Language:** English.

**Address:** Armstrong International Limited, The Courtyard, 12 Hill Street, St Helier, Jersey, JE2 4UB, United Kingdom.

**Summary:** Describes the issues surrounding the reform of the 1970 Patent Act in order to ensure its conformity with the TRIPS Agreement, existing distortions, the modifications that need to be made and the consequences for the Indian pharmaceutical industry.

- Debroy B. *Beyond the Uruguay Round: the Indian perspective on GATT*. Response Books, 1996.

**Key words:** India, patent, pharmaceutical product, essential drugs, micro-organisms, R&D, prices.

**Language:** English.

**Address:** Response Books, a division of Sage Publications India Pvt Ltd, M-32 Greater Kailash Market I, New Delhi 110048, India.

**Summary:** Developments on the exceptions of Article 27 determining non-patentable products, followed by analysis of the consequences of the Agreement in India in terms of drug prices and repercussions on essential drugs.

- Dubey M. *An unequal treaty: world trading after GATT*. New Delhi, 1996.

**Key words:** India, WTO, GATS, TRIMs, agriculture, textiles, settlement of disputes, patent, drug, licence, investments, transfer of technology.

**Language:** English.

**Address:** New Age International Limited Publishers, 4835/24 Ansari Road, Dayaganj, New Delhi 110 002, India.

**Summary:** Analyses the impact of the different agreements and the WTO system on developing countries and India in particular. History of the difficult negotiations leading up to the signature of the TRIPS Agreement and discussion of the pros and cons of the Agreement for developing countries, the special case of the protection of plant varieties and, finally, the various possibilities for making the obligations under the Agreement more flexible.

- Karandikar SM. *Indian drug industry after GATT*. Bombay: World Trade Centre, September 1994.

**Key words:** India, pharmaceutical industry, patent.

**Language:** English.

**Address:** MVIRDC, World Trade Centre, Centre 1, 31st floor, Cuffe Parade, Bombay 400 005, India.

**Summary:** Comprehensive study of the pharmaceutical industry and the Indian health system. Analysis of the consequences of the signature of the TRIPS Agreement for the Indian pharmaceutical industry and access to drugs.

- Otten A. The GATT/TRIPS Agreement and health care in India. *The National Medical Journal of India*, 1995, 8:1.

**Key words:** India, patent, pharmaceutical product, costs, R&D.

**Language:** English.

**Address:** National Medical Journal of India, All Indian Institute of Medical Sciences, Ansari Nagar, New Delhi 110029, India.

**Summary:** An attempt to respond to questions that are controversial in India, such as why the TRIPS Agreement should necessarily have dramatic effects on drug prices, and how pharmaceutical patents would lead to more R&D, to improve access to drugs.

- Krishna Iyer VR, Chinnappa Reddy O, Desai DA, et al. Report Peoples' Commission on GATT. *On the constitutional implications of the final act embodying the results of the Uruguay Round of multilateral trade negotiations*. Centre for Study of Global Trade System and Development, 1996.

**Key words:** India, WTO, GATS, TRIMs, agriculture, textiles, patent, drug, prices, licence, investments, transfer of technology, essential drugs.

**Language:** English.

**Address:** Centre for Study of Global Trade System and Development, A 388, Sarita Vihar, New Delhi 110 044, India.

**Summary:** A chronology of the national and international events that led up to the signature of the Final Act, with an historical

account of the creation of the GATT and the earlier rounds of negotiations. The Indian Government's handling of the Uruguay Round negotiations is the subject of another chapter. The bulk of the report is devoted to the critical provisions of the Final Act agreements, their political and economic impact and their constitutionality.

- Pillai AM. Impact of GATT Agreement on drug prices. *J. Indian Med. Assoc.*, March 1995, 93:3.

**Key words:** India, prices, drug.

**Language:** English.

**Address:** Journal of the Indian Medical Association, AMM House, 53 Creek Row, Calcutta 700014, India.

**Summary:** Discusses the implementation of the TRIPS Agreement, and the increase in prices that could follow as a challenge to the pharmaceutical industry, the government and the medical profession.

- Redwood H. *New Horizons in India – the consequences of pharmaceutical patent protection*. Oldwicks Press Ltd., 1994.

**Key words:** India, pharmaceutical industry, patent, prices, R&D.

**Language:** English.

**Address:** Oldwicks Press Limited, 5 Links Avenue, Felixstowe, Suffolk, IP11 9HD, United Kingdom.

**Summary:** The rise of the Indian pharmaceutical industry as a result of the Patent Act of 1970. Analysis of the myths and expectations relating to the implementation of the TRIPS Agreement in India: the introduction of patents to the Indian drugs market, the effects on prices, expectations for R&D of new products. The last part looks at possible options for the future.

- Sen B. *The Uruguay Round: implications for world trade*. New Delhi: 1996.

**Key words:** India, pharmaceutical industry, patent, prices, R&D.

**Language:** English.

**Address:** Jawahar Publishers and Distributors, New Delhi, India.

**Summary:** Evaluation of the stake of the new WTO agreements for developing countries. Focuses on the situation of pharmaceutical and biotechnological products in India.

- Rajiv Gandhi Institute for Contemporary Studies. *Indian S&T after GATT: an agenda for action*. RGICS Project No. 9.

**Key words:** India, patent, micro-organisms, plant varieties, R&D.

**Language:** English.

**Address:** Rajiv Gandhi Foundation, Jawahar Bhawan, Dr Rajendra Prasad Road, New Delhi 110 001, India.

**Summary:** Analysis of the TRIPS Agreement's influence in the field of science and technology, and some suggestions on how India can benefit from the post-GATT era.

## ITALY

- Challu PM. Effects of the monopolistic patenting of medicine in Italy since 1978. Special issue on the management of international intellectual property. *Int. J. Technology Management*, 1995, 10(2/3):237-251.

**Key words:** Italy, patent, drug prices, R&D.

**Language:** English.

**Address:** International Journal of Technology Management, 17 Beeward Close, The Leyes, Wolverton Mill, MK12 GLJ, United Kingdom.

**Summary:** The study concentrates on four fields: the impact of patents on prices, the attitude of national laboratories and the consequences for national production, the effects of the monopoly conferred by patents on the capacity for innovation, and the influence of patents on trade in pharmaceuticals in Italy.

- Scherer FM, Weiburst S. Economics effects of strengthening pharmaceutical patent protection in Italy. *International Review of Industrial Property and Copyright Law*, 1995, 26:6.

**Key words:** Italy, patent, pharmaceutical product, costs, R&D.

**Language:** English.

**Address:** IIC, VCH Verlagsgesellschaft mbH, P.O. Box 101161, D 69451 Weinheim, Germany.

**Summary:** Economic study of the consequences of the introduction of pharmaceutical patents in Italy from the standpoint of R&D expenditure, the introduction of new drugs, and direct investment by multinational companies.

## ***JORDAN***

- Badwan AA. *Implications of joining WTO on the Arab pharmaceutical industry*. Jordan, 1996.

**Key words:** Jordan, patent, mark, drug, industry, prices, competition, imitation.

**Language:** English.

**Address:** Jordanian Pharmaceutical Manufacturing Co., Jordan.

**Summary:** Overview of the main provisions of the TRIPS Agreement likely to affect developing countries and the situation of the Arab drug industry.

## **PART II**

# **THE PHARMACEUTICAL INDUSTRY, US GOVERNMENT AND WTO CRITIQUES OF WHO'S "GLOBALIZATION AND ACCESS TO DRUGS: IMPLICATIONS OF THE WTO/TRIPS AGREEMENT"<sup>1</sup>**

### **INTRODUCTION**

The request in resolution 49.14 of 1996 for the Director General to prepare a study on the implications of the TRIPS Agreement, was entrusted to the Drugs Action Programme (DAP) which published a document: "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement"<sup>2</sup> in November 1997.

The document, published by the WHO, provoked a series of violent criticisms by the Pharmaceutical Research and Manufacturers of America – PhRMA. The letter from PhRMA was followed by a letter from the Government of the United States dated 28 July 1998,<sup>3</sup> and a letter from the WTO Secretariat.

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<sup>1</sup> Copies of the letters (reproduced here) from the US government, the Pharmaceutical Research and Manufacturers of America (PHARMA) and the World Trade Organization (WTO) as well as the analysis of 3 independent Reviewers (A,B and C), included in Part III, were distributed by the WHO Secretariat, as a back ground document at the meeting of the Executive Board Ad hoc working group, which took place on October 13, 1998 chaired by the Director General of WHO and attended by representatives of the 33 Member States of the EB, WTO, WIPO, NGOs, IFPMA, WIPO the South Centre and the International Generic Pharmaceutical Alliance (IGPA).

<sup>2</sup> Velásquez, G., Boulet P., "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", WHO/DAP/98.9, Geneva, November 1997, 58 pg.

<sup>3</sup> Benkimoun P. op.cit. p. 185 Letter from the Government of the United States of America, signed by the Commissioner of Health Affairs of the FDA, Stuart Nightingale.

The three mentioned letters criticizing the book and the review of the three international experts (A, B, C) are reproduced in this Part III.

Thomas Bombelles  
ASSISTANT VICE PRESIDENT  
INTERNATIONAL

PhRMA

June 30, 1998

Dr. Jonathan Quick  
Director  
Drug Action Program  
World Health Organization  
CH – 1211 Geneva 27  
Switzerland

Dear Dr. Quick:

Received in DAP – 6 JUL. 1998			
To	Initials	Date	Reply
SV			
MNC			
JQR			
Action initiated			

As we discussed during the May World Health Assembly, PhRMA has a great number of concerns with the recently published DAP Paper Number 7, "Globalization and Access to Drugs: Implications of the WTO/TRIPs Agreement." Please find enclosed a detailed critique of the paper, which you are free to share with your colleagues in WHO.

It will be clear from PhRMA's critique that the DAP paper is a deeply flawed document that misleads its readers and creates a false impression of how the WTO TRIPs agreement will affect pharmaceuticals. The paper seeks to rationalize the continued piracy of pharmaceutical inventions, even as virtually every major developing and developed country has implemented policies to protect intellectual property for all technologies in order to benefit from both inward and foreign direct investment and to spur innovation. Indeed, while PhRMA remains concerned about challenges to intellectual property protection, and enforcement, in a number of countries around the world, we must also recognize that among major WTO members, only Argentina, India, and Egypt specifically allow for pharmaceutical piracy. Other countries around the world, including the industrializing economies of Asia, Mexico, Brazil, Ecuador, Eastern and Central Europe, characterize the TRIPs agreement and encourages WHO members not to implement adequate and effective intellectual property protection for pharmaceuticals. In so doing, the WHO not only puts itself in opposition to the 132 WTO members that have signed the agreement, but also, in PhRMA's view, takes a position that is deleterious to public health. I say this because it is intellectual property protection that fuels pharmaceutical innovation. The answer to the challenge of developing and improving access to new therapies for the developing world is more intellectual property protection, not less.

*Pharmaceutical Research and Manufacturers of America*

1100 Fifteenth Street, NW, Washington, DC 20005 • Tel: 202-835-3495 • FAX: 202-835-3413 • [tbombell%phrma@mcimail.com](mailto:tbombell%phrma@mcimail.com)

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I hope you find the enclosed paper useful and constructive, and I look forward to discussing it with you in the near future.

Sincerely,

A handwritten signature in blue ink, appearing to read "Tom Bombelles".

Thomas Bombelles

Enclosure

cc: Dr. F. Antezana/Dr. D. Broun/Mr. T. Topping/Dr. Idänpään-Heikkilä, WHO  
Dr. H. Bale, IFPMA  
Mr. K. Bernard/Mr. T. Burns, US Permanent Mission in Geneva  
Mr. R. Wilder, WIPO

**1. A CRITIQUE OF WHO DAP SERIES NUMBER 7  
"GLOBALIZATION AND ACCESS TO DRUGS:  
IMPLICATIONS OF THE TRIPS AGREEMENT" AN  
ANALYSIS SUBMITTED BY THE PHARMACEUTICAL  
RESEARCH AND MANUFACTURERS OF AMERICA**

A review of the Drug Action Program (DAP) paper "Globalization and Access to Drugs" co-authored by two members of DAP's staff reveals it to be a biased and inaccurate attack on patent protection for pharmaceutical innovations. A catalogue of some of the biases and errors makes it clear that this paper should not be the basis of any further serious discussion in the WHO or elsewhere.

**A. General Comments**

The general tone of the paper presumes a negative correlation between intellectual property protection and drug pricing and access. As can be expected with a paper that starts from this premise, the paper is filled with biased views, inaccuracies and outmoded economic theories. This critique will address some of the most significant errors and incorrect assumptions incorporated in the paper.

1. Confusion of patent exclusivity with "monopoly" power. Anyone who has passed an introductory course in economics can distinguish the limited period of exclusivity provided by a patent from monopoly power. Unlike monopoly power, patent rights promote competition by forcing development of new products to compete within a defined market. For example, consider how many anti-allergy products are currently being marketed in the United States. Many are patented, but none has a dominant market (i.e., "monopoly") status. Similarly, consider the fact that over 3 million patents are currently in force in the United States. If every patent were a monopoly, the U.S. economy would have ground to a halt a long time ago. By intentionally confusing patent exclusivity with monopoly power, the authors are hoping to cast patent rights as an "evil" to be restrained, instead of the essential stimulus to pharmaceutical innovation and facilitator of technology transfer that they have been shown to be through countless studies.

2. Confusion of infringement of patent rights with counterfeiting.

The authors reveal their lack of understanding of practical patent issues by confusing infringement of patent rights with counterfeiting of pharmaceutical products. Sales of counterfeit pharmaceutical products pose direct threats to consumers, and as such, are made illegal by drug regulatory authorities in most countries. Counterfeiting also implicates trademark rights, not patent rights. By equating counterfeiting with patent infringement, the authors are attempting to cast patent infringement as an "illegal" activity, which, in turn, would presumably carry much more onerous burdens on government authorities in developing countries. In reality, patent infringement is a private civil action initiated and conducted by the patent owner. There will not be a burden on developing country governments to enact large, complex enforcement systems to prevent patent infringement.

3. A paternalistic view of innovation in developing countries. The authors have chosen to define the needs of developing countries in the outmoded and anachronistic "north-south" economic model of the 1970s. Their "analysis" completely forecloses the possibility of domestic innovation in a developing country, either independently or arising out of joint ventures with "northern" pharmaceutical interests. They stress throughout their paper the idea that weaker patent rights are better for industries in developing countries, rationalizing that industries in developing countries are capable only of *copying* innovations made by companies in industrialized nations. Their view that developing country interests are incapable of innovation in the pharmaceutical industry is at odds with the reality of existing initiatives in many developing countries, particularly in the field of biotechnology. Adhering to this model of the world will stunt the growth of new innovation-based industries in developing countries.

4. Ignorance of what patent rights are and how patent rights are used in the process of technology transfer. The authors make the conscious error of presuming that all patent rights are identical in scope and effect and that patent rights are never licensed. These conscious errors are essential to their conclusions that patent rights can only hinder "technology transfer." In reality, patent rights are instrumental in establishing relationships that will facilitate technology transfer, as they provide the vehicle through which rights can be defined and by which

risks and benefits from successful ventures allocated. Patents are also a crucial source of scientific and technical information, given that patent disclosures are published and disseminated on a regular basis. Patents also vary widely in their scope and effect, and as a result, critical distinctions exist in licensing patterns for different types of patent rights and different technologies. Finally, the past thirty years or so of inadequate patent protection in India, Brazil and Argentina, and the resulting absence of any innovation-based pharmaceutical industry in these countries, serve to refute the authors' theory that the absence of effective patent rights will promote technology transfer to developing countries.

5. The missing link between higher prices and patent rights. One of the underlying premises of the author's paper is that patent rights are the sole determinant of drug pricing and availability, and as such, adequate protection can be equated to unaffordable drug prices. The authors conveniently ignore the primary factor that influences drug availability and drug pricing; namely, the market conditions in a particular country. Basic economic theories dictate against excessive prices for patented pharmaceuticals – selling a pharmaceutical product at a price that only a small percentage of the population can afford will yield far fewer profits than a price that 90 percent of the population can afford. The authors do not use any data to support their assertions about the missing link between pricing, availability and patent status. The National Economic Research Associates (NERA) produced a study on "The Effects of Pharmaceutical Patents on Drug Prices: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?" published in the *Journal of World Intellectual Property*, Vol I., No.2, March 1998, Geneva, Switzerland. The study examined actual price levels and trends in countries that have changed their patent laws as well as those that have not. Based on review of actual, audited prices, NERA found that changes in patent regimes had no discernible effect on pharmaceutical prices.

6. Exhaustion of patent rights does not promote better conditions for consumers. The authors promote the simplistic and inaccurate view that domestic or regional exhaustion of patent rights promotes the interests of consumers. In essence, the authors are arguing that by treating patent rights as being exhausted by sales outside a country, the

consumer will benefit by paying the lowest possible price for the pharmaceutical. In reality, a policy of expansive international exhaustion will cause two effects. First, third parties will take advantage of lower prices of the pharmaceutical in the developing country and attempt to engage in arbitrage of the pharmaceutical product through sales of the product, originally destined for the developing country market, into markets in which a higher price can be obtained for the drug. This tends to eliminate or severely restrict both the price differential and the availability of the drug, as the third party is only interested in maximizing the price differential for the drug product. Second, recognizing that a combination of lower prices and exhaustion will create a market for grey market pharmaceuticals, drug manufacturers are forced to adjust prices up, both to discourage resale of their products by third parties in their home markets and to recoup losses from the effects of secondary effects of exhaustion. Simply put, a pro-exhaustion policy will result in increased prices in developing country markets, decrease availability and discourage regional price differentiation to better match the capacity of nationals of a market to purchase pharmaceuticals.

## **B. Specific Comments**

In addition to the general defects noted above, the paper incorporates a large number of specific errors and inaccuracies. The following analysis documents the more significant instances of these errors and inaccuracies.

### *1. Section 1.4 – History of the TRIPS Agreement Redefined*

The TRIPS Agreement was incorporated into the Uruguay Round negotiations because it was recognized that differences in the levels of protection afforded to intellectual property created significant distortions in trade. The TRIPS Agreement was not designed as anti-piracy campaign, although that was foreseen as one of its eventual benefits. Rather, the overriding factor dominating the TRIPS negotiations was the recognized need to have greater uniformity in the minimum standards governing intellectual property protection.

## 2. *Section 2.1 – Generally Inaccurate Presentation of the Agreement*

The most significant defect in section 2.1 of the paper is found in the third paragraph. The authors are fundamentally confused about the relationship between the TRIPS Agreement and the Paris and Berne Conventions. They suggest that the minimal protection standards of the TRIPS Agreement are to "coexist" with those defined in the Paris and Berne Conventions. In reality, particularly on patent issues, the TRIPS Agreement defines new standards of protection well above those of the Paris Convention. For example, the patent section imposes the requirement for comprehensive product patent eligibility for all areas of technology, the twenty year patent term, the product-by-process infringement standard, etc. These standards are fully compatible with the Paris Convention; compatibility, however, should not be viewed as subservience.

## 3. *Section 2.2 – Differentiating Obligations from Objectives*

In section 2.2, the authors attempt to confuse the reader by equating substantive obligations found in specific Articles of the TRIPS Agreement with some of the hortatory statements found in the preamble and various prefaces to Articles of the Agreement. Articles define obligations; the preamble and hortatory statements help identify the tone of the negotiations and the intent of the provisions of the Agreement. At several points in this section, the authors attempt to suggest that these non-binding provisions may be a valid basis for ignoring substantive obligations of the TRIPS Agreement. Some of the more glaring examples are documented below:

- On page 12, the authors emphasize the first paragraph of the preamble to the TRIPS Agreement, suggesting that intellectual property standards are to be shaped to ensure that they do not become barriers to "legitimate trade" and must be "harnessed to the service of development." The language cited was incorporated into the preamble of the TRIPS Agreement because it was recognized that the distinctions in the substantive levels of intellectual property protection among states was itself serving as a trade barrier. By incorporating

common minimum standards, the TRIPS Agreement is *achieving the objectives that are set forth in the preamble*; namely, the commonality of IP standards as defined in the TRIPS Agreement will eliminate a significant barrier to trade. The preamble is not an invitation to WTO Members to deviate from the standards of the TRIPS Agreement as part of some "reducing trade barriers through piracy" initiative.

- Furthermore, as was recognized when the TRIPS Agreement was being negotiated, *it is a truism* that effective domestic protection for intellectual property by definition serves developmental and technological objectives. Thus, the second italicized sentence on page 12 was incorporated into the preamble without objection, because, by definition, intellectual property standards serve to promote technological and developmental objectives. Again, this is not an invitation to alter the substantive TRIPS obligations, but a recognition of why effective intellectual property systems are desirable.
- On pages 12 and 13, the authors attempt to recast Articles 7 and 8 of the Agreement into authorities to allow WTO Members to evade the substantive requirements of the TRIPS Agreement. Unfortunately, these Articles by their words cannot be twisted into this function. First, the words of Article 7 set forth another truism of intellectual property systems; namely, that they" contribute to the promotion of technological innovation and to the transfer and dissemination of technology ... " For example, patent systems provide an incentive for innovation and a means for technology transfer and dissemination, whether by serving as a source of publicly available information on technological advances or by providing a vehicle for licensing rights to technology. Thus, the statement that these systems" should" cause this effect is made a truism through the substantive standards articulated in the Agreement. Similarly, in Article 8, any suggestion that WTO Members may deviate from the substantive standards defined in the Agreement is eliminated by the clause in that article that states "provided that such measures are consistent with the provisions of this Agreement." Thus, Article 8 by no stretch of the imagination can be twisted into an authority for concluding that the intellectual property obligations of the TRIPS Agreement may be ignored or altered

on the basis of "public policy" objectives of a WTO Member. If this were true, the seven-year exercise to define substantive intellectual property standards would have been pointless.

- The authors continue their uninformed lay analysis of the TRIPS Agreement with their comments on Article 8.2. This Article reflects a standard provision found in most national or regional intellectual property systems; namely, the link between antitrust enforcement and intellectual property protection. Article 8.2 addresses the situation where a party abuses its market power by utilizing intellectual property rights. In that situation, and not to serve some general public policy objective, WTO Members may implement means to control such abuses. Article 8.2 does not stand for the proposition that a WTO Member may alter the substantive obligations of the TRIPS Agreement as part of some "necessary balance between national objectives and sectoral interests."
- Finally, the authors suggest that Article 1 of the Agreement is of "critical" importance for those WTO Members opposed to the substantive obligations of the Agreement. Article 1 was included in the TRIPS Agreement in recognition of the fact that certain countries follow a code of civil law, while others operate under a common law system. It emphasizes that WTO Members are free to implement the substantive obligations within the context of their domestic legal systems. This is not a breathtaking declaration, but an obvious requirement of any agreement of this nature. In an analogous fashion, the authors attempt to make much out of the statement that WTO Members do not have to implement standards of protection that go beyond the TRIPS Agreement. This is again a truism that is inherent in any multilateral agreement; one could remove Article 1 without changing any substantive aspect of the Agreement.

The conclusions the authors attempt to draw from their "analysis" are as flawed as their analysis of the text of the preamble and the cited Articles. By no stretch of the imagination can the author's suggestion that these provisions of the TRIPS Agreement authorize a WTO Member to establish national regulations that deviate from the substantive obligations of the TRIPS Agreement on the grounds that the

deviations are permissible because they take into account the "imperative of guaranteeing the best possible access to drugs." A WTO Member that adheres to this rationale in implementing sub-TRIPS standards will violate the TRIPS Agreement.

#### 4. *Section 2.3 – The Truth Hurts*

It is interesting to note that bulk of the authors' "analysis" of Article 27.1 avoids the substantive obligations of this Article. Instead, the authors attempt to justify the past practices of certain notorious developing countries that served as primary sources for pirated pharmaceuticals. The "history" they present, of course, is as flawed as other sections of the paper. For example, they suggest that the practices of certain developing countries in denying adequate patent protection for pharmaceuticals was a justifiable practice because of "the high prices of pharmaceuticals" and the large amount of R&D required to develop new pharmaceuticals. No evidence is provided to support the theory that higher drug prices are due to patent protection in those countries, *simply because there was no effective patent protection in those countries*. Of course, the principal reason why these countries have no domestic innovative pharmaceutical industry is because the high costs of R&D *coupled with the absence of any means of recouping investments needed to develop new drugs precluded these industries from being formed*. One can tell by reading this section that the authors are deeply disappointed by the success of the TRIPS negotiations. This can be seen by their repeated references to the discredited economic theory used to argue for weaker patent protection for pharmaceuticals, instead of the accepted basis for the Article 27.1, which was the recognition that product patent protection is an essential prerequisite to pharmaceutical innovation for all countries, not simply the industrialized countries.

Unfortunately, the authors are unable to evade the plain language of the Article 27.1; thus, they acknowledge that product patent protection must be made available for all areas of technologies including pharmaceuticals. Their concluding comments again reflect their nearly complete lack of understanding of patent systems and the dispute settlement procedures of the WTO. For example, copies of patented pharmaceuticals are not "banned" by the government of countries in which patent rights are available. Instead, the obligation is on the patent

owner to enforce its rights. The blanket assertion at the bottom of page 14 that implementation of TRIPS will require all unauthorized copies of patented pharmaceuticals to be "banned" deserves special attention as it is one of the most serious allegations made against TRIPS, and causes a great deal of anxiety among public health officials.

Simply put, TRIPS is *prospective*, not *retrospective*. As TRIPS is implemented in developing countries, and de jure patent protection extended to pharmaceuticals, only new pharmaceuticals not yet marketed in that country will be covered by the (presumably) new, TRIPS-consistent patent law. All existing copies of drugs that have valid US or other country patents will be unaffected by the change, and will continue to be manufactured and sold. A sense of perspective is also required here. Most developing countries have an average of 2,000 approved pharmaceuticals registered for sale in the market. The FDA, as one barometer, approves an average of between 25-40 new molecular entities a year. Thus, clearly, only an infinitesimal percentage of the pharmaceutical market in developing countries will be affected as TRIPS-compatible laws are implemented. By completely misstating the facts of the matter, the WHO is doing its members and constituency a grave and unpardonable disservice. The discussion on page 14 of the paper gives health officials around the world the false impression that TRIPS will require the removal of many medicines from the market. This is a false and indeed inflammatory assertion. On the basis of that statement alone, the paper must be withdrawn.

The authors also mischaracterize the WTO dispute settlement process, which focuses on deficiencies of a WTO Member's domestic legal and regulatory regime. If the system is not corrected, the ultimate penalty of commercial sanctions may become available. However, one must proceed through at least three stages of the dispute settlement process before that becomes a possibility. Experiences gained through the TRIPS-related dispute settlement proceedings shows that most deficiencies are addressed through consultations between the interested parties, consistent with the intent and structure of the dispute settlement process.

5. *Section 2.4 – A Creative But Incorrect Interpretation of Article 27.2 and 27.3*

The authors continue their efforts to cause confusion through their "analysis" of the remainder of Article 27.

First, with respect to Article 27.2, the authors incorrectly disassemble the single provision into two discrete grounds of authority for limiting patent protection. Article 27.2, correctly interpreted, provides that where a WTO Member has banned the commercialization of a particular technology due to public health, morality or environmental concerns, they may also exclude that technology from patent eligibility. Article 27.2 does not, as the authors suggest, provide two independent grounds for denying patents on categories of technology. Indeed, the logical conclusion from their analysis is absurd – under what theory would it make sense for a WTO Member to deny patents on a particular class of technology on the grounds that the technology harms the environment or poses a threat to the public, yet allow third parties to freely commercialize the technology?

Second, in their discussion of Article 27.3(b), the authors attempt to suggest that there is some confusion as to the patentability of naturally occurring organisms. A fundamental principle of patent law is that one cannot gain patent protection that is coextensive with subject matter as it is found in nature. Where the organism has been altered through human intervention, either through genetic engineering or through purification or selection techniques, it becomes patentable. The line between patentable and unpatentable subject matter is one which only the authors have difficulty in discerning.

Given their lack of understanding of these provisions, it is not surprising to see the authors suggest to developing countries that they distort the meaning of the terms biotechnology and invention to their "benefit." It is unclear what the authors are advocating, but one can assume that they are hoping that these countries implement lower standards of patent protection. This, of course, will run directly counter to the goal of maximizing the value of biological resources held by these countries by diminishing the commercial potential of those resources.

## 6. *Section 2.5 – Continuing the Confusion on Substantive Patent Standards*

Section 2.5 of the paper represents the authors' most comprehensive effort of reasoning and analysis. There are three topics addressed in this section; namely, exhaustion of rights, product-by-process protection and patent term. First of all, however, we must emphasize the grave nature of the error under 2.5 where the act of copying an invention without the consent of the patent holder (referred to as "piracy" by PhRMA) is equated with counterfeiting. As the WHO should know, counterfeiting is by definition an illegal act in which an illicit and often completely fraudulent copy of a product is represented and sold as an original. In the pharmaceutical field, counterfeiting is particularly pernicious, as the recent case of counterfeit paracetamol syrup in Haiti, resulting in the deaths of dozens of children, demonstrates. Pirated pharmaceutical products, in such countries as India and Argentina, are legitimate copies within the existing legal structures of those countries. They often carry their own trademarks, and are known to be the product of local pharmaceutical companies which manufacture and sell them as their proprietary versions of a known INN. Piracy, while a major problem for the international research-based industry, is not equivalent to counterfeiting. This statement is egregious, and betrays the authors' lack of understanding of the overall intellectual property issue.

### (a) *Exhaustion*

Of the several misconceptions spread through the paper, those pertaining to the definition and effects of exhaustion are among the most severe. In section 2.5, the authors begin by misstating the circumstances in which a patent right is exhausted. For example, they characterize the patent right as giving the patent owner the rights to the invention and not on the products legitimately resulting from the invention. Exhaustion, particularly of patent rights, is effected by a consensual sale of the product covered by a patent by the patent owner. In the United States and Europe, for example, exhaustion is equated to the notion of conveyance of implied right to use and dispose of the article purchased. Exhaustion is not automatic and unbounded; a patent owner may convey only a license to use a particular product in many situations without conveying all rights to the article covered by a patent. Furthermore,

exhaustion does not occur simply by marketing a product; it is the completed transaction of a sale, in which title is transferred to a third party that serves as the basis of domestic exhaustion.

In terms of international exhaustion, the Paris Convention dictates that members of a family of national patents are each independent. This means that acts to invalidate or affect a national patent in one country do not automatically affect a related patent granted in another country. The conventional interpretation of independence of patents is that one cannot exhaust a foreign patent through sales of a product in a domestic market, as the instrument being exhausted (the domestic patent) is independent from the foreign patent. Given that the Paris Convention has been incorporated into the TRIPS Agreement, it follows that the notion of complete freedom on exhaustion of patents under the TRIPS Agreement is misstated by the authors. The authors mischaracterize the relationship between TRIPS Article 6 and the exclusive rights conferred on a patent owner by Article 28. Article 6 does not contravene or eliminate any of the exclusive rights, including the right of importation, enumerated in Article 28. Article 6 does, however, exempt the issue of exhaustion from WTO dispute settlement.

Turning to the merits of exhaustion, the authors argue that it is beneficial to a country's interest to encourage importation of pharmaceutical products sold at lower prices in a foreign country through use of an aggressive international exhaustion policy. Unfortunately, the fact pattern surrounding exhaustion does not match the authors' arguments. In reality, the countries in which the patent rights will be deemed to have been exhausted are usually those countries in which the product is already priced lower than in other markets. Thus, it is unlikely that a pharmaceutical manufacturer will price its products for the Indian market at prices higher than in Europe or Japan (i.e., the likely sources of parallel imports).

Furthermore, one has to identify the true beneficiaries of a pro-exhaustion policy.

It is certainly not the consumers. Rather, it is the party that is able to effectively engage in arbitrage of pharmaceutical products. Recognizing that price differentials are likely to be influenced by currency

fluctuations as well as differences in national health care systems, including price controls on pharmaceuticals, it will be those third parties that can take advantage of the resulting price differences that will be the entities that profit from a policy of international exhaustion.

The authors also fail to recognize that drug pricing for particular markets is influenced by the aggregate income potential from sales in that market. If a drug manufacturer is forced to concede a significant portion of sales to third parties through parallel imports, that manufacturer will have no choice but to increase prices to offset the aggregate loss of income. This is basic economics, which the authors do not want to address directly. Their solution is to harm the overall economic interest of the innovator and the consumer, and provide benefits principally to third party drug importers/arbitrageurs, who contribute nothing to public health.

Finally, the authors are correct in suggesting that a pro-exhaustion policy will decrease the possibility for joint manufacturing and distribution arrangements between innovator drug companies and local industry. Their response, however, is to advocate use of heavy-handed government policies to force a company to choose between relinquishing patent rights directly or indirectly. In other words, let the government, rather than the market, define business relationships between foreign and domestic enterprises. These notions are inimical to a market environment that promotes investment by foreign entities.

*(b) Product-by-Process Protection*

The authors continue their ill-informed criticism of the TRIPS Agreement by attacking its requirement for reversing the burden of proof in situations involving product-by-process patent infringement. The authors argue that it is unfair to require the defendant in a patent infringement case to prove that they used a different process to manufacture a product that is identical to that produced by the patented process. Their theory is that this amounts to harassment of the defendant. In reality, as people involved in patent litigation have learned, it is nearly impossible for a patent owner to obtain evidence about the manufacturing process used by a competitor to produce a particular product. Instead, it is much simpler for the defendant to

produce evidence that they used a different process to manufacture the product. The defendant, not the patent owner, is in the best position implicate or exculpate himself.

(c) *Patent Term Criticism*

The clear language of Article 33 leads the authors to conclude that unlike other provisions of the Agreement, there is no wiggle room on the minimum term of patents. The authors do not hesitate to again reiterate their ill-informed belief that patents are monopolies, and that a longer patent term perpetuates monopoly pricing for pharmaceuticals. Consistent with their view that patent term should be minimized and patent rights severely curtailed to permit free-riding on innovation, they criticizes the patent term extension policies used in Europe and the United States.

7. *Section 2.6 – An Incomplete Discussion of the Transition Period*

The principal defects in section 2.6 are inaccuracies and omissions. The authors suggest that developing countries are free to deviate from the TRIPS standards for between five to fifteen years. They omit any discussion of the standstill provisions of the TRIPS Agreement, which specify that a member may not decrease the level of intellectual property protection during the transition period. The manner of describing when TRIPS must be complied with thus distorts the actual obligations of the TRIPS Agreement.

This section also continues the trend of inaccurate facts. The authors states that "most developing countries only grant patents for drug manufacturing processes, or possibly no patents at all in the pharmaceutical sector." In reality, a majority of countries adhered to one of a handful of European patent system models through which both process and product protection is available for pharmaceuticals. The developing countries that exclude patent protection for pharmaceuticals are a small number of powerful developing countries. The impact of their anti-patent postures is disproportionate to their number.

## 8. *Section 2.7 – Discussions of the Transition Period*

The principal errors in Section 2.7 relate to the interpretation of the transitional provisions. For example, in describing Article 70.6, the authors suggest that compulsory licenses granted before 1/1/95 are exempt from Article 31 of the TRIPS Agreement. The phrase "before the date that this Agreement became known" actually refers a date earlier than the 1/1/95, which was the date the Agreement was concluded. The compulsory licensing provisions of the TRIPS Agreement became "known" with the issuance of the Dunkel Draft of the Agreement in December 1992. Furthermore, the authors return to hyperbole and inaccuracy by suggesting that a WTO Member must "apply sanctions for any act synonymous with counterfeit" under the terms of the Agreement on the date of application of the Agreement. This is simply untrue.

## 9. *Section 2.8 – An Attempt to Revive Long-Discredited Patent Policies*

Reading section 2.8 makes one believe time has slipped back into the 1970s. The authors open this section by returning to the theory that patents are monopolies that must be confined. They then proceed to highlight Articles 30 and 31 of the TRIPS Agreement on the assumption that curtailing the strength and value of patents is a good thing for developing countries. Their description of each of these Articles is laden with inaccuracies, both as to the requirements imposed by the Articles and the likely effect of his suggested policies of misinterpretation.

First, they present Article 30 as the catchall authority for anti-patent WTO members to decrease the effectiveness of patent rights. They argue, incorrectly, that Article 30 allows a WTO Member to make an exception to the patent right where it is necessary to balance the interest of consumers and the patent owner, and that any grounds that the WTO Member deems appropriate can then be impetus for creating an exclusion.

In reality, Article 30 makes it clear that exceptions to the exclusive rights provided by a patent must be extremely limited so as not to diminish the economic value of the patent exclusivity. In practice, the

types of exceptions permitted by Article 30 concern non-commercial uses of the patented technology, such as experimentation and study of the technology or private non-commercial use of the invention. The formulation of Article 30 does not permit WTO Members to weigh general "public policy" needs for the invention against the patent owner's general economic interests. Instead, Article 30 confines the evaluation to the entity that is engaging in the unauthorized use and evaluation of the commercial significance of that use. Thus, where the proposed exception would simply be to favour commercialization of the invention by a competitor of the patent owner, the exception would not be permissible under Article 30.

The suggestion that Article 30 allows WTO members to create exceptions to patent exclusivity to promote technology transfer or to generally promote health and nutrition are completely inconsistent with the text of the Article. Of the exceptions specified in the list on page 27, only the second, third, and fourth are believed to be compatible with Article 30. As formulated, the first, fifth and sixth examples are clearly not compatible with Article 30.

Second, the authors revisit the completely discredited concept of compulsory licensing as a tool to promote technology transfer and other "general interests." Interestingly, they cite French law that authorizes compulsory licensing of pharmaceutical patent rights. The French delegation, in response to the questions on patents posed during the 1997 TRIPS patent review, stated that no compulsory licenses had ever been granted by the French Government. In fact, a grand total of four compulsory licenses were acknowledged to have been granted among the 29 countries participating in that review. This serves to severely discredit the notion that compulsory licensing is a positive facilitator of technology transfer.

The most outrageous suggestion in this section is that compulsory licenses are the "easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices." Apparently, the authors are content to ignore the reality of the past thirty years or so of practice in India, Brazil, Argentina and other countries that made compulsory

licenses easy to obtain. The principal effect of freely available compulsory licenses has been shown to be abandonment of the market by the innovator. What this causes is problems in access to the pharmaceutical and quality control problems, as inferior copycat products are produced without benefit of manufacturing know-how of the innovator.

The authors' flawed reasoning on the effects of compulsory licensing are complicated by their subsequent list of situations where granting of a compulsory license would be "appropriate." The errors in the list of scenarios on pages 28 to 30 are almost too numerous to count.

- Article 8 does not allow a WTO Member to override Article 31 constraints on compulsory licensing in situations where the government considers a pharmaceutical product to be important for public health.
- The government use basis for compulsory licensing pertains to use of the invention for the government's own needs, not to replace the commercial market for a product. Thus, the suggestion that WTO members that supply pharmaceuticals to the public could in essence expropriate the entire economic value of the patent because it is the principal source for distributing pharmaceuticals is absurd.
- The requirement that compulsory licenses be non-exclusive is intended to combat the practice of some countries that assign an exclusive compulsory exclusive license to a competitor of the patent owner, thus precluding even the patent owner from manufacturing or selling the patented product in that country. The provision does not stand for the idea that a government make one determination that a compulsory license is appropriate and then grant compulsory licenses to any and all interested parties. That practice would run counter to almost every other provision of Article 31.
- Dependent patent compulsory licenses are permitted only where the second invention is a significant technical advance over the first patented invention, and requires cross-licensing between first and second patent owners. The authors' incomplete and inaccurate characterization of that authority ignores these essential requirements.

- The authors are not content to attack intellectual property laws in his quest for harming innovator drug manufacturers. He suggests a novel use of antitrust laws; namely, a finding that whatever price is set by an innovator drug company for a new pharmaceutical, the government should deem that to be an anticompetitive practice. Once so deemed, the authors suggest it would be appropriate to compulsory license the patent rights as the appropriate sanction.

Finally, the authors expose their true intentions in their discussions of the relationship between the TRIPS Agreement, the Paris Convention and local working requirements. It strains credulity to think that after seven years of difficult negotiations aimed at eliminating the practice of granting licenses of right (e.g., India) or discriminating against importation of patented products, one could interpret the TRIPS Agreement to permit WTO members to continue these practices. Yet, on pages 29 and 30, the authors do precisely that.

First, they suggest that the Paris Convention provisions on compulsory licensing override those in the TRIPS Agreement. This is not the case. The WTO Agreement is a separate agreement that binds not only Countries but also customs unions and other entities that cannot participate in the United Nations system (i.e., cannot join the Paris Convention). A WTO member that mistakenly presumes that it can ignore the provisions of the TRIPS Agreement and rely only the Paris Convention provisions on compulsory licensing will risk violating the TRIPS Agreement.

Second, Article 8.2 cannot be stretched to justify the authors' conclusion that the decision of a patent owner to import the patented product to satisfy market demand is an abuse of the patent right. The Paris Convention formulated the concept of importation not be equivalent to local manufacture of a product at a time when products were transported primarily by boat. With modern transportation options, satisfying market demand through importation is not a problem. That is why Article 27 of the TRIPS Agreement makes it clear that the enjoyment or character of patent rights cannot be conditioned on whether patented products are imported or locally produced. The logic of the authors' argument that Article 8.2 permits a WTO Member to conclude that a failure to import

the product allows for expedited compulsory licensing practices ignores the history and substance of the negotiations on the TRIPS Agreement, as well as the plan text of Article 27.1.

The authors' third major error is their suggestion that by designating areas of technology as being "sectors of vital importance" a WTO Member can ignore the requirement of Article 31 that each compulsory license be considered on its own merits. The revival of a "license of right" would without question violate the TRIPS Agreement.

Finally, the authors' concluding paragraph reveals their desire to roll the clock back to before the initiation of the negotiations on the TRIPS Agreement. They suggest that the "question of local working is rather loosely covered in the TRIPS Agreement." How they can conclude this is incomprehensible. First, Article 27.1 makes it abundantly clear that a WTO Member cannot condition enjoyment of the exclusive rights of a patent on whether the product is manufactured locally or imported. Second, Article 31 imposes numerous conditions that require compulsory licenses to be assessed on an individualized and narrowly restricted basis. The suggestion that WTO Members can ignore Articles 27 and 31 and continue practices that were followed before the TRIPS Agreement was negotiated is blatantly misleading.

#### *10. Section 3 – Recommendations that Build on the Inaccuracies of the Analysis*

It is not surprising to see that the authors' conclusions and recommendations focus on steps to minimize patent protection for pharmaceuticals and to obviate as many elements of the TRIPS Agreement as possible. For example, their conclusions reiterate a mistaken understanding of the history of the Uruguay Round negotiations, and strive to cast the TRIPS Agreement as something forced down the throats of the developing world. They ignore the intense negotiations that produced compromises between the various interests represented in the negotiations.

Their principal recommendations are for developing countries to hang on to the old order as long as possible by invoking the full transitional periods of the TRIPS Agreement. They mistakenly assume this will

promote the domestic interests of developing countries. In reality, what it will do is drive foreign investment away from these countries and toward those countries that adhere to the new standards articulated in the TRIPS Agreement.

They continue their bad advice to developing countries by suggesting a strategy of expansive parallel importation. For the reasons noted above, this may be grounds for a WTO dispute in severe instances and at a minimum will further weaken the investment profile for a country seeking to attract foreign capital.

Their suggestion that countries adhere to a policy of requiring compulsory licenses for all drugs on the WHO Model List of Essential Drugs would also expose countries that follow their advice to a WTO dispute settlement proceeding. The policy they suggest is a clear violation of Article 31(a) of the TRIPS Agreement, which specifies that compulsory licenses are to be considered on their individual merits.

Finally, they seek to promote adoption of their inaccurate and ill-advised interpretations of the TRIPS Agreement among developing countries. This perspective ignores the differentiation in the level of development of many developing countries, and the implications of those different levels of development.

## **C. Conclusions**

The paper prepared for the World Health Organization represents a biased and uniformed attack on intellectual property standards accepted in the TRIPS Agreement. It misstates many of the key obligations pertaining to patent rights and dredges up failed economic theories and policies relating to patent rights and the pharmaceutical industry. It is obvious that the paper is a thinly veiled attack on the TRIPS Agreement standards for patent protection, using the unjustifiable theory that stronger patent rights will threaten public health interests. In short, the best advice that can be given vis-à-vis the paper is to ignore it in its entirety.

## 2. LETTER FROM ADRIAN OTTEN, DIRECTOR OF INTELLECTUAL PROPERTY AND INVESTMENT DIVISION OF THE WTO TO DR. JONATHAN D. QUICK, DIRECTOR, ACTION PROGRAMME ON ESSENTIAL DRUGS, WHO



WORLD TRADE ORGANIZATION  
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ORGANIZACIÓN MUNDIAL DEL COMERCIO

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7 May 1998

Dear Dr. Quick,

First let me thank you and your colleagues for visiting us on Monday to discuss the activities in the WHO relating to the TRIPS Agreement.

You were good enough to give us a copy of the paper being published by the WHO on "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement", and to express interest in any comments which we might have. I have had a chance to have a quick look over it and thought that you might appreciate having already our preliminary reaction, given that the World Health Assembly meets next week. We will give you more detailed comments in due course.

I have to say that I think it would have been very beneficial for both our organizations if we had had a chance to comment prior to the finalization of the piece and its distribution. I have three sorts of comment.

The first is that the paper does not seem to give due weight to the positive contribution that the patent system makes to public health by generating incentives for the invention and development of new drugs. After all, there can be no access to a drug if it has not been invented. The paper seems predicated on the notion either that there is no such positive contribution or, if there is, that each country should seek to minimize its own role in providing such incentives and to rely on others doing so. While from a purely national point of view it might be argued that such a position makes sense for some small countries, I have doubts that this is an appropriate perspective for an intergovernmental organization to adopt.

The second general comment is that I find the tone in parts somewhat polemical and less than fully objective. The third is that there are a substantial number of places where the text is inaccurate or, at any event, misleading.

An example of both these points occurs on the bottom of the first page where it states: "As soon as the Agreement comes into force in a Member State, unauthorized copies of patented drugs are prohibited, and countries which break this rule will incur trade sanctions authorized by the WTO." This key statement in the Executive Summary is, in my view, misleading for many reasons, including:

- The TRIPS Agreement came into force for all WTO Members on 1 January 1995, but the obligations referred to relating to patents only kick in at the end of the transition period relevant to the country in question (1996, 2000, 2005 or 2006).
- In the countries primarily addressed, namely those which have not hitherto granted product patent protection for pharmaceuticals, the TRIPS Agreement will not require that there be any patented drugs at the end of the transition period. All that is required is that, on that date, inventions that are the subject of applications, including in the mailbox, start to be examined in each such country for patentability. The actual grant of the patents will take some time and the number of drugs under patent on the market will in the early years be relatively small, especially when the delays between patent filing and regulatory approval are taken into account. The reader of the sort that you are hoping to inform about the TRIPS Agreement might well obtain the impression that, as of that date, unauthorized copies of drugs that are patented anywhere in the world must be prohibited.
- Moreover the phrase "unauthorized copies of patented drugs are prohibited" is itself misleading in that it might cause a reader to believe that the government would be obliged *ex officio* to prohibit them. What the TRIPS Agreement requires is that the patent owner must have the means through the national courts to prevent unauthorized use, and even then only to the extent that such unauthorized use cannot be justified under exceptions clauses.
- I find the final phrase of the sentence, "and countries which break this rule will incur trade sanctions authorized by the WTO", both unnecessarily emotive and inaccurate:
  - first, as already mentioned, there is no rule by which a government is itself required to prohibit unauthorized copies of patented drugs;
  - second, even if a country fails, at the end of the appropriate transition period, to provide the patent owner with the rights and the legal means to assert those rights that that country is required to provide under the TRIPS Agreement, this certainly does not mean that that country will automatically incur "trade sanctions authorized by the WTO". What it would mean is that another WTO Member would have the option to raise the matter through the dispute settlement system. If a mutually acceptable solution cannot be found, the matter could be the subject of panel and, if appealed, appellate body reports. If the country in question is found to be in breach, it would be offered a reasonable period of time to bring itself into conformity. If it failed to do so, it would be expected to offer compensation. Only in the event that all these steps had been gone through and no agreement on compensation could be reached would the issue of suspension of concessions or obligations ("trade sanctions" as the study puts it) arise. The experience of the dispute settlement system is that disputes are resolved without the need for recourse to such measures. As I think I mentioned to you when we met on Monday, in the 50 years of the experience of the GATT/WTO, there has been no occasion when measures of this kind have been carried out under the dispute settlement system and only once where they were authorized (which was in the 1950s).

I appreciate, of course, that in an Executive Summary it is not possible to reflect all nuances and that the next paragraph of the Executive Summary does refer to the transition arrangements (although, I regret to say, in a not fully accurate way), but I do consider that this sentence is highly misleading, especially to people who are not familiar with intellectual property rights. Moreover there are a considerable number of other places in the text where I have similar types of comments to make. As I have already mentioned, we will communicate them to you in due course.

These comments are offered to you in a constructive spirit and with the desire to develop our cooperation on these matters. I hope that you and your colleagues will not take them otherwise.

Yours sincerely,

A handwritten signature in dark ink, appearing to read 'Adrian Otten', with a stylized flourish at the end.

Adrian Otten  
Director  
Intellectual Property and Investment Division

### **3. A CRITIQUE FROM THE U.S. GOVERNMENT EXPRESSED THROUGH FDA – "GLOBALIZATION AND ACCESS TO DRUGS"**

*Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement*, published recently by the World Health Organization (WHO) attacks the World Trade Organization's Agreement on the Trade-Related Aspects of Intellectual Property (the TRIPS Agreement) directly claiming, among other things, that it "amounts to a limitation of supply and thus directly affects accessibility to products, including drugs," This ignores totally the fact that, were it not for the incentive provided by strong patent protection in many countries, most of those products and drugs would not exist. The WHO publication also repeatedly implies that nationals of developing countries will remain forever unable to develop products, including drugs, of their own when incentives exist to do so; that industries in developing countries are capable only of copying what has been developed by others – not a very flattering view of the audience for which the publication was intended, This paper tracks the sections of *Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement*, pointing out the inaccuracies and false implications with which the document is riddled.

#### Executive Summary

The "Executive Summary" of *Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement*, published by the World Health Organization (WHO), declares as its purpose "to inform people in the health sector with no particular legal background about the impact of globalization on access to drugs and especially about the WTO agreement on intellectual property (TRIPS Agreement) that may have repercussions in the pharmaceutical field." In carrying out their task, the WHO publications' authors often distort the meaning of the TRIPS Agreement's provisions, particularly the provisions on patents. At no time while they were drafting the document did the authors request comments from the World Trade Organization (WTO) Secretariat to ensure that their interpretations were accurate, nor did the WHO request the WTO's comments until the publication was printed and ready for distribution. As a result, the WHO publication, rather than inform,

simply propagandizes, an unsuitable activity for an intergovernmental organization, particular when the propaganda concerns agreements administered by another intergovernmental organization.<sup>1</sup>

The first page of the "Executive Summary" provides an example of propaganda. In describing the WTO in the second paragraph, the authors state that the TRIPS Agreement "will undoubtedly have the most impact on the pharmaceutical sector." No support is provided for this claim anywhere in the WHO publication, although the statement itself is repeated a number of times, sometimes with the word "repercussions" substituted for "impact." Because the majority of WTO Members already provide both product and process patent protection for pharmaceutical inventions that meet the requirements for patentability, the requirement to make patents available for any inventions, whether products or processes, in all fields of technology will have little "impact" on January 1, 2000. The additional 5 year transition in Article 65.4 for those countries that do not provide patent protection for pharmaceutical products means that the expiration of the general transition period for developing countries will have little impact because their patent laws generally do provide protection for processes for producing pharmaceuticals. Finally, least developed countries will have no obligations other than those regarding national and most favoured national treatment until 2006 and they may request additional time if necessary to bring their intellectual property regimes into compliance.

Further down on the first page of the "Executive Summary" there is another example of the distortion that pervades the WHO publication. The final paragraph is as follows:

"Under the TRIPS Agreement, Member States have to grant patents, for a minimum of 20 years, to any inventions of a pharmaceutical product or process that fulfils the established criteria of novelty, inventiveness and usefulness. As soon as the Agreement comes into force in a Member State, unauthorized copies of patented drugs are prohibited, and

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<sup>1</sup> A tiny disclaimer at the bottom of the "Acknowledgments" page states that the views expressed are the responsibility of the authors and that the document is not a formal WHO publication. The disclaimer notes, however, that all rights in the publication are reserved in the Organization.

countries which break this rule will incur trade sanctions authorized by the WTO.”

The intended audience for the paper, "People in the health sector with no particular legal background," are likely to conclude from the first sentence that the term of a patent is 20 years from the date on which the patent is granted. (In case they didn't so conclude, the publication repeats the sentence on the second page of the summary under the heading "Public health needs and drug patents," leaving out any reference to established criteria for patentability.) As the established criteria that must be fulfilled, *i.e.*, novelty, inventiveness and usefulness, are nowhere defined in the WHO publication, people unfamiliar with intellectual property are also likely to conclude that fulfilling those criteria is merely a formality.

The WHO publication might actually have informed the intended audience simply by stating that WTO Members would be obliged, following any relevant transition periods to grant patents based on applications filed with the responsible agency claiming pharmaceutical inventions and process inventions for the production of pharmaceuticals, but only if those inventions are new, involve an inventive step and are capable of industrial application. To truly inform, of course, "new," "involve an inventive step," and "capable of industrial application" would have to be defined, as is done for terms such as "drug regulatory authority" and "essential drugs," terms with which people in the health sector likely are familiar, even if they have no particular legal background. The WHO publication also could easily have specified that, under the TRIPS Agreement, the term of a granted patent would be at least 20 years, measured from the date on which the patent application was filed, and that grant occurs after examination of the application which generally does not begin before 18 months have expired and the application has been published, thereby disclosing the invention to all who have an interest. The WHO publication nowhere notes the benefits of such disclosure of technology.

The second sentence of the quoted paragraph has already been addressed in a letter from Adrian Otten, Director, Intellectual Property and Investment Division, WTO, to Dr. Jonathan D. Quick, Director, Action Programme on Essential Drugs, WHO. The United States Government

agrees with the Mr. Otten's comments on the "Executive Summary," including his statement that much of the language is misleading, unnecessarily emotive, and inaccurate. That characterization applies to the remainder of the WHO publication as well.

### Definitions and terminology

While the section OD definitions and terminology follows the substantive text of the WHO publication, it is appropriate to address it first as the inaccurate and alarmist definitions distort further much of the substantive text. For example, "counterfeit" is explained in the WHO publication as follows:

This occurs when an individual other than the holder of an intellectual property right or a licensee infringes upon the monopoly of that title holder. Counterfeit drugs are frequently confused with drugs of poor quality. The former are drugs which are protected by a patent and are produced and/or marketed without the consent of the patent holder. The latter are drugs, which may or may not be counterfeit that do not comply with standards of quality.

Those familiar with intellectual property and with the TRIPS Agreement do not use the term "counterfeit" to indicate a product that infringes a patent because determining what does and does not infringe patent rights, regardless of the subject matter of the invention, requires a technical and legal analysis of the product or process in question and of the patent's claims. The term "counterfeit" generally is used by knowledgeable people to describe unauthorized copies of goods bearing a mark identical to a trademark registered in relation to such goods or substantially indistinguishable from such a trademark. The TRIPS Agreement contains the term "counterfeit" used in this context. (See Articles 51 and 61.) Using the term to indicate patent infringement misleads those to whom the WHO publication is addressed.

The WHO publication's definition of "counterfeit" is wrong on all counts. While it is possible for drugs to be "counterfeit" if the trademark for a recognizable drug, including such things as capsule colouring, shape of container, etc. is copied to make purchasers think they are buying the trademarked drug when, in fact, they are getting an

unauthorized copy. Given that the purpose of such counterfeiting is usually to "make a killing" in the monetary sense, it is unlikely that the counterfeit's producer would make the investment required to produce a quality product. Such counterfeit products are usually of poor quality, if, indeed, they are even drugs at all and not talcum powder or sugar, etc. Manufacturers of legitimate pharmaceuticals, on the other hand, are likely to use strict quality control standards because they are liable for any harm that comes to a patient from a defective product and are easily identified, particularly producers of patented pharmaceuticals.

"Dependent patent" is defined in the WHO publication as "a patent that cannot be exploited without infringing on another patent." The definition goes on to claim that dependent patents are "often exploited through the use of compulsory licenses." The latter is not accurate. Many countries do have provisions in their patent laws that would allow compulsory licensing to enable the owner of a dependent patent to exploit its invention, but such provisions are not generally necessary. If a dependent patent claims a valuable invention, the holder of the dominant patent would be foolish to refuse a license. If the dependent patent is an improvement over the dominant patent, the holder of the dependent patent would be able take over the market for the product in question when the dominant patent expires. If, on the other hand, the holder of the dominant patent licenses the holder of the dependent patent, and demands a cross-license as part of the deal, both parties can compete in the market throughout the terms of both patents, competing in non patent areas such as price, delivery, and service. If the dependent patent applies to an invention that does not compete with the dominant patent's product, the holder of the dominant patent would be turning down licensing fees if it failed to grant a license for production of such non competing product. The definition of "dependent patent," therefore, is misleading.

"Exhaustion of intellectual property rights" cross references "parallel imports" but is itself misleading. Despite references to territoriality elsewhere in the WHO publication,<sup>2</sup> the definition of "exhaustion" does not make clear that it is the authorized "putting into circulation" within the particular country's territory that exhausts the patent holder's right in

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<sup>2</sup> Page 9, first paragraph under the heading "The protection of intellectual property rights before the WTO."

that country's territory because the patent law in Question creates rights only in that country's territory This is the case because patent laws are territorial, not universal. If the right applies only within a particular country's territory, the exhaustion of the right applies only within that territory. To imply that exhaustion of the patent right under the law in one country applies to patent rights in the territory of other countries would mean that the law of the country where the exhaustion occurred has primacy over the laws of other countries, a concept countries generally find offensive. Failure to note the territorial nature of patent law in the definition of "exhaustion" is misleading.

"Parallel imports" – see above.

"Patent" is defined as "a title granted by the public authorities conferring a temporary monopoly for the exploitation of an invention upon the person who reveals it, furnishes sufficiently clear and full description of it, and claims this monopoly." This definition is misleading first in that it implies that the patent holder is being given the right to exploit his invention. A patent gives its owner the ability to go to court to stop an unauthorized party, if the invention is a product, from making, using, selling, offering for sale, or importing the product or, if the invention is a process, from using the process and from using, offering for sale, selling, or importing the product produced directly using that process. Whether the patent owner is able to exploit his invention himself depends upon other factors, including, in the case of pharmaceuticals, whether the government of a particular country gives marketing approval for such exploitation so a patent does not guarantee the patent owner the right to exploit his invention. The term "monopoly" also is alarmist, implying as it does that a patented pharmaceutical has no competition. While a patent owner can seek court remedies against those who make, use, or sell the claimed invention, the patent owner has no remedy against a competitor who, in the case of pharmaceuticals, produces a different pharmaceutical for treatment of the same condition the patented product is designed to treat. The existence of a patent, in fact, often spurs research and development aimed at creating such competing products or processes if the field appears to be profitable.

"Reverse engineering" is defined as "a practice for discovering the manufacturing process of a product starting from the finished product."

The definition goes on to state, "This practice has often been used to copy original drugs in countries which do not grant patents for pharmaceutical products." If reverse engineering is being used to copy patented pharmaceuticals, the individuals using the practice are wasting resources. To obtain a patent (assuming the invention is new, involves an inventive step, and is capable of industrial application), an applicant must describe the invention in sufficient detail for one skilled in the relevant art to be able to practice the patent. Reverse engineering, therefore, is not necessary to determine the composition of a product. Even including a definition for the term in the WHO publication implies that the patented technology, in this case a pharmaceutical, is in some way kept secret. It is misleading not to inform "people in the health sector with no particular legal background" of one of the important benefits of patent systems – disclosure of technology from which others may learn and on which they may build.

"Term of protection" is defined as "the time during which the holder of the title to the invention may enjoy a monopoly of its exploitation." This is followed by "The Agreement on TRIPS imposes a minimum term of 20 years for all product and process patents." Again, no reference is made to the date from which the term is measured and no explanation is given of the time required to process an application. The WHO publication's audience is left with the impression that the term of a patent runs from the date the patent is granted.

### Introduction

Here again the statement:

"This Agreement [TRIPS] is the part of the Final Act of the Uruguay Round that could have the greatest repercussions on the production of and access to drugs, especially in developing countries."

No support is provided for the claim that even a possibility exists that the TRIPS Agreement will have any significant effect on either the production of access to drugs.

The final paragraph reveals the WHO publication's real purpose, to give "pointers on how to read the TRIPS Agreement from the perspective of

access to drugs" and to advise "how much freedom is left for Member States to regulate the protection of intellectual property, and how they can enact legislation that both conforms with the Agreement and is consistent with health policy." This paragraph, like much of *Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement*, implies that patent protection and access to drugs are at opposite ends of a continuum. The WHO publication implies that patent protection for pharmaceuticals is inimical to health policy, particularly as it relates to obtaining in developing countries pharmaceutical products on the list of essential drugs. Of course, no support of any kind is provided for this view of the world. As for "reading" a multilaterally negotiated document from any point of view other than that of the Members that negotiated the agreement is inconsistent with international law.

## **READING THE TRIPS AGREEMENT FROM THE PERSPECTIVE OF ACCESS TO DRUGS**

### General presentation of the Agreement

The final paragraph of the "General presentation" section repeats yet again the statement:

"This Agreement, and particularly the section on patents, is undoubtedly the element of the Final Act of the Uruguay Round that will have the most important repercussions in the field of public health, especially for access to drugs in developing countries."

Perhaps the authors believe that repetition will result in belief on the part of the audience they seek to sway.

### Fundamental principles and objectives of the Agreement: the necessary balance between intellectual property and accessibility

The title of the section implies opposition between intellectual property and accessibility (since a balance requires substances on either side of a fulcrum), rather than actually informing. The paragraph immediately following the "General presentation" section's repetition claims that it is

"generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products," although those who "generally" accept the concept are not identified. The special status given pharmaceutical products, the authors assert, results from the "significant social role" drugs play "in that they are an integral part of the realization of a fundamental human right – the right to health." "Accessibility," according to the authors, means "that the policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices."

With those assertions as a springboard, the WHO publication quotes the first paragraph of the preamble to the TRIPS Agreement, underlining ""taking into account the need" to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade," ignoring the fact that the word "enforcement" clearly refers to judicial and administrative procedures and remedies for infringement of intellectual property rights set out Part III of the TRIPS Agreement. International law requires that treaties be interpreted in "good faith." Claiming that "Protection of intellectual property rights under the TRIPS Agreement should not lead to any discrimination in international trade" does not represent a "good faith" interpretation of the preamble to the TRIPS Agreement. While purporting to inform those unfamiliar with the TRIPS Agreement, the statement merely implies an obligation so general as to be meaningless.

The authors of the WHO publication then skip over the largest part of the preamble, which refers to the need for new rules and disciplines related to intellectual property, and single out a subparagraph referring to "developmental and technological objectives." The authors proclaim at the subparagraph means the protection of intellectual property rights is not an end in itself but rather is "to be harnessed to the service of development." That the grant of exclusive rights is intended to encourage creativity and invention is a long-standing principle. For example, Article 1, section 8 of the Constitution of the United States of America, completed in September of 1787, gives the U.S. Congress the power to secure for limited times to authors and inventors exclusive rights in their respective writings and discoveries in order to promote the progress of science and the useful arts. To imply that anyone familiar

with intellectual property believes that protection of intellectual property rights is an end in itself is misleading in the extreme.

The authors then argue that Article 7 "clearly indicates the subordination of the protection of intellectual property rights to public policy objectives in other areas of the State's activities, especially social and economic welfare, which depends in part on national health and social policies." The argument is not valid. To begin with, Article 7 uses the word "should," rather than the mandatory "shall," indicating that the provision is what the title indicates, an objective, i.e., something to be worked toward or aspired to, not something required. In addition, Article 7 says that protection and enforcement of intellectual property rights "should contribute to the promotion of technological innovation and the transfer and dissemination of technology." It speaks of "mutual advantage" and "a balance of rights and obligations." Those terms are a far cry from "subordination of the protection of intellectual property rights to public policy objectives in other areas of the State's activities, especially social and economic welfare..." The latter, rather than a good faith interpretation of Article 7, is a deliberate distortion of the plain meaning of the words.

Likewise, the WHO publication interprets Article 8, paragraph 1 as expressly recognizing that measures might be adopted to guarantee accessibility. Article 8 does recognize that "Members may adopt measures to protect public health ...," but the key words are "provided that such measures are consistent with the provisions of this Agreement." The same words are included in the second paragraph of the Article. The Article, therefore, does not provide an exception to the obligations of the Agreement as the WHO publication implies, but mere states the obvious.

The assertion in the next paragraph of the WHO publication that Article 1 of the TRIPS Agreement "is of critical importance because it establishes that Member States are not obliged to grant greater protection than that set out in the Agreement" reflects a lack of understanding of international law. A State is *never obliged* to do more than fulfil the obligations contained in the international agreements to which it belongs. Article 1 of the TRIPS Agreement merely recognizes that principle expressly. The assertion in the WHO publication that the

final sentence of Article 1 means that Members are "entirely free within the framework of their own legal systems and practices as to how they implement the obligations to which they have subscribed" implies a far broader authorization than stating, as TRIPS does clearly, that Members are "free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." The latter statement was a recognition that the TRIPS Agreement was setting minimum standards for the protection and enforcement of intellectual property rights, not harmonizing the intellectual property laws and practices of the WTO Members. At the point in time at which the Agreement was negotiated, harmonization was not possible given the wide variety of legal regimes among the existing GATT Contracting Parties.

Patents for pharmaceutical products and processes available all over the world

The WHO publication begins this section with the following statement.

"The TRIPS Agreement requires WTO Member States to grant patent protection to all inventions in any branch of technology."

As noted before, given the audience to which *Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement* is directed, the assertion can only be considered deliberately misleading. The statement quoted can only leave the audience with the impression that Members are obliged to grant patents, without question, to inventions recognized by other WTO Members or, worse yet, that Members must grant patents to all comers claiming an invention, regardless of the merits of those inventions. As explained earlier, the authors could easily have truly informed the audience about what TRIPS requires without much additional text, had they asked participants to the Uruguay Round negotiations and of the WTO Secretariat what the obligations of the patent section and other articles of the TRIPS Agreement actually are.

The section of the WHO publication goes on to state that Article 27.1 "is expressly aimed at pharmaceutical products," because high prices for patented drugs and "the large amount of expenditure required for research and development in the pharmaceutical field" had caused some

developing countries to refuse to grant patents for pharmaceuticals, those countries choosing instead "to imitate products patented in industrialized countries ... in order to meet their national requirements for drugs at a lower cost and to develop their technology" or to buy "these copies of patented drugs at competitive prices." To imply that Article 27.1 was aimed at pharmaceuticals alone is inaccurate. Pharmaceutical inventions are only one field of technology that some countries except from patentability, others include agricultural chemicals and foodstuffs. The first part of Article 27.1 was intended to eliminate all of these exceptions to patentability, thereby eliminating a major trade distortion. The explanation given for countries' failure to provide product patent protection for pharmaceuticals, if true, merely reflects those countries' misguided motives without question, implying that the motives were rational. In a document purportedly intended to inform, those motives should be analyzed in light of relevant facts, but facts are lacking throughout the WHO publication.

The section of the WHO publication on Article 27.1 includes a chart parsing the provisions of the paragraph and making comments on each segment. In the chart, the phrase "new, involve an inventive step and are capable of industrial application" is dismissed in the comments as "conventional definition of invention" without any further explanation. As the audience presumably does not understand what these terms mean and how they are applied to determine whether an invention should be granted a patent, a further explanation is mandatory in any document purporting to "inform." The WHO publication nowhere provides such an explanation, possibly because intelligent readers would see through the WHO publication's distortions and its unsupported conclusions.

Of particular interest is the reference to "patents shall be available and patent rights enjoyable without discrimination as to ... whether products are imported or locally produced." In spite of the absolute assurance with which the authors of the WHO publication interpret TRIPS provisions viewed as favouring accessibility to drugs, the authors' comment indicates uncertainty about whether the agreement allows patent owners "to import their patented product without having to transfer the related technology" (the latter phrase a euphemism for having a compulsory license issued to a local to produce the patented product). The obligation not to discriminate based on where a product is made was intended to

make clear that importation of that product by the patent owner or with the patent owners authorization must satisfy any working requirements contained in countries' laws. In other words, the patentee may "work" the patent in the country either by manufacturing there or by importing the product from elsewhere. It is not economical for a patentee to manufacture its product in every country in the world and it would be a waste of both the patentee and countries' resources to do so if it were possible. The TRIPS Agreement reflects commercial reality. There is no uncertainty. Authorized importation into the country in question is to be treated as "working" for purposes of any provision of law authorizing compulsory licensing for non-working.

## **2.4 Non-patentable inventions: biotechnology inventions**

The authors of the WHO publication claim that "a doubt remains" as to the nature of biotechnological inventions that originate in natural organisms. Citing the 1999 review provided for under Article 27.3(b), the authors of the WHO publication assert that the question is "extremely important" for developing countries. It asserts that developing countries, "rich in natural resources, should in their new regulations, define the ambiguous terms "biotechnology" and "invention," in order to benefit from "these new provisions." It is not clear to what "new provisions" the document refers, since the TRIPS Agreement has not been amended. Also, as noted above in the discussion of the chart on Article 27.1, the terms "new, involve an inventive step and capable of industrial application" are referred to as the "conventional definition of invention." The word "invention," therefore, is not ambiguous. The word "biotechnology" is not used in Article 27.3(b), so it is not clear why a definition is needed in any country's regulations.

## **2.5 Effects of protection: a monopoly of working for 20 years**

The authors once again alarm their intended audience with this declaration:

"Traditionally, a patent confers a monopoly for working the invention upon the patent holder. Any person imitating the invention or new

manufacturing process, without the consent of the patent holder, is committing an act of counterfeit.”

The misleading use of the words "monopoly" and "counterfeit" are discussed above and will not be repeated here.

### **Attenuation of the monopoly through exhaustion of rights**

The WHO publication here claims that

“... the issue of exhaustion of intellectual property rights is expressly excluded from the scope of application of the Agreement. In other words, the Agreement does not impose any obligation on Member states on this point, which remains purely a national issue. A Member State is completely free to decide whether or not to apply the principle of exhaustion of the patent owner's rights.”

The claim is inaccurate. It should be noted that the WHO publication does not quote the text of Article 6 as done with other TRIPS Articles, perhaps because it would be clear from the text itself that the statement is misleading. Article 6 merely states that the issue of exhaustion of intellectual property rights cannot be the basis for dispute settlement under the Agreement except in the case of violation of the principles of national and most favoured nation treatment in connection with laws or practices related to exhaustion. That is considerably narrower than explained in the WHO publication.

The WHO publication goes on to advocate use of so-called international exhaustion for all patents by stating that "Member States could improve the accessibility of products, including drugs, by establishing that the exclusive rights of the patent holder may not be claimed in cases where products legally marketed in any other country are imported." As noted in connection with the comment on the definition of the word "exhaustion," the concept of international exhaustion ignores the fact that patents are territorial and that the rights they create end with at the borders of the country that granted the right. The discussion also implies that the patentee will have obtained patents in every country of the world that is a Member of the WTO and this is not likely.

The WHO publication goes on to suggest that, in some instances, it might not be a good strategy to provide for international exhaustion since this might discourage patentees from licensing locals to produce the patented product. The WHO publication suggests anticipating the possibility of parallel importation in the event of non-working locally, or if the patent holder is not meeting local demand at reasonable prices. Such a provision would, of course, be inconsistent with the country's obligations in that importation would not be treated as "working" under the TRIPS Agreement and that would be subject to dispute settlement. Advising countries to take steps that would lead them to violate their obligations under the TRIPS Agreement is not appropriate for an intergovernmental organization, whatever the motivation.

### **Strengthening the monopoly through the patenting of processes**

The WHO publication treats as something new the requirement that the owner of a patented process have the right to prevent others from using the process or from offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. In fact, such provisions have existed in the patent laws of many countries prior to the negotiations of the TRIPS Agreement, particularly countries that did not provide patent protection for products in particular fields. The authors of the WHO publication further argue that protection of products produced by patented processes could allow someone to obtain an exclusive right in a known product merely by inventing a new manufacturing process. The argument is false. All the holder of the new manufacturing process would obtain would be an exclusive right regarding the known product when it is produced using the new manufacturing process. The same product, produced using other manufacturing processes, could be offered for sale, sold, or imported without infringing the patentee's rights. The authors claim that proof that another process was used would be very difficult and costly. Such should not be the case, since the evidence of the process actually used by the defending party is in that party's possession and can merely be introduced in court. Because legal proceedings can be costly, it is also unlikely that the holder of a process patent would bring an action for infringement without significant reason to believe that the other party is, in fact, using the patented process.

The WHO publication interprets Article 34 of the TRIPS Agreement as requiring reversal of the burden of proof in process patent cases any time the product produced by the process is new or even whether or not the product is new. The latter ignores an important qualification) *i.e.*, that the patentee must demonstrate that there is a substantial likelihood that the Identical product was made by the process and that the owner of the patent has been unable through reasonable efforts to determine the process actually used. That means that the patent owner, in a legal action, would have to produce evidence in court such as some characteristic marking on the product that would always be produced by the patented process but not by other processes to demonstrate that there is a substantial likelihood that the patented process was being used. The patent owner would also have to show that serious efforts had been made to find out what process was actually used by the defendant, usually contacts made with the defendant prior to suit, to determine whether the process used was the patented process. Since the evidence of the process actually used by the defending party is in that party's possession, it is likely that, if a non-patented process were being used, the defending party would have demonstrated that process to the patent holder and there would have been no suit. Nonetheless, since the evidence of the process actually used is in the possession of the defendant, the shift of the burden of proof is appropriate if the defending party is unwilling to demonstrate prior to suit that it was, indeed, using another process.

The subsection concludes with a direct attack on the TRIPS Agreement claiming that it "amounts to a limitation of supply and thus directly affects accessibility to products, including drugs" As noted at the beginning, this ignores totally the fact that, were it not for strong patent protection provided in many countries, most of those products and drugs would not exist. The subsection also implies once again that nationals of developing countries will remain unable to develop products, including drugs, even when incentives for invention are put in place; that industries in those developing countries are able only to copy what is developed by others.

## **Extension of the duration of the monopoly**

In this section, the authors of the WHO publication argue that the requirement that the term of protection for patents be not less than 20 years from the filing date will have the logical consequence of causing drugs to be sold at high prices, "as is the case for all monopoly products," for a longer period of time and that "manufacturers of generic products will have to wait longer before they can produce the drug in question and sell it at a more accessible price." No evidence is presented that the variation between the cost of patented pharmaceuticals and the cost of generic copies is significant. In fact, many generic products are sold at close to the price of the product sold by its originator, even though generic producers do not have to recoup the costs of research and development and they are often able to obtain marketing approval for their products by riding on the coat tails of the original drug developer's application for marketing approval, thereby saving themselves the cost of developing test data on the safety and efficacy of the drug.

## **2.6 Application of the TRIPS Agreement**

In the chart on Article 65, the "Comments" state that the TRIPS Agreement "came into force on 1 January 1996. That is not the case. The TRIPS Agreement came into force on 1 January 1995 along with all the other WTO agreements. Had it not, Article 65.5 would have been meaningless where developed countries were concerned and the "mailbox" and exclusive marketing rights provisions in Article 70.8 and 70.9 would not have applied until 1 January 1996, which is not the case.

The "comment" on paragraph 2 neglects to mention that, in addition to Articles 3, 4, and 5, developing countries must comply with Article 65.5 and with Article 70.8 and .9, if applicable.

## **For developing countries: 2000 or 2005**

The first sentence of this section could imply to one who hasn't read the WHO publication carefully that countries have more than a five year period of transition for the national and most favoured nation provisions of the TRIPS Agreement. The paragraph also refers to countries having "accepted implicitly" the TRIPS Agreement by acceding to the WTO,

that acceptance of the TRIPS Agreement might have been inadvertent. There was nothing "implicit" or inadvertent about any country's acceptance of the TRIPS Agreement or any of the other WTO Agreements. Article II, paragraph 2, of the Marrakesh Agreement Establishing the World Trade Organization 'States unambiguously that the agreements and associated legal instruments in Annex 1, 2 and 3 "are integral parts of this Agreement, binding on all Members"

## **2.7 During the transitional period**

The explanation of the "mailbox" provision of the TRIPS Agreement is confused, referring as it does to how long it takes to test a new molecule and authorize its marketing, which has nothing to do with the "mailbox." Article 70.8 requires that countries provide for the filing of patent applications for pharmaceutical inventions as of January 1, 1995; apply the criteria for patentability as of the date of filing of the application or as of the priority filing date, as appropriate; and begin processing the applications when the law of the country is amended to extend product patent protection to pharmaceuticals, but in no case later than January 1, 2005, or, in the case of least developed countries, January 1, 2006.

## **2.8 How can the monopoly be limited?**

The authors of the WHO publication claim that "anxieties" have been generated by the TRIPS Agreement because of the requirement "to recognize a monopoly of 20 years to the owners of new know-how in the pharmaceutical field." That is misleading in the extreme. Any anxiety that exists is the result of ignorance of the meaning of the TRIPS Agreement, and the WHO publication does nothing to eliminate that ignorance by informing those people in the health sector with no particular legal background of the actual requirements of the TRIPS Agreement related to pharmaceutical inventions. Instead, the publication conjures "experts" (unnamed, of course) who the authors assert fear "a substantial increase in drug prices in countries which did not grant patents in the past."

With unspecified anxieties and the fears of unnamed "experts" as justification, the WHO publication goes on to assert that there are two

ways that might be used to ensure greater accessibility to essential drugs (very few of which are protected by patents anywhere in the world).

## **Exceptions**

The WHO publication asserts that Member States are "left a considerable latitude" under Article 30 of the TRIPS Agreement in implementing their obligations. The three limitations cited include that any limitations "must be duly justified," a phrase not mentioned in Article 30. The Article requires that any limited exceptions allowed "not unreasonably conflict with a normal exploitation of the patent." The authors then use phrases lifted from Articles 7 and 8 of the Agreement arguing that those lifted phrases "could justify derogation of the patentee's exclusive rights," ignoring the fact that the emphasis in Article 30 is on avoiding conflicts with the normal exploitation of the patent and with not prejudicing the patentee's legitimate interests. Negotiators actually had in mind in drafting Article 30, exceptions such as those listed on page 27, but excepting the reference to parallel imports. Negotiators, however, considered only the conduct of tests prior to the expiration of a patent to be a limited exception pursuant to Article 30, not authorization to produce and stockpile the product protected by the patent. The latter practice is the subject of dispute settlement brought by the European Communities against Canada.

## **Compulsory licences**

As in other sections, the WHO publication advocates use of particular provisions of the TRIPS Agreement, as interpreted by the authors, in the name of "accessibility." In this subsection, the authors state the following:

"The Achievement (sic.) of the objective of accessibility, already mentioned, requires adequate exploitation of such possibilities for use without permission of the patent holder in order to guarantee satisfactory conditions of supply. Compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices."

Once again, patent holders are vilified without evidence and actions are advocated without even the suggestion that the grant of compulsory licenses might be limited to situations in which there is actual evidence of anti-competitive practices such as those named. Article 31 (k) expressly recognizes that where anti-competitive practices are found to exist, compulsory licenses may be granted without the need to comply with provisions in subparagraphs (b) through (f).

### ***Ex officio* licence on the grounds of public health.**

In this paragraph, the WHO publication states that Article 8 of the TRIPS Agreement should authorize the grant of licenses *ex officio* "if a new pharmaceutical product introduced to the market were to constitute an important innovation or play an essential role in health policy." The phrase "provided they are consistent with the provisions of this Agreement" is ignored. It would be possible to grant a compulsory license in such a situation but only in accordance with the requirements of Article 31. The perceived importance of an invention does not provide an exception to the obligations and to imply otherwise is misleading.

### **Utilization by governments**

The authors of the WHO publication advise in this paragraph that countries that supply drugs directly to their citizens may authorize compulsory licenses for these products. They further assert that in the case of government use "it is not necessary to fulfil the condition that a voluntary licence must first be applied for." Neither statement is correct as written. The TRIPS Agreement does not specify reasons for which compulsory licenses may be issued; it establishes the conditions that must exist for a compulsory license to be issued, whatever the reason, and it authorizes a few limitations regarding those conditions. Whether or not a government is supplying drugs directly, that government may issue a compulsory licence in connection with a patented pharmaceutical so long as all the conditions of Article 31 are met. Implying that only governments that are supplying drugs directly may do so is misleading. As noted above, the purposes for which compulsory licenses may be authorized are not limited by the Agreement; only the conditions under which any license can be granted is specified. The statement that in the

case of government use, it is not necessary to seek a voluntary license from the patent owner before issuing a compulsory license is overly broad. It is only in cases of public non-commercial use that notification suffices. If a country is selling the drugs commercially, it would be obligated to seek a voluntary license from the patent holder in accordance with Article 31 (a) in the same manner as any other party seeking a compulsory license.

### **Non-exclusivity**

The WHO publication states that the requirement that any compulsory licenses be non-exclusive means that "any interested person may apply" is not correct. The requirement in Article 31 (d) that licenses be non-exclusive is intended to ensure that the patentee and those authorized by the patentee will not be prohibited by any compulsory license from making, using, offering for sale, selling, or importing the patented product.

### **Licences granted on the grounds of anti-competitive practice**

The WHO document recommends in this section that laws aimed to prevent anti-competitive practices "must include artificial price increases and price discrimination practices." No definition of either term is provided and it, therefore, implies that simply using the terms with any standards a country might decide upon would make the grant of a compulsory license consistent with Article 31's requirements. Such an implication is misleading and could subject a country adopting such a resolution to dispute settlement.

### **Abuse of rights and local working of the invention**

The WHO publication states that the TRIPS Agreement does not annul the provisions of the Paris Convention and therefore non-manufacture in the country in question should be considered an abuse of the patent holder's rights. Article 8.2 is quoted selectively as justification for this interpretation. The WHO publication suggests that "some Member States might establish in their legislation that for 'sectors of vital importance', if the patent holder does not manufacture the product locally and is still only importing it after three years, he could be

required to grant a compulsory licence for local manufacture with a view to improving supply of the domestic market or price conditions." Other countries, the WHO publication suggests, it might be more appropriate to authorize importation. While the final paragraph speculates about whether or not Article 27.1's requirement that patent rights be enjoyable without discrimination as to whether products are imported or locally produced recognizes the "legality of import monopolies" and suggests that the issue can only be decided through dispute settlement. This is misleading at best.

Articles 1 through 12 and Article 19 of the Paris Convention are incorporated by reference into the TRIPS Agreement by Article 2.1. As discussed earlier, the provision in Article 5.2 of the Paris Convention is permissive, *i.e.*, a Paris Union Member may provide that non-working is an abuse of exclusive rights, but it is not required to do so. Article 27.1, however, requires that patent rights be enjoyable without discrimination as to whether the product is locally produced or imported. Good faith interpretation of treaty provisions requires that one read the provisions of a treaty in good faith, not creating an inconsistency where none exists. Reading the TRIPS Agreement in that manner, it is clear that Article 27.1 requires that importation of a product into a country be considered "working," *i.e.*, exploiting, the product for purposes of Article 5.2 of the Paris Convention. It is only if the holder of a patent in a country fails to make the patented product available at all in that country that the patent rights may be considered abused. To suggest that there is uncertainty in that regard is irresponsible for an intergovernmental organization.

### **3. Conclusions: Issues at Stake and Constraints on Access to Drugs**

#### **3.1 The drug patents debate**

The WHO publication argues in this section that the TRIPS Agreement "marks a radical break with the earlier GATT strategy of differential and more favourable treatment for developing countries adopted at the Tokyo Round." The transition periods are brushed aside in a parenthetical phrase, their significance ignored. In addition, no recognition is given to the positive benefits that will flow to nationals

and economies of the developing countries when the required rights become available to nationals in their own countries. Perhaps those with the education and skills necessary to do research and development in the field of pharmaceuticals will no longer feel the need to leave their homeland and emigrate to other countries where they can obtain some benefits from the use of their knowledge and skills.

The WHO publication rails against the incorporation by the TRIPS Agreement of the substantive obligations of the Paris Convention as amounting to requiring those that have not signed a treaty to fulfil its obligations. In the context of the WHO publication, this ignores that the Paris Convention does not even require that a country have a patent law, much less protect pharmaceutical inventions. The majority of the obligations of the Paris Convention deal with trademarks and unfair competition. The provisions on patents are procedural and apply only to those countries that have a patent law.

The WHO publication states that in the Uruguay Round "developing countries were constrained to accept commitments sometimes running counter to their economic and social development." This ignores the benefits already flowing to economies of developing countries that already have improved their intellectual property regimes, *e.g.*, Chile, Korea, Singapore, and Thailand. The WHO publication also ignores the fact that the TRIPS Agreement was part of a package of agreements, others of which included significant benefits for developing countries, *e.g.*, agreements on market access, agriculture, and textiles.

The subsection ends by declaring as "imperative" that the audience "be aware of the possible consequences of the WTO Agreements, especially the TRIPS Agreement in the area of pharmaceuticals," and, although none of these "possible consequences" has been more than speculated upon in the WHO publication which is supposed to inform, "to optimize the legal gaps in these agreements." That is tantamount to urging countries to breach the obligations they have undertaken.

### **3.2 Some recommendations**

Reciting unsupported speculation about the effect the TRIPS Agreement might have on "equitable access of populations to health and to drugs,"

the WHO publication urges developing country Members of the WTO to "make the fullest use of the periods of transition." In addition, the WHO publication recommends that revisions of patent laws "should cover the possibility of authorizing parallel importation of patented drugs sold at lower prices in another country or establish that any drug on the WHO Model List of Essential Drugs should be an object of a compulsory licence for public health reasons." Further alarmist calls for joint positions and for national drug policies "to define strategies and guidelines today for the new regulations on patents, the new conditions for the transfer of technology, the new orientation of R&D."

Rather than merely informing "people in the health sector with no particular legal background" about the TRIPS Agreement's provisions, it is clear that authors of *Globalization and Access to Drugs: Implications of the WTO TRIPS Agreement* had preconceived prejudices which are reflected glaringly in the WHO publication and that, despite the tiny disclaimer at the bottom of the "Acknowledgments" page, the WHO has determined to espouse those prejudices. Had the purpose truly been to inform, the authors would have sought the cooperation of the WTO Secretariat in drafting the document and they would have sought objective support for any assertions made regarding the likely effects of the TRIPS Agreement in the pharmaceutical sector, including the benefits. Were the WHO not espousing the prejudices of the authors, it would have sought comments from the WTO Secretariat on the WHO publication's first draft, and not waited to make a *pro forma* request when the publication was already printed and ready for distribution.

# **PART III**

## **REVIEWS FROM THREE INDEPENDENT EXPERTS SELECTED BY WHO**

### **INTRODUCTION**

In light of the attacks on the WHO document "*Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement*" by Phrma, the US Government and WTO; the Director General of the WHO, G.H. Brundtland, decided to send the document to be revised by three independent academics specialized in intellectual property from the University of Louvain, Belgium; University of Buenos Aires, Argentina and the Vanderbilt Law School, USA.

The experts concluded that the WHO's document is technically correct and fully consistent with the TRIPS Agreement.<sup>1</sup>

### **1. REVIEWER A**

#### **Summary**

A requested, I have analyzed WHO document "Globalization and access to drugs: implications of the WTO TRIPS Agreement" (DAP Paper No.7) and the letter by Phrma dated June 30, 1998. I enclose comments on said letter. Briefly stated, my opinion is that the WHO document is a clear, well-structured and informative document on the TRIPS Agreement, extremely useful for health authorities and other readers in developing countries.

Phrma criticism is unjustified. It misinterprets authors' statements as well the TRIPS Agreement itself. The WHO document argues for the full compliance with the TRIPS Agreement, in a manner that is also

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<sup>1</sup> Benkimoun P. op.cit p. 187, 188

consistent with public health requirements. Phrma does not offer a reasoned analysis of the document, but voices the position of Phrma's members without any objectivity and disregarding the public health concerns that have inspired the preparation of the WHO document.

The weakness of Phrma's letter is evidenced by its frequent recourse to personal and disrespectful considerations on the authors, as well as by the abundance of ideological arguments lacking a solid theoretical or empirical basis.

The WHO document, in sum, is technically correct and provides a useful guidance for implementing WTO obligations in the area of intellectual property rights related to pharmaceuticals. With a couple of clarifications, as indicated in the attached comments, the document should be made widely available.

I understand, finally, that WHO is not only fully competent to study all issues that may affect health in developing countries, but that this is also one of its main responsibilities. WHO should be commended for the preparation of the commented document and encouraged to continue with this important work.

#### COMMENTS ON PHRMA'S LETTER OF 30.6.98 RELATING TO DAP PAPER No. 7, "GLOBALIZATION AND ACCESS TO DRUGS. IMPLICATIONS OF THE WTO TRIPS AGREEMENT"

Reviewer A

The purpose of this paper is to comment on the Phrma's letter of 30.6.98 addressed to the Director of the Drug Action Program of WHO, in which Phrma criticizes the DAP Paper No 7 on the TRIPS Agreement, authored by Dr. G. Velasquez and P. Boulet (hereinafter "the WHO document").

This paper considers, first, Phrma's general comments and, second, the observations made on particular sections or paragraphs of the WHO document, following the numbering of Phrma's letter. Finally, the main conclusions of the analysis made are presented.

It should be noted from the outset that the commented letter contains numerous misinterpretations of the WHO document and of the TRIPS Agreement itself, and many arguments that are not technically grounded. The letter frequently employs arguments **ad personam**, that is, personal considerations (often disrespectful) against the authors not the ideas they have presented. The purpose of this paper, however, is not to defend or judge the authors, but to objectively consider the information and arguments that they have given in the WHO document and the pertinence and accuracy of Phrma's reply.

### General comments

A.1. Phrma's vehement criticism on the contents of this paragraph is completely unjustified. Anyone who has studied industrial economics and market structure knows that patents are a source of monopolistic power. Since patents confer exclusive rights, they permit to obtain monopolistic rents. The generation of these rents provides the economic rationale for the patent system. Internationally recognized economists, such as Scherer and Mansfield, have affirmed and studied the monopolistic nature of patents. For instance, Mansfield has stated, that

"a firm may acquire a monopoly over the production of a good by having patents on the product or on certain basic processes that are used in its production" (Edwin Mansfield, *Applied Microeconomics*, Chapter 11 "Monopoly", W.W. Norton Co., New York, 1994, p. 343.

Similarly, Scherer has noted that the owner of a patent

"must expect some degree of protection from competition, or some monopoly power" (Scherer, F. and Ross, D., *Industrial market structure and economic performance*, Houghton Mifflin, Dallas, 1990, p. 622)

The use of the term "monopoly" to describe patents can be also found in specialized legal literature, as well as in decisions by national courts. See, for instance, Chapter 6 "Scope of monopoly" of *Intellectual Property* (Sweet & Maxwell, London, 1989) by W. Cornish, one of the most distinguished British authors on intellectual property rights. See

also, W. Fugate (*Foreign Commerce and the antitrust laws*, Vol. II, Little Brown and Co., Boston, 2nd Edition, 1990), who affirms that

"within the scope of the patent claims, the patentee has a recognized legal monopoly" (p. 8.5)

A.2. In the English version of the WHO document the French word "contrefaçon" – used to mean "infringement" has been translated by "counterfeit". On the use of the word "contrefaçon" see, for instance, Michel de Haas, *Brevet et médicament en droit français et européen*, Litec, Paris, 1981, pp. 412-418.

This is, therefore, a purely semantic problem and not a conceptual mistake as Phrma's letter argues. In fact this purely translation issue is overstated by Phrma, that largely grounds its criticism to WHO document on this point.

A.3/4. These points simply express Phrma's view on the impact of patents on innovation and technology transfer. Such a view is not shared by the majority of those who have **academically** studied those issues. J. Nogués, for instance, a World Bank economist, has affirmed that pharmaceutical patents are likely neither to increase innovation in nor technology transfer to developing countries (see annexed list of bibliography). See also the conclusions of a study by Scherer and Weiburst, published in the prestigious Max Planck lie Journal (see annexed list of bibliography).

The WHO document, in sum, finds support in a solid and vast economic literature on the impact of patents, particularly on pharmaceuticals, in developing countries.

A.5. Here again Phrma employs an extremely controversial argument. It justifies its opinion on a study made by a group of consultants (who had previously expressed in other works a clear pro-patent view). The referred study applies a flawed methodology that does not prove the authors' alleged conclusions.

This explains why NERA's results contradict most academic studies conducted in developed and developing countries. Such studies predict

price increases in medicines as a result of the introduction of product patents. They only differ on the estimated percentage of price increases, but all of them anticipate a negative impact of product patents in terms of prices. Higher prices are a logical, consequence of patent grants. If the patent owner were not able to obtain a price higher than under competitive conditions, why a company would bother about obtaining and enforcing patent, sometimes investing millions of dollars in lengthy litigation?

A.6. The convenience or not of allowing parallel imports is another matter of opinion. Phrma strongly advocates the restriction of such imports. The WHO document argues that such imports should be allowed in order to foster competition. Many authors, governments, industrial and consumer groups and other organizations, share this latter view. Parallel imports (based on the concept of "exhaustion of rights") facilitate competition and thereby improve the access to medicines. Parallel imports of patented products have been deemed legitimate by many recent laws (e.g. Argentina, Andean Group countries, South Africa) and by decisions of the European Court of Justice and of the Supreme Court of Japan. Parallel imports of trademarked products have been allowed by the US Supreme Court as well. If Phrma's protectionist view were accepted, patent holders would be permitted to fragment markets and apply different prices for the same product in different countries, at their sole discretion. As noted below, the TRIPS Agreement (article 6) does allow that a WTO Member country adopt a pro-competition approach, as indicated by WHO document, by allowing parallel imports of legitimately traded products.

### **Specific Comments**

B.1. The WHO document brief historical description is essentially correct. Instead, Phrma's statement ignores the strong disagreements that characterized TRIPS negotiations. Though such negotiations started in 1986, until 1989 developing countries even refused to work on a draft text! These countries finally agreed to discuss a text not by conviction on the advantages they might obtain, but on the perception that adopting an agreement on TRIPS was unavoidable. On the history of TRIPS, see T. Stewart, *The GATT Uruguay Round. A negotiating history* (1986-1992), Kluwer Law and Taxation Publishers, vol. II, pp. 2245-2313.

B.2. Again the WHO document is correct. There is no doubt that the Paris and Bern Conventions are to coexist, and in fact several authorities, like Prof. Geller, have already analyzed the problems that such a coexistence may create (see Paul Geller, "Intellectual property in the world marketplace. Impact of TRIPS dispute resolution", *The international lawyer*, Spring 1995; see also Ricketson S. "The future of the traditional intellectual conventions in the Brave New World of Trade-Related Aspects of Intellectual Property Rights, *IIC. vol. 26. No.6, 1995, pp. 872-899*). The WHO document does not deny that the TRIPS Agreement defines new minimum standards. On the contrary, the whole document is about such standards.

B.3. Phrma's argument is surprising for any reader with a legal background. It pretends that articles 7 and 8 of the TRIPS Agreement are non-binding but merely "hortatory statements". They are however, an integral part of Part I ("General provisions and basic principles") of the Agreement and not of the Preamble.

Phrma's interpretation of the language used in the Preamble and articles 7 and 8 deliberately ignores that the TRIPS negotiations were one of the most difficult and controversial issues during the Uruguay Round.

Phrma's dogmatic view of intellectual property – "by definition intellectual property standards serve to promote technological and development objectives" – ignores the dramatic differences in the levels of technological and economic development among countries, and the different impact that IPRs may have according to the circumstances of each case. Phrma's opinion is contested by a large number of objective, academically conducted, analysis on the economics of IPRs and on the impact of TRIPS on different categories of developing countries (see annexed list of bibliography).

Phrma's comments on pages 12 and 13 distort what the WHO document actually says. Nowhere the document states that the TRIPS Agreement may be ignored; it simply argues for the need to obtain a "balance between national objectives and sectoral interests". This is perfectly correct and in line with article 7 of the TRIPS Agreement.

Finally, it should be noted that article 1 of the TRIPS Agreement is more than "an obvious requirement". Its importance is well acknowledged in the WHO document. Phrma conveniently overlooks that many developing countries have been threatened or subjected to commercial retaliations (grounded on actions initiated by Phrma itself) under section 301 of the US Trade Act, based on demands for IPRs standards that go beyond TRIPS obligations.

The importance of article 1 is also evident in the light of said section of US Trade Act which is amended in 1994, states that a country may be subject to unilateral retaliations "notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the TRIPS Agreement".

B.4. Phrma's letter ignores the wide, solid and recent body of literature on the impact of patents in developing countries, particularly in the pharmaceutical sector. It overlooks, for instance, that the developing countries that were able to establish some significant production capacities in pharmaceuticals, were those where product protection did not exist or was only recently introduced, such as Argentina, Egypt and India. Available studies also indicate that it is very unlikely that the introduction of patents would help the development of a local pharmaceutical industry in those countries (see annexed list of bibliography).

The statement in the WHO document on copies that will be "banned" as a result of the new rules simply seems to put, in simple language, what the effects of the implementation of the TRIPS Agreement will be. The expressed intention of the document has been to describe in a comprehensible way issues which are new and complex for people in the health sector in developing countries. Why is Phrma so vehemently advocating for the recognition and strengthening of patent rights? Just because Phrma's members are concerned with the health of people and the development prospects of developing countries? Or is it because they actually want to prevent any imitation of their products by exercising the **ius prohibendi** conferred by patents?

Of course, neither the existence nor the absence of product patent protection can, by itself, explain the different performance of developing

countries in the pharmaceutical sector. It is a fact, however, that no developing country that introduced product patent protection before the 1990s has developed any significant local pharmaceutical industry or attracted foreign direct investments in that field.

The outcome of the exercise of product patents rights will be, as the WHO document states, that "copies" will be effectively banned. Phrma also disregards that in some countries patent infringement may be a public offense in terms of criminal law, i.e. actions may be initiated by a public prosecutor and not necessarily by the patent owner. Hence, copies may be banned even in the absence of action by the title holder.

B.5. It is incorrect the allegation that authors "disassemble the single provision into two discrete grounds". The WHO document just indicates – in the second paragraph of the "Comments" included in a purely descriptive Box – which are the justifications allowed by the Agreement. No other implication may be derived from the text, as Phrma suggests. The discussion of article 27.3.b) in the document is also correct. Merely purified biological organisms may be patentable in some jurisdictions, like the USA. But many national patent laws do not accept this expansive concept and do not admit the patentability of substances existing in nature (see Brazilian patent law, 1996; Decision 344, of the Andean Group; 1993; Argentine patent law, 1995). Furthermore, the WHO document is not assertive on this point. It employs a cautious language indicating that there are "doubts" on the matter.

B.6. Section 2.5 There is here no "grave error", as Phrma argues. The use of "counterfeiting" simply seems to be the result, as mentioned above, of translation from the French original document, where the word "contrefaçon" is used. "Contrefaçon" covers both infringement and acts that may mislead the public about the origin, quality, etc. of a product. However, in order to avoid any confusion, an Erratum to the English version of the WHO document may be included.

B.6.a) Again, no "misconception" is found in WHO document on the doctrine of "exhaustion of rights". The document is perfectly correct on this point. A different thing is that Phrma dislikes and clearly opposes the concept, which aims at promoting legitimate competition. The international exhaustion of rights, if established under national law, is

fully consistent with the TRIPS Agreement (article 6), as indicated above.

B.6.b) Nowhere the WHO document says what Phrma states in its letter. This paragraph contains another intentional misinterpretation of said document.

B.6.c) The document is correct. See comments on point A above.

B.7. The criticism is unjustified. The standstill provision is clearly reflected in the Box.

B.8. The wording of article 70.6 is quite unusual in an international instrument. Phrma's assertion that this article should be interpreted as saying December 1992 is absolutely incorrect. At that time there was no "Agreement" at all, and a lot of uncertainty about the future of GATT negotiations existed. Moreover, the draft Dunkel text was modified before being agreed upon in December 1993. The latter is the date that, in my opinion, should be considered as the date in which the Agreement was known for the purposes of article 70.6.

B.9. The WHO document correctly deals with article 30. Phrma misinterprets both the document and said article.

Phrma's statement that exceptions under article 30 are only for non-commercial uses is false. The patent laws of developed countries contain many types of exceptions – so far unchallenged under the WTO rules – for **commercial** purposes. Thus, the US law permits experimentation with a patented pharmaceutical invention to obtain approval for later commercialization of a generic product ("Bolar exception"). European law admits experimentation on a protected invention as a means of encouraging innovation.

The first exception indicated by the WHO document is allowed by article 6 of the TRIPS Agreement, and regularly accepted in Europe on a regional scale.

The fifth exception is included in most laws in developed and developing countries. It was also proposed by WIPO's Secretariat in the draft Treaty on the Harmonization of Patent Laws.

The sixth exception is admitted, as mentioned, in the United States since 1984. It is also accepted in Argentina and Israel.

Likewise, Phrma's comments on the compulsory licenses are incorrect and manifestly biased. Note, for instance, that Argentina is quoted as a country where the compulsory license system failed. But Argentina did not recognize such licenses till the very recent reform of its patent law, in 1995.

As argued by one of the outstanding British authorities on intellectual property, the fact that few compulsory licenses have been granted does not imply that the system was ineffective (Cornish, *op. cit.* p. 205).

The WHO document analysis of compulsory licenses is essentially correct. It provides an interesting idea on the way of interpreting article 8.1 in conjunction with article 31. This idea may be debatable, but it does not reflect a "flawed reasoning" as Phrma affirms.

With cautions reservations, the WHO document indicates possible ways of interpreting article 27.1 with respect to compulsory licenses for non-working. It is a fact that article 5A of the Paris Convention has not been derogated, and that article 27.1 contains a last minute compromise with a lot of ambiguity. Brazilian government, for instance, interpreted that such article does not prevent compulsory licenses for non-working. The issue may be debatable, but the WHO document is correct in indicating possible interpretations. It should be noted that, according to the Dispute Settlement Understanding, recommendations and rulings by the DSB "cannot add or diminish the rights and obligations provided in the covered agreements" (article 3.2) and that when the interpretation of a provision of the Agreement results in ambiguity, if a government has chosen one of the permissible options, the international body should allow the government to continue with that option (see Jackson, J. *The World Trade Organization. Constitution and jurisprudence*, The Royal Institute of International Affairs, London, 1980, p. 90).

B.I0. The recommendations of the WHO document are balanced and reasonable, and take many of the concerns of developing countries into account. They constitute an important contribution for countries that face the difficult task of implementing the TRIPS Agreement in a manner consistent with its provisions and public health objectives.

## **Conclusions**

The WHO document indicates how the TRIPS Agreement can be implemented in developing countries in a manner that is consistent with its provisions, taking into account, at the same time, the public health objectives of such countries. Since it is addressed to non-specialists in IPRs, it employs simple language to discuss complex issues.

The WHO document is essentially correct in the interpretation of the TRIPS Agreement. It contributes to the understanding of the Agreement and of its implications for the pharmaceutical sector in developing countries. It provides valuable guidance for ensuring the compliance by developing countries with the Agreement, using the room for manoeuvre that the Agreement leaves to adopt different solutions in respect of many aspects relating to pharmaceutical patents. Phrma criticism, though addressed to the WHO document, in fact seems to be against what the TRIPS Agreement actually provides for – as reflected by the authors of the WHO document. The industry represented by Phrma has voiced since the Dunkel text was known, its disapproval of the TRIPS Agreement, which was deemed a "flawed" instrument in many respects (see the presentation by Pfizer's General patent Counsel in the name of the "Intellectual Property Committee before the Subcommittee on Trade of the Committee on Ways and Means of the U.S. House of Representatives, 23.1.92, p. 88-97).

For instance, Phrma attacks the document on the issues of exhaustion of rights and on compulsory licenses, but its attack is to the Agreement as such rather than to the document, which simply explains, in an accessible form, what the Agreement provides for.

Phrma's letter is full of misinterpretations of the WHO document, it attributes the authors' statements that they do not make, and provide an inaccurate interpretation of the TRIPS Agreement.

Phrma tries to disqualify the authors and thereby the WHO document, by using a fallacious reasoning (**ad personam**). One of the authors of the WHO document, qualified as ignorant by Phrma, holds a Master in economics of the Université de la Sorbonne and has got his PhD on health economics cum laude at the same university. It would be good to know what is the academic background, if any, of those who prepared the letter commented here.

The disrespectful language used in the letter indicates that it is inspired by political aims, rather than by the search of a serious debate on the matter. Phrma's exclusive concern seems to be how to interpret the TRIPS Agreement in order to further expand and strengthen the market power based on the use of patent rights, a point of departure significantly different from the public health concerns that are behind the WHO document.

Phrma's letter, in sum, is neither an objective analysis of the WHO document nor of the TRIPS Agreement. In my view, the WHO document should be widely distributed, perhaps with an erratum on the two points indicated above (the translation of "contrefaçon" and the date from which the Agreement was known).

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## **COMMENTS BY THE FOOD AND DRUG ADMINISTRATION ON THE WHO DOCUMENT "GLOBALIZATION AND ACCESS TO DRUGS. IMPLICATIONS OF THE WTO/TRIPS AGREEMENT"**

### **Summary**

The analysis made by the FDA (letter of July 21, 1998) provides a different view on the subject dealt with in the WHO document. This U.S governmental agency disagrees with the implications pointed out by the authors of said document. Most of FDA arguments indicate differences in the premises upon which the impact of the TRIPS Agreement is assessed, rather than objections to the interpretation of the Agreement as such.

FDA comments overstate or misinterpret many parts of the document. It provides its own understanding of the TRIPS Agreement, which is likely not to be necessarily shared by other WTO members.

In my opinion, the examined comments do not undermine the basic accuracy of the information provided by the WHO document, nor its value for policy makers in the health sector in developing countries.

### **Specific comments**

#### **Executive Summary**

The first para of the letter attributes the authors' implications that they have not presented in the document ("nationals of developing countries will remain for ever unable to develop products ...").

FDA incorrectly assumes (second para.) that the WTO Secretariat is the only authority for the interpretation of the TRIPS Agreement. A definitive interpretation of the Agreement can only be decided by the Member countries; even a panel decision does not create a legal precedent for non-disputant Members (J. Jackson, *The World Trade Organization. Constitution and Jurisprudence*, The Royal Institute of International Affairs, 1998, London, pp. 83-84).

The criticism on the Executive Summary focuses on some simplifications in language (which seems justified for a document written for a non-informed public), and indicates differences of opinion. The considerations made in the fifth para of the letter clearly exceed what an "Executive Summary" may contain.

### **Definitions and terminology**

Like Phrma's letter, FDA gives an excessive weight to the translation inaccuracy in respect of the French term "contrefaçon". This problem can be easily solved with a Corrigendum.

The FDA statement about dependent patents seems to ignore that the TRIPS Agreement specifically provides for compulsory licenses for the use of such patents. The WHO document reproduces the wording of the Agreement (article 31,1). The criticism by FDA is addressed to the Agreement itself rather than to what the authors of the WHO document correctly say.

Similarly, the analysis by FDA of the definition of "exhaustion of rights" made in the document contradicts article 6 of the Agreement, which clearly allows for the application of that doctrine on an **international** basis. It is known that the U.S pharmaceutical industry opposes that concept. The FDA argument – possibly reflecting the views of that industry – fails to demonstrate that the WHO document is inaccurate on this important subject.

There is nothing wrong with the definition of "reverse engineering", since it refers to the information about the process of manufacture, not the chemical entity which is disclosed.

## **Introduction**

FDA claims in para. 16 – as well as in other paras. of its letter – that no support or evidence is provided. It is not possible to expect in a document of the type produced by WHO to give support to each of the statements made. The document contains selected bibliography that the reader may consult. The comments by FDA indicate a disagreement with the basic position of the WHO paper: health interests should be given precedence over commercial interests. It is also unfair to say that the authors are arguing for an implementation of the Agreement in violation of its provisions. The authors have tried, on the contrary, to reconcile health interests with those of patent holders, and this is the main merit of the document.

## **Fundamental principles and objectives...**

The interpretation of the Preamble and of articles 7 and 8 in the WHO document are essentially correct. FDA criticism reflect a different opinion on the goals of IPRs and of the Agreement, which are legitimate, but do not invalidate the authors own views. If article 8 were as obvious as alleged by FDA, why was it included and supported by all negotiating countries? The WHO document does not say that this article provides "an exception to the obligations of the Agreement", but a framework to interpret and implement the Agreement in the area of health.

The importance of article 1 of the Agreement is also well underlined by the WHO document. Though its content may be obvious for some international lawyers, it is good to recall policy makers in developing countries that any request beyond the TRIPS Agreement is not legitimate. By the way, it is notorious that the US government (to which FDA belongs) has demanded many developing countries unilateral concessions on IPRs matters exceeding the TRIPS Agreement standards.

## **Patents for pharmaceutical products and processes...**

The reading of the WHO document – as reflected in para. 26 of the letter – is not accurate. FDA comments are based on the alleged "impression" given, and not an objective interpretation of what is actually said.

FDA interpretation of article 27.1 is debatable. This rule is not as clear as FDA pretends. If – as FDA itself recognizes – the patent holder only has negative rights (i.e. rights to exclude others) why should article 27.1 be understood as referring to locally produced or imported products of the patentee and not of third parties? In fact, article 27.1 – as indicated by the WHO document – is not crystal clear. It was the outcome of a difficult, last minute compromise.

The purpose of the WHO document was not –as far as I can understand – to provide a text book on patents. If the comments made in para 24 were followed, the authors would have to explain every detail in patent law. This may be, perhaps, a future task for the WHO Secretariat in relation to pharmaceutical-related patents.

### **Non patentable inventions...**

The WHO document is correct. The concept of "invention" has been – and still is one of the most debated concepts in patent law. The TRIPS Agreement does not define it, and leaves Members considerable room to do it, in a manner consistent with the Agreement.

### **Effects of protection...**

I do not find a misleading use of the term "monopoly" here (as indicated in my comments to the Phrma letter).

### **Attenuation of the monopoly...**

The FDA clear rejection of the "international exhaustion of rights" principle is made clear in paras 32-35. The WHO document provides a balanced discussion on the matter.

### **Strengthening the monopoly...**

The reversal of the burden of proof, though accepted in many nay laws, was far from being a common feature in patent law before the TRIPS Agreement. It is true that the holder of a process patent can only prevent the commercialization of the product directly produced with that patent. In some cases, however, broadly defined process claims may in practice

be used to threaten competitors. Thus, Professor J. Barton, of Stanford University, has called attention to the "strategic litigation" that some large firms undertake to deter smaller competitors (J. Barton, "Adapting the intellectual property system to new technologies", *International Journal of Technology Management*, vol. 10, No. 2/3, 1995, p. 163).

The comments made in paras. 37-38 show the own preferences and views of FDA on the patent system, but they do not disqualify the WHO document, in which other views – were expressed. The WHO document views are supported by a large body of literature, which is partly indicated in the document's Annex (see also the list of bibliography attached to my comments on Phrma's letter).

### **Extension of the duration...**

The argument used by FDA is somehow surprising. There is abundant evidence on the fall in the prices of medicines after expiration of the respective patents. There are cases in which the former patent-holder may keep prices high for some time (usually based on the advantage conferred by its trademark), but once the product is in the public domain, competition may take place.

### **Application of the TRIPS Agreement/During the transitional period**

The WHO document is perfectly correct when it indicates that the general date of entry into force of the Agreement is 1.1.96 (see article 65.1). The few exceptions provided for in the Agreement do not alter this rule. The explanation of these periods is essentially appropriate.

### **How can the monopoly...**

For literature on price increases that may result from the introduction of pharmaceutical product patents, see the bibliography attached to the comments on the Phrma letter. FDA does not obviously share the WHO document's opinion, but it does not provide any evidence either to substantiate it.

## **Exceptions**

How can FDA know what the negotiators (all of them?) had in mind when drafting article 30? I participated in the TRIPS Agreement negotiations and I personally had in mind – like probably many other negotiators – the kind of exceptions listed in the WHO document and that – in fact – are recognized in most patent laws in developed and developing countries.

## **Compulsory licenses**

I agree with the comment made by FDA stressing that the TRIPS Agreement does not limit the grounds for granting compulsory licenses. The WHO document is not misleading in this respect or in the interpretation of other aspects of article 31. FDA provides its own interpretation on several points, but it does not need to be shared by everybody. For instance, FDA seems to limit the "non-exclusive" character to the competition by the patentee or his voluntary licensee. As indicated by the WHO document, however, such a character also implies that more than one non-exclusive compulsory license may be granted. I disagree with the subjective comment in para. 55 of the letter suggesting that the authors of the WHO document are "urging countries to breach the obligations" of the Agreement, since the spirit of the document is to indicate how to comply with the Agreement in a manner consistent both with its obligations and with public health priorities.

## **Some recommendations**

The last paras of the letter also provide a subjective opinion on the document.

## **2. REVIEWER B<sup>1</sup>**

### **COMMENTS RELATED TO THE WHO DOCUMENT “GLOBALIZATION AND ACCESS TO DRUGS: IMPLICATIONS OF THE WTO/TRIPS AGREEMENT” AND TO THE REACTIONS OF THE USFDA, PHRMA AND THE WTO**

First of all, I wish to express my gratitude for your trust in consulting my opinion on this matter.

In your mail of 27 July, you had specified that you were only expecting general comments from me at this stage at least, and not a detailed analysis of the WHO document and of the criticism that it triggered. I will therefore follow your request but wish to say that the subject in question of access to medicines and of the current patent system is vast and particularly complex, involving varied and huge interests, which probably explains today's “animated debate”.

If I may, I will start by making a series of general observations before briefly reviewing some of the criticism expressed in the American documents, mostly in the one of the USFDA, and finish with some brief personal conclusions.

#### **General observations**

I wish to first express my surprise concerning the tone and the style used in both US documents: the extremely polemical, and sometimes aggressive tone, close to impoliteness and petty accusations at times is astonishing and do not seem to present the serenity needed for a serious debate.

The authors of both American notes are reproaching to the authors of the WHO document some activism which seems to be animating them too...

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<sup>1</sup> Reviewer B submitted comments in French. This is an unofficial translation of the document.

As to the substance of the issues, I would like to recall a few key elements:

1. The TRIPS Agreement, as clearly indicated by its name, only relates to trade-related aspects of intellectual property rights, which means, in my opinion, that there are other essential aspects (e.g. cultural or health) which go beyond trade issues.

The drafters had exactly that in mind when drafting Article 7 (Objectives) and 8 (Principles). Therefore, it seems obvious to me that WTO Member States may – must? – take into account other elements than those strictly related to patents, as they adapt their legislations to TRIPS standards.

2. I believe it is also important to read the contested document in light of its natural objectives: to examine the role of TRIPS on access to drugs. This question obviously leads to the problem of most impoverished populations of developing countries, etc... e.g. not only to the incentives for innovation and development of new drugs (conditions for innovation), but also to the economic context needed so that populations – and in particular the poorest – can afford the medicines needed for their health (conditions for access).

In addition, the disputed document does not pretend to be a book on patent law but rather a work document of few dozens of pages, hence necessarily limited, incomplete and not always nuanced enough.

3. It seems clear to me that in many instances, there is room for interpretation of the text of the TRIPS Agreement; hence one should avoid peremptory views on the interpretation to give to one or another provision, before implementation shed some light on such interpretation.

4. I must admit to being quite surprised to see a State, which ever be it, aligned so much with the position of industry and not taking the least step backwards with regard to its interests.

5. The document was written in French, if I'm not mistaken, and translated to English, and there seem to have been a few translation problems. Just taking the example of the executive summary, the French

text states that “l’accord sur les ADPIC est sans doute celui qui aura les conséquences les plus importantes dans le domaine pharmaceutique”. “Sans doute” was translated to “undoubtedly” which means in French “indubitablement”, i.e. without any doubt, whereas “sans doute” is rather translated “probably” (which also means “probablement” in French).

The English version therefore seems much more unequivocal and leads Mr. Stuart L. Nightingale, to accuse the text of being “an example of propaganda”, whereas writing that the TRIPS Agreement is probably the agreement that will have the most important consequences in the pharmaceutical field, seems to be a reasonable appreciation that can be made without being accused of propaganda. I could comment similarly on the US criticism of the use of the word “counterfeit” (contrefaçon).

More broadly, the question seems rather to be whether the debate should focus on the wording or on the fundamental issue raised by this document which is that of the impact of the TRIPS Agreement on access to medicines.

6. Indeed, I perceive in the American texts an intention to create controversy, and in any case, to interpret the WHO document as “aggressive with an anti-patent propaganda” (see for instance paragraph 5 of the American government letter).

Personally, I do not read this document as being “anti-patent” but as seeking only to demonstrate that WTO Member States have some margin of manoeuvre to adapt their legislation and are not obliged to adopt necessarily the interpretation proposed – dictated? – by the pharmaceutical industry of developed countries. I personally fully support this approach.

That being said, in my opinion, a number of objections can be formulated on the document:

a. The report could – should? – have better described its scope from the outset and underscore more the fact that it does not cover all aspects of the patent system, nor of the TRIPS Agreement, but only analyses the latter with the sole perspective of access to medicines.

Similarly, it may probably have been useful to recall some positive elements of the patent system such as, for instance the disclosure obligation that is imposed on the applicant.

In short, the WHO report should have been better put in perspective, spelled out its limits and insisted on the fact that the patent system has some positive aspects.

b. The report lacks nuances in several occasions and I think, in that respect, that M. Otten’s observations are overall relatively founded.

The report is too often a little brief as is the case on the subject of exhaustion of rights or when it brings out the positive aspects of non-voluntary licenses (in respect of which I have serious doubts).

The report would gain from being more nuanced and cautious in its assertions.

### **Brief analysis of the document of the American Government**

It should be noted that we are focusing our observations on the document emanating from the American government because its critics are about similar to those formulated by the American pharmaceutical industry and it is much more important because it originates from the American government.

I have not, at this stage, done a systematic review of the critiques formulated in the report of the American government, notably because several of these are just pure polemic.

What is striking when reading the document is that there is an underlying permanent and almost systematic critic of the WHO document, based on the fact that it does not adhere to the “dogma” according to which strengthening of patent holders’ rights is better for the public interest.

1. Dependent patent

It is true that the text of the WHO document lacks nuances and the comment of the American government is quite largely founded.

2. Patent Definition

The American text blames the WHO document for using regularly the term “monopoly” which would be alarmist.

We cannot share this perspective and it seems normal to “call a spade, a spade”. The term monopoly is by the way largely used in several countries such as France or Belgium.

3. As an example, the generalization of patentability of pharmaceutical products and processes on a world scale is of such a high importance that it justifies in itself the consideration that the TRIPS Agreement has a big impact on production and access to medicines, at least in countries where patents on pharmaceutical products and processes did not exist at the time of entry into force of the Agreement.

4. Paragraph 17 of the American document clearly illustrates its questioning of the motives of the WHO paper: I however believe that it is not only normal but also dutiful of the WHO to be preoccupied by the question of whether a new international agreement – whichever it may be – will enhance or decrease access to medicines, and also to question how to better implement it in order to improve access to medicines. There is nothing “inimical” here.

5. Paragraphs 21 to 25 of the American document

Without any intention to raise polemics with the American government on whether IPR protection is an end in itself or not, and if, as other regulations, IPR should be subject to State development, one can only note the excessive criticism of the American document vis à vis the WHO document. The latter could certainly have been more nuanced (but nuance is often difficult especially on such a complex topic), but it does not state anything wrong when it concludes in paragraph 2.2 (page 14) “With a social and health policy perspective, these provisions opens

the possibility for putting in place national regulations addressing the imperative of ensuring the best possible access to medicines”.

5. Paragraphs 26 to 29 of the American document include criticism which falls within polemic rather than scientific debate, and so I won't discuss these. I wish however to formulate one comment on the equation of importation of patented product to local production. No one would seriously deny that it would be counter-economical to obligate one company to manufacture in each country where it has patent rights. The issue is rather if the same protection (or the same privileges to use an old terminology) should be granted to a company that produces locally than to a company that only imports. This question would be worth a debate in my opinion.

6. Paragraph 30

The wording of this paragraph in the American note falls again more within polemic than scientific debate. How can one pretend to ignore that several developing countries have “natural resources” of high interest to the pharmaceutical industry... and that these questions touched upon by the WHO report are thus legitimate issues for these countries?

7. Paragraphs 32 to 35 of the American document

The WHO text could be more nuanced but does not include any gross error. This being said, the debate on exhaustion of intellectual property rights, – especially in relation to patents – is a complex one that cannot be fully addressed by a few polemical statements.

8. The reflections in paragraph 36 of the American document regarding the issue of strengthening the monopoly of process patents seem well founded and should be taken into consideration. However, this issue seems to be rather secondary, in my opinion, in light of the objectives of the WHO report.

9. The critique in paragraph 39 of the American document seems to be rather founded in that the WHO document is a little too unequivocal.

10. Paragraph 43 of the American document is polemical but it is true that the wording of the WHO text is too affirmative and should be nuanced.

11. Where the American text refers to the intent of negotiators in paragraph 44, it seems to be thinking of the American negotiators rather than those representing developing countries.

12. Paragraphs 45 and following of the American document

I remain sceptical regarding the effectiveness of compulsory licensing and that's why the whole debate on government use licenses seems worthless and artificial to me. Once again, the American government gives the impression of fault-finding when it criticizes in paragraph 49 the lack of definition of 'artificial increase of prices' and of 'price discrimination practices': definitions abound in economic, and to a lesser extent, legal literature...

13. Paragraph 55 of the American document

I don't think anyone can be blamed for "optimizing legal vacuum of agreements", and doing that does not mean challenging its signature!

These are a few quick and necessarily succinct reflections, based on my first reading of the American document.

In conclusion, I think that if the WHO document can be criticized in some aspects, and particularly regarding its lack of nuances and some overly radical statements, it does not contain any substantial error that would fundamentally modify the conclusions or recommendations it makes.

Overall, I do not have any fundamental critique to make to the WHO document, but it would probably be better, for its perception in some circles, if it could be more nuanced and if a certain number of "secondary" errors could be corrected.

Lastly, I think the three observations contained in the WTO letter dated 7 May 1998 can be met with a few additions and editorial corrections, as

I already outlined for the first two (that the document does not underscore enough the positive contribution of the patent system as an incentive to innovation, and that the tone is sometimes too polemical).

With regard to the third observation related to errors and lack of nuances, I think this can be made without fundamentally modifying the substance of the document.

I hope I have met your expectations and remain at your disposal to collaborate, in the future, on the improvement of the document, which in my opinion, remains very useful given the fundamental importance of the issues it raises, which are relevant not only to patent law specialists but to all citizens of the world.

### **3. REVIEWER C**

As requested by WHO, I have reviewed the Report entitled *Globalization and Access to Drugs – Implications of the WTO/TRIPS Agreement*, HEALTH, ECONOMICS AND DRUGS, DAP Series No.7, WHO/DAP/98.9, Nov. 1997, in light of certain criticisms that have 'been raised' by external sources. For the sake of convenience, I have separated my analysis of Phrma's objection from those of the USFDA and the WTO; and for the sake of efficiency, I have focused on Phrma's letter of June 30, 1998, because my observations in that context should carry over to the other responses. References are to the paragraphs in the various letters as numbered by Dr. Velasquez in his prior transmission to me.

#### **I. Phrma's Objections**

##### **A. Executive Summary**

###### **1. Letter from Thomas Bombelles stating that WHO seeks to rationalize confirmed piracy (Cover letter, para. 2)**

The accusation that WHO's Report endorses piracy is groundless and gratuitous. As the Executive Summary makes clear, the purpose is to "inform people in the health sector with no particular background about the impact of globalization on access to drugs, and especially about the WTO Agreement on Intellectual Property (TRIPS Agreement) that may have repercussions in the pharmaceutical field." (Executive, Summary, p. i) This effort to explain the issues in plain language for health specialists not familiar with technical intellectual property concepts partly explains why the document lacks much of the conceptual baggage that might be needed to fend off the technical and policy arguments levelled by Phrma, and it may also account for one of the document's chief weaknesses, i.e., little mention of views different from those of the drafters.

Nevertheless, the document clearly states that "the TRIPS Agreement establishes minimum standards in the field of intellectual property," and

that "all member states have to comply with these standards by modifying their nation's regulations to accord with the rules of the Agreement." (Executive Summary, p. i). This is hardly an invitation to civil disobedience, let alone "piracy."

2. Moreover, the summary of the TRIPS provisions set out in the Executive Summary, at p. ii, is essentially accurate, although it is not sufficiently attentive to legal nuances. For example, developing countries (as distinct from least-developed countries) will have only five years of transition with respect to patentable subject matter previously recognized in their laws, whereas a term of ten years is available only for new patentable subject matter to be recognized by the developing countries' amended laws. This is not clearly stated. The statements summarizing the "mailbox" rule also appear a bit fuzzy and unrefined, especially since the WTO Appellate Body's decision in *U.S. v. India*<sup>1</sup> which must have come down after this document was prepared.

I point this out because a fully accurate, one-paragraph summary, like that on pp. ii of the Executive Summary, would require much thought and careful drafting by the best legal experts; and this summary does not meet that standard. This lack of legal tightness probably reflects WHO's efforts to reach a non-legal audience, but it also makes the study vulnerable to tightly knit legal attacks. However, the *principles* summarized in the Executive Summary are essentially accurate. More to the point, the summary of "the certain amount of freedom" left to developing countries in the last paragraph of the Executive Summary is accurate in both law and policy; nor is it radical or devious in tone or method. It contains not the slightest hint of endorsing "piracy." Therefore, while it might be desirable to tighten the summary of the technical rules at the top of p. ii, there is nothing in the Executive Summary that merits serious concern. Clearly, Phrma's cover letter is inaccurate with regard to the Executive Summary.

## **B. Phrma's Letter, Part B – Specific Comments, paras, 9-55**

1. In my view, Section 1.4 of the WHO paper ("the protection of intellectual property rights before the WTO") is neutral and unbiased. The position affirmed in paragraph 10 of Phrma's letter represents the views stated in the negotiating positions of some developed countries.

Articles 31 and 32 of the Vienna Convention on the Law of Treaties require international adjudicators to focus on the letter of the, Agreement, and not on the background views of the participant states or of their constituent interests, while the WTO Appellate Body's decision in *U.S. v. India* (1997) confirms this application of the Vienna Convention to TRIPS. See, e.g., J. H. Reichman, *Securing Compliance with the TRIPS Agreement After U.S. v. India*, 4J. INT'L ECON. L. \_\_\_\_ (forthcoming December 1998). The insistence of Phrma, in paragraph 10, on their viewpoint as distinct from the black letter rules actually adopted, is symptomatic of the flawed and partisan reasoning that permeates their letter as a whole. It is largely a biased diatribe favouring certain policy positions that are as yet undecided either in law or at the 'level of respected scientific debate.

2. The "general presentation of the Agreement" in Section 2.1 is generally accurate and unbiased, although its lack of technical legal refinements makes it vulnerable to self-serving misinterpretation. It would have been better to say that while the choice of means of implementation are left to the states, the results must conform to the TRIPS' minimum standards, which supplement the Paris Convention, and that is the sense in which the two Agreements co-exist. (Indeed, Paris is now binding on all WTO members, whether signatories of Paris or not). However, that paragraph should be read in the light of paragraph 1 of Section 2.1, which clearly states that the Agreement "aimed at strengthening and harmonizing certain aspects of the protection of intellectual property at the global level." Merely because the Section is not stated with the bias Phrma would have given it is not to say that, as written, it is either wrong or biased.

3. The statement of "fundamental principles and objectives" in Section 2.2, while, indeed, a "lay analysis," as Phrma says (rather than a technical, legal analysis) is essentially correct. It expresses a view that favours developing countries concerned about their health systems in the post-TRIPS environment, in language that is inelegant from the technical, legal perspective, but not incorrect, erroneous, or even tendentious. The thesis is that intellectual property rights before and after TRIPS represent a balance of public and private interests, and that developed and developing countries remain free to strike a different balance within the confines of the new international minimum standards

themselves. Indeed, I have just published a long article to this same effect, which argues that developing countries should adopt a "pro-competitive" approach to application of the TRIPS Agreement, which would emulate the strategy of the U.S. before it converted to a high-protectionist philosophy in the late 1980s. See J. H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. INT'L. L. & POL. 11, 26-93 (1997) ("A Pro-Competitive Strategy for Implementing the TRIPS Agreement"). See also UNCTAD, *The TRIPS Agreement and Developing Countries* UNCTAD/ITE/1 (1996) (endorsing this same approach). Doubtless, Phrma would criticize my point of view, as it does that of WHO, but that does not make either of us wrong.

Specifically, the WHO document's references to the Preamble of the TRIPS Agreement is accurate and not inconsistent with the Vienna Convention on the Law of Treaties, which allows Preambular recitals to clarify ambiguities in the legal rules. I see no implication that member states can tolerate substantive violations of the agreed standards, contrary to Phrma's paragraph 12; but, rather, there is a policy objective that member states should achieve the best health policy they can within the prescribed legal limits.

Phrma's own paragraph 13 is a tendentious interpretation of the Preamble. The truth is that the Preamble is cast in vague, abstract terms that paper over real differences in interests between developed and developing countries, and WHO's reading is consistent with the views of developing countries.

Similarly, the Document suggests that domestic intellectual property rights best serve technological development when properly balanced against the public interest in health and other objectives, and that some (but not necessarily all) intellectual property rights serve to promote technological and developmental objectives. This is far more of a "truism" than the hard protectionist line espoused by Phrma in paragraph 13. For qualified and respected legal opinion that questions the Phrma viewpoint, see, e.g., A. Samuel Oddi, *TRIPS – Natural Rights, and a "Polite Form of Economic Imperialism,"* 29 VAND. J. TRANSNAT'L. L. 415-470 (1996) (citing authorities); A Samuel Oddi, *The International Patents System and Third World Development: Reality or Myth?* 1987.

DUKE L. J. 831 (1987) (citing authorities); A. Samuel Oddi, *Un-Unified Economic Theories of Patents – the Not-Quite Holy Grail*, 71 NOTRE DAME L. REV. 267 (1996) (citing authorities); see also J. H. Reichman, *Compliance with the TRIPS-Agreement: Introduction to a Scholarly Debate*, 29 VAND. J. TRANSNAT'L. 363, 370-73 (1996) (contrasting and comparing Phrma-like views with contrary views and advocating a middle road for developing countries).

I do not agree that WHO's treatment of TRIPS Articles 7 & 8 on pp. 12-13 is either tendentious, radical-or inaccurate, even if it might have been better to phrase the authors' viewpoint in tighter, more defensive legal language and even if there are some minor technical inaccuracies. For example, when WHO states that basic provisions "clearly indicate the subordination of the protection of intellectual property rights to public policy objectives in other areas of the state's activity, especially social policies," they should have cited Article 8(1) and not just Article 7. This reflects the kind of technical looseness it would have been better to avoid, but the principle is not otherwise inaccurately stated (contrary to Phrma's paragraph 15).

WHO's interpretation of Article 8(2) is also essentially correct, for the reason that most countries interpret the grounds for "abuse" much more broadly than is the practice in the U.S., and Article 40(2) of TRIPS reconfirms that states may adopt their own policies concerning "abuse" so long as they do not violate an express standard of the Agreement. It is true that WHO does not mention the possible adverse effects on both foreign investment and local innovation if a low-protectionist regulatory framework is adopted, and this advice might have strengthened their analysis. But their point is to advocate "a balance between the rights of patent holders and their obligations vis-a-vis society," and to urge states to establish regulations that achieve this balance without violating the TRIPS Agreement. This advice is unexceptionable.

As, regards the specific legal impact of Articles 7 & 8, which will remain uncertain for years; I have repeatedly maintained that these are safeguard clauses, which can be invoked in appropriate instances of hardship, to obtain limited waivers from full compliance, if good faith efforts to comply are otherwise evident. Professor John Jackson has noted my view with interest. If it is correct, only time will tell. WHO's

own interpretation of these clauses is not technically refined or cautious, and might have been stated more defensively, but it is not unacceptable or tendentious (contrary to Phrma's paragraphs 15-16).

Similarly, WHO does not misinterpret TRIPS Article 1, as Phrma asserts, in their paragraph 17. On the contrary, it warns developing countries against being bullied into higher than negotiated standards (for which no trade concessions have been paid). I regard the Phrma letter and that from the USFDA supporting it, as instances of the kind of bullying that Article I was meant to avoid.

In reality, it is Phrma's paragraphs 15-18 that are biased, insofar as they espouse a high-protectionist viewpoint that is popular in the U.S. (only since the 1980s) and in the E.U., but that has not been accepted either by the rest of the world or by a very large and respected segment of academic opinion. Nor does the WHO document reach the erroneous conclusions that Phrma says it does, even though it declines to reach the conclusions Phrma would like it to espouse.

**4. Section 2.3 – Patents for Pharmaceutical Products** – this strikes me as a poorly written and edited section, and the message it conveys, while not inaccurate, is incomplete. Phrma exaggerates when it insists on distinguishing between "banned copies" (non-technical term and the enforcement of patent rights. But Phrma has a point when it faults WHO for not adding a more complete statement of the potential effects of Article 27(1), as Phrma interprets this provision in paragraph 21 (p. 7) of their letter.

Like Phrma (paragraphs 19-21), I am troubled that WHO points out only the *benefits* of copying under a no-patent system but fails to mention the social costs of doing so, which include: a weakened system of local innovation; lessened capacity to discover cures for local maladies; lessened access to up-to-date foreign technology; lessened incentives for foreign investment; an overall weaker set of aggregate incentives to invest in pharmaceutical inventions (now magnified by the emergence of truly global incentives for inventions sold on a global market); and weaker access to that global market by local firms. WHO also fails to mention the benefits that accrue to developing countries when, after 20 years, new pharmaceutical inventions come off patent protection and

become available to all the world without any intellectual property protection. For a good statement of this thesis, see Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provisions in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507-534 (1996). This lack of editing and balance reflects badly on WHO because it suggests a kind of "concealment by half truth." Although I am sure that was not the intention, more balance was needed here (compare, e.g., the more balanced evaluation of social costs and benefits in UNCTAD's *The TRIPS Agreement and Developing Countries* (cited above)).

It does not follow, however, that WHO need adopt the rosy view of social benefits espoused by Phrma in the same paragraphs 19-21. For example, while Adelman & Baldia rightly conclude that India's generic drug industry cannot mature into a modern drug sector without better patent protection, see Adelman & Baldia, *supra*, at 510, 525-30, I have elsewhere pointed out that the emergence of India's generic drug sector also represents a set of successful social policies that will become harder to duplicate under the TRIPS "no copying" regime. See Reichman, *Compliance with TRIPS*, *supra*, at 379-81. I also note E M. Scherer's own doubts about the abilities of developing countries to compete in this sector in view of his study of Italy's lacklustre performance with regard to pharmaceuticals (EM. Scherer & Sandy Weisburst, *Economic Effects of Strengthening pharmaceutical Patent Protection in Italy*, 26 LLC. 1009, 1023-24 (1995)).

The point is that while Phrma's views in paragraphs 18-21 are one-sided, tendentious, and not scientifically rigorous, WHO's truncated, non-legal presentation in Section 2.3 leaves it vulnerable to similar complaints. However, I do not agree that WHO mischaracterizes the dispute settlement process, as charged in Phrma's paragraph 22, even though WHO does not fully explain that process.

5. In contrast, I see nothing wrong with WHO's **Section 2.4 – Non-Patentable Inventions: Biotechnology**, except, perhaps, that, as before, it is incomplete in the sense that it ignores the social costs of following a perfectly legal low-protectionist strategy. It also fails to elaborate technical legal arguments (well-known to Phrma) that would support such a position. Otherwise, I see no serious flaws in the

substantive analysis and do not agree with Phrma's paragraphs 23-25. WHO is clearly right about the room to manoeuvre in respect to biotech patents (*see* Reichman, *Free Riders to Fair Followers*, *supra*; at 36-38); However, Phrma is right (paragraph 25) when it says that WHO does not discuss the social costs of low protection (*see* Reichman, at 38 ("Policy makers need to weigh the consequences of such a [low-protectionist] strategy against the overall objectives of a given state's national innovation system, however"))).

Another flaw is that WHO insufficiently differentiates the prospects for developing countries from those of least-developed countries (LDCs), an error that Phrma also commits. While Phrma seems to pretend that all developing countries are more or less in the same position as the four Asian tigers, WHO does not differentiate between developing countries that increasingly resemble the four tigers (pre-crash) and the basket cases that have no prospects for developing a viable pharmaceutical sector in the foreseeable future.

**6. Section 2.5 – Effects of Protection.** Unfortunately, Phrma's paragraph 26, complaining about use of the term "counterfeiting" as derived from the ambiguous French "contrefaçon" is correct, if gratuitously strident. The correct term is "infringement" or "violation of an exclusive right." I disagree that this discredits the author, although it does raise some doubt as to whether WHO's editorial staff has sufficiently geared up to deal with a new legal topic. A Corrigendum should suffice to remove this blemish.

#### (a) Exhaustion

More silly stuff has been written on this topic than any other TRIPS subject, and Phrma's letter is no exception. True, there is a slight misstatement on WHO's p. 17 (top), which confuses the scope of the patent with the first-sale doctrine; but the Overall presentation is one of the clearest and most accurate I have ever read, and the abovementioned flaw is not important in the overall context.

The worldwide debate about both the legal limits of exhaustion and the economics of exhaustion has reached such a level of hysteria that the International law Association (which met in Taipei in June) is still too

conflicted to issue a final report, after two years of drafting. Still, the draft report is much closer to WHO's position (because the trade law people favour free trade) than to Phrma's position (which is to globalize the new exclusive right to import). On the legal issues, Phrma's arguments in paragraph 26 are no better than the. counter-arguments, noted in your Report and elsewhere, and until a WTO panel rules on the relations between exhaustion and the exclusive importation right, all of these views remain speculative.

To its credit, WHO also recognizes that there are social costs to a broad doctrine of exhaustion (pp. 17 bottom – 18 top) which is a more balanced approach that makes its suggested strategy interesting. Unfortunately, I do not think WHO's assessment of social costs digs deep enough because, as Phrma states in paragraphs 29-31, an aggressive policy of exhaustion decreases the patent owner's incentive to price discriminate in favour of developing countries in order to gamer market share. If this favourable practice ends up hurting their yields on developed markets, the patentees may simply apply world market prices everywhere, to the detriment of poor countries (UNCTAD's own economists noted this risk). Nevertheless, the existence of this risk does not invalidate the strategy that WHO suggests on p. 18, though it does raise additional questions.

#### (b) Product-by-Process Protection

Phrma's paragraph 33 is unjustified, and there is nothing objectionable about WHO's treatment on pp. 18-19; From an editorial perspective, however, I find the last two sentences in the first full paragraph on p. 19 to be unclear, and some words seem to be missing from the last sentence of that paragraph. Once again, lax editorial standards are evident, but the overall treatment is solid.

#### (1) Extension of Duration

The WHO text is correct and well-presented, while Phrma's paragraph 34 seems childish. The social costs of patent monopolies are well-known and are not disputed by respected economists. The debate centres on the extent to which these costs are offset by social benefits, and how

best to maximize benefits and minimize costs in specific developing countries.

Here, I would criticize WHO for not going farther by suggesting that least developed countries may have a case for obtaining waivers for hardship (under other provisions of the WTO Agreement) that could help them postpone having to implement a full patent system under TRIPS if they avoid becoming havens for pirates. *See, e.g., J. H. Reichman, Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L. LAWYER 345, 386 (1995) (citing authorities).

## **7. Section 2.6 – Application of the TRIPS Agreement**

WHO's pp. 20-22 are excellent and editorially sound. Phrma's paragraphs 35-36 are too trivial to deal with. WHO cannot be faulted for not producing an exhaustive legal treatise on every subject.

## **8. Section 2.7 – Discussions of the Transition Period**

I see no serious technical errors in WHO's discussion on pp. 22-25, although I might-have stated its findings with greater caution and more reservations. At the time WHO's authors were writing, we did not know enough about the ambiguities in these provisions, which the WTO's Appellate Board's opinion in *U.S. v. India* have clarified. This section would benefit from revision in the light of that case, and should mention the standstill provision, as Phrma states in paragraph 37. As to the other issue raised in that paragraph, "the date that this Agreement became known," there are no right answers until a WTO panel picks one, but the different views should be noted.

## **9. Section 2.8 – How Can the Monopoly be Limited?**

I have read WHO's text on pp. 25-30 in light of Phrma's criticism in paragraphs 38-49, and find the latter altogether unconvincing. WHO's discussion is neither a legal treatise nor a brief for trial; it is a sound, accurate, non-technical description of the existing situation that frankly admits the many ambiguities that future litigation may have to clarify. In contrast, Phrma's paragraphs 38-49 are a legal brief supporting

intervention by developed countries into the internal affairs of developing countries, which the latter should resist, if necessary by bringing well-chosen cases of their own to the Dispute Settlement Board.

I do not mean to suggest that the WHO presentation is flawless. For example, I do not understand the third sentence at the top of p. 26. Moreover, while WHO properly notes that exceptions "must be limited," it would have helped to add that new types of exceptions that deviate from widespread state practice may encounter more resistance from WTO tribunals (unless justified by changing conditions) than older types of exceptions that some or many mature patent systems have long recognized (such as the right of a prior user to continue to use the invention, recognized on p. 27, which many countries admit and Phrma criticizes merely because the U.S. has no such exception).

Moreover, WHO is clearly right that the TRIPS Agreement left developing countries a much wider range of options for compulsory licensing than most observers (including me) expected. Here, Phrma's complaints sound like sour grapes. However, there does seem to be an editorial flaw on WHO's p. 27, in that the first two paragraphs under "compulsory licenses" seem to talk about two different things, whereas I think they must address the same point. Also, Phrma is correct that WHO does not sufficiently address the social costs of compulsory licenses, and some good economists from developing countries have real fears in this regard. (This lack of attention to the social costs of their preferred policy options weakens the persuasiveness of the WHO paper, as I have elsewhere indicated, without necessarily invalidating the opinions it conveys).

Phrma's paragraphs 38-49 are a legal brief in support of future positions they will take before WTO panels. They need not and should not deter WHO from sustaining opposite views that are equally well-grounded in law and policy, although both views should be noted. For example, is failure to work a patent locally still an actionable-abuse under the Paris Convention, or is it overridden by the new exclusive right to importation? Since the drafters did not tell us, both views remain plausible until a WTO panel decides one way or the other. Here, WHO does recognize that imports may be economically more efficient (p. 30).

WHO also recognizes that any of its policy options may become unavailable if the Dispute Settlement Board ends up agreeing with Phrma's brief in paragraphs 38-49.

What else should WHO do? Should it not advise developing countries to maximize their rights until proven legally wrong? Should it turn the health ministries over to Phrma? Here Phrma overreaches by attempting to intimidate WHO from supporting options that disinterested legal scholars find reasonable, even if neither side can be sure of the final legal outcome if specific practices are challenged before the Dispute Settlement Board. Phrma has the right to press its views; it has no right to try to suppress the views of WHO.

## **10. Section 3 – Conclusions**

The WHO material on pp. 31-33 is excellent, both in substance and editorially. However, the recommendations on p. 34, while reasonable and art the whole supportable, seem much too hurried and unnecessarily confrontational. Once again, a greater interest in the offsetting social costs of these recommendations would have made them more credible. For example, the suggestion to apply compulsory licenses to a list of essential drugs would only be good policy if it was not held illegal by a WTO panel (Phrma paragraph 53) or if it did not drive foreign investors away (Phrma paragraph 51). These risks should have been acknowledged.

Moreover, more nuanced and conciliatory policies should also have been explored. For example, Article 31 requires discussion with patentees before imposing a compulsory license, and if the patentees agree to reasonable pricing and supply policies (as they should), why impose the compulsory license (with all its possible economic detriments)? Similarly, if foreign investors are willing to forge links with local firms and transfer up-to-date technology under joint ventures, why not respond with more favourable policies for such companies? (Notice that more favourable *laws* for one government or another are not permissible under MFN; but more favourable treatment of cooperative, enlightened *companies* would not appear to violate MFN, and sector-to-sector cooperation should be encouraged.) Again, why not resort to the Council for TRIPS in order to discuss hardships arising from the

protection of foreign pharmaceutical patents before imposing compulsory licenses?

Finally, Phrma's paragraph 54 is a valid criticism, and one that I have mentioned before. WHO tends to simplify the concept of developing countries", when actually they are all at different levels of development, and no one set of policies fits all. So, I would agree that more could have been done with the recommendations, even if there is little objectionable about them as, they are (except as indicated).

**B. Phrma's General Comments (para. 1-8 and Conclusion (para. 55))**

I have deferred commenting on these philosophical disputes because my detailed analysis of the paper already addresses most of the relevant issues. Phrma takes a high protectionist view favoured by big companies in the U.S., Japan and the E.U., a view that was disfavoured by both the U.S. and Japan until the late 1989s. WHO espouses a low protectionist view with respect to pharmaceuticals that is shared by many small and medium-sized firms even in the U.S. and the E.U. which view prevails at any given time is likely to change with the business cycle, the evolution of the global economy, and the continued growth of developing countries. Both Phrma and WHO err in-overstating their respective cases and by assuming that we should expect to find "one, size fits all" answers. But the notion that WHO should, adopt, Phrma's ultra-protectionist view or withdraw from the field is insulting and unmerited, as is their conclusion that WHO's paper should be scrapped.

In reality, WHO's paper is a worthwhile endeavour that raises the consciousness of developing countries about these issues in non-technical terms. It does not pretend to be an in-depth study so much as a call for further thought and action to address crucial concerns of the World Health Organization.

Future efforts by WHO will require greater legal expertise and better editing, and more reviews by outside experts, with greater attention to the economic consequences (especially social costs) of various options. In this connection, the assistance of reputable scientific bodies, such as the U.S. National Institute of Medicine (of the National Research Council) and the International Council for Science (ICSU) may be

desirable.

Nevertheless, the WHO document is a credible and helpful first essay whose major fault is its unawareness of the need to better protect itself against the kind of attacks it has engendered. It would be tragic if any group of private companies could drive WHO out of this area merely because it refused to adopt the philosophy or legal positions of those companies.

## **II. Views of the U.S. Government Expressed Through FDA (Letter to Dr. Quick)**

The U.S. government's letter is both disconcerting and instructive. It is disconcerting because it largely restates Phrma's objections in more neutral, even-handed, scholarly, and diplomatic language, which makes it a more credible and acceptable vehicle. Yet, it remains as one-sided and biased as the industry diatribe, with the added nuance that U.S. government displeasure could result in consequences for WHO. Arguably, FDA can walk softly because it carries a bigger stick.

The letter is instructive because it exemplifies the tone and style that WHO might have used to avoid some of the criticism it has engendered. It is stylistically measured and editorially refined, which allows it to seem less tough than it is. One could argue that WHO would be well advised to adopt a similar tone and style in future documents pertaining to TRIPS, if only because such controversy IS inevitable and WHO should assume a pondered and deliberative guise.

Apart from a more mature style and the detection of some inaccuracies (e.g., the fact that the WTO Agreement took effect in 1995 and not 1996), the weakness of the U.S. government's letter is precisely a lack of balance and, indeed, a lack of concern for either the needs or the outlook of the developing countries. It seems a polite way of suggesting that these countries (and U.N. organs) should toe a party line, and it could be read to imply a threat of consequences if they do not. Despite its soft tone, in other words, it is unbalanced, partisan, and not scholarly in substance.

That criticism, however, also applies to the WHO document itself. I, for one, do not believe that all public documents must lack conviction, intensity, and an underlying sense of urgent concern. That is, they need not sound like public documents issued in Anglo-Saxon countries.

At the same time, they need not sound unnecessarily polemic, one-sided, or “anti-” any particular group or philosophy. The more concerned and intense the views expressed on WHO's behalf, in short, the more one would want them to be tempered by objectivity, balance, and scholarly concerns, and cast in a measured editorial style. My detailed remarks suggest that the WHO's study could have been much improved in this respect. It makes no greater effort to examine the social benefits of pharmaceutical patents and the social costs of a low-protectionist strategy than either Phrma or the U.S. government make to examine the social costs of such patents and the social benefits of a low-protectionist regime for many, if not most, developing countries.

In this and other respects, the WHO study and the criticisms levelled at it are engaged in what the Italians call “un dialogo dei sordi” (a conversation between deaf persons). If WHO wants to make a greater contribution in the future, it will have to acquire a greater mastery of the legal and economic nuances of this complex field, and it will have to express them with greater caution. Whether it would reach different overall conclusions is another matter. But that is the point. More attention to form and style, and a review of all sides of the issues, will make such conclusions seem better founded and less impressionistic than they really are.

Indeed, I personally think the WHO study is a solid and worthwhile endeavour that raises important issues. But I do wish it had been subject to more levels of internal and external review, to more stringent editorial supervision, and to more technical review by legal experts.

### **III. Letter from Adrian Otten**

I know and admire Adrian Otten, and I think his letter is both constructive and written in good faith. He is certainly correct to suggest,

in paragraph 3, that you might have benefited from their comments at an earlier stage.

In my experience, WTO staff scrupulously limit themselves to providing accurate statements of law, without hiding the ambiguities that may be present, and without presuming to suggest what any government's policy decisions should be. *See, e.g.,* Adrian Otten and Hannu Wager, *Compliance with TRIPS: The Emerging World View*, 29 VAND. J. INT'L L. 391-414 (1996). One can, therefore, profit from their technical advice without compromising one's own position, in the knowledge that it is better to know the pitfalls ahead than to discover them later on.

Otten's most telling criticism is in paragraph 4, in which he notes the WHO study's lack of interest in the benefits of the patent system. I have expressed a similar view throughout this paper.

While I agree with the points he makes in paragraphs 6-10B, I would add that I do not think the study is either wrong or misleading in these respects, so much as imperfectly expressed and edited. Surely, it would have been better to express the points in question in the manner that Otten does; but Otten has been doing this for years, and for WHO to do that would have required considerable expense and time.

Because I personally believe that the WHO document presents an essentially correct statement of the TRIPS rules and that it does not mislead its audience, I doubt that the defects of its style have seriously impaired its underlying substance and message. However, the lack of technical mastery and the tendency to simplify complex legal analysis of which Otten complains does weaken the credibility of the document, as does its lack of a greater scholarly apparatus. In WHO's defense, however, I would stress that the document is meant to be non-technical in nature and more of a warning about problems to be dealt with than a full-dress inquiry into those problems. In this regard, it is successful, if incautious.

I hope these remarks prove helpful, and I remain at your disposal for any further clarification.

The publication in 1998 by the World Health Organization (WHO)'s Essential Drugs Department of the document "Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement" marked a point in time in the movement to ensure access to essential medicines for all. It had been drafted to implement a 1996 World Health Assembly resolution that constituted the first mandate given by countries to WHO to work on intellectual property in relation to health. The publication, often referred to as "the WHO red book", marked the beginning of an international policy process to address the issue of innovation and access to essential medicines.

The WHO publication triggered a series of reactions never seen before from the pharmaceutical industry, the US Government and the World Trade Organization, reproaching WHO for stepping out of its role. In light of these attacks, the then Director General of WHO, G.H. Brundtland, decided to send the document to be revised by three independent academics specializing in intellectual property. The letters and documents criticizing the WHO publication as well as the review by the three international experts are reproduced in this book.

People living with HIV/AIDS in developing countries were dying because they could not afford the life-saving new antiretroviral treatments priced between USD10,000 and USD12,000 a year. Today, an increasing number of new medicines are protected by patents in the developing world and remain priced out of reach of patients and governments, as illustrated by cancer drugs and the new, very effective drug against hepatitis C priced at USD1,000/pill in the US. The escalation of prices of new patented medicines is already leading to unjustifiable medical access restrictions even in developed countries.

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