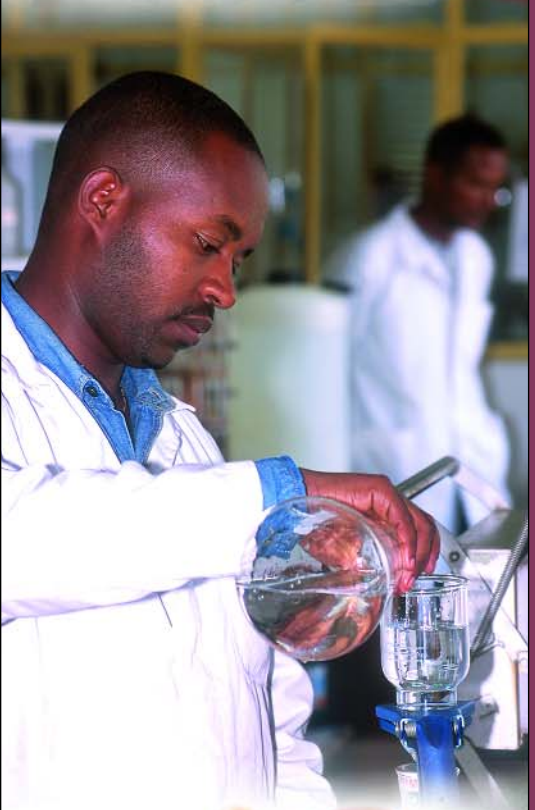

Centrale Sanitaire Suisse Romande

Intellectual property and access to medicines

Under the direction of Andrea Onori

The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) over access to essential medicines

Preface by Germán Velásquez

Associate Director of the Department of Technical Cooperation for Essential Drugs and Traditional Medicine
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Summary

Intellectual property and access to medicines
Centrale Sanitaire Suisse Romande 2006

Preface

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(translated from Spanish)

In 1994 the creation of the World Trade Organization caused the implementation of a new treaty, the largest ever adopted, on the rights of intellectual property. It is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). For the first time this Agreement relates questions of intellectual property with commercial questions, and sets up a multilateral mechanism of dispute resolution between States. The TRIPS Agreement demands that all the WTO Member States introduce into their legislation minimal universal standards for almost all rights in this field, for example the copyright, patents and brands*. Moreover the Agreement limits considerably the freedom enjoyed so far by countries to elaborate and apply their own systems of intellectual property**. According to this Agreement all the WTO members are from now on compelled to protect by a patent for a period of 20 years minimum any invention of a product or of a pharmaceutical process which meets the criteria of novelty, invention and usefulness. Such an obligation did not exist under the previous international agreements. Indeed in the past every nation was considered to have the right to legislate in this field. The international agreements prior to the TRIPS Agreement did not set any minimal standards relative to intellectual property rights. Before the TRIPS Agreement 40 countries did not protect pharmaceutical products by a patent; many did protect by a patent the processes but not the products, and in many countries the patents duration was largely inferior to 20 years.

At present it is recognized that the regime in force of protection by "globalized" patent through the TRIPS has important repercussions on the pharmaceutical sector. Moreover one is concerned by the fact that the standards specified in the TRIPS Agreement are not necessarily adapted to the countries fighting for the satisfaction of their needs in matter of health and development. For this very reason the British Commission of rights advised, in its 2002 report, the countries to see to it that their regime of protection of intellectual property does not jeopardize their public health policy, that they be coherent with their policies and that they promote them.

A patent is a title granted by official authorities on the basis of which a temporary monopoly is given for exploiting an invention to a person who publishes it, describes it sufficiently clearly and completely and claims a monopoly over it. The criteria required for granting a patent demand that the product or the manufacturing process meets the necessary conditions for being able to be protected by a patent, i.e. novelty, inventive characteristics and usefulness.

The world had never had at its disposal such a large array of treatments for fighting the diseases plaguing mankind. At the same time very many persons die through lack of certain medicines and/or vaccines. This situation is due to emerging diseases but also to the serious threat represented by the accrued resistance to the medicines used against common lethal diseases such as AIDS, paludism, tuberculosis, bacterial meningitis and pneumonia.

For developing new medicines some mechanisms will have to be found which promote the innovation and development of new products and which, at the same time, make sure that patients have a fast access to the results of this research.

* Velásquez et Boulet, *Journal de l'OMS* 1999, 77 (3) Essential drugs in the new international economic environment.
** Correa, *Journal de l'OMS* 2001, 79 (5) Health and Intellectual Property rights.

The increasing concern as to how the international trade agreements, in particular the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), could limit the access to medicines led to the adoption of the Doha Ministerial Declaration relative to the TRIPS Agreement and public health. The Doha Declaration was a milestone in the discussions on intellectual property rights and access to medicines by stating that the TRIPS Agreement will have to be interpreted and applied so as to support the right of WTO members to protect the public health and in particular to promote the access to medicines for all. In this sense the Doha Declaration consecrates the principles defended by WHO and promoted publicly throughout many years, i.e. reaffirming the right of WTO members to apply fully the safeguard dispositions foreseen by the TRIPS Agreement, so as to protect public health and promote access to medicines.

From 1999 in the successive resolutions of the World Health Assembly WHO was asked to make sure that its pharmaceutical strategy deals with the important question of the effect of international trade agreements on public health and access to medicines. So the World Health Assembly asked WHO to cooperate with the Member States and the international organizations in view of monitoring and analysing the pharmaceutical and sanitary consequences of international trade agreements; this was done in order to help Member States to evaluate and develop pharmaceutical and sanitary policies and regulations which optimise the positive effects of these agreements and attenuate their negative ones. By these resolutions WHO was given a mandate which can be summarised in this way: 1) analyse and monitor the effects of globalisation on public health, the intellectual property rights and the trade agreements and report to the Assembly; 2) help the Member States to reinforce their pharmaceutical policies and practices; 3) provide a technical assistance and a support to Member States to apply the protections and flexibilities in matter of public health foreseen by the TRIPS Agreement.

More recent resolutions did concentrate in greater detail on the central aspect of these general objectives. In its resolution WHA56.27 of May 2003 the World Health Assembly declares itself «mindful of concerns about the current patent protection system, especially as regards access to medicines in developing countries», and urges Member States «to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)». The Report of the intellectual property Commission created by this resolution is already available and contains important recommendations to countries on this topic. Moreover resolution WHA57.14 of the 22nd May 2004 urges Member States «to take into account in bilateral trade agreements the flexibilities contained in the Agreement on Trade-related Aspects of Intellectual Property Rights and recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001)».

WHO has elaborated political prospects on trade agreements, public health and access to essential medicines. These prospects orientate and ensure the coherence of awareness and support for WHO countries. WHO's political prospects deal with questions relative to the TRIPS Agreement, intellectual property rights and access to medicines. They can be summarized in this way:

- Access to essential and good quality medicines is a human right;
- The price of essential medicines is a public health priority;
- Essential medicines are not basic products like other ones ;
- Patents must be administered in an impartial way, protecting the interests of the patent owner and preserving public health principles, what makes it essential that flexibilities and safeguards foreseen by the TRIPS Agreement are used adequately.

Even if all the analyses and comments of this book do not necessarily represent WHO's views, this booklet of the Centrale Sanitaire Suisse Romande is an excellent contribution to understanding the problem of access to medicines in the present international context. From the creation of the Action Programme for Essential medicines the Swiss Cooperation has played an important role in supporting WHO's action in different countries. This is why we are most happy with this initiative of the Centrale Sanitaire Suisse Romande with which WHO is pleased to collaborate.

Intellectual property and access to medicines
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Foreword

A century ago thanks to the progress in preventing and treating diseases and to the revolution brought by Pasteur medical doctors were rather optimistic about the future health situation. Today despite substantial progress regarding health for all there are still severe inequalities with respect to disease and death, as was underlined by Gro Bruntdland, former Director-General of WHO: «*More than a billion persons reach the XXIst century without benefitting from the health revolution : their lifespan remains short and hampered by disease.*»[1]

The world health context has changed considerably during the last century. The World Health Organization (WHO), created on the 7th April 1948, has planned at the world level the fight against the most lethal diseases on the planet, among which poliomyelitis, tuberculosis, smallpox and many others. Its main aim has been to bring immediately all people of the earth to the highest possible level by guaranteeing the access to treatment and to essential drugs. From its creation in 1995 the World Trade Organization (WTO) has been involved in the health sector working out an Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS)[2]. This agreement was approved at Doha at the end of 2001[3] and the tenets of the neoliberal economy and the rights of intellectual property now cover fields which had so far not been considered purely commercial among which are pharmaceutical products.

As soon as this document was approved it caused strong reactions and it appears to constitute the main problem in the health sector at the eve of the third millenium[4]. It has triggered numerous discussions among all the concerned groups. Though there is at present a vast bibliography on the Agreement its real impact on the access to essential drugs and vaccines[5] remains uncertain. But as was recently stated by the WHO : «The desperate situation of most persons among the poorest in the world due to the difficult access to essential drugs[6] and to vaccines is absolutely obvious. It is clear that the high price of any new medication or vaccine will bear heavily over its availability in the Developing Countries (DC)[7]. High prices can be explained by many reasons, one of them being patents ; but – considering the fact that patents define monopoly rights on the market – it is obvious that they are the cause of a major concern»[8]

With this document the Centrale Sanitaire Suisse Romande (CSSR) wishes to inform readers eager for a deeper understanding and to offer a tool to persons professionally involved in this Agreement. That is why a series of quantitative data derived from various works of experts will be used; this will enable a reflection along four distinct axes.

The first part of this work presents the main aspects of the problem and the stakes of the Agreement. A brief summary of the most significant events will be given and a description of the parties involved. This Agreement consists of a large number of legal dispositions which will be explained.

Secondly it will be attempted to foresee the consequences of this Agreement on the access to essential drugs in the DC and on the relations between the main institutions concerned (WTO and pharmaceutical firms on one hand, WHO and national health services on the other hand).

[1] Ramonet (2003).

[2] OMC (1994). Trade related aspects of intellectual property rights (TRIPS).

[3] Doha (2001), Correa (2002) and Niveaux (2002).

[4] OMS (2001a), Velasquez (2003).

[5] A fairly complete view of the relation between *globalisation* and *health policy* (a more general framework than that of the TRIPS Agreement) is found in Lee *et al.* (2002); see in particular Ranson *et al.* (2002), Buse *et al.* (2002).

[6] For the definition of *essential drug*, see the Glossary; for the selection criteria of essential drugs see WHO (2002); for fair access to essential drugs, see WTO (2004a).

[7] *Developing countries* (DC's), *less advanced countries* (LAC's) and *industrialised countries* are referred to in agreement with the list established by the United Nations Development Programme (UNDP). This list was worked out on the basis of the Human Development Indicator (HDI) and consists of three elements : the life span measured according to life expectancy at birth; the education level measured for two thirds by the literacy rate of adults and for one third by the gross rate of combined schooling; the living standard measured by the gross domestic product per inhabitant (expressed in parity of buying power (PBP).

[8] OMS (2004), p.1

Thirdly as far as possible case studies will corroborate the points of view put forward in this text so as to maintain a strong link with the field situation. The situation in several countries will be analysed in detail.

Eventually as our conclusion the third part of this document will propose several approaches in view of stimulating the discussion on the consequences of this Agreement and how they could best be addressed.

Readers will find in the introduction an official text of WHO : *Protection of intellectual property : impact on public health*. This text was first published in 2005 in English. This document constitutes the starting point of the reflection effort in this work.

In the Appendix one can find a report written by Anne-Lise Lelong in 2004 during a stay at WHO when she was a student for a Master of Law in information techniques and communication of Poitiers. This text, *TRIPS Agreement and its consequences on access to essential medicines*, deals with the impact of the Agreement on access to essential medicines and public health.

Let us also mention that readers eager to examine this problem in greater depth would be well advised to refer to the CIPIH final report (Commission on intellectual property rights, innovation and public health). This document entitled *Public health, innovation and intellectual property rights* was published in April 2006 and is 239 pages long (French version). It can be downloaded from the CIPIH site where it is available in the 6 official languages of WHO: www.who.int/intellectualproperty/documents//thereport/en/.
Finally just after this report was published the *Bulletin of the World Health Organization (The international journal of public health)* issued a number devoted to the presentation of the report and to critical discussions (among which the position of the official representative of the pharmaceutical industry). This publication (in English only) can also be freely downloaded from the WHO site: www.who.int/bulletin.
A particularly important aspect of the present debate about the TRIPS Agreement, that of the flexibility of Agreement 1 for the DC's (see 1.2.2, 1.2.3) is treated in detail in a recent joint publication South Centre-WHO: F. Musungu and C. Oh: The use of flexibilities in TRIPS by developing countries; Can they promote access to medicines?, Geneva, South Centre-OMS, 2006.
These three publications constitute a mandatory source of information for any organization trying to be active in the field of access to medicines in the DC's, encompassing the possible flexibilities of the TRIPS Agreement and the Doha Declaration, and the realtions between research, innovation and introduction of generic medicines.

Introduction

Access to Medicines

Intellectual property protection: impact on public health

(Official text of WHO: WHO Drug Information, vol. 19, N° 3, 2005, pp. 236-241)

Public health principles, in the context of access to medicines, are supported by a range of national and international legal and policy instruments, including the Constitution of the World Health Organization (WHO). From a human rights perspective, implementation of intellectual property rules should be governed by those principles which support public health goals and access to medicines, thus ensuring:

- a rapid and effective response to public health needs and crises;
- supply of quality medicines at affordable prices;
- effective competition through a multiplicity of potential suppliers;
- the provision for a wide range of pharmaceuticals to meet the basic health needs of the population;
- equality of opportunities for countries in need, irrespective of their membership in the WTO, level of technological capacity, or lack of manufacturing capacity.

In 2001, World Trade Organization (WTO) members drew up the Doha Declaration to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In particular, concerns had been growing that patent rules might restrict access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, such as HIV, tuberculosis and malaria.

Although the impact of intellectual property on access to affordable medicines predated the TRIPS Agreement, the impending expiry of deadlines for implementing the TRIPS Agreement by developing countries has added impetus to the debate. Legal challenges by the pharmaceutical industry to legislation enabling parallel imports of medicines, and provisions enacted on compulsory licences, highlighted the differing interpretations of the TRIPS Agreement obligations. That this was taking place against the backdrop of the HIV/AIDS pandemic afflicting the developing world further fuelled the need to focus international public attention on the manner in which intellectual property protection impacted areas of public health.

Affordability of essential medicines

The HIV pandemic and consequent urgency to make treatment available for millions of people brought to the fore the issue of affordability of antiretroviral therapy. When patent-protected antiretroviral treatments were first introduced, the cost was over US$ 10 000 per patient per year, putting them out of reach of the vast majority of HIV patients in developing countries where over three billion people live on less than US$ 2 a day. Although efforts have been made to reduce prices by pharmaceutical companies, including proposed donation programmes or heavy discounts, the scale of the crisis in developing countries clearly demanded a more systematic and sustainable strategy. The announcement in 2001, by a pharmaceutical manufacturer to supply a generic version of antiretroviral triple therapy at US$ 350 per patient per year, together with the subsequent entry of other generic manufacturers into the arena, has brought about market competition resulting in significant reductions in prices

of antiretroviral therapy. Additionally, there has been increased reliance on low-cost generic antiretroviral therapy as a strategy for treating patients in developing countries.

However, a debate continues on the comparative relevance of patents in determining access to medicines. The pharmaceutical industry underscores the importance of effective patent protection as an incentive for continued investment in the discovery and development of medicines. While it is not denied that the patent system provides incentives for pharmaceutical innovation, the market exclusivity conferred by patents leads to company profits that often outstrip the associated research, development and production costs altogether. The patent system has also not provided sufficient incentive for research and development of new medicines needed for diseases that afflict public health, including neglected diseases and orphan drugs, because forecasts deem the market too small or commercially unattractive.

In many developing countries, the current concern is how adoption of intellectual property regimes as required under the TRIPS Agreement can be balanced with efforts to maintain public health treatment programmes while boosting multiple sources of pharmaceuticals and controlling cost.

Although patent protection systems for pharmaceutical products are available in most developing countries, multinational companies have not patented their products in all of them. This may be because companies may not think it worth the expense to obtain and maintain patent protection in countries where the market is small and the risk of infringement low. The prevalence of patents is often higher in countries where a substantial market and technological capacity exists. None the less, even if patents do not exist for particular products and countries, the patent system may still have an effect on access to medicines. The existence of patents in potential supplier countries may allow the patentee to prevent supplies being exported to another country. This is why companies may patent selectively in countries that are potential suppliers.

Key provisions of TRIPS

Generic production is possible for the great majority of essential medicines, since they are currently not protected by patents in developing countries. However, this is not true for new medicines.

The TRIPS Agreement introduced global minimum standards for protecting and enforcing nearly all forms of intellectual property rights (IPR), including those for patents. International conventions prior to TRIPS did not specify minimum standards for patents. At the time that negotiations began, over 40 countries in the world did not grant patent protection for pharmaceutical products. The TRIPS Agreement now requires all WTO members, with few exceptions, to adapt their laws to the minimum standards of IPR protection. In addition to the minimum protection standards, the TRIPS Agreement also introduced detailed obligations on the enforcement of intellectual property rights.

The role of WTO and the impact of patents on access to medicines

The World Trade Organization (WTO) is an international organization of 148 Member countries dealing with the rules of trade. In joining the WTO, Members adhere to specific agreements. Of these agreements, Trade-Related Aspects of Intellectual Property Rights (TRIPS) establishes minimum standards for a set of intellectual property rights that WTO members institute through national legislation. It also contains provisions that allow a degree of flexibility and sufficient room for countries to accommodate their own patent and intellectual property systems and developmental needs. Patents on medicines have been one of the most hotly-debated topics since the adoption of the TRIPS Agreement because patents grant exclusivity for the duration of the patent term and result in patent holders having control over the production, supply, distribution and, by virtue of exclusivity, price.

It is argued that patents are crucial for pharmaceutical innovation and that without them there will be no financial incentive to fund the costs of discovery and development of new medicines. However, medicines prices in developing countries are often well above production costs. Developing countries account for a very small fraction of the global pharmaceutical market and the generation of income to fund more research and development is not dependent on profit from these markets. Indeed, until now, the patent protection system has provided very little incentive for research and development of new medicines needed for diseases afflicting developing countries and highlights the ineffectiveness of relying solely on the private sector to develop essential medicines. In many countries where payment for pharmaceuticals is "out-of-pocket" and health insurance is rare, escalating and unrealistic prices play a central role in denying access to patients of life-saving medicines.

Public health crisis management and patents

Anthrax

At the height of the Doha negotiations, mysterious anthrax attacks were causing panic in the USA, and health authorities began building stockpiles of ciprofloxazine to treat exposure. Concerns about the price and the patent holder's ability to produce adequate quantities of ciprofloxazine to protect its citizens led US and Canadian authorities to consider granting compulsory licences for generic production. In the event, significant price reductions and guaranteed supplies were finally negotiated with the manufacturer. *(t'Hoen, E.: TRIPS, pharmaceutical patents and access to medicines: Seattle, Doha and beyond.* Chicago Journal of Inernational Law*, 2002; 31(1).)*

Avian flu

Current concerns of a possible avian flu pandemic are now raising similar questions on the need for access to antivirals. As countries work out plans to prevent a human flu outbreak, the question of cost and availability of existing treatments under patent is once again being balanced with the need to call on public health measures to contain a highy pathogenic disease and ensure adequate protection of populations.
(Tsang, KWT. : H5N1 influenza pandemic: contingency plans. Lancet, 2005; 366: 533-534.)

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Patent protection

The TRIPS Agreement requires WTO Members to provide protection for a minimum term of 20 years from the filing date of a patent application for any invention including for a pharmaceutical product or process. Prior to the TRIPS Agreement, patent duration was significantly shorter in many countries. For example, both developed and developing countries provided for patent terms ranging from 15 to 17 years, whilst in a number of developing countries like India, patents were granted for shorter terms of 5 to 7 years.

The TRIPS Agreement also requires countries to provide patent protection for both processes and products, in all fields of technology. Before TRIPS, many countries provided only process – but not product – patents. Product patents provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and the process or method of manufacture. Protection for process patents would not prevent the manufacture of patented products by a process of reverse engineering, where a different process or method from that which has been invented (and patented) is used. For example, national legislation requiring only process patent protection has enabled manufacturers in certain countries to make generic versions of patented medicines. These countries have opted to make use of the transition period that permitted countries to delay, until 2005, patent protection in the areas of technology that had not been so protected before the TRIPS Agreement. (See transition periods below).

Protection of data submitted for the registration of pharmaceuticals

As a condition for permitting the sale or marketing of a pharmaceutical product, drug regulatory authorities require pharmaceutical companies to submit data demonstrating the safety, quality and efficacy of the product. The TRIPS Agreement requires that WTO Members protect undisclosed test data, submitted to drug regulatory authorities for the purposes of obtaining marketing approval, against unfair commercial use. Since countries have considerable discretion to define "unfair commercial use", it is argued that countries can meet their obligations to protect test data by prohibiting "dishonest" use of data. Use by government authorities to assess the efficacy and toxicity of a pharmaceutical would not be affected, in this case. However, it is now argued that data exclusivity is a requirement of the TRIPS Agreement. The data exclusivity approach grants the originator exclusive rights over their test data and prevents regulatory authorities from relying on the test data to register generic substitutes.

Prior to the TRIPS Agreement coming into force, most countries allowed reliance on originator test data to approve generic products. Once test data was submitted by the originator company, the regulatory authorities could rely on the data to approve subsequent applications on similar products, or to rely on proof of prior approval of a similar product in another country. Generic manufacturers need only to prove that their product is chemically identical to the brand-name, original product, and in some countries, that it is bioequivalent. This approach enabled swift introduction of generics into the market without registration data-related costs. Within the data exclusivity approach, once a company has submitted original test data, no competing manufacturer is allowed to rely on these data for a period of time.

Data exclusivity could thus pose an obstacle to effective use of compulsory licences, as the entry of the generic product would be delayed for the duration of the exclusivity period or for the time it takes to undertake a new compilation of test data. The public interest in limiting data protection is to promote competition and ensure that data protection does not become the means to block timely entrance of affordable generic medicines of public health importance.

Transition periods

The TRIPS Agreement provides for transition periods, permitting developing countries additional time to bring national legislation and practices into conformity with TRIPS provisions. There are three main transition periods. First was the 1995–2000 transition period, at the end of which countries were required to implement the TRIPS Agreement. The 2000–2005 transition period allowed certain countries to delay providing product patent protection in the areas of technology that had not been so protected at the time of the TRIPS Agreement coming into operation in that country. These countries were allowed a further 5 years to put in place a product patent regime for pharmaceuticals and agro-chemicals.
The third transition period allowed least-developed countries (LDCs) until 2006 to implement their obligations under the TRIPS Agreement in view of their economic, financial and administrative constraints. In addition, this period may still be extended by the TRIPS Council on request of an LDC Member. This transition period has been further extended to 2016 with respect to patents on pharmaceutical products and exclusive marketing rights by the Doha Declaration (see below).

The transition periods have meant that pharmaceuticals or medicines patented before developing countries implemented their TRIPS obligations will not receive patent protection, and thus generic competition is possible. Medicines patented after developing countries have implemented their TRIPS obligations are progressively coming onto the market and will constitute an increasing share of marketed medicines. A substantial change is expected after 2005, when all developing countries will be required to provide patent protection for pharmaceutical products and the mailbox patents are processed.

Public health considerations

The current minimum standards in the TRIPS Agreement – historically derived from those of developed countries – may not necessarily be appropriate for developing countries struggling to meet health and development needs. The new obligations have dramatically changed the legal framework for the production, supply and access to affordable medicines in developing countries.

The role of the Doha Declaration

Although the TRIPS Agreement affords considerable discretion on how its obligations are interpreted and implemented by governments, developing countries have faced obstacles when seeking to implement measures to promote access to affordable medicines. Thus, developing countries sought to clarify –

through adoption of the Doha Declaration – that the provisions in the TRIPS Agreement did provide sufficient flexibility and discretion to ensure access to medicines in the interests of public health.

The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights. These are briefly described below.

The TRIPS Agreement allows the use of compulsory licences. Compulsory licensing enables a competent government authority to licence the use of a patented invention to a third party or government agency without the consent of the patent-holder. Article 31 of the Agreement sets forth a number of conditions for the granting of compulsory licences. These include a case-by-case determination of compulsory licence applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary licence and the payment of adequate remuneration to the patent holder. Where compulsory licences are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived in order to hasten the process, such as that for the need to have had prior negotiations to obtain a voluntary licence from the patent holder.

Although the Agreement refers to some of the possible grounds (such as emergency and anticompetitive practices) for issuing compulsory licences, it leaves Members full freedom to stipulate other grounds, such as those related to public health or public interest. The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Parallel importation is importation without the consent of the patent-holder of a patented product marketed in another country either by the patent holder or with the patent-holder's consent. The principle of exhaustion states that once patent holders have sold a patented product, they cannot prohibit the subsequent resale of that product since their rights in respect of that market have been exhausted by the act of selling the product.
Article 6 of the TRIPS Agreement explicitly states that practices relating to parallel importation cannot be challenged under the WTO dispute settlement system. The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical product sold in different markets.

Paragraph 6 of the Doha Declaration

Although existing provisions of the TRIPS Agreement permit the grant of compulsory licences to enable generic production of medicines, countries without domestic manufacturing capacity cannot avail themselves of this flexibility. The option of importing generic medicines is hampered by the restriction in the TRIPS Agreement that requires production under compulsory licence to be predominantly for the supply of the domestic market. This has raised concern that exporting countries may have difficulties exporting sufficient quantities to meet the needs of those countries with insufficient or no manufacturing capacity. The WTO solution is essentially a waiver of the export restriction, thereby allowing the total amount of production under a compulsory licence to be exported. Whether countries may export and import generic versions of patented medicines under the system adopted in the WTO Decision will depend on the extent to which national laws allow for it.

A number of potential exporting countries have amended national laws to enable the production and export of generic medicines under compulsory licence. Canada was the first country, followed subsequently by Norway. The European Union is currently considering its draft regulation.
India, has also included a provision on compulsory licences for production and export in the amendment of the patent law. However, there has not been any notification by countries to the WTO in respect of their intention to use the system as an importer. There may be a number of possible reasons for this. First, the threat of compulsory licensing for production of competing generics has led pharmaceutical companies to offer larger discounts. Secondly, the granting of compulsory licences under the system may appear to be too complex and burdensome for developing countries.
In addition, there may not have been a need. Where there is no patent in force in the exporting country, production and export may take place without a compulsory licence. This has been the case with exports from India, where until recently, the absence of product patent protection enabled the production of generic versions of medicines. In the post-2005 environment, when almost all countries are obliged to provide product patent protection, the effectiveness of the WTO decision may well be put to the test.

Conclusion

The TRIPS Agreement does not prevent Members from allowing generic substitution. But if the wording and implementation of TRIPS-compliant national legislation and regulations are inappropriate the introduction of new generic drugs can be delayed. Prompt introduction of generic drugs can be facilitated by drafting appropriate legislation and regulations on patentability; use of exceptions to exclusive rights which permit early testing and approval of generics (including allowing access to pre-registration test data); and compulsory licensing.

Whilst the adoption of the Doha Declaration marked a watershed in the debate on intellectual property and access to medicines, there remain major challenges for developing countries to interpret and implement the TRIPS Agreement and other intellectual property rules in a manner supportive of their efforts to protect public health and promote access to medicines for all.

Next steps

It is vital for countries to be informed of their options in implementing the TRIPS Agreement. Through its technical cooperation programme, WHO can provide independent advice and technical assistance to countries to help them develop informed approaches to addressing the health implications of trade and intellectual property devices.

WHO's focus is on awareness building for policy makers and independent evaluations of the health impact of international trade agreements for countries, leading to effective participation in international and regional negotiations. In this way, developing country needs and interests will be adequately taken into account.

WHO assistance will also include review of national health, pharmaceutical and intellectual property policies, legislation and practices, with a view to promoting the development and incorporation of TRIPS safeguards within the national policy and legal framework, followed by monitoring and analysis of access to essential medicines, including the impact of new trends and developments at the regional and bilateral levels.

1. Context

1.1 History and status

The extension to the pharmaceutical market of the rules of Intellectual Property (IP) as they were established in the TRIPS Agreement will have repercussions on a complex world health situation. As a preamble to this work of information here is a description of the context and concerned parties. This is a necessary step to understanding the difficult question of access to essential medicines. A short history of the most significant events will be given up to the present situation and the main stakes of the various parties will be described. This double presentation should enable us to reveal the complex and thorny nature of this problem.

The TRIPS Agreement was concomitant with the birth of WTO; it is one of its pillars. In 1993 the long negotiation cycle of the Uruguay Round (from November 1982 to December 1993) resulted in the transformation of the former GATT (General Agreement on Tariffs and Trade) into WTO; this is a new multilateral entity and main organ for market globalisation. At the initiative of industrialised nations and following the pressure exerted by some multinational pharmaceutical firms the regime of IP defined by the TRIPS Agreement was from now on to be applied to the drug field so as to protect the patents of pharmaceutical products and of manufacturing processes of medicines. Indeed the problems of "piracy" and international counterfeiting, even in the field of medicines, had become substantial. From now on each medicament or patented process will be protected against any imitation for a period of twenty years pending trade sanctions imposed by WTO. This monopoly situation enables the patent holder to set his price at will. This extension can be explained by the fact that «most of these large conglomerates [had] to face the patent expiry of their leading product(s) in the public field. [...] From 1999 the number of molecules whose patent [was going] to expire was going to increase rapidly, in average by 5 to 6 per year over the 1990-98 period; this number [was going] to increase to more than 10 and represent a turnover of 9 billion dollars in average each year between 1999 and 2005 against 3 billion dollars for the previous period. This "generic" risk [could have] reduced the turnover of some laboratories by up to 30 %»[9]. The Research and Development (R & D) sector is obviously the main beneficiary of this Agreement because the profits made during the long lifespan of the patent make up for the initial financial investment[10].

However the official version is rather different: it is stated that «Protection of intellectual property shall not become an obstacle to legitimate trade and not cause inconsiderate distortions»[11]; article 7 reaffirms the subordination of intellectual property rights to the aims of public policy. But the true motivations of the signatories did not go unnoticed at WHO: «as a monopoly for exploiting the invention the agreement boils down to a limitation of offer and has a bearing on access to the products and among these to essential medicines [...]. The logical consequence of this disposition is that essential medicines will be sold at high prices [...] during a longer period of time and that the firms producing generics[12] will have to wait a longer time before producing the medicament referred to and selling it at a more accessible price»[13]. It is strongly feared that the inequality of access to essential medicines which existed before the agreement is going to increase.

[9] Lamoine (1999).
[10] Haajer-Ruskamp *et al.* (1991) p.24.
[11] OMS (1999), p.18.
[12] For a definition of the term *generic* please refer to the glossary at the end.
[13] OMS (1999), p.18.

However the gap between industrialised countries and DC's is already gaping: in 1996 80 % of pharmaceutical products was only consumed by 24 % of the world population[14]. As far as vaccines are concerned WHO warns: «Important differences exist in the number of available vaccines for the children of industrialised countries and those of the DC's... It is estimated that a child in an industrialised country gets in average eleven vaccines whereas a child in a DC is privileged if he gets half as many.»[15] The part of GDP devoted to health expenses is in average 4 % in the DC's against 8 % in the industrialised countries (13 % in the United States, 10 % in France or Switzerland, 7 % in Great Britain). During the last ten years of the twentieth century in twenty five industrialised countries each inhabitant had $137 at his disposal for buying essential medicines; the inhabitants of thirty two nations of the Middle East were spending $26.8, i.e. almost the same amount as in thirty three countries of Latin America ($26.4). Then the figures drop substantially when observing what takes place in Asia ($11.8 for thirty three countries) and in Sub Saharan Africa (only $7.8)[16]. If on top of that we consider the absence of a health or social system or social insurance schemes in the DC's[17] it is easy to imagine the difficulties that the population has to face for purchasing essential medicines. For example the African income is only 2 % that of the inhabitants of the industrialised countries and 1/3 the population is not in a position to buy essential medicines which may cost up to thirty times as much as the monthly average income. The dramatic social, economic and sanitary situation in these territories can easily be demonstrated. A population increasing steadily, a lacking water supply, the appearance of new diseases and severe political crises put DC's in a real emergency health situation. So according to WHO 90 % of the 14 million deaths per year caused by a pathological infection (half of them consisting of AIDS and paludism) take place in the DC's[18]. Life expectancy in Guinea Bissau is 39 years and in Japan it is 78; between Malian and Swedish children the ratio of infant mortality is 1 to 30; the mother mortality rate shows that mothers in West Africa are two hundred times more likely to die than French mothers. But inequalities also prevail within underprivileged countries : in the rural areas of Ecuador the life expectancy is 34-47 years whereas in the cities it is 56-71 years.[19] The universal access to essential medicines is also threatened by the unchecked rise of prices. In Latin America from 1988 to 1992 the price of pharmaceutical products increased by 27.6 %[20]. Moreover it seems that many products cost more in the DC's[21] than in the industrialised countries with strong regional disparities: in its 1996 enquiry WHO remarked that the same product can cost up to 328 times as much from one nation to another one in South East Asia![22]. So the populations most exposed to lethal diseases are paradoxically those that must pay the highest price for their medicines where they are available.

The TRIPS Agreement was first contested by the European Commission in February 2000; the direct impact of the Agreement on the price of essential medicines which had been observed over several years was recognised at the ministerial conference in November 2001[23]. On top of that the situation is made worse by the forced application of the Structural Adjustment Programmes (SAP) to the DC's. At the beginning of the eighties the World Bank (WB) and the International Monetary Fund (IMF) decided to impose some conditions on the loans to the DC's so as to remedy the drying up of their financial resources, the crises of their public finances and their growing debt. From now on the monetary help to the DC's was to be subordinated to the adoption of measures reducing their public spending and their external debt. The approach of these institutions can be called mercantile since it aims at reducing social expenses through a forced privatisation of some public sectors. In view of readjusting state budgets these measures hope to boost efficiency and profit but enable first a better integration of these countries into a highly competitive world market. In the field it has resulted in a progressive dismantling of state structures and a forced privatisation of all public sectors.

In countries where the economy was already burdened by a heavy international debt, by the constant fall in the price of raw materials, by the reduction in foreign investments the starting phase of these SAP's took a long time. Restructuring inevitably touched upon the health sector: from 1980 to 1985 the Interamerican Development Bank recorded a reduction in the part of the GDP devoted to health in nine out of seventeen countries of the area concerned by the SAP's.[24] The role played by public authorities in the production and distribution of health care was redefined and limited. However the results obtained were at variance with those expected and social effects were disastrous. Social and health inequalities between the richest and the poorest social strata of the population did not stop growing in the Northern hemisphere and in the Southern one as well. This only caused the health inequalities to increase, what is confirmed by numerous works some of which even come from those very institutions responsible for this situation in the first place. «The health sector is found among the sectors most affected by the policies planned at the international level [...] Neoliberal policies enable the well off categories to enjoy benefits of a higher quality but worsen the gap with those who cannot afford them»[25].

The SAP's thus imposed a reduction in the state financing of social sectors and consequently caused a decrease in social protection. «When, in order to comply with the demands of international banking institutions, the indebted states reduce their social, educational and health expenses, it can be understood to which extent the world economic situation and the international power play determine the food and health state of the population»[26]. All sector activities, be they regulation, production, information, training or price control, undergo the consequences and the supply of essential medicines deteriorates. The health indicators tell about this degradation; for example when considering the data of infant mortality one notices that «in some countries progress had been made regarding the health level (decrease in the infant mortality rate) from 1965 to 1980, but the situation was reversed during the eighties when many of these countries adopted measures of budgetary austerity»[27].

After the DC's state economy itself the national health services are logically the second sector to have suffered most from these budget restrictions. Taking into account the quasi non existence of private funding or health insurance schemes in these countries the only economic resources was those coming from the state and from the international aid as well. Despite some forms of community self financing such as the Bamako[28] Initiative promoted by UNICEF in 1987 these local health centres underwent a strong reduction

[14] Whereas in 1976 76 % of medicines were destined to 27 % of the world population: the gap continues widening as time goes by; see IUED (2001), p.20.
[15] OMS (2001), p.2.
[16] WHO (1997), p.33.
[17] Here health only gets 1.6-7 % (12.5 % in the industrialised countries) of state budgets.
[18] OMS, 56th assembly (EHA56.27), pt. 14.9 of the agenda, 28 May 2003.
[19] Fassin (200), p.24.
[20] WHO (1996), p.9.
[21] For example one hundred units of 250 mg of erythromycin cost more in India, in Nepal, in Indonesia and in the Philippines than in Canada. *Ibidem*, p.36.
[22] *Ibidem*, p.37.
[23] The preoccupations caused by the TRIPS Agreement and the generalisation of intellectual property rights concern not only the prices and availabilty of medicines but also the prices and availabilty of vaccines. Recently WHO organized an international meeting on «Intellectual property rights and vaccines in the DC's», see WHO (2004), WHO/IVB (2004).
[24] OMS (1995), p.56.
[25] Fassin (200), p.56.
[26] *Ibidem*, p.30.
[27] WHO (1996), p.35.
[28] Later on we shall come back to this Initiative.

in their budgets; this could only cause negative repercussions on their main objectives, i.e. a universal access to essential medicines and to health facilities, a supply of products, an efficient distribution and an equitable financing of benefits. For example, «privatisation reforms in Chile have prevented many individuals from getting the care that would have improved their quality of life»[29]. These national health services undergo the pressure put upon their governments by the big international institutions. These states are faced with a dilemma: on one hand they are under the yoke of conditional aid by the WB, the consequence of which is a reduction in health expenses and forced privatisations, and on the other hand they are forced to maintain a certain equality and efficiency in managing their national schemes. In these circumstances a balance is practically out of reach at short or medium term especially when they find themselves in emergency.

The WHO is undeniably the other main victim of the political and social changes caused by the TRIPS Agreement. Up to now WHO had been very active in the question of access to health care, emphasising «Health for all» from the Alma Ata conference of 1978 and supporting training in primary health care in Third World countries and establishing the famous list of «essential medicines». The WHO, agency specialised in this sector, finds itself removed from power and deprived from planning and controlling the world health strategies in favour of the WTO. Perhaps against the will of its representatives WHO witnessed the rising power of the three other institutions (WTO, IMF and WB) which took over its competence and took measures regarding health strategies which were rightly in its own mandate. Now WHO limits itself to supplying methodological advice and analysis and evaluation tools. It is paying a very high price for «limited political and economical means and for its fluctuating style of mangement».[30]

The large pharmaceutical firms control the market alone. They reacted fast so as to offset the financial losses incurred by the sale of generics. Arguing that protection by patent is necessary to finance research programmes the multinational firms managed to protect their patent and thus their monopoly by means of a global legislation. But in fact the research is focused on the needs of industrialised countries (chronic diseases, age related disease, problems of quality of life or comfort). Less than 5 % of the global research budget is devoted to AIDS, to tuberculosis or to paludism (less than 1 % in the case of Pfizer or Glaxo-Smithklein-Beecham, the 2 leaders); in 2002 only 10 % off the 60-70 billion dollars of the global R & D budget was devoted to diseases which concern 90 % of the world morbidity load and 0.001 % to neglected diseases (diseases which affect mainly or exclusively poor countries)[31]. On the other hand the income from selling to DC's only represents a small part of the multinationals' income. Finally the research which is financed directly or indirectly by public money is predominant. So the protection by patents of medicines indispensable to DC's cannot be justified by the need to guarantee the funding of research. The states (India or Brazil for example) which were technically capable of producing and selling for a price accessible to local populations found themselves suddenly deprived of their right. The data about the world production of medicines underline this monopoly situation of the industrialised countries. 38.6 % of the global production is concentrated in

[29] OMS (1991), p.30.
[30] *Ibidem*, p.72.
[31] Lorelle (2003); see also WHO (2005).

Access to medicines: some important dates

1975 WHO invites its member states to draw up their list of essential medicines (among which many generics).

1978 Alma Ata Conference, WHO launches its Primary Health Care with the slogan «Health for all in the year 2000» (access becomes easier).

1982 The IMF and the WB impose on the governments of the DC's the Structural Adjustment Programmes, which foresee a limitation of expenses in the health sector.

1987 Bamako Initiative, promoted by UNICEF, sick persons must pay directly for their care (paradox: the poorest pay most).

1994 In April within the framework of the Marrakesh agreements marking the creation of the World Trade Organization (WTO), signature of the Agreement on trade related aspects of intellectual property rights (TRIPS). They also cover the medicines industry and grant an enormous power to pharmaceutical laboratories. A struggle then starts between the defenders of economic interests protected by this agreement and the partisans of health for all, fighting for a price reduction, a larger access to essential medicines and research programmes focussed on the people's needs.

1997 The South-African government adopts an amendment enabling it to produce and import generic medicines; by doing so it draws on itself the wrath of 39 laboratories which lodge a complaint.

1999 Médecins Sans Frontières launches its campaign for access to essential medicines and is rewarded with the Nobel Peace Prize.

1999 In August the WHO publishes its report Globalisation and access to essential medicines. Though the United States ask for it to be withdrawn it is amended and republished. Its author receives death threats.

2000 In May UNAIDS in partnership with WHO, WB and five pharmaceutical companies launches the «Accelerating Access» initiative, which must enable poor countries to obtain medicines at a cheaper price. In 2002 only a few thousand persons benefit from this initiative.

2001 On the 19th April in Pretoria the 39 laboratories which had lodged a complaint against the South-African government withdrew it.

2001 At the G8 summit in July in Genoa creation of the World fund against AIDS, tuberculosis and paludism.

2001 In November in Doha the WHO adopts a declaration which recongizes the primacy of health over patents and opens up possibilities of access to essential medicines for all.

North America, 29.2 % in Europe and 14.2 % in Japan; so 14 % of the world population produces 82 % of medicines[32]. In 1999 the first five pharmaceutical groups of the world controlled 20 % of the world turnover (i.e. 325 billion US$): 4.6 % of the market share for Merck & Co (Europe) and Aventis (Germany/France), 4.5 % for Glaxo-Wellcome (Russia), 4.3 % for Novartis (Switzerland) and 3.7 % for BMS (USA)[33]. The first twenty firms in the world, ten of which with headquarters in the United States, were controlling the whole market. Out of eighty drug manufacturers in the world sixteen were covering close to 95 % of global exports thanks to sales for more than 100 million US$ each[34]. With the reduction in the role of WHO and the preeminence of that of international organizations such as WTO, the World Bank and the International Monetary Fund one notices a «systematic predominance of economic trade preoccupations with respect to requirements of social equilibrium and promotion of health»[35]. After all the language used by these institutions speaks for itself. For example «fight against poverty» is ambiguous: does one want to fight the absence of wealth or a whole underprivileged category of the world population? One does not talk about inequality or social justice, about narrowing internal and external gaps. However the World Bank has become the first investor for health during the nineties[36].

As time went by NGO's have become an unavoidable interlocutor in the development field. In the framework of access to essential medicines these organizations are first involved in supplying the products, training the medical staff, making the local populations aware of health problems, controlling the prices without forgetting the funding of health centres. Some like Médecins Sans Frontières for example talk about «global comanagement with governments»[37]. They intend to become «the real counterweight of multilateral macropolicies » and to fight « for moral equity»[38], so as to improve the living conditions of the underprivileged populations. When the political situation permits the latter to succeed in setting up associations of patients (or of consumers according to the point of view).

But most of the time the excessive price of products forces the populations to find other means and ways to buy essential medicines outside the official sources. First the apparition of parallel sale networks is noticed. Through national and sometimes international channels essential medicines are distributed by mobile salesmen and sold in retail on markets as happens for example in Senegal. «Far from being marginal this phenomenon concerns the whole of the popular masses and involves considerable sums of money. In this case survival is at stakes; it is not only an economic problem.»[39].

The problem of patents raises a new question, that of traditional medicines, of local know-how facing the pharmaceutical industry and its power.

Some multinational firms have decided to take patents on medicinal plants from the South like for example Indian mustard (Brassica campestris), known by Indians since more than 5000 years but on which there are 16 patents. So despite the Convention on Biodiversity which came into force in 1993, was ratified by 169 countries (except the USA) and foresees an equitable share the multinationals pocket the profits from the riches of the South without their

[32] Lamoine (1999), p.29.
[33] *Ibidem* p.56.
[34] WHO (1996), p.67.
[35] IUED (2001), p.117.
[36] *Ibidem*, p.72.
[37] IUED (2001), p.107.
[38] *Ibidem*, p.107.
[39] Fassin (2000), p.152.

2002 WHO, MSF, Aventis and Bayer (two large pharmaceutical corporations) agree to produce treatments against the sleeping sickness so as to answer the world needs during five years.

2002 In December under the pressure of the pharmaceutical lobby, Washington defines a limited list of diseases covered by the Doha Declaration. On the 20th the negotiators of 143 member states of WTO are faced with the opposition from the United States regarding the implementation of the Doha Declaration.

2003 The Commission on intellectual property rights, innovation and public health (CIPIH) was created in May 2003 at the 56th World Assembly through the adoption of Resolution WHA56.27. It was given the task of studying the links between IP, innovation and public health, so as to elaborate means of stimulating the creation of new medicines for curing DC's diseases.

2003 In July during the international AIDS Conference in Paris the European Union envisages to increase to 1 billion dollars per year its contribution to the World Fund, the annual needs of which are estimated to be 10.5 billion dollars. Indian, Brazilian, French, Kenyan, Malaysian research institutes create with MSF the Medicines for Neglected Diseases Initiative[40] (DNDI) – campaign aimed at developing medicines and vaccines for neglected diseases.

2003 On the 30th August a compromise is reached on the implementation of the Doha[41] Declaration.

2004 In December the EU did not pay its contribution to the World Fund. WHO envisages treatments for 3 million AIDS patients from now to 2005. In 2003 3 million persons died of AIDS – i.e. 8000 per day, and 5 million were infected by the virus.

2004 After the failure of the WTO Ministerial Conference in Cancún in September 2003 the WTO Members launched a new initiative at the beginning of 2004 and on the 1st August 2004 in Geneva they finally succeeded in taking the necessary operational decision to carry on with the Doha Round of negotiations.

2005 Sixth WTO Ministerial Conference in Hong Kong, December 2005. Outside the summit meeting the WTO members approved a permanent amendment of the TRIPS Agreement enabling the incorporation of the 30th August 2003 «derogation». This measure was to be formally incorporated into the Agreement after two thirds of the WTO members have ratified the modification (delay: 1st December 2007). But the members disagree on the degree of fidelity with which the modification should take the derogation and on the way of treating the declaration made by the chairman when the General Concil adopted the decision. The derogation remains in force up to this date.

2006 In April publication of the CIPIH report: Public health, innovation and intellectual property rights.

[40] See:
www.msf.fr/site/site.nsf/pages/dndihistoire
[41] See:
www.wto.org/french/news f/pres03 f/pr350 f.htm

"owners" (Amazonian communities, people of the Pacific) reaping any profit: «Like in times of the colonial conquest pharmaceutical companies and Western research laboratories use the services of indigenous people, scientists or traditional doctors»[42].

[42] Demenet (2003).

1.2 Description and explanations

1.2.1 The TRIPS Agreement

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) constitutes one of the main pillars of the Uruguay Round agreement. It is also one of the most controversial. This Agreement reinforces the intellectual property rights (IP), relates them to trade and introduces a world standard of binding power. The rights of IP thus become compulsory and the WTO procedures can be used to enforce them.
Article 27(1) of the TRIPS Agreement demands that patents be available for any invention, product and process in all technological fields, i.e. that the IP field extends to pharmaceutical products. The Member States of WTO are thus required to modify their legislation so as to conform to the Agreement and to ensure a protection by patent of a 20 year duration to the pharmaceutical inventions and to manufacturing processes of essential medicines as well. Different delays were granted to the member states of WTO to put into their national legislation the rules of the Agreement according to their economic and social conditions:

1) 1996 for industrialised countries;
2) 2000 for DC's and countries in transition towards an open market economy;
3) 2005 for DC's foreseeing no protection by patent at the time of the coming into force of the TRIPS Agreement (1st January 1995). The countries wishing to benefit from this delay must notify the TRIPS Council (Article 70). Such notifications had already been received at the end of 2004, coming from Argentina, Cuba, Egypt, the United Arab Emirates, India, Jordan, Turkey and Uruguay;
4) for the LAC's first 2006, then in Doha in 2001 defferred to 2016.

During the intermediate period the mailbox rule applies. Mechanisms must be established by the countries concerned enabling the reception of patent requests, the registration of these requests priorities and the granting of exclusive distribution rights when the prescribed conditions are met. Once the legislation has come into force the products in waiting will receive automatically a patent for a 20 years duration.
According to the TRIPS Agreement a patent grants the firm holding it the monopoly over the product for a duration of 20 years; this means that other firms are not allowed to produce, use or commercialise the product referred to (or its copy) without the authorization of the above mentioned firm. A patent does not forbid producing, using or commercialising a different product for the treatment of the same disease.

The agreement benefits first the technologically advanced countries. According to estimates the industrialised countries hold 97 % of patents and the multinational firms 90 % of all patents of technology and invention. Due to their low research and development capabilities the DC's hardly benefit from the protection brought about by the TRIPS Agreement.
Up to now in many DC's the national legislation excluded intentionally essential medicines from patenting (only processes could be patented) so as to encourage the local production of generic medicines and their marketing at reasonable prices. The copy of patented medicines had started in many countries without the big laboratories reacting. With the TRIPS Agreement which authorizes also the patenting of pharmaceutical products the local firms no longer have many possibilities to produce cheap replicas of essential medicines.

Most of the DC's with a low income depend upon the import of essential medicines. Some of these DC's which at present do not grant patents on medicines are entitled to obtain their cheap essential medicines from countries producing non patented medicines (either because they did not have an IP law when these medicines were invented or because the multinational firms did not take a patent on their products in these countries) and do not apply any restriction on the import/export of essential medicines. The introduction of patents (which will apply to medicines in waiting in the mailbox and to new medicines as well) will be an impediment to supplying these countries. Indeed the patent holders will be able to:

1) (*importing country*) prevent a generic from entering;
2) (*exporting country*) control the distribution of their products.

It is worth noting that in this context the Doha Declaration is not clear on the application or not of the *mailbox* to LAC's.

The implementation of the TRIPS Agreement causes sooner or later the following problems as far as the distribution and access to essential medicines in the DC's and LAC's is concerned:

1) significant increase in the cost of new medicines;
2) slowing down of technology transfers to the DC's. Available studies show that in general toughening up of patents leads to the concentration of the pharmaceutical industry. This phenomenon was noticed in latin America: a few years ago there were pharmaceutical laboratories in all countries. Nowadays they are only found in Brazil, Argentina or Mexico;
3) decrease in the supply of generic products;
4) persistence of financial difficulties in obtaining patented medicines.

However the TRIPS Agreement contains some safeguards for public health which include:

A. Compulsory Licences

The TRIPS Agreement allows for the granting of compulsory licences. One refers to compulsory licences when the judicial or administrative authorities grant a licence (of import and/or export) without the authorization of the patent holder for various reasons of public interest provided the interests of the patent holder are not damaged in an unjustified manner. The compulsory licence is given against a fee paid to the patent holder.

Using the compulsory licence effectively or as a threat over the production, import and export of patented medicines is generally considered as the most important tool at the disposal of DC's against the side effects of the patenting of pharmaceutical products on the price and access to essential medicines. The effective use of compulsory licences by DC's and LAC's is limited by a certain number of criteria. The obstacles limiting this use and the possible means to remedy this situation are described below.

B. Exhaustion of rights/ Parallel imports

The TRIPS Agreement permits the governments to authorize parallel imports under the regime of exhaustion of the rights of IP of the patent holder. Using this right enables to import a product from a first country where it is protected by a patent towards a second country where it is sold at a lower price and then towards a third country without the agreement of the patent holder. The member states of WTO are relatively free as far as the regime of exhaustion of rights is concerned. The possible options are:

a) a regime of national exhaustion: The right of the patent holder expires as soon as a product has been commercialised in the country;
b) a regime of regional exhaustion (e.g. EU, Andes Community): the right of the patent holder expires as soon as a product has been commercialised in a country of this region;
c) a regime of international exhaustion which applies to the products put on the market in any member state of WTO.

C. Bolar exceptions

These exceptions enable the manufacturers of generic products to start the production and the regulatory procedures before the patents expiration so that the products can be put on the market as soon as the patent expires instead of having to wait for the patent's end to start the lengthy preparatory phase.

1.2.2 The Doha Declaration

The Ministerial Doha Declaration on the TRIPS Agreement and public health was made during the WTO Ministerial Conference held in Doha in November 2001[43]. This declaration is valid in the member states of WTO and in the WTO bodies in particular the *Dispute Settlement Body* and the *Council for TRIPS*.
The Doha Declaration reaffirms that the TRIPS Agreement must be interpreted and implemented in a way which supports the right of the WTO member states to protect public health and in particular to promote the access of all to essential medicines.
The Doha Declaration recognizes the undesirable and dangerous side effects of the TRIPS Agreement, reinforces the existing measures so as to neutralise them and clarifies the existing freedom of manoeuvering in its provisions.

[43] See Correa (2002).

A. Compulsory Licence (Chapter 5 of the Declaration)

«Every Member has a right to grant compulsory licences and the freedom to determine the grounds on which such licences are granted.»

«Every Member has a right to determine what constitutes a national emergency situation or other circumstances of high emergency provided that crises in the domain of public health, including those that are related to HIV/AIDS, to tuberculosis, to paludism and to other epidemics, can present a national emergency situation or other circumstances of high emergency.»

So there is no limit to the freedom granted to member states to determine the reasons for which compulsory licences can be granted and what constitutes a national emergency situation or other circumstances of high emergency. Nothing in the text limits the notion of state of emergency in the country that establishes it (in other words granting a compulsory licence in a country can have an effect in another country which then finds itself forced to export a part of its production to the above mentioned country). Regarding a complaint from a member state about the definition of an emergency situation or of a critical situation the onus of proof falls on the country lodging the complaint that the said situation does not exist. In the case of an emergency situation the country can issue a compulsory licence without preliminary negotiations with the patent holder.

For example the constitutive law of the Andes Community (i.e. Bolivia, Colombia, Ecuador, Peru, Venezuela) stipulates that compulsory licences can be granted on the following grounds: Public interest, national or health emergency, and non competitive practice. Other criteria are applied in other countries, for example: non use or use according to non reasonable terms, obtaining a patent on non reasonable grounds, lack of domestic efficiency.

A compulsory licence must be granted for a product which is first priority on the domestic market. So the countries with an insufficient market in terms of demand and buying power as well are limited because they do not have any guarantee of a sufficient return on their investment. In this context the DC's have asked that exports of medicines be authorized according to Article 30 of the TRIPS Agreement (limited exceptions). The limits to an efficient use of the right to a compulsory licence in the DC's and LAC's are described further below.

B. Exhaustion of rights/ Parallel imports (Chapter 5 of the Declaration)

«The effect of exceptions of the TRIPS Agreement related to the exhaustion of intellectual property rights is to leave each Member the freedom to establish its own regime regarding this exhaustion without being contested pending the the reservation of exceptions about the treatment of the Most Favoured Nation (MFN)[44] and the national treatment of Articles 3 and 4.» The Doha Declaration thus confirms the freedom of every country to adopt its own rules regarding the exhaustion of IP rights and the use of a parallel market.

[44] WHO members are bound to grant to products of other members a treatment no less favourable than that granted to products of any other country. This is done in order to promote the WTO concept of non-discrimination.

Paragraph 7. Granting of a supplementary 10 year delay (i.e. up to 2016) to the LAC's to implement the TRIPS Agreement (change of legislation and setting up the necessary administrative stuctures).

In this context it is important for the countries concerned to develop a framework for exercising this right and the ad hoc administrative and legal structures.

1.2.3 Why some States do not use compulsory licences

Efficient and/or compatible use with the TRIPS Agreement of a compulsory licence faces a series of problems for various reasons:

1) lack of legal and administrative structures and of financial means necessary for transformations;
2) fear of bilateral or multilateral sanctions;
3) insufficient size of a domestic market;
4) lack of the know-how necessary for analysing patented medicines and for producing them without the help of the patent holder;
5) lack of means of credible pressure or threat towards the patent holders. However Brazil (within the framework of its national AIDS programme) succeeded in using efficiently the threat of a compulsory licence in negotiating with the pharmaceutical industry thanks to its research capability in estimating its own production costs under a compulsory licence;
6) opposition from the member states and the industrial groups concerned;
7) preference given to agreements with industry rather than to an "aggressive" use of the compulsory licence.

A compulsory licence has to to be authorized first for the domestic market[45] *Article 31(f)*. This clause restricts simultaneously the availability of exported medicines (especially in the countries which do not possess the capability to produce themselves a medicament and which then depend on imports) and the flexibility to make a profit out of exports (in the countries without a sufficient domestic market in terms of needs and of financial capabilities as well). The following solutions to go around this limitation can be envisaged:

1) parallel emission of a compulsory licence by the exporting country;
2) use of the exception for export (article 30);
3) creation of regional arrangements, of groups of countries establishing a common regime of patents and from then on submitted together to a compulsory licence;
4) use of article 31(k) which exempts compulsory licences issued against anti-competitive practices of the obligations of article 31(f).

[45] The interpretation is not clear: more than 50 % of the production/import? or the main fraction of what is produced/imported compared to other countries related to this product?

2 Problems generated by the TRIPS Agreement

2.1 Limited access to essential medicines

«Health may not, in the absolute, be the ultimate personal good, but it tends to become it as soon as one loses it»[46]. In the ideal aim that the WHO has tried to attain since a few decades health, which cannot be reduced to an absence of disease or infirmity, represents a state of physical, mental and social well-being. A good health for all populations is the largely accepted objective at an international level so as to enable a sustainable economic development. Numerous instruments of international law recognize health as a human right. Paragraph 1 of Article 25 of the Universal declaration of human rights states that «every person is entitled to a standard of living sufficient to ensure his/her health and those of his/her family, in particular for food, clothes, housing, medical care and necessary social services as well». The International Pact on economic, social and cultural rights contains the most exhaustive article in international law as far as right to health is concerned. On the basis of paragraph 1 of Article 12 of the Pact the participating States recognize «the right of every person to benefit the best physical and mental state that he/she is capable of attaining». Essential medicines play a significant social role because they are an integral part in implementing a fundamental human right, i.e. that to health. Thus pharmaceutical products cannot be regarded as an ordinary good.

«The essential medicines are those that satisfy the needs of the majority of the population regarding health care. They must be available at any time in a sufficient quantity and in the appropriate pharmaceutical form.»[47] Their quantity and use must be adequate. The access to medicines is determined by the availability of pharmaceutical products and their economic and geographical accessibility. Availability is essentially depending upon political factors, the world trade system and the world health system. Accessibilty is conditioned by the financial situation of the population and the economic and political conditions of the country. So as to ensure the access to essential medicines people must be able to obtain easily essential medicines at a convenient price and at any time. Whereas this ideal situation prevails globally in the developed countries the majority of the population in the DC's does not have access to essential medicines, at best has a partial access. The WHO estimates that by improving the access to essential medicines and to existing vaccines about 10 million lives could be saved every year[48]! Access to medicines in the DC's is limited by different factors: lack of resources devoted to health, absence of research and development for diseases affecting essentially DC's, weakness of local health services and high price of medicines.

[46] Guillod (2002), p.28.
[47] Velásquez *et al.* (1999), p.60.
[48] WHO (2004), p.1.

2.1.1 Economic and structural inequalities

The health crisis in the DC's is preoccupying: contrary to the developed countries transmissible diseases (HIV/AIDS, tuberculosis, malaria etc) continue to be a major cause of death and invalidity. The causes of the health crisis in the DC's are many and related to each other: bad nutrition, water insalubrity, lack of sanitary installations, armed conflicts, economic crises, insufficient means devoted to health, logistics problems etc. An insufficient access to essential and vital medicines is a fundamental aspect. According to the World Health Organization more than a third of the world population does not have a regular access to essential medicines. In some African and Asian countries more than half the population does not have access to them.[49]

[49] WHO (2004).

Having no access to medicines is determined by several factors: availability of funds, demand, status of stocks, conditions set by suppliers (production time, delivery time, billing, customs procedures, quality control, distribution and storage constraints). On top of that there can be an inadequate selection and an irrational use, too high prices, a lack of structural funding and an insufficient and unreliable system of pharmaceutical procurement[50]. Moreover by lack of qualified staff and resources it often happens that a small number of poorly qualified persons manage the whole process. On top of the overwork caused by this situation corruption easily crops up.
The price of medicines constitutes a crucial element of the crisis. 2.8 billion human beings live with less than 2 dollars a day, out of these people 1.2 billion live with less than one dollar[51]. Whereas in the developed countries medicines are for most of them publicly financed through reimbursement and the insurance scheme in the DC's only a minority can benefit from such a structure. The average cover reaches 35 % of the population in Latin America, 10 % in Asia and less than 8 % in Africa[52]. In most DC's patients must pay cash for their medical expenses out of their own pocket[53]. The supply of medicines by the State remains usually selective and limited by available resources. The medicines price has therefore a direct impact on their availability. An increase in the price of essential medicines influences directly the families income and diminishes their buying power. If a sick person has to pay for a more expensive pharmaceutical product he/she will have fewer resources at his/her disposal to acquire other essential goods such as food and housing. According to WHO medicines in the DC's represent the greatest part of medical expenses of households and are in the second place in public health spending[54]. Governments can partially be held responsible for insufficient allocation of financial resources to the offer of essential medicines for the majority of the population.

Inequalities are striking. In developed countries the antibiotic treatment for curing a pneumonia is equivalent to a salary of 2 to 3 hours (In the DC's 50 to 90 % of pharmaceutical expenses have to be taken care of by households). The treatment of an HIV infection during a year represents 4 to 6 months salary. The majority of the costs is reimbursed. In the DC's a complete antibiotic treatment to cure a pneumonia costs the equivalent of one month's salary. If it is available the treatment for an HIV infection costs 30 years of income. Insufficient spending for health care in the DC's and the lack of sanitary infrastructures necessary for managing medicines in a safe and efficient way are elements which determine access to essential medicines.

Globally reinforcing the health system and increasing the related resources are essential preconditions for answering adequately the medical and pharmaceutical needs of the population. But it is practically impossible for countries with a large external debt and a weak economy. It is essentially due to the fact that pharmaceutical expenses and all health expenses as well are strongly correlated to the economic development of a country. Increasing health expenses is therefore conditioned by an increase in the GDP. The GDP fraction devoted to

[50] WHO (2002a), p.20.
[51] UNDP (2002).
[52] UNDP (2002), p.5.
[53] WHO (2002).
[54] WHO (2002).

public health expenses in the DC's only represents 25 to 50 % of those in industrialised countries.[55]

Often medicines which are not essential are largely provided. Resources which are already limited are therefore exhausted and used in an inefficient way. In the DC's insufficient infrastructures pose a considerable problem which can lead to cheap medicines not being used or badly used thus contributing to the emergence of a virus or of pharmacoresistant pathogens[56]. Inefficient and even noxious use of medicines is often due to an insufficient training of the supplier, a biased information and fallacious beliefs among suppliers and consumers.[57]

[55] OMS (1998).
[56] BCIPR (2002), p.31.
[57] WHO/EB (2003).

2.1.2 The price of medicines: imperfect competition

The price of medicines from which an equitable access depends is determined by the market and state interventions. A stronger competition reduces prices to levels making essential medicines more accessible. For example the competition created by generic products enables the price of medicines to be reduced by 75 to 95 %. In the United States the average price of a medicine falls to 60 % of its initial value when a competitor enters the market and falls to 29 % when ten producers enter into competition[58]. Price reductions can also be obtained through therapeutic competition among several products of a branch belonging to the same therapeutic class[59].

Economists think that a perfectly competitive market must meet several conditions:

1) competitors on the market must be numerous and unable to influence prices;
2) products must be homogeneous and perceived by potential customers as substitutable;
2) mobility of resources must be perfect and the market open to other competitors;
2) the market must be transparent so that the information be available.

Thus only are market prices determined by supply and demand. In reality no market meets entirely these conditions but the model helps to determine how imperfect a market is. In an open market a producer cannot set the price of a product above its marginal cost if he wants to attract new producers who will drive prices down. In setting a high price in a competitive market a producer undermines his long term own profit and thus encourages supplementary offers.

Any market intervention on the market upsets free competition and prevents prices from being set at their "natural" equilibrium. The adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which reinforces and extends at a world level the patents protection on pharmaceutical products and processes distorts free competition[60]. In protecting the owner a patent enables him to increase the price of a medicine and to keep it at an artificially high level up to the patent expiry. Having the capability of excluding copies the producer of a patented product will attempt to set prices higher than otherwise possible and to enjoy thus the profit of a monopoly. By granting monopoly rights patents play an essential role in setting

[58] WHO(2004), p.3.
[59] *Ibidem.*
[60] OMC *et al.*(2002), p.1.

the prices of new patented medicines as it is the case for example for essential medicines treating HIV/AIDS.

So it can be noticed that applying a protection by patent causes automatically an increase of the payments by the DC's to the pharmaceutical companies of the USA, Europe or Japan. These financial movements out of a country are a direct consequence of the monopoly situation enjoyed by the patent holders[61]. Monopolising the market widens thus the gap between the industrialised countries and the DC's at the access level and limits the local manufacturing capabilities. The health policies aiming at a larger use of generic products reduce costs substantially when a patent expires.

[61] QUNO (2001), p.7.

2.1.3 Research & development on DC's diseases

Patents constitute a protection for the research and development sector (R & D). In the pharmaceutical field R & D costs are particularly high and thus call for considerable investments[62] which the patents system permits to recover. Patents are supposed to stimulate an innovative spirit, encourage progress and promote innovation.

The apparition of generics is the logical consequence of the protection end by patent. But the introduction of a generic substitute on the market is the more likely since the potential market is relatively large and a sufficient number of sales can be anticipated to cover the initial investment[63]. Very little effort is put into R & D for the diseases of the poorest populations. For pharmaceutical industries the poor do not generate enough income. Pharmaceutical research in the private sector is driven by commercial considerations. If the market demand is weak it is of little interest to devote resources to these needs. The populations of the poor countries do not represent a sufficient maket to generate an R & D effort which answers their needs[64]. The DC's account for 80 % of the world population but represent only 20 % of the global pharmaceutical market[65].

The DC's depend on generics. With the introduction of a protection by patent they are deprived of a good quality source at a low price. As a group the DC's are net importers of technology, the greater part of which is supplied by developed countries[66]. The application of the dispositions of the TRIPS Agreement reinforces the value of patents and benefits mainly the developed countries which are patent holders. The application of patent rights in the world gives a considerable advantage to holders of patent rights at the expense of users of technology and protected goods from the DC's. The high price of new medicines blocks the funds and the energy devoted to the research of a new technology and the development of a product or process obtained.

The R&D carried out by the private sectors is motivated by the size of the potential market and not by the protection levels of intellectual property. Even if a large part of the essential medicines created for the markets of the North are also important for the markets of the South the demand for medicines from the DC's shows characteristics clearly different from those of the developed countries[67]. There is an urgent need of increased investments in diseases which

[62] Velásquez *et al.* (1999), p.61.
[63] Scherer (2001), p.6.
[64] MSF (2003), p.6.
[65] MSF (2001), p.16.
[66] BCIPR (2002), p.21.
[67] Correa (2001), p.19.

affect essentially the DC's and which afflict every year millions of people. According to a WHO estimate less than 5 % of the funds devoted to pharmaceutical R&D are concerned with diseases which prevail mainly in the DC's[68].

In the TRIPS Agreement nothing compels the pharmaceutical industries to use the economic rent received thanks to the supplementary protection for research purposes on diseases of the DC's. No mechanism exists so as to avoid that the supplementary income be spent in R&D on sophisticated medicines meant essentially for consumers of the North. The pharmaceutical firms are free to set the income fraction which will be devoted to promotion and advertising. There is no limit to the level of executive compensation. The pharmaceutical industry enjoys a public policy instrument which proves very powerful – the TRIPS Agreement.

On the other hand the protection by patent represents a high hurdle for research and development in the DC's. Ideally the production of generics should enable the DC's to bypass the difficulty and cost of research and to decrease considerably the pharmaceutical costs. The investments accompanying the introduction of a generic substitute are much lower than those called for the discovery and the development of a new medicine. But the DC's contribution is hampered by the high level of protection which bars any potential manufacturer from entering the market and thus prevents these countries from developing and maintaining a local pharmaceutical industry ; it also prevents them to have at their disposal generics adapted to the local demand and at affordable prices.

Lacking local pharmaceutical industries the DC's also find themselves deprived of the possibility of using some flexibilities of the TRIPS Agreement, in particular compulsory licences. Indeed granting a compulsory licence is dependent upon the existence of a local pharmaceutical production capacity[69]. If a local good quality production is economically possible and supported by good manufacturing processes it can lead to lower price levels.

In facilitating the introduction and promoting the generics competition the DC's could limit the costs and distortions of the patents system in favour of the population, thus facilitating the supply of medicines. Technology transfer can ease this process provided there is a receptive environment. In India, Brazil and Thailand the generics firms offered to low and medium income countries their help for producing local retroviral medicines through technology transfer under South-South cooperation.[70]

[68] OMS (2001b), p.79.
[69] Musungo *et al.* (2004), p.3.
[70] WHO (2004), p.4.

2.1.4 Supply difficulties

HIV/AIDS is the most important cause of mortality in the DC's. Together with tuberculosis and paludism which account for almost as many victims these diseases caused six million deaths in 2001 and generated debilitating diseases for millions of people[71]. The existence of treatments does not slow down this tendency. These treatments are only accessible if the people can have at their disposal health services capable of delivering them. The treatment of AIDS by antiretroviral (ARV) medicines or by medicines treating infections associated

[71] OMS (2002b).

to this disease is dependent upon the economic accessibility. The minimum annual costs of ARV therapies exceed by far the annual health expenses per capita in most DC's.[72] The present health expenses per capita in the low income DC's are about 23 dollars per year, but the cheapest ARV triple therapies cost at present 200 dollars per year[73]. In 2002 WHO estimated that less than 5 % of those who needed a treatment for HIV/AIDS received ARV medicines, i.e. 230 000 persons out of 6 millions[74]. With an increase in treatment costs the situation can only worsen.

There are many different supply systems but whichever system is adopted the main phases consist of:

1) selecting medicines with the best cost/effectiveness ratio in agreement with the national list of essential medicines;
2) specifying the products (therapeutic and galenic formulation, packaging...);
3) quantifying the needs on the basis of information supplied by distributors and local health providers as a function of the stocks status, of past consumption, of epidemiological tendencies, etc.;
4) preselecting potential national and/or international suppliers, who will be sent an invitation to tender;
5) calling for tender, evaluating (technically and financially) the proposals received, negotiating and signing contracts;
6) carrying out the quality control of the medicines purchased;
7) distributing locally, storing, managing stocks;
8) prescribing and using the medicines.

Most of the DC's must rely upon imports to obtain medicines. As long as there is no patent protection the importing countries have the possibility to import generic products. According to the dispositions of the TRIPS Agreement the new medicines and those for which patents were requested after 1994 will be patentable and consequently the possibility of importing them will decrease with time[75]. Compulsory licences could represent an effective instrument for counterbalancing the exclusive rights of patent holders and for acquiring cheap generic versions of the new patented medicines. When the production capabilities of a country are insufficient or inexistent using this instrument will prove problematic. A country without a production capability or with an insufficient capability will be forced to turn to manufacturers of a third country to acquire the said medicine. On the basis of the territory principle (the patent validity is limited to the national territory) the importing country will become dependent upon the status of the said patent in these third countries. To obtain such a medicine abroad this product must neither be patented in the exporting country nor be covered by a compulsory licence[76]. Article 31, paragraph f imposes a supplementary condition since it states that «any use of this kind (compulsory licence) will be authorised mainly for supplying the home market of the Member which authorised this use». The main part of the production must be destined to internal consumption and must be sold on the home market. Cooperation among the DC's could constitute an effective tool to balance economical and political powers. A well coordinated action of the DC's pooling their orders of medicines can enable them to increase their buying power on the world market.

[72] BCIPR (2002), p.31.
[73] MSF (2002).
[74] OMS (2002c).
[75] BCIPR (2002), p.36.
[76] Reinhard (2002), p.2.

It is thus essential that each country has at its disposal a legal framework governing the whole process, i.e. in particular intellectual property rights in accordance with the TRIPS Agreement for member countries of WTO. A national medicines policy must be formulated by the public health authorities and an essential pillar of this policy is the compilation of a national list of medicines. Too often legal framework and health policy are inadequate which together with a lack of infrastructures, of financial resources and of qualified staff impede the smooth supply and availability in adequate quantity of medicines of good quality at accessible prices at the proper place and time.

Market segmentation and setting of differentiated prices confer to the countries a broader access to essential medicines. From the economic point of view the setting of differentiated prices constitutes a rational way of maximising profits for products which are sold at the same time on a low income market and a high income market. Differentiated prices should also enable poor populations to obtain the cheapest products. Setting fair prices is essentially important when it concerns new medicines which are still protected by patents or other instruments which grant exclusive rights to a manufacturer on this market. Adapting prices to the development level and buying power of the purchasing country not only makes it easier for DC's to access medicines but it also enables suppliers to sell a larger part of their production[77].

[77] WHO (2004), p.3.

2.1.5 Conclusion

The high cost of treatments in the DC's and in particular of medicines represents the main obstacle preventing the population from having access to the health service. Many new medicines essential for the survival of millions of people are already too expensive for the majority of the population. Moreover the investment in R & D destined for diseases of DC's is paralysed. These countries do not represent sufficiently profitable markets to motivate investments aiming at fighting diseases such as paludism or tuberculosis.
Applying the TRIPS Agreement will cause another price increase whereas an increased investment destined to the health needs in the DC's remains unlikely despite a higher protection level of intellectual property[78].

Traditional and complementary medicines are often more easily accessible and confidence in experts of traditional medicine, especially in rural and remote areas, is greater, which is why they are consulted by the majority of patients. Traditional medicine can thus play a considerable role in the health system for some aspects of health care[79].

Access to treatment of diseases in DC's is problematic. Either medicines are too expensive, have lost their effectiveness because of resistance to pathogenetic agents or they are not adapted to local conditions and constraints. Problems of logistics, storage, quality, selection, production, inappropriate use and prohibitive prices limit the medicines availability.

The nations which will be most affected by the new TRIPS environment will be those which will have developed a domestic generics industry as well as

[78] Ellen *et al.* (2003), pp.41,42.
[79] WHO (2004), p.4.

those without a domestic production which will have actively encouraged the import and use of generic substitutes. The impact of patents systems will be felt in particular in the countries which have set up solid generics industries with a certain competition level, thereby keeping prices at a low level. The reduction in competition on the market and the increase of imports represent a significant cost to the consumers and producers of medicines. Consumers and states have to pay more for essential medicines that are protected by a patent whereas potential manufacturers are barred from entering the market. DC's can take advantage of protection by patent provided they have the capability to obtain licences granted by multinational firms[80].

[80] BCIPR (2002), p.38.

2.2 Essential medicines: the programme in danger

Created in 1977 and having become «*special programme*» of WHO in 1979 the Action Programme for Essential Medicines has seen resounding successes all along its existence. It was designed so that «all could acquire, wherever they are and at the required time, medicines of good quality, effective and safe at affordable prices and which they use in a rational way»[81]. Today 156 countries have established a list of essential medicines, among which WHO suggest including generics[82]. These are preferable because almost always[83] cheaper than the *original* ones, the reduction being 50 to 70 %[84]. Recently WHO calculated that the percentage of the world population having access to essential medicines has doubled over the last twenty years[85].

However it would appear that the advent of the TRIPS Agreement could put into question the efficiency of the Programme by impinging on the availability of and access to generic medicines. If one considers that generic medicines can cover up to 60 % of the market even in an industrialised country such as Denmark or 20-40 % in the USA, in England, in Germany and in the Netherlands[86], it is easy to understand the fears of the national health directors. On the lists of essential medicines many generic products are found and it is estimated that in any case for 300 of the non generic essential medicines the patents will soon expire[87], what would make it possible to produce them locally as generics. The extension to 20 years of the protection duration by patents derived from the TRIPS Agreement would delay the possibility of producing these medicines in their generic form «as is the case for any product being part of a monopoly and that the firms making generic products will have to wait a longer time before being able to manufacture such a product and sell it at an accessible price.»[88]

Since active or intermediate principles can be patented just like finished products the whole local production is jeopardised with the TRIPS Agreement[89]. It is the more worrying as «an emerging market of generic medicines in a certain number of DC's represents successful social policies, which might be difficult to duplicate with the TRIPS Agreement»[90]. Extending the life span of patents to twenty years entails great risks for the WHO programme for Essential Medicines. Access to the products for the populations could likely be still more limited[91] because of the price and restricted choice of products ; supply would face limitations due to the apparently inevitable price increase; rational use of adequate products is far from being assured, thus causing serious risks of a resurgence of certain diseases. To cut a long story short «the market [...] normally shows costs and private profits at the expense of social costs and profits. For this reason an open market cannot be expected to go towards social objectives such as equity (in fact such markets could ultimately stimulate income inequalities causing in turn greater disparities)»[92]. Indeed governements can use the legal dispositions foreseen by the TRIPS Agreement «so as to avoid the excessive use of intellectual property rights by their holders»[93], but the legal constraints which they contain limit their ability to act and offer many guarantees and a great latitude for manoeuvering to the other part. For example the European Union could easily summon Canada before the WTO body for dispute settlements for its "*excessive*" exploitation by this country of the «*Bolar*» exceptions; Canada carried out tests in view of producing a generic drug before the expiration of its patent and creating stocks of this drug. The special group stated that it was not allowed for a state to create thus a stock of generics before the patent expiration of the original drug[94].

In summary it can be stated that to this day the WHO Action Programme for Essential Medicines is in danger. All its main objectives are directly threatened by the increased patent protection, be it access, supply, rational use, quality or choice of products. Compulsory licences, exhaustion of rights, parallel imports or Bolar exceptions (which can authorize production tests of a patented medicine before the relevant patent expires and before being able to produce it as a generic drug for the local market) will not serve much purpose if there is no real will of all parties concerned to maintain the good results that have been achieved in terms of health by this programme during the last thirty years.

[81] OMS (1995), p.20. The site of Médecins sans Frontières, www.accessmed-msf.org (in English), gives a lot of useful information on essential medicines.
[82] OMS (2000), Essential medicines are defined as those chosen by WHO for its list of «appropriate for local pathologies», whereas generic medicines are defined as those which are not (or no longer) covered by a patent. The two terms are often used as synonymous, which sometimes causes interpretation difficulties. As for the importance of generics on the market, see Mamou (2004).
[83] OMC/OMS (2002), p.104.
[84] WHO (1996), p.52.
[85] OMS (1999), p.70.
[86] WHO (1996), p.55.
[87] OMS/OMC (2002), p.106. Note that the USA, Israel, Canada, Hungary and Australia registered diligently in advance a certain number of generics.
[88] OMS (1999), p.27.
[89] OMS (1995), p.59. *Active or internediate principles* are all substances which are essential in production of a patented medicine and which can as well be covered by a patent.
[90] OMS (1999), p.20.
[91] «In the developing countries medicines are today so expensive that they represent between 25 and 70 % of the total health expenses, against less than 15 % in the high income countries.», OMS (2004), p.2.
[92] OMS (1998), p.23.
[93] Article 8 (Principles), point 8.2.
[94] Decision N° WT/DS114/1.

2.3 Towards confrontation or collaboration?

The commercial interests of the major pharmaceutical firms which are supported by WTO seem to be in opposition or at least at variance with the health objectives of WHO and the national health services. This discrepancy is found within a deeply unbalanced situation between industrialised countries and DC's in fields of research and production and in the access to pharmaceutical products granted to populations as well. All these elements deserve further examination in view of better understanding and foreseeing the evolution of this international problem.
First it is worth recalling briefly the motivations which led to the elaboration of this Agreement. By introducing the intellectual property rights into the action programme of the Uruguay Round the industrialised countries were aiming at reducing counterfeiting of several items among which medicines. The profit losses were important for the main firms, especially regarding the amortization of R&D costs; officially the protection of intellectual property related to pharmaceutical products was put forward and formalised in view of protecting these costs and promoting technology transfer to the DC's. Thanks to a major protection granted to medicines the well-being of populations could have been improved, according to the authors of the present Agreement, through a wider spectrum of products and better protected from any bad imitation noxious to the health of consumers. Among other problems the "*brain drain*", i.e. the highly qualified staff, from the DC's to the industrialsed countries would have been slowed down after an improvement in the working con-

ditions in the underprivileged states. Moreover a network of regional organizations for the defense of intellectual property was reinforced: the African Regional Industrial Property Organization (ARIPO) and l'Organisation Africaine de P.I. (OAPI), respectively active since 1976 in East Africa and since 1977 in West Africa, have seen an increase in their members and number at present 29 Sub-Saharan countries; to this day in Africa only Angola and Erythrea do not have a regime of intellectual property for medicines[95]. In South America the Andean Pact Countries promoted the adoption of similar I.P. rules for Bolivia, Colombia, Peru, Venezuela and Ecuador.

The advantages brought about in terms of health for the populations of these countries should not be neglected. However it is indispensable to consider a series of accurate data before passing any judgment on such a controversial topic. A WTO[96] study raises doubts as far as positive fall-outs for pharmaceutical laboratories of DC's are concerned when these laboratories have already got the necessary infrastructures at their disposal : when the costs destined to R&D only represent 20 % of a firm's income it is reasonable to question which firm in a DC can benefit from an increase of funds for R&D bearing in mind that the production cost of a new medicine will be in excess of 500 million dollars US[97]?! Such a sum can only be supplied by laboratories of industrialised countries which, among other things, will orientate their research towards the production of medicines able of curing with priority diseases of their country, where markets assure a constant profitability with respect to production costs. Undeniably the protection granted to the R&D sector only benefits the laboratories of the richest firms.

The interests of the multinational pharmaceutical firms and those of the States oppose each other; the former ask WTO to intervene globally so as to protect their R&D sectors and the latter refer to WHO fearing to have to limit the access to essential medicines of their populations. «No discrimination» against «Health for all», the fundamental principles of WTO and WHO respectively, face each other here. At present there are few reliable studies at our disposal for evaluating precisely the real, quantified and documented impact of the Agreement effects on the price of pharmaceutical products; such an evaluation would require quite a lot of time. However some experts of WHO and IMF share the same preoccupation. Dr Pascale Brudon, of the Programme for Essential Medicines, states that even if the price increase is not noticed immediately it will be inevitable[98]. According to his analyses M. Subramanian of the IMF thinks that in Argentina after the standards of the TRIPS Agreement came into force the sale prices of pharmaceutical products have increased by 71 % and that the consumption has decreased by 50 %[99]. Nevertheless it would be unfair to attribute all the causes of limited access to the extension of the patent protection. It is correct to recall that several measures can be envisaged in view of reducing sale prices. The Health Ministries can: check prices at a national level; negotiate reductions when purchasing large quantities of medicines; reduce their import taxes; facilitate the information on the ingredients used for production; limit the supply and distribution costs; all this accompanied by a relevant selection and rational use of medicines[100].

Words can turn into good indicators which can reveal the interests, which are

95 Thorpe (2002), Tankoano (2002).
96 OMS/OMC (2002)
97 *Ibidem*, p.102.
98 IUED (1998), p.93.
99 OMS (1999), p.98.
100 Thorpe (2002), pp.97 and 105.

sometimes hidden, of the different parties. After close examination it is possible to distinguish the various points of view of this problem motivating the respective positions. So it can be shown that WTO takes health into account at the level of principles. On the basis of old GATT rules WTO foresees that its members have the right to determine the health protection level that they deem appropriate[101]. Paragraph 6 of the Doha Declaration reminds us that «the WTO rules and the health policies must go hand in hand»[102], what underlines efficiently the gap between the principles of the TRIPS Agreement and its objectives, among which no health problematics is found. Here a lacuna is to be filled since health is a fundamental human right, contrary to trade. In parrallel it is to be deplored that the term «trade» is only present in the WHO documents to underline fears regarding the future: «There are undoubtedly important commercial questions which call for an examination from the public health point of view. WTO does not have the required competence»[103]. The 1996 world Assembly of WHO can still be quoted for «asking for a report on the impact of the WTO activities regarding pharmaceutical national policies and essential medicines»[104]. This absence of reciprocal recognition between WTO and WHO derives from a poor knowledge of the principles and objectives of the other. It would be most desirable that in the coming official documents of these organizations the following terms could be found: *health* and *trade*, *access to medicines* and *protection of patented products*, without omitting that of *populations*. In the future one should not read any more statements such as those of Mssrs York and Grubb, Novartis executives, certainly ignorant of the facts if not full of bad will when saying «it is not allowed to grant compulsory licences in a certain particular sector such as that of medicines»[105]; «the Less Developed Countries [...] whose development level is such that they are unlikely to represent important markets even in ten years time»[106] can still not rely on technology transfers because «pharmaceutical industries cannot register patents in each country and an improvement of patent protection in these countries is unlikely to be of a practical importance»[107] or still «it is high time that India does away with its nefarious postcolonial mentality and joins up to the other Asian countries which understand that economic development goes hand in hand with a strong patent protection»[108]. These quotations speak for themselves.

The legal dispositions of the Agreement meant to «prevent the excesses of Intellectual Property rights»[109] have been mentioned and described; they are visibly in favour of the health services of the DC's. Though very few such countries knew how to use them and benefit from them up to now[110] compulsory licences, «Bolar» exceptions and parallel imports are also a matter for discussion between WTO and pharmaceutical firms on one hand and WHO and governments on the other hand. The managers of some firms do not question the use of these exceptions but their very existence: «clearly granting discriminatorily compulsory licences must be suppressed»[111]. It even happened that the WTO dispute Rules were activated. In 1997 39 pharmaceutical firms reported the discriminatory use of the standard on the parallel imports that South Africa exercised in its fight against HIV/AIDS. This legal controversy ended in 2001 and was a success for the Pretoria government. «From now on it is urgent to realize the possible consequences of the WTO agreements, in particular of the TRIPS Agreement in the pharmaceutical field and to fill the legal gaps in the agreements»[112]. Harmonizing the trade and health questions in these agreements is not yet complete.

101 *Ibidem*, p.33.
102 *Ibidem*, p.33.
103 Mrs Gro Harlem Brundtland, director-general of WHO, OMS (1999), p.73.
104 *Ibidem*, p.7.
105 IUED (1998), p.106.
106 *Ibidem*, p.109.
107 *Ibidem*, p.109.
108 *Ibidem*, p.112.
109 Own words of WTO, as pronounced by Phil Thorpe, Thorpe (2002), p.2.
110 *Ibidem*, p.23. 60 % of DC's have legalised the regional and national exhaustion right, 40 % the international one, but 80 % are *ready* for the Bolar exceptions.
111 See note N° 70.
112 OMS (1999), p.34.

2.3.1 Conclusion

To conclude this chapter devoted to topics of confrontation which divide the two camps to this day we propose a series of initiatives aiming at reducing the gap and finding a common ground. First the common objective presented by a joint study of WTO and WHO: «the human sustainable development»[113]. Let all the concerned parties realize that at the beginning of this second millenium, characterized by a forced globalization and the domination of the neoliberal trade logic no party would be able to take trade laws out of its short or medium term initiatives; on the other hand it is irresponsible to ignore the resurgence of large epidemics of paludism, tuberculosis and HIV/AIDS and the repercussions on an access to medicines which is already endangered for a third of the world population[114].
How to separate economic growth and good health status of a nation? How can a State be forced to choose one or the other? How to avoid that the WTO standards be perceived as an obstacle to the access to medicines? Perhaps in improving the particular status devoted to health questions and transforming the exceptions into real dispositions of the TRIPS Agreement. Perhaps in recognizing the use of patents as an increased protection of the R&D sector, even for that of generics manufacturers, but that this research effort is more oriented towards fighting the diseases prevailing in DC's. Again a mutual recognition becomes necessary at the normative level (more health terms in the WTO texts and more trade related terms in the WHO resolutions) and at the functional level as well. The creation of intersector Committees and Working Groups is already encouraged by WHO and WTO[115], so that synergies can be arrived at and complementary measures of form and substance can be promoted. For this purpose the presence of WHO inside decision making bodies of WTO should also be reinforced. A «Committee for access to medicines compatible with trade» should possibly be envisaged.

Priorities of States and of WHO (Social priorities)	Priorities of firms and of WTO (Economic priorities)
- Guarantee access to medicines; - improve the legal dispositions at the disposal of DC's inside the TRIPS Agreement; - limit the price increase of medicines; - promote health for all.	- Extend the duration of patents; - reduce the impact of legal exceptions present in the Agreement; - increase financing for R&D; - stress the principle of non discrimination (countries cannot establish any discrimination between their commercial partners).
Price control, Access, Health	**Earning power, Profit, Growth**

Proposals for easing present tensions

1) Favor a greater mutual recognition between WHO and WTO, each organization attaching a greater importance to the priorities of the other in its respective texts;
2) set up more intersector working groups between the two Organizations;
3) carry out more technical studies as to the impact of the Agreement on the price of medicines.

[113] OMS/OMC (2002), p.5.
[114] *Ibidem*, p.17.
[115] *Ibidem*, p.167

It is useful to give an overview of the present situation as far as R&D and the production of medicines and vaccines for DC's is concerned.

WHO thinks that at present a third of the world population does not have access to essential drugs and that more than 50 % of the inhabitants of the poor countries of Africa and Asia do not even have access to the most elementary essential drugs. Access to essential drugs and vaccines depends on four determining elements: rational selection and use, sustainable financing, reliable supply systems and affordable prices[116].
Price is thus one of the critical factors for access to essential drugs and vaccines in particular in the DC's. But two other critical factors also play a role: delay in R&D on diseases which affect mainly the DC's[117]; and the low interest in producing medicines and vaccines for fighting or immunising against such diseases.
This is due to the fact that the vast majority of medicines and at least a part of the vaccines at present on the market come from private pharmaceutical industries. These are submitted to imperatives of cost effectiveness and in general have neither the need nor the will to provide a large access to medicines and vaccines related to «neglected» or «forgotten diseases», which concern essentially hardly solvent and thus little cost effective markets.

In a detailed presentation of this unbalance between industrialised countries and DC's[118], Bernard Pecoul, director of the Campaign for access to essential drugs of Médecins sans frontières, underlined two significant data:

1) between 1975 and 1999, 1393 new medicines (not necessarily essential) were put on the market, out of which only 13 (i.e. less than 1 %) related to tropical diseases and three related to tuberculosis;
2) out of these 13 medicines related to tropical diseases five were the result of veterinary research, two were developed by the United States army and three only were the result of "traditional" R&D. Finally two were only adaptations of preexisting medicines.

In the DC's one is confronted to the absence or insufficiency of R&D and production of pharmaceutical products necessary for answering the peoples' needs and managing the public health policies.

As far as R&D is concerned the diseases in which the pharmaceutical industry invests most in terms of efforts and budgets are the «universal diseases» (cancers, cardio-vascular, metabolic, articular affections...), which afflict the whole world population but much more the industrialised countries and the «life style related diseases» (impotence, obesity, stress...), which are almost exclusively treated in the industrialised countries. To a certain extent there are still «disappeared diseases» (e.g. paludism, tuberculosis) which have for a long time been regarded as eradicated in the industrialised countries and which still afflict mainly the DC's; they still constitute today a restricted market for the pharmaceutical industry.

Finally there are «neglected diseases» and «ignored diseases»[119] (sleeping sickness and Chagas disease, Burundi ulcer, leishmaniosis, leper...) which afflict mainly the DC's[120] and for which R&D and the production of adequate medicines are almost null[121].

2.4 Are only "diseases of the North" treated?

The TRIPS Agreement and the "neglected" diseases in the poor countries

2.4.1 The present situation

[116] *Ibidem*, p.17; see alsoOMS (2000).
[117] These diseases will be referred to as neglected or forgotten diseases.
[118] Pecoul (2002).
[119] WHO (2005).
[120] See in particular Pecoul (2005).
[121] See the page of the recent Drugs for neglected diseases initiative (DNDi), www.dndi.org.

A. Research and development

We have seen that only 1 % of the medicines developed during the last quarter of the XXth century was destined for treating tropical diseases. This remark is worth all the speeches of the pharmaceutical industry[122]. On the other hand less than 10 % of the world medical research is oriented today towards the diseases which prevail in the DC's despite the fact that these represent close to 90 % of the world population[123]. The ten largest world pharmaceutical firms devote less than 5 % of their R&D budget to the three most lethal pandemics : paludism, tuberculosis and AIDS. As far as the two world leaders are concerned, Pfizer (USA) and Glaxo-Smithklein-Beecham (UK), less than 1% of their R&D budget is devoted to them[124]. As for the «neglected diseases» in 2002 they only received 0.0001 % of the global research effort[125].

B. Production

As far as production is concerned the favourite medicines of the laboratories are those that yield more than a billion dollars per annum (*blockbusters*)[126]. Conversely manufacturing those which treat less profitable diseases is often suspended. It is worth giving here two concrete examples:

1) The oily Chloramphenicol - a remedy easy to use and effective against the bacterium generally responsible for epidemics of meningitis in Africa - stopped being produced for reasons of non profitability in 1995. Only thanks to pressure from MSF and the Red Cross its production was restarted in 1998 by a non-profit making organization to which the manufacturer accepted to transfer his technology[127].
2) The Eflornithine (Ornidyn), treating the sleeping sickness, was finalised in 1985. The American firm Merell Dow later on suspended its production. In January 2000 MSF hoped to restart production - at least partially. Eventually the medicine will be saved because it is part of the composition of Vaniqa, a depilatory facial cream[128].

[122] Petite (2003).
[123] Pecoul (2005).
[124] Jennar (2003).
[125] Lorelle (2003).
[126] Lorelle (2003).
[127] See www.science-generation.com and «MSF Campaign: Access to essential»
[128] Bulard (2004), pp.62-66.

2.4.2 The presumed effects of the Agreement on the diseases of the South

The previous considerations describe the present unbalanced situation between industrialised countries and DC's in the field of public health. Of course this situation has existed for a long time and thus predates the TRIPS Agreement. But it is now important to analyse more specifically the foreseeable consequences of the Agreement on this unbalance regarding R&D, production and access to medicines and vaccines for diseases affecting mainly DC's. Can a reduction or on the contrary a worsening of this unbalance be expected[129]? It is sensible to ask the question whether an increased protection of the intellectual property rights is going to stimulate positively in the future the private R&D and production (essentially concentrated in the industrialised countries) related to «neglected and forgotten diseases». The partisans of the Agreement say so, their main argument being that abiding by the patents in the DC's – and the profits thus guaranteed on the DC's markets – can only stimulate the interest of pharmaceutical industries for these diseases and these markets.

[129] See Assoumani (2005).

Let us quote here in particular a joint study published by the WHO and WTO secretariats: «When the incidence of the protection given by patents on the access to medicines and vaccines is evaluated, the balance must be analysed in the field of patents between:

1) the encouragement effect on the discovery, implementation and marketing of new medicines caused by the patent and its incitement to R&D;
2) the limitation effect on access to existing medicines and vaccines»[130]

Regarding the R&D encouragement if the positive role of protection by patents is generally admitted it is arguable to which extent this protection constitutes a supplementary encouragement in the DC's. In this respect two questions crop up: firstly to which extent a world prescription with the aim of protecting the inventions of pharmaceutical products at the level of TRIPS standards does boost the general level of incitements to R&D for diseases in general and, secondly to which extent does such a prescription act upon on the incitements in the case of diseases prevailing in the DC's?

On the other hand even after the TRIPS Agreement has been implemented one is worried that the patent system does not constitute a sufficient incitement to R&D for neglected diseases[131]. Indeed it seems that the economic and social conditions of most DC's make unattainable the hope for a positive effect of the patents system on the health situation of DC's. The profitability of a market, much more than its possible abiding by IP rights, seems to be the determining factor for the choice and investment level in R&D and production of pharmaceutical products. In such a context explicit and appropriate health policies going beyond IP rights would be necessary for certain resources and capabilities of the pharmaceutical industries to be allocated to R&D for «forgotten diseases».

Several analyses of this problem are now available. For example in 2004 WHO organized *a workshop on the IP rights and vaccines in the DC's*[132]. The legal adviser who presented the preparatory document for this last meeting summarizes the situation in the following way: «It is not possible on one hand to distinguish the efficiency of the IP system for stimulating the R&D from the market dynamics, to which it confers monopoly rights, and on the other hand the market acceptance where this R&D is said to guarantee the patents IP. There is no point in saying that there is no relation between the affluence of a market in human terms and that in terms of profit; this last aspect alone really counts in the functioning of the IP mechanisms.»[133].
Examining the situation of the last twenty-five years seems to demonstrate that the market logic and the increased profits provided by the IP rights do not work when markets are poor or non-existent. Indeed when the medicines effective protection has increased on average by six years in the member states of the OECD and when the total number of registered products has slightly increased during the same period the average innovation index has remained unchanged[134].

Moreover between the encouragement effect for R&D and the limitation effect of access to medicines and vaccines the danger lies in the fact, with the TRIPS Agreement, that the prices of medicines and essential vaccines in the DC's increase significantly and thereby offset any hypothetical increase of R&D.

[130] OMS/OMC (2002), p.23.
[131] OMS/OMC (2002), p.100; the Box N°14, p.101, broadens the analysis on this theme.
[132] OMS-IVB (2004).
[133] Garrison (2004), p.29; Christopher Garrison is a legal adviser at WHO.
[134] Trouiller *et al.* (2002).

For example some of the new medicines which are more effective against HIV/AIDS, paludism and tuberculosis, diseases causing huge human and economic losses, were invented after 1995 and thus can claim a patent protection in a larger number of DC's[135].

[135] OMS/OMC (2002), p.107.

2.4.3 Medicines and vaccines, sometimes different problematics

It is worth taking note that the consequences – expected or feared – of the TRIPS Agreement on the health perspectives in the DC's are not necessarily identical when it comes to medicines or vaccines, in the field of R&D and in that of production and distribution as well[136].

Undoubtedly the production of vaccines suffers less from the patents system than that of medicines; indeed 70 % of the vaccines for UNICEF are produced at present in the DC's through public-private joint ventures. Waiting for a vaccine to be patent free so as to produce it at a low cost can in some cases prove dangerous for public health. With respect to the necessities of DC's in the field of public health it is unacceptable to wait for a patent to have expired, considering how important the needs are in the field of public health. Any promising vaccine should be developed in a fast and effective way[137].

In theory the TRIPS Agreement foresees mechanisms enabling competition during the validity period of a patent, for example the compulsory licence. But in the case of vaccines the production demands a certain *know how* which is not described by patents and cannot be transferred under a compulsory licence. The result of this is a gap between the know how of the OECD vaccines manufacturers and that of the manufacturers of emerging countries[138].

The fact that patents can block the access to end products and to processes as well constitutes an important obstacle in the case of vaccines. Indeed for a vaccine there exist different protection levels on "properties" as diverse as for example DNA sequences, adjuvants, *delivery devices* or excipients etc. So to get the right to produce a vaccine under compulsory licence – which does not mean having the capability or the know how – multiple licences must be obtained from multiple partners. Such an effort calls for knowledge and administrative and financial means as well out of reach of most DC's.

[136] See «Differences among Vaccines and other pharmaceutical products in the framework of the TRIPS Agreement», Box N°15, in OMS/OMC (2002, p.107; see also OMS-IVB (2004).
[137] Garrison (2004), p.39.
[138] Garrison (2004), p.3.

2.4.4 Conclusion

Contrary to what its defensors say it is unlikely that the TRIPS Agreement and more generally an increased patents protection at the world level stimulate R&D on medicines production and vaccines for forgotten diseases as well. In all cases it is very unlikely that a positive effect of the TRIPS Agreement, if there is any, offsets the expected negative effects in terms of access to medicines and public health in the DC's.

To stimulate interest for neglected diseases it would be necessary to implement explicit and well focused health policies independently from adopting an increased patent protection within the framework of the TRIPS Agreement.

3 Case studies

3.1 Introduction

This document attempts to keep a tight link with the real situation experienced in the field. This is why this chapter presents specific cases of certain countries where the effects of the TRIPS Agreement were felt by the population and the main health actors. Four case studies are described to explain, depict and foresee the possible consequences caused by the adoption of this Agreement.

The study on the Bamako initiative goes back to an action undertaken by UNICEF almost twenty years ago. Though it is not about measures taken recently they enable us to visualize the possible and foreseeable repercussions of the TRIPS Agreement on the local populations of DC's which would be left exposed and abandoned with respect to the supply of medicines.

Another "positive" case analysed was that of the 2004 Canadian legislation. This second study shows how industrialised countries can operate by promoting laws which guarantee IP rights and at the same time respect the access of products to other less privileged areas of the world.

The pages devoted to India and Chile describe the introduction of new dispositions protecting the patents in two DC's. India shows us the repercussions on the production of generics in the country and raises the question of supply. As for the study on Chile it examines closer the political stakes related to the Agreement revealing some questionable practices carried out by one of the most influential industrialised country.

3.2 The Bamako Initiative

In 1978 the WHO conference at Alma Ata launched the campaign *Health for all in the year 2000*. Its objective was to provide access to care and availability of efficient health structures to the whole world population. The Primary Health Care Centres were the main axis. With this in mind the 37th session of the WHO Regional Committee, held in Bamako (Mali) in September 1987, worked out the process of community participation in the health sector through the cost recovery of primary health care. Under the aegis of UNICEF and WHO this initiative was aimed at relaunching and revitalising the primary health care systems so as to make them geographically and economically accessible to the whole population. Afterwards many African countries applied the approach foreseen by this Initiative. In the absence of a third paying party (health insurance) and according to the principle «health has no price but a cost» each beneficiary was invited to take charge of a part of the medical care. The global cost recovery was to be done under the supervision of the community of the dispensary users[139]. It was then really a community self-financing scheme, the participation of the local population being indispensable for the system survival. The scheme foresaw mainly three types of payment: outright payment: single price whatever the disease, cost, diagnostics and treatment, payment by medicine and by act and an annual contribution.

This case study was chosen to show how the effects caused by the TRIPS Agreement could go astray as for the access to medicines in certain African countries where local communities were cornered into paying themselves their medicines and financing their own health centres. Launched almost 20 years ago the Bamako Initiative constitutes a concrete analysis element which can demonstrate what could be the long term consequences for individuals invited to resort to self-financing so as to safeguard their access to medicines and health care. Twelve years after the Initiative was launched two studies were carried out by UNDP in Mali, in Burkina Faso and in Uganda so as to evaluate the impact of measures taken previously[140]. The results are far from encouraging.

The first findings concern the access to medicines. It reveals that the less privileged people remain unable to pay for the products they need. A part of the least privileged population, from 5 % to 30 %, does not have the financial means to have access to health care. On the contrary a direct payment by users carries a supplementary financial burden for households which already bear the brunt of the Structural Adjustments of the nineties. In Uganda people have to sell their personal goods and go into debt.

There are two types of care exclusion: a temporary one due to a lack of resources at a certain time of the year and another one – much more severe – of a permanent nature. Though the financial viability ensuring the permanence of structures and staff is often underlined a direct payment by users only marginalised ever more the underdogs. Any insurance system, be it either mutual or with prepayment, only generates a very limited income which benefit only a small fraction of the participants and certainly not the poorest. These only go to a Health Centre as a last resort and only rely on the compassion of the staff to obtain free medicines. In such a context it is not surprising that they prefer to contact first traditional doctors sensibly cheaper and more easily accessible.

139 http://bioltrop.org/00-entete/ib.htm
140 Ridde *et al.* (2004). All the following data come from the same document.

The lack of information and the masses low awareness have a doubly negative effect. On one hand community participation, indispensable for constituting Management Committees of the Centres, has been very limited, taking into account that these very communities had not been contacted during the programmation phase of the Initiative. On the other hand no methodological element was established to identify with certainty the real poor inside of a population. Indeed handicapped persons, widows, the aged and beggars are often quoted but no statistical tool was used for reference; consequently today the poorest can hardly be identified and reached. Moreover in Mali and Uganda as well the most underprivileged are not aware of the exemption possibilities which only benefit 1 % of the population.

At the time of launching of the Initiative it was hoped to obtain an increase of the services spectrum of primary health care. Unfortunately the present cost recovery does not enable it. The amounts obtained thanks to the users fees hardly cover the expenses caused by the purchase of essential medicines, the payment of the staff salaries and the equipment maintainance. To all these difficulties must be added the phenomenon of corruption, easily forseeable in such a context deprived of accurate functioning standards. Many persons questioned by the authors of this study stated that they had to bribe the sanitary staff in order to get some care on top of the medicines.

The TRIPS Agreement is likely to cause an increase of the medicines cost. The economic weight of this increase might incite many DC's to adopt the Bamako Initiative precepts, that is to improve the access to medicines in order to overcome the State financial shortcomings and to involve the populations in the management of SSP's through the sale of essential medicines and the payment of consultations[141]. The risks to run with this approach can be summarised as follows:

1) increased marginalisation of the underdogs;
2) low community participation;
3) indebtedness and deprivations of certain underprivileged parts of the population;
4) temporary or permanent exclusion of this fraction of the population from primary health care;
5) spectrum of medical care always limited;
6) corruption phenomena.

3.3 Brazil

Among the DC's like India and Thailand, Brazil is a big manufacturer of generics. It has adopted an original public health model which can be explained by its very particular geopolitical situation and by the history of its present health system as well. This huge country was numbering more than 180 million inhabitants in 2004 and shows very large disparities in development and income[142]. So the introduction in its 1988 constitution of a unique health system, Sistema Unico de Saúde (DUS) and of the universal and total right to health in the whole country[143], – claimed by the *Movimento sanitarista*,

141 Marquet (2003). Other informations are found in Ridde *et al.* (2004), and on the sites: www.cedim.uqam.ca/articles/mukonde.pdf and www.bioltrop.org/00-entete/ib.htm.
142 anRs (2003).
143 Andrade (2005).

movement coming from the communist party – is considered as a decisive conquest for this health organization which is now regarded as model.

From 1991 Brazil has instituted a universal and free access to treatments against HIV/AIDS[144]. In 2003 the access to antiretroviral medicines touched 135000 patients[145]. A 2003 detailed report suggests that savings in hospital and ambulatory costs surpass largely the cost of the prevention programme and free treatment in the fight against AIDS. But the UNAIDS report[146], updated in 2004, indicates that the epidemics propagates in all socio-economic groups and all regions of Brazil despite an efficient health policy – a high prevalence correlates positively with a lower socio-economic level. However the survival of AIDS patients has been considerably extended. A recent study shows that the survival median is hardly lower than five years (fifty eight months) for the persons whose AIDS was diagnosed in 1996 whereas it was only eighteen months for those whose diagnostics was made in 1995.

The coming into force of the TRIPS Agreement has modified the access to medicines in the country. Up to the beginning of the year 2005 many developing countries have continued importing generic medicines from India at affordable prices. From now on it is no longer possible since India joined the TRIPS system. The price of the antiretroviral Kaletra, one of the main medicines used against AIDS for example, was renegotiated in June 2005. Brazil finding that the price set by the firm holding the patent (the US firm Abbott) was excessive alleges the public health clause and threatens to manufacture a generic. Abbott refers to the prevalence of AIDS in Brazil, which is not much different from that of industrialised countries, and to the fact that Brazil is in an economic boom and that consequently no reason can justify a price at level with those granted to the poorest countries such as the African ones. The Abbott representative suggests that the demands of the Brazilian health Ministry reflect more the demagoguery of the Brazilian Government than the real care for the well being of its people. However one is entitled to imagine that the relatively favourable situation of Brazil with respect to the pandemic is directly related to the health policy of Brazil and that without free treatments the effort put into prevention and education the situation would be far worse.

After being threatened by economic retaliation over other export products Brazil renounced breaking up the patent of Abbott's Kaletra[147] and accepted the reduction granted by Abbott on the price of Kaletra. The patent will be expiring in 2015. At such a time Brazil will be able to produce freely its generic. But in the mean time more and more medicines distributed in the country will be bought under patent, therefore will be more expensive.

Generally speaking the health problems of the population which have become worse with the coming into force of the TRIPS Agreement are likely to worsen further. This is at least the prognosis of MSF. As the present medicines have lost their efficiency and when the AIDS virus will have developed some resistance – process already under way – the second line, even third line products will all be manufactured under a patent and consequently will be dearer than those presently available. More than ever the situation calls for alliances among DC's to negotiate with the countries supplying the patented medicines[148].

144 Reinhard (2003a).
145 Regards (2004).
146 ONUSIDA/OMS (2004).
147 *Libération*, 18 July 2005.
148 MSF (2005c).

For this purpose the Brazilian diplomacy passes agreements with emerging countries like China, India and South Africa to reinforce their front and reduce their commercial dependency versus the European Union and the United States. At the beginning of 2005 the Brazilian diplomacy played an important role in the adjournment of the creation of FTAA (Free Trade Area of the Americas, in Spanish ALCA). The FTAA claims to establish among all American countries – with the notable exception of Cuba – (34 Latin American and Caribbean countries) a free trade area, the aim of which is to «liberalise trade, increase investments by freeing markets, increase competition, do away with restrictions to free trade (including subsidies to local industries, aids to trade...) [and] to movement of capital and businessmen»[149]. As a leader in opposing the FTAA Brazil is also opposing broadening Mercosur[150], regional area of economic cooperation in the South Cone (South Cone market) so as to include almost all the countries of this area, but the regional cooperation remains difficult. Against the new constraints imposed by the agreements on IP at the level of the world market, the extension of opportunistic diseases, the new contaminations by the HIV/AIDS virus one of the solutions proposed is «South-South cooperation». A network is being organized between China, India, Brazil, Nigeria, South Africa, Russia and Thailand which should facilitate bilateral or multilateral agreements in the field of medicines production, laboratory products and vaccines[151].

As was seen recently in a last resort the price of a medicine is generally negotiated bilaterally between an importing country and the country holding the patent (or the pharmaceutical firm). The terms of the negotiation are not disclosed to the public at large. Only the result is made known and it seems to be often the result of strong arm tactics between a DC threatening to obtain a compulsory licence so as to market a product still protected by a patent and a developed country or a phramaceutical firm which threaten with retaliation measures on raw material bought from this country. This is what seems to have happened with Kaletra in 2005 where a final agreement was passed for a price higher than that asked for by the Brazilian government but lower than what the firm Abbott was proposing at the beginning of negotiations.

Despite the advantage derived from its health organization, its fight against AIDS and its dominant role among the developing countries versus the hegemony of developed countries Brazil had a few shortcomings. In putting its legislation in conformity with the TRIPS agreement Brazil seems not to have taken advantage of the flexibility provided by the Agreement.

In compliance with Article 6 of the TRIPS agreement the WTO member states can adopt one or the other regime of exhaustion of intellectual property rights over patented products. The patent holder loses some prerogatives over the patented product as from its first put into circulation[152]. The regime chosen can be adopted at the national, regional or international level. Brazil opted for the exhaustion of rights at the national level, what practically forbids parallel imports. But this last mechanism allows importing medicines at advantageous prices from other WTO member states[153,154].

149 Chapter 2, article 1, subparagraphs 1 to 5 of the FTAA draft agreement (November 2003), quoted in CETIM (2004).
150 The Mercosur, Mercado del Sur, the Southern Common Market, is a regional integration process between Argentina, Brazil, Paraguay and Uruguay.
151 Archimedes (2004).
152 Velásquez *et al.* (1999).
153 ICTSD (2002).
154 Oliveira *et al.* (2004a).

Up to 2005 Argentina and Brazil had at their disposal a five years transition period for putting their legislation in conformity and putting into force the TRIPS Agreement. Brazil only used one year to develop its industrial capacity in the field of medicines, after which it adapted its legislation on patents. This rapid putting into conformity with respect to the demands of the TRIPS Agreement deprived the country from a possibility of becoming more competitive and therefore more autonomous with respect to external suppliers[155].

Today Latin american countries thwart once more FTAA and seem to resist the neo-liberal constraints that the American government and the American firms wish to impose upon the whole economy of the South via free-trade treaties. These agreements constitute one of the key elements of the United States strategy in toughening up intellectual property standards, well beyond those which were established in 1994 by WTO, thereby instituting for the DC's regimes more binding referred to as «TRIPS+»[156]. In view of the enormous difficulties presented by the regional integration Venezuela, Brazil and Argentina make concrete advances so as to promote bilateral agreements. Venezuela has oil, wealth that it uses smartly at the national and international level as well. It sells oil cheap and at favourable financial conditions. Argentina and Brazil each play their role trying to solve difficulties or internal necessities: the former attempts to solve its energy deficits due to a lack of investments and the latter tries to expand the markets for its industrialists and its conquering agrobusiness. The fifth visit of Chávez in Argentina at the beginning of 2005 resulted in strategic agreements between Caracas and Buenos Aires, which also imply among other things that Venezuela starts replacing some American suppliers by Argentinian ones. The agreements signed include energy, commerce, communications and agriculture sectors. An agreement was passed between the Argentinian society Enarsa and the Venezuelan Pdvsa (public national oil societies) to develop projects of exploration, extraction, refining, commercialisation and transportation. This rapprochement was carried out in view of joining the Brazilian Petrobras so as to form a gigantic regional oil conglomerate which would be called Petrosur. Argentina will build four tankers for Venezuela at a total cost of 240 million dollars, in exchange of liquid hydrocarbons for generating thermal energy[157].

Undeniably Brazil has a key role to play in this integration process. But as a strong country in the region – it possesses an important structure for industrial production and an advanced technology – it already faces the very large disparities existing among the different States. One of the stumbling blocks for regional integration derives from the subordination of almost all governments to the big firms – national or multinational – which take governments as hostages. These in turn do not show themselves eager to get away from their influence. The question to ask is the following: can regional integration be achieved on the basis of free-trade? Integration, «thought of as a free-trade area, designed mainly as the setting up of an economic space for free circulation of goods and capital», as was mentioned by the Venezuelan sociologist Edgardo Lander has no reason to be favourable to the people of this continent. An integration project whose objective is to open further the economies is dedicated to increase the present inequalities and to guarantee the success of the strongest by exploiting and excluding the weakest.

155 *Ibidem.*
156 Krikorian (2005).
157 Zibechi (2005).

Do the present Latino-American experiments and integration projects represent today effective alternatives and options versus the logic of neo-liberal globalisation[158]? For the Urugayan journalist Raúl Zibechi[159], free-trade generates intrinsically differences, social and spatial inequalities inside every country from the very moment when it is guided by profit and managed by big firms. It not only causes tensions between social sectors by widening the gap separating the rich from the poor but it also generates development poles and pockets of marginalisation and poverty as well. It brings prosperity to a few areas of the country but at the same time excludes others or disindustrialises them. During the nineties the economic growth in Brazil was achieved to a certain extent on the set back of the Argentinian industry.

Brazil is an emblematic case of emerging country which among the DC's enjoys some advantages (developed and relatively democratic health system, fairly developed economy, resources) which grant it some power in this area and against the international powers. Up to now the stability of the health system was assured by the relative autonomy of the country which was manufacturing the generics necessary for treating AIDS. With the coming into force of the TRIPS Agreement and the «TRIPS+» this stability is in jeopardy. So there are big and multiple challenges for Brazil and the South Cone in its entirety: internal struggle for reducing inequalities versus health and struggle against AIDS; support for the opposition to the neo-liberal plans of the United States, the European Union and the big firms; vigilance versus the application of the Agreement; and overcoming contradictions in view of setting up a Mercosur covering the whole area.

158 Lander (2004).
159 Zibechi (2005).

To know more about Latin America please consult in particular:
http://www.choike.org/nuevo/
http://osal.clacso.org/

3.4 Canada

On the 14th May 2004 Canada adopted a law empowering Canadian pharmaceutical firms to export some patented pharmaceutical products to DC's thanks to a compulsory licence. So Canada became one of the first countries in the world to implement the WTO General Council decision accepting paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health. This paragraph 6 enables any WTO member state to export pharmaceutical products within compulsory licences. This enabled the DC's not having the means to buy essential medicines at the patent price or to manufacture their own products to import such medicines from Canada, under certain conditions, at a reduced price. This case study will examine the content of the Canadian legislation, its positive and negative aspects as well.

The Canadian law which modifies the laws on patents, foodstuffs and drugs[160] has the declared objective of «facilitating the access to pharmaceutical products so as to limit the public health problems impeding the DC's development, particularly those which are plagued by HIV/AIDS, tuberculosis, paludism and other epidemics»[161]. This law enables the export of 56 pharmaceutical products with a make under patent towards any WTO member state and towards DC's under certain conditions.
The list of 56 products meeting these conditions is essentially identical to that of the WHO essential medicines[162]. However new products can be

160 Canada (2004).
161 *Ibidem.*
162 That can be found on the site:
http://mednet3.who.int/eml/eml_intro.asp.

added to this list if they are considered adapted to the local pathologies by the local governments and if they «can solve problems of public health...». A great importance is attached to medicines destined for treating HIV/AIDS, tuberculosis, malaria and other epidemics.
Obtaining a compulsory licence must be a specific request by any interested person and be submitted to the patents commissioner. This request carrying the product name, quantity, patent number, patent holders, country of import and name of the associate who imports the product. The applicant must confirm that an attempt at obtaining a voluntary licence was made towards a patent holder during the last thirty days proposing «a proportionate remuneration» to the patent holder and that this attempt has failed. The pharmaceutical firms holding the patents benefit from a certain protection against compulsory licences concerning their products. If the average price of the exported product is equal or superior by 25 % of the average price of the product patented in Canada the patent holder can appeal to the Federal Court of Canada to have the licence cancelled or to receive a compensation from the dealer under the claim that the agreement is «more commercial than humanitarian». If the average price does not exceed the supply cost of the product by more than 15 % the court will not cancel the permit. If it exceeds it the court must decide if the agreement is "commercial" or not taking into account – among other factors – «the neccessity for the applicant to make a reasonable profit which enables him to continue participating in a humanitarian initiative».

Once a compulsory licence is granted the patent holders receive a compensation under the form of a fee. The latter is directly proportional to the rank held by the importing country in the UNO classification on the index of human development[163]. The highest fee is 4 % of the product value to be paid by the importer. So in general the producers of essential medicines know the fee they will have to pay and can thus calculate it in advance.
Once a compulsory licence is granted it is valid for two years It can only be renewed once and for two supplementary years. To have it renewed the applicant must certify that the quantity of the pharmaceutical product agreed upon originally has not been totally exported during the first two years.
When developing this legislation the Canadian government consulted a certain number of non governmental organizations, public interest groups and private firms such as the Unified Canadian Church, the Canadian Medical Association, the Canadian Trade-Union Congress and others – and was put under pressure. Discussions took place between the Generics Canadian Association, the interested NGO's and the pharmaceutical firms based in Canada. The public opinion was largely sought about the definition of Rules related to this new law. This large participation led to some amendments in the legislation. The abrogation of a «right of first refusal» project was noted; this right would have enabled the patent holding firms to enter directly the process of granting a compulsory licence instead of the applicant. The NGO's also incited the government to make less restrictive the list of countries habilitated to import, including some DC's which are not members of WTO.
The NGO's action has not been as successful regarding the list of products covered by the legislation. Though the governement can add to this list and a ministerial consultative committee was set up to examine possible additions some NGO's fear that this possibility to complete the products list constitutes

163 That can be found on the site: http://hdr.undp.org/reports/global/2004/.

a means of pressure on the government, that the big pharmaceutical patents holders could use to delay or even reject some proposals. The government took into account these fears by including in the list all retroviral medicines sold at present in Canada. However the process required to add other medicines to the list was not changed. At present the NGO's still play an active role as far as this legislation is concerned. A year after it was accepted by the Canadian Parliament the law still has to be ratified.

There is a certain number of obvious advantages in the Canadian approach for the access to pharmaceutical products in the DC's and for the Canadian firms producing essential medicines. This approach opens the way to a general improvement of the public health level in making easier the access to medical care in the DC's. However a certain number of ambiguities and worries remain within this law. A major worry remains: that of seeing products reexported or diverted from the humanitarian objectives for which they were destined. Indeed some essential medicines of a national list might be sold to another country. Measures are foreseen to prevent this diversion as for example the automatic stop disposition if a product has been reexported in full knowledge of the dealer. Canada has also imposed regulations demanding that products for export bear inscriptions distinguishing them from those destined to the home market and a number for tracing the products exported from Canada. However one can imagine that these measures will not be enough to prevent all abuses.
The export to countries which are not WTO members must be considered on a case by case basis. For the poorest DC's the national governments must imperatively declare that the products which they import will not be used for commercial purposes and that they adopt measures in agreement with the Doha Declaration to prevent reexporting the said products to other countries. The countries which are not WTO member states must meet other conditions such as those of national emergency or of extreme emergency. For some countries this "ad hoc relief" is too specific and of little use for a public health policy in the DC's. It can also be argued that this situation leads to an unjustified double standard, one applying to the WTO member states and another one to non-member states. On the other hand the Canadian legislation demands that all who seek to obtain a compulsory licence first try to get it through a voluntary acceptance by the patent holder though within a relatively short delay of thirty days.

Despite these few restrictions Canada is regarded as a pioneer in its national application of the Doha Declaration. The legislation foresees a parliamentary ratification within two years after its coming into force. From now on it will be possible to see if modifications will be needed or not. Some parliament members thought that access to cheaper versions of medicines is not sufficient, they think that it must be accompanied by other measures. For example without well trained health services and adequate infrastructures the DC's will not be able to slow down the diseases[164] progression. This shows that Canada works towards helping these countries to improve the running and efficiency of their health systems. The Canadian government reaffirmed its commitment in this process and invited other nations to share its commitment thereby encouraging other countries to show as much commitment for public health without further delay. The adoption and implementation of this Canadian initiative in other countries could contribute to a more equitable access to medicines throughout the world[165].

164 Carroll (2004).
165 Other informations are found in Acharaya *et al.* (2004), Aidslaw (2004), Brady *et al.* (2004) Canada (2004), (2004a), Pei (2004) and Roberts (2004).

3.5 Chile

The question of access to generic medicines in Chile lies in a context set by the United States policy foreseeing the signature of regional and bilateral free-trade agreements with the DC's. The aim of this policy is to reduce the flexibility offered by the TRIPS Agreement. These bilateral agreements impose systematically to the signatory countries IP dispositions, referred to as «TRIPS+», more binding than those of the TRIPS Agreement.

After the military coup of the 11 September 1973 against the constitutional government of Salvador Allende Chile became an experimental and test ground for all the neo-liberal projects of Milton Friedman's Chicago Boys[166].

The free-trade agreement with Chile, signed on the 6 June 2003, constituted for the United States the precedent on which were based the negotiations with different countries of Latin America, of the Caribbean and other areas of the world[167]. So the Chilean negotiators turned into ambassadors of the bilateral way in going to the following countries : Colombia, Costa Rica, Honduras, the Dominican Republic, Guatemala, Nicaragua and Ecuador. They taught these governements how to «negotiate well» with the USA. For this reason and as a «model to imitate» Chile participates actively in the negotiations for creating FTAA[168].
This ultraliberal economic policy, strictly related to the US interests, represents the most important legacy left by Pinochet to the new Chilean democracy. In the health Sector the ultraliberal movement, of which the bilateral agreement is only one aspect, continues gathering momentum nowadays.

A. The «TRIPS+» measures

These measures are included in the bilateral agreements between the US and Chile. They are much more binding than those of the TRIPS Agreement on medicines. Among other things these dispositions «TRIPS+» regard:

a) the extension of the protection duration of patents beyond the twenty years required by WTO. The Free-trade Treaty (TLC in Spanish) recognises the possibility of extending the duration of pharmaceutical patents to recover the unjustified delays in the recognition of a patent or the unjustified reduction of a patent duration due to the authorisation process for commercialisation. In no case is there a maximum extension duration what can lead to a total protection duration in excess of twenty-five years;
b) a relaxation of the patentability criteria or their extension;
c) the FTAA does not say anything on the possibility to accept parallel imports of generics from abroad, protected by patents, without the authorisation of patent holders or on the granting of a compulsory patent from the state without the consent of the patent holder. These practices, admitted by the TRIPS Agreement, are fought against by the US;
d) establishing a link between patents presentation and obtaining a marketing authorisation from pharmaceutical firms;
e) the patent exception accepted in the TRIPS for reasons of public interest is not recognised;
f) the treaty compels to give an exclusive rights extension of five years on the data, presented in view of obtaining the marketing authorisation for pharmaceutical products which are recognised as new chemical entities (information not divulged);
g) it establishes a strict correspondence between patent and health register. It will be sufficient to demonstrate the existence of a patent to deny the registration of a pharmaceutical product even if the applicant possesses all the parameters required for its approval. This measure exists neither in the United States nor in Europe. So Chile will give pharmaceutical firms more rights than their home country.

All these obligations and these "silences" aim at reinforcing the rights and prerogatives of the US pharmaceutical firms which hold patents by facilitating the arbitrary price control of medicines and the practices against competition. These firms block the introduction of generics of a comparable quality and lower cost by making practically impossible a health policy which increases the prescription of generics.

B. The importance of generics on the Chilean market

In 2004 the generics represented 40 % of the sales of medicines, with 48 million dollars on a global market of 568 million dollars, therefore less than 10 % of the total value. For the year 2002 the following data are available:

a) generics: 65 million units sold (average price: $0.59 per unit);
b) brand[169] generics: 63 million units sold (average price: $3.85 per unit);
c) brand (patent): 36 million units sold (average price: $5.96 per unit);

C. The Chilean pharmaceutical industry and the « TRIPS+ » Agreement

It is necessary to examine the structure of the Chilean medicines market (in 2003) in order to understand the impact of «TRIPS+». The Chilean pharmaceutical industry depends almost entirely from the multinational firms of this sector since all the brand medicines and most active principles needed for producing the generics and the brand generics are imported.

From the point of view of production and distribution of the Chilean medicines market the following actors are noticed:

a) the multinational firms (Pfizer with 4.7 % of the Chilean medicines market, Glaxosmithkline 3.8 % and Roche 3.2 % etc). The foreign laboratories with hardly 25 % of sales represent almost 50 % of the turn-over because they only sell imported brand products;
b) Laboratorio Chile SA, national leader in this sector appears as a Chilean industry. It was privatised 100 % in 1988 and bought in 2001 by IVAX Corporation, a pharmaceutical industry with headquarters in Miami. As leader in the sector of makes with 25.7 % of the market in prescribed medicines it is also the largest producer of generics with 50 % of the market;

166 These are the young Chilean economists trained at the Chicago school of Milton Friedman, Nobel prize winner, and who were the authors of the ultraliberal economic policy of massive privatisation in all sectors, including that of health, during the Pinochet dictatorship (1973-1990).

167 Singapore, Jordan, Bahreïn, Guatemala, Honduras, Nicaragua and Costa Rica (within the agreement for Central America) have already signed such agreements. Negotiations are running with the Andean countries (Colombia, Ecuador, Peru and Bolivia), the South African Customs Union (SACU, Botswana, Lesotho, Namibia, Swaziland and South Africa), Thailand. 34 Latin American and Caribbean countries are concerned by this agreement with the American countries.

168 Area de Libre Comercio de las Américas (FTAA: Free Trade Area of the Americas).

169 In Chile they are called: "Similares de marca", they are copies of the active principle of a medicine whose patent has expired, they are sold under a new trade name and, in principle, produced by laboratories which belong to the three main chains of Chilean pharmacies.

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c) The Chilean laboratories represent the second actor in the production sector. They produce mainly generics and at present find themselves in difficulty as they are fragmented by the «TRIPS+» agreements and the three big chains of pharmacies;
d) the three big chains – Farmacias Ahumada, Salco-Brand and Cruz Verde – total more than 91 % of the retail sales. Traditional local pharmacies have practically vanished. These chains exercise their power of blackmail mainly on the weakest Chilean laboratories, but they also produce more and more their own brand generics, which they sell at a price higher than normal generics. The national producers lodged a complaint to the anti-monopoly Commission but without any success.

Mr Leopoldo Drexler, vice-president of ASILFA[170], stated in 2002, before signing the bilateral treaty with the United States that «if the country does not take care of its national pharmaceutical industry the sum total spent by Chileans and the State on purchasing medicines is going to quadruple. The medicines of foreign origin are three to four times as expensive and if they remain alone on the market they will be ten times as expensive». He was hoping for a new law on patents which would allow continuing the production of generics and brand generics without giving an unreasonable protection to foreign laboratories. In fact the project was much more restrictive than the agreements signed by Chile in this matter. So C. Silva wrote in 2005: «Without doubt the new standards of «ADPIC+» will have serious consequences on offer and access to essential medicines. The important generics production in Chile and the competition in this sector are going to decrease. These two factors will surely increase the price of medicines in general and that of essential medicines in particular. The question is not to know whether prices are going to increase but by how much they will go up. The regulatory mechanisms of competition must be activated by the government to avoid monopolistic practices, failing this price increases will make the access to medicines more difficult for many Chileans. In summary the new law on IP [...] openly favours the foreign pharmaceutical industry at the expense of the right to health of Chileans[171].»

D. Conclusion

The free-trade treaty between Chile and the United States appears at an unfavourable moment for Chilean consumers. For several years Chileans have been buying less medicines at higher prices. This lesser access has proved unequal due to the strong increase of inequality in income distribution in Chile.

All the factors at play – competition among brand medicines and generics; among generics and brand generics; concentration of pharmacies chains which off set competition; and the consequences of the treaty limiting the presence of low cost generics on the market – will lead to a price increase. Already in 2003 a decrease in medicines consumption and a bigger reduction in the access to essential medicines for the more underprivileged strata was noticed. This phenomenon can only grow bigger.

[170] www.asilfa.cl/inicio.asp.
[171] Siva C. (2005a) and www.derechosdigitales.org/hipatia/mes_septiembre_2005.php

3.6 India

With more than a billion inhabitants India is at present the second most populated country after China. Its population increases by almost 2 % each year and its average annual income is less than $450 per inhabitant, this is why economic and health problems related to the people's food and to the medical prevention and care as well are enormous. However the life expectancy has gone from 37 years in 1951 to 65 years in the year 2000; infant mortality has decreased substantially from 146/1000 to 70/1000 during the same period; smallpox has been eradicated, polio and leper are disappearing. Among the reasons of this success there is a resolute and coherent political will of the Indian government in favour of the local production of cheap medicines and vaccines.

From the 1970 patents Law a large spectrum of essential medicines could be manufactured in India as generics at a low cost and on a large scale and even exported to other countries[172]. For example «generic medicines against AIDS, produced by Indian industries and used at present by patients of 200 countries, enabled the price of antiretroviral therapy to come down from 12 000 dollars per year to 140 dollars»[173].

In 2003 it was estimated that about 22000 Indian industries were producing generic medicines; an economic sector in fast growth where «very populated States like India, Brazil, South Africa or China, encourage the birth of a copied medicines industry»[174]. In 2002 it was estimated that in India this sector was creating more than two and a half million jobs[175].

This situation is changing rapidly because of India joining WTO and the consequences of it, among which those to abide by the TRIPS Agreement and to recognise IP for all the medicines and vaccines put on the market after January 1995. Already in the year 2000 a "new pharmaceutical policy" was announced by the government to take into account the risk faced by most modern and effective medicines of falling under the patents regime and of becoming consequently more expensive. The "new policy" was proposing a higher investment level in R&D and in particular in the R&D focused on endemic or frequent diseases of India. The objective in mind: the development of new medicines and production techniques which would have enabled India to become self sufficient and in this way to evade the most dangerous clauses of the TRIPS Agreement[176].

This endeavour for a "new pharmaceutical policy" led in 2002 to a first Amendment to the Patents Act of 1970 according to which India was considering that any patent on a product or manufacturing process would in the future have a 20 years validity as from the moment the patent request was introduced; however the Indian government was keeping the right to grant "compulsory licences" in case of necessity, of non commercial use or non availability in India of a patented product[177].

Unfortunately the derogations that WTO conceded to India in favour of essential medicines production as generic medicines expired on the 1st January 2005. On the 23rd March 2005 despite intense national and international protests[178] the Indian parliament voted an amendment to the Patents Act assuring the respect by India of the standards of the TRIPS Agreement, without an explicit

[172] The patents law wanted to «protect the inventors interests and at the same time stimulate the social interest towards research and the consumers interest with respect to the low costs of the results of research.» Keayla (2004), p.20.
[173] NYT (2005).
[174] Mamou (2004).
[175] Gerster (2000).
[176] Keayla (2004), p.13.
[177] Keayla (2004), p.22.
[178] e-med (2004), NYT (2005), Shiva (2005); see also the documents of the *Joint action committee against amendment of the Indian patent act*, which can be telecopied from Patents (2005).

reservation for the Indian government as from now to use the right of the "emergency clauses" and the "compulsory licence" requests for production in case of necessity[179].

Even the New York Times, in an unsigned Editorial entitled «India's choice», recognised that: «The voted Amendment is so biased in favour of the pharmaceutical industry that it [India] does not even use the rights they possess within the WTO framework to protect public health»[180]. The Amendment was defined as a «TRIPS Plus» by several observers since it enables a pharmaceutical firm to obtain additional patents when one discovers that one of its medicines, already patented, can be used for fighting a new disease; in this way the period during which a firm can monitor the production and distribution of the above mentioned medicine is automatically extended[181]. And it was quoted a figure of more than 7000 requests already submitted by pharmaceutical firms to the Indian government within the framework of the new Act[182].

It is useful reading the critical arguments relative to this Amendment which were presented by the Fédération Genevoise de Coopération and by the Déclaration de Berne in a letter of the 26th February 2005 to Mr Manmohan Singh, Indian prime minister, a few weeks before the Amendment was approved by the parliament: «Once the amendment is approved the new rules will practically prevent any industrial copy of new medicines. For the poor of the world this will have a double impact: lack of access to low cost medicines and removal of competition on generics which drives down the price of medicines with a known make [...] We thus acknowledge the inclusion in the amendment of a new section on compulsory licences for export to countries which do not possess their own production capacities; we deplore that the procedure for obtaining a compulsory licence was not simplified. Getting a compulsory licence for India will prove slow and difficult [...] Though medicines developed before 1995 will remain free from patents other medicines are in danger, in particular the new "second line" medicines among which the antiretroviral medicines against AIDS since the resistance against present medicines keeps on increasing. The proposed amendment to the Indian patents Act will thus have global implications for the health and well-being of millions of women, men and children not only in India but also in the world»[183].

The Amendment and all the legislation that the Indian government pledged to promulgate in accordance with its acceptance of the TRIPS Agreement will have far reaching consequences, i.e. a possible shortage in the supply of essential medicines and an important price increase. For example the Amendment introduced an essential modification of the 1970 Patents Act. Indeed the latter stipulated (Section 3(j)) that «will not be considered as an "invention" any medical, surgical, creative, prophylactic procedure or any other treatment of a human person and any similar procedure for animals or plants as well when the aim is to make them immune from diseases or to increase their economic value». The Amendment eliminated the expression plants from this article and thus opened the door to the possibility of introducing patents requests for any method or procedure which improves a plant's productivity[184].

[179] see Patents (2005), where the text of the Amendment can be telecopied from.
[180] NYT (2005).
[181] Kumara (2005). It must be borne in mind that the protection duration by a patent is 20 years, as counted from the moment a patent request is introduced.
[182] New (2005).
[183] FGC/DB (2005), two similar letters were also sent by MSF and Oxfam (see MSF (2005), Oxfam (2005)).
[184] Shiva (2005).

4. Conclusion

The TRIPS Agreement causes a lively discussion that this document has attempted to explain and illustrate by digging deeper into it and denouncing the unfair aspects. The questions asked, the different domains examined and the various actors involved make this Agreement one of the main problems of economic and health policy at the beginning of this millenium. The topic complexity justifies coming back briefly on this problem before formulating some responses. Some useful links will be given for those who wish to find some more detailed information.

4.1 The actors and their role

An "invisible" confrontation takes place between WTO, WIPO and the pharmaceutical industry on one hand and the DC's health ministries on the other hand. "Invisible" because there is no clearly stated opposition. WIPO, the World Intellectual Property Organization, lets WTO and WHO play the first role in trade and health respectively. WHO sees its programme for Essential Drugs severely threatened considering the delay imposed by the new IP rules for reproducing original medicines in the form of generics. The dispositions of the Agreement which might offer the DC's solutions in case of health emergency are poorly known and difficult to implement in these countries when they are not prevented by the signature of bilateral agreements with industrialised countries; such agreements compel governments of the South to reinforce their legislation in matter of IP related to medicines.
For the attention of readers in the field we come back hereafter on the different actors involved in the globalisation affecting the population's health and their respective roles.

4.1.1 WTO, WIPO and their joint actions

WTO comes first. During the negotiations leading to the creation of WTO the Agreement was negotiated and finalised[185] and its successive transformations and adaptations were decided[186]. Its Internet page proves very useful to access the official texts of the most important documents and get informed about the ongoing negotiations[187].

The collaboration programmes and responsibilities distribution regarding the Agreement application, in particular with WIPO and the national organizations for IP, are worked out and defined within WTO. WTO remains a prime actor in any action pertaining to access to essential drugs since the problems related to patents for medicines and vaccines are part and parcel of the vast domain of patents and IP protection following any discovery and industrial invention.

Even if WIPO[188] seems to play a minor role in the ongoing discussions on the Agreement modifications wanted by the DC's it is present in the TRIPS Council and in all the other bodies concerned by the Agreement and having a decision making or consultative power. WIPO could have a very important position in the sense that IP constitutes the common denominator between the pharmaceutical companies and the access to their products by the population, between R & D protection and Right to health. At a local level the role of WIPO is played by the different national organizations for IP; in Switzerland, for example,

[185] The TRIPS Agreement was published as an IC Appendix to the Marrakesh Agreement creating WTO, 15th April 1994; see WTO (1994).
[186] In particular the Doha Declaration on the TRIPS Agreement and public health; see Doha (2001); and the Declaration on the implementation of Paragraph 6 of the Doha Declaration; see WTO (2003).
[187] Information about TRIPS: www.wto.org/french/tratop_f/trips_f/trips_f.htm
[188] The Convention creating WIPO is available at: www.wipo.int/treaties/fr/agreement/index.html.

by the Federal Institute for Intellectual Property (IFPI) which gives out on its Internet site a very complete information on the Agreement and the ongoing *rounds of discussion* (Doha, Cancún, Hong-Kong, etc.)[189].

On the 1st January 1996 a cooperation agreement between WTO and WIPO came into force via the TRIPS Council. This agreement foresees a cooperation in three big fields, i.e. «the notification and translation of national laws and regulations, and the access to these texts as well, the implementation of procedures in view of protecting national emblems and the technical cooperation»[190]. Two years later the task is more clearly stated: it is to "help" the DC's to abide by the end dates of the Agreement: «WTO and WIPO unite their efforts in helping the DC's to conform to the deadline of year 2000 set for respecting the commitments regarding IP[191]». Three years later the task remains unchanged: «(A joint initiative of WTO and WIPO) launched in 2001 aims in the same way at helping the less advanced countries to respect their deadline date of January 1st, 2006 [...]», but it is added «[...] and to use the IP protection for their economic, social and cultural development»[192].

189 www.ifpi.ch.
190 www.wto.org/french/tratop_f/trips_f/trips_f/intel3_f.htm.
191 www.wto.org/french/news_f/press98_f/pr108_f.htm.
192 www.wto.org/french/tratop_f/trips_f/trips_f.htm.

4.1.2 WHO

The position of WHO is totally different from those of WTO and WIPO; rather than «helping the less advanced countries to abide by their deadline date of January 1st, 2006» it proposes to «offer the necessary technical assistance and support to the Member States so as to stimulate an implementation of the TRIPS Agreement which is coherent with the protection of public health and the development of access to medicines. This activity is guided by the political prospect of WHO, which considers public health and access to medicines a priority[193].

Hence the meetings between WHO and WTO and their joint study on the *WTO agreements and public health*[194], and the 2004 Workshop (with WIPO) on *IP rights and vaccines in the DC's*[195]. Within this framework defined by WHO it was possible to reach in 2001 the ministerial Doha Declaration, which stipulates that the Agreement «should be interpreted and implemented in such a way as to protect the public health and promote the access to medicines for all. [...] The Declaration safeguards the principle which was preconized by WHO during the last four years, i.e. restating the right of WTO members to use fully the dispositions of the TRIPS Agreement to protect the public health and improve the access to medicines»[196].

But the most interesting WHO initiative likely to stimulate reflection and dialogue on the problem of access to medicines in the DC's was the recent implementation of the Commission on intellectual property rights, on innovation and public health (CIPIH).

In the CIPIH are grouped experts from WHO, UNCTAD, UNAIDS, WIPO, WTO, the pharmaceutical industry and the civil society. Launched by WHO in February 2003 on the basis of a resolution of its world Assembly it has the task to collect data and proposals coming from different concerned parties and to work out an analysis of IP rights, of innovation and public health; this analysis

193 www.who.int/medicines/press/policy/globtrade/en/print.html.
194 See WHO/WTO (2002).
195 See WHO-IVB (2004).
196 Correa (2002); see also WTO (2003).

must include the question of adequate financing and of mechanisms facilitating the creation of new medicines and other active products against the diseases which affect the DC's in a major way. The final status report of CIPIH was presented in its final form during the world Assembly of WHO in May 2006.

The CIPIH aims at «collecting data and proposals coming from different concerned parties and at working out an analysis of IP rights, of innovation and public health; this analysis must include the question of adequate financing and of mechanisms facilitating the creation of new medicines and other active products against the diseases which affect the DC's in a disproportionate way»[197]. The life span of CIPIH seems to be limited to presenting its final report; however, its existence could be extended, in particular if a large number of NGO's considers its activity useful and efficient and makes it known.

During its first years of existence the CIPIH activity was intense; the Commission went to several countries and promoted a large variety of «discussion and analysis forums» on its Internet site and in thematic meetings[198]. Let us note in particular the contributions stimulated by CIPIH and relative to "ignored diseases"[199] or to the frequent practice of *evergreening* which enables a pharmaceutical firm to extend a patent simply by changing the appearance or the colours of its product[200]. Other institutional actors expressed themselves on the topics put under discussion by CIPIH; in particular WIPO which formulated some «preliminary comments» on the activities and proposals of CIPIH[201] which are worth examining.

CIPIH has no decision making power but it is our opinion that it should play a precious role of go-between among the actors most directly related to the power structures on one hand and the governments, the health ministries of DC's and the NGO's which represent the interests of the civil society on the other hand. The DC's NGO's in particular would be well advised to register themselves on the CIPIH's site[202] to remain well informed about all the activities proposed, to participate via Internet in its forums and studies, to benefit from the possibility of submitting proposals and to share their experience.

197 See for example CIPIH (2004), (2005); it is clear that the task assigned to CIPIH is much larger than the reflections and analysis of the Agreement and its consequences on the access to medicines.
198 Consult the CIPIH site (in English); www.who.int/intellectualproperty and its specific pages: /events, /documents, /forum, /links, /studies, /seminars, /submissions, /topics.
199 See Smith (2005) and Towse (2005); see also Lanjouw (2005) and Musungu *et al.* (2005).
200 See CIPIH (2005a), for example.
201 WIPO (2004).
202 Interested organizations and individuals can visit the site: www.who.int/intellectualproperty/contact/form/.

4.1.3 The governements and health ministries of DC's

Despite their role and the weight of their decisions the governments and health ministries of DC's often seem indifferent to the health problems of their country. In accepting the Agreement they pay little attention to the restrictions and obligations it implies. One could expect that they use all the exception possibilities foreseen by the Agreement, which is far from being the case. More interested in signing free-trade agreements with industrialised and rich countries, whereby they explicitly renounce the safeguard clauses of the Agreement[203].

This calls for a more vigilant action by local NGO's versus their governments through a direct action or through contacts with the health institutions of DC's.

However, there are some cases of consultation between government and civil society, as proposed by governments, like Chile for example:
«The general Direction of economic international relations of the Chilean

203 Several such cases were presented in Chapter 2.

ministry of foreign affairs invites all institutions and organizations of the Chilean socitey (among other the academic, professional, women's, indigenous people's organizations [...]) to present their opinion on the commercial topics relative to the negotiation and implementation of the free-trade agreements.»[204]

[204] *Convocatoria permanente a la sociedad civil* (2005): www.direcon.cl/index.php?accion=sociedad_civil_05.

4.1.4 NGO's

The NGO's of industrialised countries – the most influential representatives of the civil society – can often put pressure to bear in a stronger and better coordinated way than the DC's on the international institutions and on their own government as well.

In Switzerland the Bern Declaration (DB)[205] is an interesting example. It intervened about the free-trade agreements negotiated by Switzerland with the DC's: «Obtain from the five South African countries the most severely affected in the world by HIV/AIDS [...] that they reinforce their legislation in matter of intellectual property on medicines beyond the already binding rules set by the TRIPS Agreement of WTO? This is what Switzerland is trying to obtain through a bilateral free-trade treaty. However, this is not what these countries need of which 20 to 40 % of the adult population carries the AIDS virus. To treat their whole population they must, on the contrary, have a sufficient manoeuvering latitude to obtain the cheapest anti-retroviral generics [...]. Far from public view and without a true parliament control Switzerland concludes with developing countries bilateral free-trade agreements containing dispositions in matter of intellectual property which reduce further the access to essential and vital medicines in developing countries. [...] This is a grave and poorly known problem in which the DB is actively engaged»[206]. Oxfam[207] takes similar initiatives.

For several years Médecins Sans Frontières (MSF) has been organizing a *Campaign for access to essential medicines*[208] and acts in the field during its interventions in the DC's and at an international level by stimulating the collaboration with other NGO's and the organization of joint meetings with other institutional actors[209].

On the 28 August 2003 MSF called upon the countries of America «to reject the United States' efforts aiming at reinforcing the protection measures of intellectual property beyond the global standards in the negotiations of the Free-Trade Area of the Americas (FTAA). MSF launched a campaign asking the signatory countries to exclude from this Agreement any disposition relative to intellectual property – a position which was put forward publicly by Brazil as well. The ongoing FTAA negotiations aim at creating the largest free-trade area in the world, which represents a market worth one thousand billion dollars and covers 34 countries distributed over North America, Central America, South America and the Carribean. The FTAA draft agreement also includes proposals of clauses on intellectual property which would reduce drastically the access to affordable medicines by imposing rules on intellectual property much stricter than in other regions of the world [...] However, the FTAA draft agreement goes much further than the standards established in the TRIPS Agreement. For example the United States propose to extend the monopoly duration of a patent beyond the 20 years foreseen in the TRIPS Agreement and to limit the granting of compulsory licences. These «TRIPS-plus» clauses would have as a consequence to limit drastically the access to essential medicines at affordable prices in the Americas.»[210] Recently MSF has been very active during the first consultation phase started by CIPIH (February 2005), through a *Technical briefing document* on the effects of a deadline date (2005) for the Agreement implementation and through a contribution presented at a meeting organized by WIPO (April 2005)[211].

During a collaboration between several NGO's a *Geneva Declaration on the future of WIPO* was recently worked out which underlines clearly what are the present emergencies and which defines the role that the civil society organizations have to play with respect to the institutional bodies: «The delegations representing the WIPO member states and the WIPO secretariat are being asked to choose a future. We want a change in orientation, new priorities and better results for mankind. We cannot wait one more generation. It is time to seize the opportunity and move forward»[212].

[205] Site of the Déclaration de Berne: www.evb.ch

[206] www.evb.ch/cm_data/public/viderdoha.pdf; see WTO *et al.* (2002) and Reinhard (2004).

[207] www.oxfam.org; see Oxfam (2004).

[208] www.msf.be/fr/news/access_campaign/news; see mainly Pecoul (2002), (2005).

[209] See for example the Proceedings of the meeting organized in collaboration with Consumer Project on Technology, Oxfam, and Health International on the implementation of the Doha Declaration, 27th February 2002, in Moon (2002).

[210] www.msf.be/fr/news/access_campaign/news/ftaa.htm.

[211] MSF (2005a), (2005b).

[212] www.cptech.org/fp/wipo/futurompi.doc.

4.1.5 The regional pressure groups of Latin America and Africa

A. Latin America

The Oficina de Coordinación para la Salud en América Latina y el Caribe (which is part of the Acción Internacional por la Salud (AIS)[213] is an international network which seeks to promote a universal access to essential medicines and their rational use[214].

B. Africa

In Africa an important mobilisation exists, often directly related to the devastating problem of AIDS on this continent and to the very limited access of the population to extremely costly treatments, a situation which has grown worse after the Agreement implementation.

The example of Kenya can be quoted where the flexibility of the Agreement was included in the IP Act 2001 partly through technical assistance and pressure on the government exerted by local NGO's and in particular by the Kenya Coalition for Access to Essential Medicines (KCAEM), a group of local and international NGO's. These organizations studied different intellectual property laws and published a report putting in evidence the different flexibilities and means of safeguard, most of which were eventually included in the IP Act 2001. It is to be noted that the government also received a technical assistance from WIPO and WTO but that, according to a case study published by the DFID Health Systems Resource Centre in September 2004, it consisted essentially in putting models of laws at the government's disposal and was therefore without any real meaning in the local context[215,216,217].

At a regional level (South-East Africa) the Southern and Eastern African Trade Information and Negotiations Institute (SEATINI) based in Zimbabwe is an important example of a network in a civil society

[213] Responsible Roberto López Linares, Oficina de Coordinación AIS LAC, Aptdo. 41-128, Lima Perú); robertolopez@aislac.org.

[214] www.aislac.org.

[215] Lewis-Lettington *et al.* (2004).

[216] AFP (2001).

[217] SAPA-AFP (2001).

having played a key role in the domain of intellectual property and public health. SEATINI makes an effort to inform and make the public and the institutions concerned aware of the pressures exerted by industrialised countries on the African governments and to help those to resist them; they do so in supplying them with technical aid. The network promotes actively the regional coordination and organizes many international conferences for the different parties concerned[218,219].
The Regional Network on Equity in Health in Southern Africa (EQUINET) is also important. It is a network composed of individuals from all concerned parties and whose general aim is the promotion of equitable health systems.

SEATINI and EQUINET collaborate tightly over many projects from which can be quoted a recent programme carried out with the Center for Health Policy in South Africa. Its aim is developing the promotion and protection of equitable health systems in Tanzania and Zimbabwe, in a context of political pressures for trade and investment liberalisation (*Promoting health in trade agreements*), which are related to the TRIPS Agreement and the access to medicines (in particular to ART). After two years of activity the results of this programme were judged satisfactory, even if the relevant information for the local context is sometimes lacking and the dissemination of adequate information to the parties concerned remains problematic. To overcome these weak points the participants wish at present to:

a) develop new educational supports, better suited and destined either to the general public or to the different actors concerned;
b) translate these documents into the different indigenous languages;
c) develop the communication media (radio, etc.). The participants also wish to be involved more concretely in actions and to intervene henceforth at the political level (ministers, members of Parliament). They also want to extend the programme to the neighbouring countries of South-East Africa[220,221,222].

[218] Masungo *et al.* (2004).
[219] www.seatini.org/.
[220] CHP (2005).
[221] www.equinetafrica.org/.
[222] Training and Research Support Centre, www.tarsc.org.

4.1.6 The regional pressure groups of Asia

In Asia the case of India can be quoted where the civil society has been and continues being active in protecting the benefits of a well developed and of quality generics industry, which is not only indispensable to India but also to numerous DC's. In the framework of revising the patents law in view of making it compliant with the TRIPS Agreement by the 1st January 2005 a national and international campaign, the Affordable Medicine and Treatment Campaign (AMTC) was launched; it aims at protecting the access to medicines and treatments at affordable prices. In India and in the countries importing medicines from India organizations of the civil society, NGO's, groups of patients and health staff participate in this campaign. The participants watch continually the evolution of discussions and denounce the dangerous aspects for public health by intervening with the decision-makers on the basis of solid and broad knowledge of the different domains and stakes.

AMTC denounced the project of adopting dispositions going well beyond what was demanded by the TRIPS Agreement and exercised some pressure to obtain:

1) simplified procedures for granting a compulsory licence;
2 the suppression of provisions allowing the granting of new patents to products already known under the pretext of a new use or new dosage of these products;
3) the adoption in its totality of Paragraph 6 of the Doha Declaration and of the *30th August Decision* regarding this paragraph (determining the export modalities to countries without a capacity for local production) [223,224225].

The fight of India to save its generic medicines flourishing industry was studied in detail in Chapter 3 «Case studies».

In Thailand some NGO's, two of which are active in the defense of AIDS patients, got together to lodge a complaint against Bristol-Myers Squibb (BMS) regarding the didanosine ARV for which the firm had registered a new patent only on the basis of a different dosage of constituants. In October 2002 the Thai Central Intellectual Property and International Trade Court (CIPITC) rendered its judgement in favour of the plaintiffs and the patent was withdrawn. This judgement was a first event in the sense that it referred explicitly to the Doha Declaration and to the safeguard of public health according to the TRIPS Agreement. However, not only BMS but also the Thai Department of Intellectual Property (DIP) appealed against the verdict[226].

[223] Healthgap (2005).
[224] Independent Media Center India, http://india.indymedia.org/en/.
[225] See CL (2004).
[226] Ramachandran (2003).

4.2 Prospects

The Agreement signed during the Uruguay Round of WTO which was held from 1986 to 1994 introduced for the first time rules relative to intellectual property in the multilateral commercial system. This WTO Agreement aims at attenuating the differences in the way these rights are protected throughout the world and to submit them to international common rules. In the case of medicines it extends the life span of patents up to twenty years; this is done – officially – to guarantee to R & D a return on investment and protect it from the dangers of counterfeiting. But as this document has shown this Agreement generated more problems than it has brought solutions. In certain cases it caused a medicines price increase, complicated supply, marginalised further the less privileged in the DC's, sabotaged the local production of generics and jeopardised the WHO programme for essential medicines. The intrusion of WTO in the health domain has weakened the role played by WHO in matter of public health at the international level. Moreover the technology transfer towards the DC's which was to be assured by the Agreement has not taken place. A confrontation surged between public health and profit, the main victim being the access to medicines. It was mentioned before in which way the adoption of this Agreement has widened the gap between South and North. In the long term it is difficult to see efficient solutions since the priorities of different parties diverge without much hope of conciliation. In the most deprived countries where most of the time there is no health system and where health costs are the responsibility of users it can be noticed a marginalisation of the poorest, an indebtedness of most households, a reduction in the access to health care and in parallel an encouragement to corruption.

In order to avoid negative consequences for the populations of DC's, as far as the supply of products indispensable for their survival is concerned, a real willingness of collaboration between all the concerned parties is mandatory. One can understand the necessity of financing R & D and protecting the medicines market from counterfeiting, the more this activity has nefarious effects for the producing countries of the North and for the DC's populations as well. However, this does not justify the race to profit in the indifference to vital needs and the negligence of R & D for specific diseases of DC's. Despite the difference of interests and influence of the actors present on the scene where The Agreement is played the general interest would be better served by guaranteeing the access to medicines up to the DC's populations and at the same time protecting IP rights and consequently R & D.

At all levels there exist possibilities to act in this direction. We invite for example the responsible persons of NGO's based in the DC's to participate actively in discussion forums on Internet (in particular *[e-med]*[227], French-speaking forum on essential medicines where many health professionals of DC's exchange information and opinions, or – in English – *Ip-health digest*[228] which reports on discussions and events at the world level). These instruments enable to follow-up the implementation of the Agreement and its avatars, to collect data relative to actions taken by organizations of the civil society, to bring together NGO's of DC's working in a same region on common themes and to provide any individual interested in this topic with information. In its capacity the Centrale Sanitaire Suisse Romande will contribute to this work of information, prevision and counsel and will try to answer the questions it receives[229]. So all these protagonists contribute to a thorny discussion where different interests conflict with each other, but the outcome could prove positive if all parties did recognise the principal subject: man.

227 http://list.healthnet.org/mailman/listinfo/e-med.

228 http://lists.essential.org/mailman/listinfo/fp-health.

229 Centrale Sanitaire Suisse Romande,
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Appendices

Summary

The Agreement on TRIPS and its consequences on access to essential drugs

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1 Introductory questions

In the days following World War II and in parallel to the creation of the International Monetary Fund (IMF) and the World Bank of Reconstruction and Development (WBRD), there arose a will in the international community to give an institutional framework to international trade. Negotiations between 23 countries led to the implementation, in October 1947, of a General Agreement on Tariffs and Trade (GATT). The International Trade Organization, also under negotiation in 1947, was finally not brought to fruition.

The key objective of the GATT was to promote the liberalization of (and competition in) international exchanges by reducing barriers to trade in goods, such as tariffs or quotas on imported and exported goods. Accordingly, the initial agreement was gradually completed by additional agreements adopted during 8 «rounds» of negotiations.

1.1 What is the WTO?

The World Trade Organization (WTO) was established during the last round, the «Uruguay Round» (1986-1994) by the signing, on April 15, 1994, of the Final Act in Marrakesh (Morocco) by 128 countries. Entered into force on January 1, 1995, the WTO now counts 147 members (April 23, 2004 data).

The Act signed in 1994 includes the main agreement establishing the WTO but also other agreements in appendices on various topics such as trade in services and goods, intellectual property, dispute resolution or the monitoring of States' respect of their commitments.

Except for the Agreements on Trade in Civil Aircraft and on Government Procurement, all are «multilateral agreements»: all States willing to join the WTO were obliged to accept them (and, thus, agree to include their rules into their national laws) and the same would apply to those States willing to join the organization in the future.

In particular, this applies to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): A State's adhesion to the WTO's charter makes it compulsory to adhere to the TRIPS agreement: it is not possible to be a WTO member and not to adopt, or to adopt only partially, TRIPS provisions. It is «all or nothing»!

1.2 What is the TRIPS Agreement?

Intellectual property rights, trade marks, geographic indications, industrial drawings and models, patents, integrated circuits diagrams, etc. are, amongst others, areas in which States have defined common standards by signing this agreement. Similarly to the GATT and to the agreement establishing the WTO, the TRIPS agreement introduces the Most Favored Nation and the National Treatment clauses. The Most Favoured Nation clause requires that every WTO member State granting a special commercial benefit to another member State should grant the same benefit to all other members.
The National Treatment clause forbids member countries to discriminate foreign products circulating in their territories in favour of their own national products: for example Switzerland is not allowed to decide that the medicines it produces will be protected by longer lasting patents than imported Italian medicines. As will be described later, it is mainly this appended agreement that has consequences on the pharmaceutical sector.

2 The new rules of the game : the TRIPS Agreement

2.1 What was the situation prior to the TRIPS Agreement?

Prior to the signing of international agreements on intellectual property, each State was free to organize the protection of intellectual works on its territory, including in the pharmaceutical sector. Hence, certain countries granted patents only to products while others recognized only the protection of processes. In any case patent protection lasted from 5 to 10 years and only very rarely 20 years.
Finally other countries, including most developing countries, had excluded the whole pharmaceutical sector from the scope of application of patents. In these countries manufacturing copies of patented drugs, imports... were fully authorized: no exclusive rights, therefore neither protection for inventors of drugs nor forbidden acts for third parties.
This lack of protection made the manufacturing of drugs at a lower cost possible since in the absence of patent protection, no payment was due either in compensation for the patent use.

Most industrialized countries were already protecting pharmaceutical products and processes by 20 year patents before the TRIPS agreement.
Certain principles of the 1947 GATT were influencing intellectual property, in particular imports and exports. However, until the TRIPS agreement, no international trade agreement had explicitly dealt with intellectual property.

A. Harmonization of national legislations

In pursuance of the TRIPS agreement, all WTO member countries must align their (intellectual property) legislations to mutually agreed minimal standards. This is not some type of incentive or recommendation to comply with the rules but a real obligation for the States.

Indeed State «A» is entitled to lodge a complaint to the WTO Dispute Resolution Body if it considers that the legislation of State «B» is not TRIPS-compliant. State «B» will then be obliged to comply with the Body's ruling or otherwise endure commercial sanctions.

B. Transition periods

Given the large disparity in national legislations, alignment could obviously not be achieved immediately nor at the same pace in all countries.
This is the reason why the agreement provides for transition periods: these are time spans during which States should modify their laws but are not yet in infringement if they fail to respect the provisions of the agreement (during that period).

- industrialized countries: 1 year (until January 1, 1996);
- developing countries or countries in transition towards a market economy: 5 years (until January 1, 2000);
- developing countries lacking patent protection in the pharmaceutical area prior to the TRIPS agreement: 10 years (until January 1, 2005);
- least advanced countries: 11 years (until January 1, 2006).
  Let us mention that this transition period was extended until January 1, 2016 by the Doha Declaration adopted in 2001.

The system put in place in 1995 establishes minimum levels of protection that all States are obliged to adopt. These compulsory standard rules are:

- Respect of the Most Favoured Nation clause and of the National Treatment clause, in pursuance of which it is forbidden for one State to grant favours and other opportunities to another State in order to obtain and benefit from patent rights.
- Invention patents should be recognized in all technological fields, including in the pharmaceutical sector. Hence, it is compulsory that pharmaceutical products and processes be susceptible to protection and these should not be excluded from patentability as such.
- Patents must be granted for at least 20 years starting from the application date.

Hence, States are not entitled to grant special protection to medicines: medicines are grouped with usual goods, such as dish washers, cars and other consumer goods, without taking into account their essential, therapeutic and often life saving characteristics. Third parties not authorized by the patent holder will not be allowed to:

- for product patents: manufacture, use, offer for sale, sell or import to that effect the product of interest;
- for process patents: use the process or use, offer for sale, sell or import to that effect at least the product directly obtained by this process.

Patents on processes provide far-reaching monopolies as not only the manner in which a product is manufactured but the product itself is protected by them. If «A» holds a patent on the manufacturing process of a drug x, and if «B» invents a new way to manufacture x, «B» will not be able to manufacture product x without asking the permission from «A» (and «B» will have to pay for it). Let us mention that this provision greatly extends the protection normally conferred by patents on processes, which should not prohibit manufacturing a product by a new process. Hence, process patents grant the same level of protection as product patents. Indeed in both cases payment is due to the holder for manufacturing finished products.

However, considerable freedom is left to States as to the implementation of the minimum levels of protection. They can therefore adopt laws which guarantee a balance between international intellectual property rules and public interest. In particular, it is up to them to define in their legislation what an invention is, what innovation means and industrial applications (conditions for patentability). Article 27 of the TRIPS agreement also states that certain inventions may be excluded from patentability, namely those which should not be marketed «to protect public order or morality, including to protect human, animal or plant life or health»: for example, a State could refuse to grant patents for essential or vital medicines or for antiretroviral drugs but, to date, such a legislation has never been adopted.
On the other hand, States are free to establish regulations that are more protective than the standards defined in the TRIPS agreement.

2.2 What are the States' new obligations imposed by the TRIPS Agreement in terms of patent?

2.3 Why is patent recognition necessary?

On one hand, recognition of their creative work and payment gotten out of their commercial monopoly are supposed to encourage the creators of patented inventions and, therefore, stimulate research. Hence, patents promote innovation (by offering a reward to inventiveness) which, in turn, is supposed to have a beneficial impact on the quality of human life (at least for those who have access to this technical or medical progress).
On the other hand, in return for the protection granted to the patent holder, the latter has to «disclose» its invention, that is to say to describe it in an official document (the patent application). This description has to be clear and precise enough for a professional in the field to be able to reproduce the invention based on these indications. Hence, the technical knowledge base is enriched on an ongoing basis with information on every new patented invention. Future inventors will be able to draw inspiration from this knowledge base for their creations. Trade secrets (manufacturing secrets, industrial secrets...) lack this advantage.
Insofar as nothing is revealed on the invention itself, trade secrets hinder technical progress and do not contribute to increase the global level of inventiveness. The Coca-Cola company, for example, did not patent the recipe of its famous drink so as not to have to disclose all the ingredients used. Its recipe is protected by secret and is therefore protected from exact copies: it has not been released into public domain at the end of a 20 year protection period. As Coca Cola was created at the end of the XIXth century, anyone would have been able to market "genuine" Coca Cola for more than a century now!

Finally, Research and Development in the medical area is very expensive: very large numbers of molecules must be tested before a single of them turns out to be really relevant for the therapeutic effect of interest. Then, the road up to the final arrival of the drug on the market is still very long. Hence, pharmaceutical companies take out patents on the medicines they are developing in order to make sure that they get a return on investment thanks to the commercialization licences which they will be able to grant.

3 The enemy of patents: public health

The generalization of patents in the pharmaceutical sector, brought about by the signing of the TRIPS agreement, allows a better protection of the laboratories and industries designing them. Before international harmonization, pharmaceutical companies with limited financial resources were nevertheless able to meet the majority of population health needs thanks to copies of original medicines or the development of new processes.
As the TRIPS agreement reduces these opportunities, one has to worry about what happens to the quality of access to medicines and health care, in particular in developing countries.
In spite of the agreement the overall population health status should not suffer from these new provisions and lives should not be sacrificed for the benefit of intellectual property rights. For this reason, and as is acknowledged in the agreement itself, public health objectives can be opposed to patent rights.

3.1 What is public health?

The right to health has long been considered as one of the fundamental human rights. Already in 1946, WHO wrote down in its constitution that: «The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition».

In 1948 the Universal Declaration of Human Rights stated that: «Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other cases of loss of means of subsistence in circumstances beyond his control».
Since then a number of other international treaties and resolutions have reaffirmed this essential right to access to treatments and health care.

Public health covers all actions and recommendations relating to the protection of citizens' health at a regional or country level and relying on the community. Hence State authorities must endeavor to guarantee a good overall community health status through the implementation of preventive and repressive laws. That may include, amongst others, the implementation of screening rules, the determination of prevention and treatment methods, vaccination campaigns or the adoption of such concepts as the one of *essential medicines*.

3.2 What is an essential medicine?

On this concept WHO has based, since 1975, its pharmaceutical strategy: essential medicines are, according to the then Director General, «those which are of prime, fundamental importance and which are indispensable to satisfy the population health needs». Because of the pressing needs of these populations, emphasis should be put on the supply and distribution of these medicines. Each State should select the medicines which it deems most important and urgent in view of priority health problems affecting particularly its inhabitants: most States thus establish a national list of essential medicines and refer to clinical instructions to define their health policy.

3.3 How are essential medicines selected?

Essential medicines are selected according to some principles and criteria:

- Identification of the major diseases affecting the country (epidemiological overview based on population monitoring and surveys);
- definition of all the medicines used against these diseases;
- Based on this preliminary list, selection of essential medicines: Several criteria are reviewed for a qualification as such:

    a) Public authorities are certain of the effectiveness and harmlessness of the medicine;
    b) the medicine demonstrates a good «total cost/effective treatment» ratio;
    c) it is available in a form, the quality and stability of which may

be guaranteed (in particular in view of expected storage and usage conditions).

The final lists must be regularly updated by the States in order to take into account therapeutic progress, changes in the epidemiological status, cost of medicines... Since 1997 WHO has been publishing every two years a model list of essential medicines.

3.4 What is the use of the lists of essential medicines?

They constitute a basis for governments on which to orientate their health policy towards a better access to essential medicines. In setting priorities they allow aid to be focused on a broader availability of these medicines at all times and for all inhabitants, which include, in particular, regular supplies and appropriate information. The procurement and distribution of medicines in the public sector, the selection of health insurance reimbursements, the management of donations and of international aid as well as the organization of local production capacities are thus facilitated by the existence of such a guide.

These lists are also widely disseminated in the country health care facilities as well as to all physicians and pharmacists of the public and private sectors. The objective is improved information of all, both professionals and users. Finally they serve as a basis for teaching public health and the rational use of medicines to students and professionals in continuing education.

4 Economic consequences of the TRIPS Agreement

4.1 Obstacle to free competition

This agreement requires that States grant patents on medicines and their manufacturing processes. The existence of a patent provides its holder with an operating monopoly on the drug in question. The «owner» is then the only one to decide who is entitled to produce its drug, commercialize it, import it, ... and under which conditions, in particular pricing policies.

There is a concern that the holder is then (legally) entitled to keep for himself all the market shares he desires or even the whole market:

- either by requesting excessively high financial compensations for licences, so that no partner would be in a position to afford one;
- or by deliberately not granting any licence.

As the unique supply source, the holder will not suffer from any competition and nothing will prevent him from setting the sales price that suits him for his drug. Patents therefore constitute a real danger for the access to medicines: even if manufacturers have no interest in setting too high prices if they want to reach as many customers as possible, most prices will remain largely unaffordable to the populations of developing countries.

4.2 Ban on the production of copies of drugs

A. What is the difference between patented drugs and generic drugs?

Original drugs are patented and sold under brand names by pharmaceutical companies. The term «generic» is used in opposition to this term «patented». Indeed, generic drugs are manufactured from molecules released into public domain at the end of the legal duration of the patent that protected them. A generic drug is the exact replica (copy) of a drug initially patented, which may be freely manufactured by anyone given that the monopoly has expired. For example, Brazil has been granting patent protection to pharmaceutical products only since 1996. Prior to this date, molecules patented in other countries could not be patented in Brazil (because the country did not grant protection to drug inventors). This means that in the past Brazil was free to produce generic medicines from these unpatented molecules.
Similarly, aspirin, which has not been under patent for a long time, may be produced by all the industries that wish to do so. However the term «generic» is often used erroneously. For example, in the context of the parallel imports authorized by the TRIPS agreement, imported drugs do not have to be generics: this may be the case if the drug is no longer patented in the exporting country (import is therefore of interest because prices will be lower), but they may very well be original drugs sold at a lesser price in this country.
Similarly the use of the term «generic» in the context of compulsory licences is not appropriate: the confusion is easy to make because these drugs are copies of original drugs (manufactured under compulsory licences) but they are not generics because, by definition, the patent has not yet expired.

B. Why are generic drugs manufactured?

When a patent has expired, the former holder is not allowed anymore to prevent certain actions of third parties: molecules and basic active principles are free of rights:

- anyone can arbitrarily decide to manufacture and/or market them;
- the former holder is not entitled anymore to obtain a financial compensation for the exploitation of his molecule.

Hence, in essence, a copy is less expensive than the copied material, which constitutes a significant advantage for developing countries. This is actually the reason why most of these countries had not implemented the patentability of pharmaceutical products and processes before the implementation of the TRIPS agreement.

In addition manufacturing generic drugs requires preliminary research to determine the composition, dosage... of the patented drug: this is what is called reverse engineering. This practice, often used in developing countries, enabled them to maintain a research capacity and, hence, to contribute to the ongoing development of their researchers' knowledge as well as to the maintenance of research laboratories and local production units.

C. What does the ban imposed by the TRIPS agreement consist of?

As we have seen, many developing countries used to grant only patents on processes, which allowed them to produce copies of drugs legally, something

that is not possible with patents on products. Copies will no longer be authorized in any WTO member country from the moment the agreement is in force, because they would be violating the monopoly of recent patent holders. The only available medicines will be the ones manufactured and marketed by the latter or by third parties to whom licences have been granted. However, generic production will be legal again once a patent has expired, after 20 years.
Nevertheless and considering the recent progress in terms of HIV/AIDS treatment, this global ban is highly deplorable: new therapies, protected by patents, will not be available as generics before many years. Until then millions of infected individuals will have died because they were not able to afford patented medicines.

4.3 Production cluster in industrialized countries

The pharmaceutical sector of developing countries consists mostly of small, local production units of generic medicines and of underdeveloped Research and Development capacities by lack of financial resources. As the production of copies of patented drugs will be banned once the TRIPS agreement has come into force, developing countries will have to give up this already weak production capital.
On the other hand it is unlikely that they will be in a position to purchase licences from pharmaceutical companies. Since infrastructures are often inappropriate for large scale drug production and manpower is poorly qualified, the upgrading of pre-existing industries seems to be unachievable considering, once more, available resources in these countries. The use of new technologies in recent manufacturing processes will only increase the gap.
As a consequence developing countries will be increasingly dependent on industrialized countries: their drug production down to nothing, they will have to obtain all their supplies from exporting countries, at the prices that these will be willing to consent.

5 TRIPS flexibilities: possible exceptions from patents

The TRIPS agreement provides that exceptions from the monopoly conferred by a patent may be included in national legislations. These exceptions should, of course, remain limited, be explained and justified and they should not unreasonably prejudice the legitimate interests of the patent holder (article 30). States are free to adopt them or not.

5.1 Manufacturing and marketing of products in exceptional circumstances

A. The granting of compulsory licences

1) What is a compulsory licence?

A licence is a contract by which the patent holder authorizes a third party to carry out one or several actions which are normally forbidden because they violate his monopoly.

If company «A» holds a patent on drug x, it is entitled to grant a licence to company «B» authorizing it, for example, to market drug x. The (licence) contract between «A» and «B» defines the conditions under which «B» is authorized to market x. Without this contract, «B» would be making an act of counterfeiting if it decided to sell drug x.

A *compulsory licence* is the authorization granted by public authorities to a third party to use or market a patented invention without the holder's agreement. It is indeed a licence as it is aimed at the (total or partial) licensing of an operating right, however, it is compulsory given that it has not been consented by the patent holder who is compelled to grant it. Even so, the owner receives a financial compensation.

2) What are the circumstances in which such licences may be granted?

States are free to define the reasons justifying the use of these exemptions. The agreement states a certain number of them but the list is not limitative:

- The refusal to negotiate (or to attempt to obtain a voluntary licence): when the holder is not willing to grant a licence with reasonable commercial conditions and that, for example, this makes the procurement of a drug impossible;
- a national emergency situation or other extremely urgent circumstances or a non commercial public utilisation of a drug: when there is an imminent threat to public health, following a natural disaster, a war or an epidemic, for example;
- government use (or authorized third parties): for example in order to secure a fair access to health care and medicines to those most in need;
- anti-competitive practices: in particular, artificial price increases or other abuses of dominant position by the holder;
- the lack or insufficient use of an invention.

B. Exhaustion of rights mechanism

1) What is the exhaustion of rights?

In principle, as for any other commercial practice, the import of a patented product requires prior authorization from the patent holder. This act is part of his monopoly.
However, the law may partially exhaust this right by the so called «exhaustion of rights» mechanism. When recognized by States, this legal theory which has as a consequence that the holder is not entitled anymore to control the movement of his product after it has first been put into the market, be it made either by himself or agreed by him. He is neither entitled to oppose its import in other countries, nor to obtain payment for such use.

Let us assume that a drug x is patented in both country «A» and «B» (both of them recognizing the exhaustion of rights). Company «C1» located

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in country «A» holds a patent on drug x and decides to market it in State «A». Thanks to the exhaustion of rights, company «C2» located in country «B» is free to import drug x from «A» and to resell it in State «B», without the authorization of «C1». This constitutes a parallel import.

This mechanism is justified by the fact that since the patent holder has already been rewarded once for putting his product into the market, he is not entitled anymore to control what happens to his product.

2) Consequences of parallel imports

The advantage arising from this exception is that it hinders patent holders' discriminatory practices in terms of pricing: as the product may be available on all national markets, buyers will get their supplies from the market offering the product at the best price worldwide. This decrease in price has favorable consequences, in particular in terms of health care: drug imports from countries providing the lowest prices lead to an improved access to these medicines for the patients of importing countries.

However, since pharmaceutical companies generally grant lower prices to developing countries, one may fear that they will stop these preferential practices to avoid seeing a significant drop in their revenues from importing countries. A standardization of prices agreed with all partners would follow, which would be very much against their interests.

5.2 Exceptional use of products

In principle and as has been seen before, a patented medicine cannot be commercialized without the holder's authorization: a third party is not free to use the product, for any purpose whatsoever.
However, States can implement exceptions as long they are not unreasonable in view of the holder's exclusive rights: for example, the exception of acts accomplished in private and for non-commercial uses or in cases of unit drug preparations by a pharmacist and on prescription by a physician.
One of the most interesting exception is the so called «Bolar» clause.

A. The «Bolar» exception

By way of this exception the law authorizes generic drug manufacturers to carry out clinical trials on a patented drug without the holder's authorization and that prior to the 20 year protection expiry.
This anticipated use allows them to create the generic drug corresponding to the patented drug and, hence, to organize its manufacturing and marketing as soon as the patented product is released into the public domain.
The fast market entry of generic versions, once patents have expired, leads to a competition between different products: drug prices decrease which improves patients' access to these treatments.

The Agreement on TRIPS allows the countries to bypass the intellectual property rights if the health situation of a country demands it.
This is what Thailand tried to do in 1998: because of the large number of deaths due to an AIDS related sickness, it organized the production of a generic drug capable of treating it. But the United States, influenced by Pfizer (the pharmaceutical firm holding the copyright on the original drug) forbade the commercialisation of this drug, by threatening to tax the Thai most important exports (wood, jewels, microprocessors...) if they did not abandon the production of this generic drug.
South Africa too suffered from the pressure of pharmaceutical firms. In 1997, for instance, it tried to fight the AIDS epidemics hurting its population by passing a law that made use of the flexibility of the Agreement on TRIPS, that could have allowed for the import of generic drugs. But the implementation of that law was blocked (February 1998) by a judiciary action, undertaken by 39 world pharmaceutical firms (among which Boehringer Ingelheim, Bristol-Myers Squibb, Glaxo Wellcome, Merck and Roche). They denounced, as a matter of fact, South Africa for the alleged violation of its international commitments on intellectual property rights; the Pretoria High Court started the hearings on March the 21st, 2001. However, the international pressure forced the 39 firms, on April the 19th, to abandon their charges. Nowadays, generic versions of antiretrovirals are imported from Brazil, but the South Africa situation is far from being solved.

6 Prospects

6.1 Remainder: the difficult implementation of the Agreement on TRIPS

6.2 What is the position of the international community with respect to drug access?

Confronted with the numerous difficulties created by pharmaceutical firms, the international community found it necessary to clarify which were the countries' rights with respect to intellectual property rights.
In November 2001 the WTO member countries adopted a Declaration in Doha (Qatar) on the Agreement on TRIPS and public health. This declaration was meant to answer the preoccupations that had been expressed, on how that accord could have made the access to certain drugs more difficult for patients from poor countries. It constituted a real victory for the developing countries that had expressed those preoccupations, as it strongly advocated an efficient use of the flexibility of the Agreement on TRIPS for what regards the bypassing the intellectual property rights on drugs.
As a matter of fact the international community recognized that, while the obligations defined by the Agreement on TRIPS had surely to be implemented into the ensemble of national laws, they should never compel countries to work against the objectives and priorities that they have defined on public health and drug access. Therefore, a country could authorize the violation of some intellectual property rights in special circumstances, defined autonomously and related to public health (for instance, in case of national emergencies or other situations of extreme need).
The Doha Declaration therefore affirms that public health has precedence over intellectual property rights, and besides encourages the different countries to make use of this disposition.

6.3 The after-Doha: can a country import drugs, when it is unable to produce them under a compulsory licence?

In November 2001 the WTO member countries had agreed, in their Declaration on the Agreement on TRIPS and public health, that the problems of public health and drug access should have precedence over intellectual property rights.
However a subsidiary question was left open. The principle of compulsory licences was certainly confirmed: this principle allows countries in need to organize the production of drugs needed, in particular in case of health emergencies. But the agreement limits this right to the needs of the national market: drugs produced under a compulsory licence should not be exported to another country. Hence the following difficulty crops up: how could countries unable to produce their own generic copies satisfy their needs if they cannot import the drugs? As a matter of fact those countries are just the very countries which need cheap drugs the most.

The problem is two-fold: there will be countries that have a strong need for drugs, but cannot produce them for lack of materials, suitable industrial compounds and financial funds; and there will be other counties which, on the contrary, possess those instruments but cannot produce the drugs for lack of a large enough internal market. Supply and demand cannot match in such national markets, but calls for the two national markets to join, so that people in need could have access to some essential drugs.

This question should have been solved before the end of 2002 by the WTO member countries. A compromise draft agreement (called «de Motta») was prepared under the control of rich countries – the United States and the European Community – and accepted by developing countries under strong pressure. But it was a text largely against their own interests, as it contained a reinforcement of administrative procedures, limitation of the compulsory licences to certain listed diseases, exclusion of all vaccines and other sanitary hardware other than drugs from the licences. Anyway the United States refusal to abandon the establishment of a 'diseases' list' led later on to the abandonment of the text; finally no international agreement was reached.
An agreement was indeed reached on August the 30th, 2003. It recognized the right of member countries to import compulsory licensed drugs, should they be unable to produce them; but at the same time it was inadequate to the needs of developing countries. It even reduced the rights acquired under the Doha Conference agreement, by establishing, for instance, the need of simultaneous licensing of the exporting and the importing countries, by introducing constraining procedures, by allowing for possible opposition from other countries when a compulsory licence was implemented, and so on.

The Cancun Summit that followed the above mentioned agreement (September 10th to 14th), during which problems other than drug access were also discussed, did not produce any new agreement either; it should have constituted a mid-term assessment of the Doha Agenda, but in the end the commercial negotiations were interrupted.

Therefore, at present we can really doubt the efficiency of negotiations at the international level, in particular for the developing countries which, when unable to resist the pressure from the rich countries, are forced to accept agreements that go against their own interests.

6.4 After Cancun: bilateral agreements

Now a new tendency can be noticed. Since 2002, the United States and the European Community have preferred the signing of bilateral conventions with developing countries. These free-trade agreements allow rich countries to obtain, from developing countries, concessions that they would be unable to obtain through WTO negotiations. They can offer more enticing promises, and thus obtain that developing countries abandon their rights on the limitation of intellectual property rights.

A free-trade zone is an area composed of several countries, inside which quotas and other custom duties are eliminated. Trade among those countries is therefore totally free, with no obstacle to the free circulation of goods, services, capital and persons.

These agreements provide some new opportunities to developing countries, but, however, are an instrument for rich countries which can ask poor countries to adopt complementary measures that are favourable to the former, in particular for what regards intellectual property rights. As a matter of fact these agreements cover many various fields, but always contain a section on property rights. Against the promise of trade opportunities rich countries obtain from poor ones changes in their laws that make intellectual property rights even more constraining that those implied in the Agreement on TRIPS: protection periods extended to more than 20 years, protection of data relative to the experimental phases... (this last point cancelling the possibility of asking for a compulsory licence, as the local production units will be unable to copy a drug as they cannot be informed on the production techniques of the original one).

At present the United States are negotiating with several countries (from Central and South America: Chile, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua; from the South of Africa: Botswana, Lesotho, Namibia, South Africa, Swaziland; from the South of Asia: Singapore, Thailand; and others); several bilateral agreements have already been signed.

As an example the fee-trade agreements between the United States and Morocco, signed March 2nd, 2004, after more than a year of negotiations; this agreement largely restraints the possibilities for Morocco to ask for compulsory licences. Morocco was thinking of organizing a compulsory health insurance in order to optimise drug access and health care. Now it has to lower its objectives, and its national pharmaceutical industry, which at present second among the African countries, is expected to decline rapidly.

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Abbreviations and acronyms

(The abbreviations and acronyms are translated and presented in three languages in the following order: French/English/Spanish)

ADPIC/TRIPS/ADPIC	Agreement on Trade-Related Aspects of Intellectual Property Rights.
ARV/ARV/ARV	Anti Retro Viral (treatment).
BM/WB/BM	World Bank.
CA	Turnover.
EU/USA/EU	United States of America.
FMI/IMF/FMI	International Monetary Fund.
G8	The Group of Eight (G8) coalition of eight countries among the twenty richest countries of the world: Canada (admitted in 1976), France, Germany, Italy, Japan, the United Kingdom, the United States of America, and the Russian Federation (admitted in 1998).
GATT	General Agreement on Tariffs and Trade.
MSF	Médecins Sans Frontières.
MST/STD/DST	Sexually Transmissible Diseases.
OCDE/OECD/OCDE	Organization for Economic Cooperation and Development.
OMC/WTO/OMC	World Trade Organization.
OMS/WHO/OMS	World Health Organization.
ONG/NGO/ONG	Non Governmental Organization.
ONUSIDA/ UNAIDS/ONUSIDA	United Nations programme on HIV/AIDS.
PAS/SAP/PAE	Structural Adjustment Programme.
PED/DC/PVD	Developing Country.
PI/IP/PI	Intellectual Property.
PIB/GDP/PIB	Gross Domestic Product.
PMA/LAC/PMA	Less Advanced Country (designated as such by the United Nations Organization and at present numbering 50).
R&D/R&D/I&D	Research & Development.
SIDA/AIDS/SIDA	Acquired Immuno Deficiency Syndrome.
UE/EU/UE	European Union.
USD	American dollar.
VIH/HIV/VIH	Human Immunodeficiency Virus (causing AIDS).

Glossary

Patent
Legal title granted by a state or by a group of states in a regional patents office (OAPI, ARIPO) for its only territory, assuring a monopoly for a limited duration (in general 20 years) for the production, sale and importation of an invention on its national territory. It is a right of intellectual property on an invention, either for a product or a process likely to lead to an industrial application. After the limited duration the invention "falls into the public domain" and can be exploited by anyone without an authorisation.

Patented medicine
Medicine manufactured and sold exclusively by the laboratory holding the patent and marketed under a brand name. The first patents for antiretroviral drugs of the first generation will expire in 2007, the third generation ones in 2013.

Patent of product vs process
In the pharmaceutical sector a process for obtaining a molecule can be patented but also a molecule itself. It is then possible to block any marketing of this molecule even if it is obtained through a new process.

Generic medicine
1) Copy of an original medicine made possible by the arrival of the initial patent in the public domain at the end of the legal protection period or because it never was protected by a patent. It is thus possible to produce and use it under its common international denomination (CID which corresponds to the molecule's chemical name) at a price lower than that of a brand name medicine.

2) Medicine marketed outside of a patent monopoly. When a patent is not registered in a country copies of the medicine are found which are commonly referred to as generics even if they can sometimes benefit from a brand name.

Essential medicines
Definition by WHO, in WHO(2002)
«Essential medicines are those which satisfy the first needs of a population in terms of health. They are chosen taking into account their usefulness in public health, the data on their effectiveness and harmlessness and their cost/effectiveness with respect to other medicines. Essential medicines aim at being available at any time within the framework of functional health systems, in a sufficient quantity, in an appropriate form, with an assured quality, accompanied by an adequate information notice and at a price accessible for individuals and communities. It is up to every country to determine which are exactly the medicines which are deemed essential.» (WHO(2002)). From 1997 there is a (*Model List of Essential Drugs)* worked out and regularly revised by WHO so as to guide the elaboration of national lists. Let us remark however that there are medicines which are considered essential from the health point of view but are excluded from the WHO list because of their high cost, as e.g. antiretroviral drugs.

Parallel imports (of medicines)
Imports of patented medicines in a third country (e.g. which does not have a production laboratory) at a price lower than that conceded by pharmaceutical firms to certain countries. Such imports take place within the framework of rights depletion: after a first licit marketing of a patented product in a country any import of this product in another country (in which it is also patented) is possible even without the consent of the patent holder. These imports are not authorised in countries which do not recognise the theory of rights depletion, in which only the patent holder has the right to import a patented product. Let us note that within the European Union parallel imports are largely used and considered as an efficient way of reducing prices. On the other hand from the creation of WTO the American government has adopted an aggressive position against these imports.

Voluntary licence
Authorisation for the production, sale and import of a product by a patent holder to a firm or a government. It is a kind of a negotiated contract which can include an obligation (e.g. like the payment of a discretionary sum for the purchase of the licence).

Compulsory licence
Administrative legal procedure included in the TRIPS Agreement through which a governement issues a licence authorisation for a patent. The judiciary or administrative authority thus authorises the production, sale and import of a product without the permission of the patent holder. So in an emergency situation a state can manufacture a product without abiding by the ordinary patents right. At the time of the Doha Declaration it was proposed that emergency situations in public health be part of these exceptions but establishing a list of emergency diseases remains problematic. Moreover these exceptions only apply to countries which have the capcity to produce generics and the fate of numerous countries which have great needs for medicines but no production capacity remains problematic. Finally let us note that the United States and the European Union correspond to the two regions of the world that issue most compulsory licences.

Index

Intellectual property and access to medicines

Impact of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) over access to essential medicines

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The Member States of the World Trade Organization (WTO) signed the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights). This Agreement contains in particular the restrictions related to patents on medicines and the extension of their duration. All member states are concerned, and even the poorest ones are included. WTO membership of a country and the application of the Agreement impose a compliance of the national legislation which often proves very demanding through lack of professional, financial and infrastructure resources. Undergoing the pressures of rich countries and pharmaceutical groups the governments of developing countries sometimes find themselves shackled and do not use the flexibilities foreseen in the Agreement to their advantage, what makes the health situation of their population still more precarious.

This document presents the TRIPS Agreement to non specialists and proposes that they read it critically. Accessible to all it is intended in particular for the persons active in the health sector and health policy. The main actors and important phases of the Agreement negotiation are described, as well as the different adapations made under the conflicting pressures of the numerous protagonists. Explanations on the mechanisms in play and the possible consequences of the coming into force of the Agreement are given. Through case studies the problem complexity is shown and also the disastrous consequences on the public health or the development of a country when its leaders care little about the well-being of its population.

This booklet was designed as a tool of awareness and can serve as a basis for discussion by theme, according to the specific interest of each reader. Numerous references can be found, among which those of the official work of the World Health Organization (WHO) on this topic, as well as those of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) and of the South Centre.

The Centrale Sanitaire Suisse Romande (CSSR) is an NGO which finances and carries out projects in the field enabling the development of access to health care for populations of certain developing areas. Its objective is to reduce social, political and economic injustice which prevents an equitable access to the necessary conditions for a healthy life for poor and dominated populations.

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