

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 investment¹⁰.

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 generics¹² 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.

1. Context

1.1 History and status

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 population¹⁴. 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's¹⁷ 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's¹⁸. 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's²¹ 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 Asia²². 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 2001²³. 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 Bamako²⁸ 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 availability of medicines but also the prices and availability 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 management».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 medicines³². 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\$ each³⁴. 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 nineties³⁶.

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 (CIPRH) 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 Initiative⁴⁰ (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 Doha⁴¹ 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 Council adopted the decision. The derogation remains in force up to this date.

2006 In April publication of the CIPRH 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

1.2 Description and explanations

1.2.1 The TRIPS Agreement

“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.

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 deferred 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.

The Ministerial Doha Declaration on the TRIPS Agreement and public health was made during the WTO Ministerial Conference held in Doha in November 2001⁴³. 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 manoeuvring 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 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.

1.2.3 Why some States do not use compulsory licences

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 structures).

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.

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 be authorized first for the domestic market⁴⁵ *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?