

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 Case studies

3.1 Introduction

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 users¹³⁹. 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 previously¹⁴⁰. 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/lib.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 programming 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 foreseeable 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 consultations¹⁴¹. 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.

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 income¹⁴². 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 country¹⁴³, – claimed by the *Movimento sanitaria*,

3.3 Brazil

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/lib.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/AIDS¹⁴⁴. In 2003 the access to antiretroviral medicines touched 135000 patients¹⁴⁵. 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 report¹⁴⁶, 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 Kaletra¹⁴⁷ 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 medicines¹⁴⁸.

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 Mercosur¹⁵⁰, 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 vaccines¹⁵¹.

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 pharmaceutical 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 circulation¹⁵². 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 suppliers¹⁵⁵.

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 Pdvs (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 energy¹⁵⁷.

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 globalisation¹⁵⁸? For the Urugayan journalist Raúl Zibechi¹⁵⁹, 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.

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 drugs¹⁶⁰ 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 medicines¹⁶². However new products can be

¹⁵⁸ Lander (2004).

¹⁵⁹ Zibechi (2005).

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

3.4 Canada

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 necessity 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 development¹⁶³. 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 government 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

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 diseases¹⁶⁴ 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 world¹⁶⁵.

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

¹⁶⁴ Carroll (2004).

¹⁶⁵ Other informations are found in Acharya *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 Boys¹⁶⁶.

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 world¹⁶⁷. 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 governments how to «negotiate well» with the USA. For this reason and as a «model to imitate» Chile participates actively in the negotiations for creating FTAA¹⁶⁸. 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) brand¹⁶⁹ 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, Bahrein, 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.

- 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 ASILFA¹⁷⁰, 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 Chileans¹⁷¹.»

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 countries¹⁷². 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 jobs¹⁷⁵.

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 Agreement¹⁷⁶.

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 product¹⁷⁷.

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 protests¹⁷⁸ 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 necessity¹⁷⁹.

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 extended¹⁸¹. 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 Act¹⁸².

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 productivity¹⁸⁴.

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).