From TRIPS to "TRIPS Plus" provisions.

Patents protection and public health promotion in developing countries: raising the stakes for drugs accessibility.

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1. Introduction

According to the latest UNAIDS estimation (2008), about 33.2 million people are living with HIV/AIDS in the world in 2007, mostly in developing countries. More than 2.5 million people were newly infected this year and 2.1 million people died of AIDS. Due to prevention programme and changes in behaviour, the epidemic seems to peak in the 90s. Yet, the Sub-Saharan region still bears the largest burden with 22 million people infected. Zimbabwe, Namibia, South-Africa, Botswana, Lesotho, Swaziland and Zambia are particularly hit by the epidemic where between 15 and 26% of adults are infected by HIV/AIDS. Beside, due to the demographic factor, more and more people are infected and prevalence rate are growing in East and South-East Asia. Today, 4.9 million people live with HIV/AIDS in this region, especially in India and China. Concerning Latin America, 1.7 million adults and children are infected.

Whether no vaccine exists to cure the infection, about a score antiretrovirals (ARVs) treats the infection and enables people to live with the infection. Among the first drugs available, AZT was used to treat the infection and prevent the transmission from mother to child during the delivery. Since the 80s, many treatments were developed to treat HIV/AIDS. Significant improvements have been made since the single therapies developed in the late 80s to the multi-therapies recently developed to overcome the occurrence of resistance to treatments. Nowadays, patients benefit from single, bi and tri-therapies, suffer less from resistances and improve the quality of their everyday life.

Accordingly, the access to ARVs has become crucial in developing countries where the epidemic causes dramatic socio-economic impacts as estimate the micro and macro-studies released on households and economic growth (Over, 1992, Ainsworth, 1993, Bonnel, 2000, Dixon & alii, 2001, Drouin & al., 2003). On the whole, the HIV/AIDS epidemic reminds that the accessibility issue is not new in developing countries. Since the 1970s, the World Health Organization (WHO) has been working for the *"right of all to health"* by essentially increasing the access to essential drugs for people in poor countries. In this perspective, the first list of essential drugs was laid down in 1977. The list elected the least expensive products that could cure the most predominant diseases in developing countries. Since then, drug is defined as a specific and essential good, which had to be made accessible for the greatest number at a reasonable price. To specifically achieve the accessibility to medicines for patients infected by HIV/AIDS in developing countries, the WHO and the United Nations for AIDS (UNAIDS) have launched the "3 by 5" initiative in 2003. The goal is to provide ARVs to three million infected people in low and middle-income countries by the end of 2005. It is a step towards the larger goal of ensuring universal access of HIV/AIDS treatments for all who need them as a human right in poor countries where national health coverage are definitely lacking.

For that reason, the WHO issues and revises comprehensive guidelines for a public health approach of ARVs procurements in countries where resources are limited (WHO, 2006). Concretely, in those guidelines, every public health authorities can find information about when beginning an anti-AIDS treatment, which first line regimen may be the more suitable for adolescents, adults or pregnant women regarding mainly the potency of all therapies, their side effects and their prices. WHO indicates also when patients must switch to another therapy because of resistance to a first line regimen or intolerable side effects. Tri-therapies are highly recommended since drug resistances are notably reduced.

Yet, the access to medicines in developing countries hit by dramatic epidemics such as HIV/AIDS actually questions the patent status of these life-saving drugs. Therefore, the recent evolutions of intellectual property rights (IPRs) regimes in the world matter. Accordingly, the paper intends to discuss the influence of IPRs evolution on drug accessibility in developing countries. Precisely, building on a review of the two main sources of IPRs evolution in the world, i.e. Trade Related aspects of Intellectual Property rights (TRIPs) agreement and the USA Free-Trade Agreements (FTAs), the paper indicates how international agreements may seriously undermine accessibility and affordability in developing countries. The argument stresses on the fact that many provisions may help to extend market exclusivity holds by firms, prevent the competition of generic makers and at last defer the launch of more affordable medicines in developing countries.

The objective, principles and flexibilities of the TRIPs agreement will be first presented (§2). Beyond the obligation to settle a strong IPRs regime, concerns about public health are expressed and flexibilities are provided for circumstances where drug accessibility is crucial, especially in developing countries. Then, the content of some USA FTAs will be examined. In particular, the provisions devoted to patent extension and generic competition prevention will be listed as means that may roughly damage drug accessibility. Finally, some evidence concerning the link between IPRs regime, competition and drug accessibility will be reminded. Building on Indian case studies, elements about the drastic decrease of ARVs prices due to the generic competition will be related. Besides, impediments to the supply of affordable ARVs in Thailand will be described.

2. The strengthening of IPRs regimes: from TRIPs agreement to Doha ministerial declaration

Since decades, IPRs regimes have been reinforced in the world. Mostly, ratified in 1994, the TRIPs agreement is progressively implemented in developing countries, members of the World Trade Organization (WTO). In the pharmaceutical sector, this agreement sets up a strong IPRs regime by providing patents for both process and product, extending the duration of patent to 20 years at least and its geographical coverage to all members of the WTO, including developing countries (Nogues, 1990, Desterbecq & Remiche, 1996, Abbott, 1996, Boulet & Velasquez, 1999, Correa, 2000). Accordingly, national patent laws must be amended to be compliant with TRIPs provisions.

2.1. TRIPs agreement: objectives and principles

In the early 1980s, arguing that regulatory delays reduced the effective life of patents, the US pharmaceutical industry began to plead for the extension of the patent term. In 1984, the USA acceded to the request of the pharmaceutical industry by increasing patent duration to 20 years after filing for a patent[1]. Europe initiated a similar trend a few years later, following the French example. In 1990, France instituted the *Certificat Complémentaire de Protection* (complementary protection certificate), which extended the patent duration by 5 years at the most. In 1992, Europe adopted likewise the *Certificat Communautaire* (EC certificate), extending the duration of patents by maximum 5 years (Mfuka, 2002).

Besides, an increasing number of studies underlined the prejudices that the pharmaceutical industry seemed to bear. The attention was focused on the increasing costs of R&D programmes. Millions of dollars were required to take a drug from the research on the therapeutic qualities of a molecule up to its launch on the market (Grabowsky, 1982, DiMasi & alii, 1991, Goozner, 2005). Developing countries were so under pressure from developed countries. For instance, India was accused of piracy, which prejudices multinationals' profits and endangers the development of new drugs[2]. Developed countries intervened through forums that governed international trade to push developing countries to reinforce patent protection. Yet, India and Brazil were fighting to avoid negotiation about IPRs during the Uruguay Round. Unfortunately, in 1986, the Member States agreed to launch a negotiation programme on several trade policy issues, including trade in services and IPRs.

The Uruguay Round lasted 8 years and ended in April 1994 with the establishment of the WTO and the ratification of the TRIPs agreement in Marrakech. Any member (or country who wishes to join the WTO) must submit to its rules and observe the content of this agreement. Otherwise, contraveners may be subject to trade sanctions.

The WTO primarily lays down that the **objective** of the TRIPs agreement is to implement international minimum standards for the protection of intellectual property (Velasquez & Boulet, 1999, Raizada &

[1] Or 14 years after obtaining marketing approval.

[2] The accusation was fallacious, since these were, in reality, legal activities allowed by a weak IPRs system under which for instance patents were provided only for process.

Sayed, 2002). Thus, the agreement does not set-up a single and universal IPRs system: members have to respect these minimum standards through the ways and means they choose and they are free to adopt a more stringent regime than the one required by the TRIPs agreement (Article 1).

Further, there is no *"absolute and unique obligation"* in this objective (Velasquez & Boulet, 1997). On the contrary, WTO acknowledges the need for members to meet objectives regarding development and public health. Accordingly, the protection of patents has to fall within a national space in which governments are responsible for meeting these objectives. Thus, patent protection *"should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to ensure a balance of rights and obligations"* (Article 7).

It follows that members can legislate in respect of **principles** such as the promotion of *"public health, (...), and public interest in sectors of vital importance to their socio-economic and technological development"* (Article 8-1). Similarly, they can exercise "*appropriate measures" to "prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."* (Article 8-2). The TRIPs agreement is therefore not merely governed by an unconditional protection of IPRs.

Article 27 prescribes what is **patentable** and what is not. It states that *"patents shall be available for any inventions, whether products or processes in all fields of technology"* (Article 27-1). Henceforth, it is no longer possible for a country to exclude products or specific industrial fields from patentability. Further, patentability criteria are fixed: products or processes must be "*new, involve an inventive phase and can be used for industrial application"*. Besides, criteria for patentability exclusion are defined such as the protection of *"public order or morality"* and *"serious prejudice to the environment"* (Article 27-2). Finally, "*diagnostic, therapeutic and surgical methods for the treatment of humans or animals"* are not patentable (Article 27-3).

In addition, process and product patents will be valid for at least 20 years, beginning with the date on which the application was first filed (Article 33). The patent holder obtains a monopoly over the use of his (or her) innovation for a period of 20 years. Concretely, drugs discovered and patented after 1995 can be patented in WTO's Members States. In case of a dispute, the onus is not on the patent holder to prove the validity of his (or her) patent (Article 34). The "copier" would have to bring in such a proof.

Article 27 forbids members from resorting to discrimination in the issue and use of a patent by its holder. In respect of the National treatment principle (Article 3), the use of a patent shall be possible *"whether products are imported or locally produced"*. The notion of ***"working patent"*** widely adopted in developing countries is therefore weaken in the TRIPs agreement. For instance, the Indian patent law prescribed till recently that local production could only validate the effective use of a patent, and patent holders were thus required within three years to exercise their rights through an effective local production. Otherwise, patents could be revoked (Guennif, 2004).

As TRIPs agreement intends to implement an adequate protection of IPRs that fits with the public health priorities of developing countries and the dissemination of innovation in the world, they provide flexibilities. Patents may be circumvented in particular circumstances.

2. 2. Flexibilities provided by the TRIPs agreement

First of all, whereas developed countries have implemented TRIPs agreement since 1995, a **transitional period** is granted to developing countries (and eastern countries undergoing a transformation towards free-market economy) (Article 65). Later, the transitional period has been fixed to 2005 for developing countries such as India, China and 2015 to least developed countries. However, this transitional period can be extended *"in view of the special needs and requirements"* and merely *"their need for flexibility to create a viable technological base"* (Article 66-1). Accordingly, for instance African countries will have to cope with TRIPs requirements at last in 2015 if the transitional period is not extended[3].

In accordance with the principles of the TRIPs agreement, a country may override patents in order to promote public health objectives, such as access to medicines. *"In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use"* (Article 31b) or

[3] In detail, the transitional period is not that favourable since it concerns developing countries where till 1994 no patent law provided patent for product and process in the pharmaceutical sector. In other words, as part before 1994 of an international agreement under which patents are acknowledged for process and product, a country may suffer from a shorter transitional period.

"to remedy a practice determined to be anti-competitive" (Article 31k), a country may use the rights conferred by the patent, without any authorisation from the holder. But the patent holder may be informed of the country's intention to use these rights within a reasonable time frame and may be adequately compensated. Consequently, in the event of an HIV/AIDS, malaria or even tuberculosis epidemic, or/and given the prohibitive prices or inadequate quantities provided, a country can issue a **compulsory licence** (CL). There would be no need to try and seek a voluntary license (the voluntary transfer of rights against royalties negotiated between actors). A CL can be used by a public organisation or a private firm. A country may authorise a government agency or a private firm to produce a drug to deal with a national emergency and supply the generic version of a medicine available finally at lower price and/or greater quantity. The agreement acknowledges also that States have full discretion to define what a national emergency is.

According to the TRIPs agreement, a patent owner has the right to manufacture, use, offer for sale, sell or import his (or her) product (Article 28a). He (or she) also has the right to transfer these rights through licensing contracts (Article 28b). The right to import is governed by the principle of rights exhaustion under which a patent holder may lose or exhaust certain rights. The principle covers three scenarios:

- First, national exhaustion entails the limitation of the right of goods circulation in a country. If the patent owner accepts the marketing of his (or her) product in a country, national exhaustion forbids any export of the product to another country.
- Second, regional exhaustion calls for the limitation of the right of circulation of the product in a region. If the patent owner agrees to market his (or her) product for example in the European Union (EU), regional exhaustion would limit the product's circulation within the EU. Export of a product from one member country to another member country would be lawful. On the other hand, exports from a member-country to a country outside the EU would be prohibited.
- Third, international exhaustion does not call for any limitation on the flow of the product. Once the patent owner has accepted that his (or her) product be marketed in a country, international exhaustion authorises its export to any other country.

In case of international exhaustion, **parallel import** (PI) is so lawful. A country "A" can purchase a drug from a country "B" if the price of the drug is lower in that country. Precisely, if the suitable principle is adopted in the two countries to permit PI in country "A" and parallel export in country "B". In case of regional exhaustion, countries "A" and "B" must belong to the same region: the EU, the African Regional Industrial Property Organization (ARIPO) for East Africa, the African Intellectual Property Organisation (AIPO) for West Africa, the North American Free Trade Agreement (NAFTA), the Association of South-East Asian Nations (ASEAN), and so on. Also, the principle of PI is a regulatory measure that makes it possible to fight against anti-competitive and discriminatory practices, extensively condemned by the WTO, for restoring competition, especially when the prices are deemed prohibitive and/or the quantities available are determined to be inadequate.

The TRIPs agreement does not give any prescription concerning the principle that members may choose: *"nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights"* (Article 6). Members have free scope to specify the principle of exhaustion that they wish to adopt in order to fight against anti-competitive practices and promote public health. There are animated debates about the principle members should adopt. On the one hand, international exhaustion is viewed as a mean that may enable members to fight against anti-competitive practices and facilitate people's access to treatments by proceeding with PI. On the other hand, it may be feared that international exhaustion may induce firms to opt for a single price strategy for fighting against PI. In this way, firms prevent undesirable parallel exports from countries where a product is marketed at low price to countries where the product is marketed this time at higher price. Rationally, this single price would be close to the one prevailing in developed countries, whence an upward revision for developing countries. Finally, some recommend national exhaustion.

At the end, the TRIPs agreement stipulates a number of things: patents can be provided for products and processes for at least 20. However, several points remain vague, left to the discretion of members: the definition of a national emergency or the principle of rights exhaustion adopted for instance.

2.3. The Doha declaration: public health must prevail over IPRs

Given the difficulties and pressures encountered by developing countries in making effective use of flexibilities provided by the TRIPs agreement, due for a part to the imprecision and ambiguity

surrounding some provisions, members reaffirmed at Doha their commitment to the principle of IPRs protection as the driving force behind innovation by recognizing that *"intellectual property protection is important for the development of new medicines"* (Article 2 of the Doha ministerial declaration).

Then, the principle following which IPRs protection was subordinate to the principle of public health was reiterated: *"We agree that the TRIPs agreement does not and should not prevent members from taking measures to protect public health", (….), "Accordingly, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all"*. (Doha Ministerial Declaration, paragraph 4). Thus, the possibility for members to recourse to PI and CL in case of national emergencies, and the sole discretion to define what *"constitutes a national emergency"* was strongly reaffirmed (Paragraphs 5b and 5c). On the one hand, members are free to establish their own exhaustion principle for IPRs (Paragraph 5d) and to settle the scope of the practical resort to PI. However, on the other hand, faced with the objections raised by African countries, which were unable to grant CL due to insufficient or null manufacturing capabilities in their territory, the ministerial WTO conference held at Doha instructed members to find a solution before the end of 2002 (Paragraph 6).

In August 2003, a few months before the Cancun summit, an agreement was reached. An additional flexibility was introduced: the possibility for members to import medicines under CL. Thus, a country like Tanzania can issue a CL and ask a firm established in a third country to manufacture the drugs and export them to its territory enabling it to deal with a national emergency. Strict conditions were set out: a predetermined production volume, unequivocal identification of products, notification of these conditions and the country of consignment as well as adequate remuneration to the patent owner as provided by the TRIPs agreement (in Article 31h).

Yet, the issue of innovation dissemination in the world and especially technology transfers to developing countries is still questionable. Possibly, the implementation of a global minimum legislative framework for the protection of IPRs ensures on one side firms to recover the resources invested in the development of new medicines (Arrow, 1962, Demsetz, 1967, Grabowsky, 1982, Mansfield, 1986, Levin & al., 1987, Scherer, 1998, Cohen & al., 2000, Crampes, 2000). As a consequence, a strong IPRs regime is considered to uphold innovation and favour the rising of social welfare through the supply of new drugs (Cutler & MacClellan, 2001, Grabowski, 2002, Lichtenberg, 2002, NIHCM, 2002). On the other side, technology transfers may be promoted and provide developing countries with new technical and therapeutic innovations (Mansfield, 1994, Saggi, 2000, Correa, 2001, Lall, 2003, Maskus, 2004, Correa, 2005, Maskus & Reichman, 2005, Gallagher, 2005).

However, compared to practical tools implemented to protect the rights of patents holders, in the field of technology transfer intentions are governing. Article 66-2 of the TRIPs agreement notes that *"developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base".* Besides, the paragraph 37 of the Doha Declaration agrees *"to an examination, in a Working Group under the auspices of the General Council, of the relationship between trade and transfer of technology, and of any possible recommendations on steps that might be taken within the mandate of the WTO to increase flows of technology to developing countries"*. With the forbidden of any working patent provision, there is virtually no tool that may foster the dissemination of innovation and the transfer of technology towards developing countries.

While animated debates govern the progressive implementation of TRIPs agreements in developing countries and high concerns are expressed about the way those countries should amend their law in a way that favours the full use of flexibilities provided by the agreement, attention is more and more focusing on the distinct path followed by the USA. For the past five years, far from the logic of "*multilateralism*" followed by the WTO, numbers of USA FTAs are being signed with the perspective to undermine severely the capability of developing countries to benefit from TRIPs flexibilities, and so promote public health and access to medicines.

3. Free trade agreements: drugs accessibility under higher standards

Definitely, TRIPs agreement results for developing countries in significant loss of policy regarding drug accessibility. Before the ratification of this agreement, patents were not granted for product in most of developing countries. Cheaper generic drugs could be manufactured in those countries. However, flexibilities exist: to ensure drug accessibility whenever national emergency or anticompetitive practices arise, developing countries can issue a CL or permit IP. Beyond the vivid discussions about the impact of TRIPs agreement on socio-economic development and especially access to medicines in developing countries, numbers of bilateral and regional FTAs between USA and other developing countries are expanding. Their content drive commentators and analysts from different fields to qualify them as "TRIPs plus" agreements; the IPRs regime implemented under the aegis of the WTO is notably strengthened in FTAs.

3.1. Bilateral and regional USA Free Trade Agreements

For the past five years, numerous FTAs were signed and others are about to be signed between developed and developing countries. In particular, USA has negotiated and is currently negotiating bilateral and regional agreements with developing countries. A bilateral agreement was settled with Jordan in 2000. Two other bilateral agreements were signed in 2003 with Singapore and Chile. Then Australia, Bahrain and Morocco reached a bilateral agreement with USA in 2004. During 2006, bilateral agreements were signed with Oman, Colombia and Peru. Other bilateral agreements are under discussion with Panama, Thailand, United Arab Emirates, Malaysia or Korea as recall the demonstration organised here and then by the civil society or the comments made by public authorities to complain on the content and the impact of such agreements.

Also, regional agreements have been settled. Since the trade agreement signed between Mexico, Canada and USA in 1993 (refereed to as the North American Free Trade Agreement, NAFTA), other regional agreements were negotiated or are presently negotiated. Especially, the US-Central America FTA (CAFTA) was reached in December 2003. The agreement involved the US, Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua. In parallel, the USA separately negotiated a bilateral agreement with the Dominican Republic, with a view to folding the deal, and the country itself, into the US-CAFTA scheme.

Others regional agreements are under discussion. Since 2003, a FTA between US and the Southern African Customs Union (SACU), composed of South Africa, Botswana, Namibia, Lesotho and Swaziland, is negotiated[4]. Besides, negotiations have been launched since 2004 to reach a regional FTA with the Andean countries of Colombia, Peru, Ecuador and Bolivia. Since then, five rounds of negotiations have taken place with Colombia, Peru and Ecuador. And ongoing negotiations between the USA and the United Arab Emirates will serve to promote a regional FTA, the Middle East Free Trade Area (MEFTA) initiative to "advance economic reforms and promote trade among countries in the Middle East and the Persian Golf" as ensured invariably USA trade representatives. For the moment, USA is expanding deepening economic ties through Trade and Investment Framework Agreements (TIFAs), Bilateral Investment Treaties (BITs), and comprehensive FTAs with countries like Egypt, Kuwait, Qatar, Saudi Arabia, Tunisia and Yemen.

To sum up, USA is leading at the same time negotiations with developing countries through bilateral and regional FTAs with the purpose of implementing FTAs on the largest geographical scheme. Accordingly, the bilateral and the close regional agreements signed or negotiated between USA and countries from Latin America should help to implement in the future the larger Free Trade Area of the Americas. In the same vein, in order to uphold a regional agreement with the Association of South-East Asian Nations (ASEAN), US are expanding the number of FTAs signed and actually negotiated with members of the association. The ten-members of the ASEAN (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam) represent collectively the fifth largest trading partner of the USA. In order to achieve this large regional agreement, the USA intends hence to develop a network of bilateral FTAs with ASEAN countries.

In other words, every time, negotiations within a regional agreement become difficult, bilateral links with one or more partners of the regional FTA are activated in order to build various bilateral agreements that may be folded into a larger agreement. And more and more developing countries are

[4] Founded in 1969 and based on custom union arrangements, the SACU aims to promote economic development for the Southern Africa area. Since 1994, SACU's trade with the US has grown more than 300 percent. It exports to the US amounted to US$ 1.7 billion and imports to US$ 2.5 billion in 2002.

signing trade agreements with USA on a bilateral basis and/or a regional basis; the list given above is not exhaustive.

3.2. Objective and purposes of FTA

Every FTA contains a chapter on IPRs[5]. This chapter does not clearly spell out the objectives and purposes of these agreements. Precisely, TRIPs agreement and the Doha ministerial decision put forward the appropriate balance to find between the protection of IPRs, the promotion of innovation and the transfer and dissemination of technology on one side and the promotion of socio-economic welfare on the other side (Musungu & Oh, 2006). In contrast, the FTAs do not spell out such objectives and unsurprisingly provisions are viewed as serious ways to undermine the full use of flexibilities provided by the TRIPs agreement regarding drug accessibility in developing countries. The practical resort to those flexibilities may ease the supply of generic drugs at lower prices and favour accessibility through affordability and availability.

On this point, developing countries seems to consider that a net gain can be obtained in exchange for concessions about IPRs. Larger market access in developed countries by way of reduction in import taxes should give bigger earnings on agriculture products (and other sectors) and increase gross domestic production and gross national income per capita. At the end, people should be able to afford higher cost medicines[6].

In some bilateral or regional agreements (CAFTA-DR-USA FTA, Chile-USA FTA for instance), initial provisions are set-up and objectives are then defined. *"The objectives of this Agreement, as elaborated more specifically through its principles and rules, including national treatment, most-favored-nation treatment and transparency, are to:*

> *a) eliminate barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties;*
>
> *b) promote conditions of fair competition in the free trade area;*
>
> *c) increase substantially investment opportunities in the territories of the Parties;*
>
> *d) provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory;*
>
> *e) create effective procedures for the implementation and application of this Agreement, for its joint administration and for the resolution of disputes; and*
>
> *f) establish a framework for further trilateral, regional and multilateral cooperation to expand and enhance the benefits of this Agreement"*.

Thus, any reference to the protection of IPRs in a way consistent with the economic and social welfare of population by mean of public health protection for instance is missing. FTAs focus on the promotion of trade and stress mostly on the need to remove barriers to trade and set-up an effective protection of IPRs. This point relies in the peremptory position adopted towards IPR, implicitly or explicitly as in the Chile-USA FTA where *"the protection and enforcement of intellectual property rights is a fundamental principle of this chapter that helps promote technological innovation as well as the transfer of and dissemination of technology to the mutual advantage of technology producers and users, and that encourages the development of social and economic well-being"* (Chapter 17, preamble). While researchers still question the effect of IPRs on industrial development and socio-economic welfare in southern countries (Maskus & Reichman, 2005, Gallagher, 2005), the protection of IPRs as an efficient mean to promote trade and sustainable development is postulated in USA FTAs.

At the end, considering the fact that the USA FTAs neglect substantially to spell out objectives and principles, it becomes thus difficult for Party to interpret the content of this agreement in the light of public health promotion. On the contrary, as settled in the TRIPs agreement and reaffirmed in the Doha ministerial decision, members must interpret the provisions and the protection of IPRs in regards of the public health promotion.

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[5] The starting point of these FTAs is the "special 301" which lists the countries where legislation, policy or practices damage USA economic interests. On the basis of the "Priority watch list", countries are subject to USA commercial pressure. Finally, this mechanism leads to the conclusion of FTAs between USA and developing countries during the 2000s.

[6] Still, the subsidies issue is neglected in this debate: USA keeps on subsidising among others domestic producers of cotton giving rise to disputes within the WTO. Even the benefits expected in agriculture may be thus over-estimated.

In addition, alike the Morocco-USA FTA, some agreements state that parties can implement *"a more extensive protection and enforcement"*, i.e. a more stringent IPRs regime than the one required by a bilateral or a regional FTA: *"A party may provide more extensive protection for, and enforcement, of intellectual property rights under its law than this chapter requires, provided that the additional protection and enforcement is not inconsistent with this chapter"*. As TRIPs agreement, FTAs provide minimum standards for the protection and enforcement of IPRs and Parties are free to implement more constraining provisions. In fact, these minimum standards give rise to higher standards compared to those required by the TRIPs agreement.

3.3. The Provisions incriminated

In bilateral and regional FTAs, some provisions may be considered as serious threats to the ability of developing countries to fully resort to the flexibilities provided by the TRIPs agreement. These flexibilities concern chiefly the patentability criteria, the protection of clinical data, CL and PI. Here, large references will be made to the CAFTA-DR-USA FTA and the Morocco-USA FTA, the latter being defined as the higher level of IPRs protection ever obtained by USA within a FTA. Several provisions are devoted to the extension of market exclusivity for a firm and to the prevention of generic competition by means of patent and data protection.

Following the TRIPs agreement, the Morocco-USA FTA admits the need for **non-patentability criteria**. In order to *"protect ordre public or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment"* (Article 15-9, paragraph 1), party may exclude some inventions from patentability. But where the TRIPs agreement indicates what members *"may prevent"* from patentability (Article 27), the Morocco-USA FTA prescribes that parties *"may only*" exclude from patentability inventions on the basis of the criteria given above. In other words, non-patentability criteria are narrowed in the Morocco-USA FTA, and may be so in other FTAs; other circumstances than the one defined above cannot be put forward to forbid the grant of a patent.

On the other side, going beyond the prescription of the TRIPs agreement, FTAs intend this time to favour a broad interpretation of the **patentability criteria**. As stated in the TRIPs agreement and the Morocco-USA FTA, patents shall be available for any inventions, in any field for product and process. Yet, the definition of an invention is enlarged to include "*any new uses or methods of using a known product, including new uses of a known product for the treatment of humans and animals*" (Article 15-9, paragraph 2). As a consequence, if a firm is granted a patent for the development of a drug, precisely for one medical indication, it can obtain a second patent for a new medical indication and so on. This article enables so firms to extend the scope of protection attached to a product by simply declaring new medical indications. Extending the scope of patent may contribute to the evergreening of patent in developing countries. Even though the product is not really new, it can be granted numerous patents for successive incremental innovations. This delay again and again the launch of generic medicines and keep prices high out of reach for public health authorities, Non-Governmental Organisations (NGOs) and patients in developing countries.

On this point, the Morocco-USA FTA fixes that a new product is *"one that contains a new chemical entity that has not been previously approved **in the Party's territory**"* (article 15-10, paragraph 1). So, if a medicine is not very new in the world for the reason that it was developed and patent for instance in USA in 1999, for lack of patent application in Morocco till today, this product will be considered as a new one and be proper for patentability. There is no regulatory delay commending a firm to patent its product in a country "A" and then patent it in country "B" within a certain time.

All put together, these provisions offers large opportunities to obtain patent for product and delay accordingly the launch of less expensive generic drugs in developing countries as competition is hindered. More debatable, even for drugs developed and patent before 1995 and not patentable under the TRIPs prescriptions, a firm may obtain a patent in developing countries because: (1) the firm did not ask for a patent in this country and asserts so that its drug is new under FTAs' considerations; or (2) the firm claims for a new use of its drugs under FTAs provisions. At the end, the complexity and the confusion arising from TRIPs agreement and FTAs may be such that a firm may be basically able to ask for a patent and devote resources to defend its point of view in court, during a dispute settlement for instance. Adversely, generic makers may not have the resources and time necessary to challenge and invalidate patent claims.

Finally, where a limited interpretation of the patentability criteria may ease the prevention of evergreening strategy and favour the launch of more affordable generic drugs in developing countries, the Morocco-USA FTA reveals the willing of USA to promote a broader interpretation of such criteria and enlarge the scope of patent. This aim is perfectly consistent with the objectives of multinationals in

the pharmaceutical sector: gaining new and successive patents for the same chemical entity, prolonging their market exclusivity and at last delaying the launch of competitive generic drugs in developing countries with ultimately a negative impact on accessibility.

The effective **patent duration** may be undeniably reduced due to regulatory requirements: the review of clinical data takes time and reduces accordingly the effective exploitation of a patent. This evidence gives rise in the 80s to an extension of the patent duration in USA under the Hatch-Waxman Act and in other developed countries as stated before. For developing countries, the CAFTA-USA FTAs provided for instance that *"a Party shall adjust the term of a patent to compensate for unreasonable delay that occurs in granting the patent.* An unreasonable delay is *"more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made"* (Article 15-9, paragraph 6a). Thus, the restoration of the patent term may defer the date of patent expiration, so delay the entry of generic competitors on the market and finally postpone the supply of more affordable medicines due to the market exclusivity provided by the patent. Beyond patent, protection of data may also help firms to build and extend market exclusivity at the expense of generic competitors and mostly patients.

When a firm wants to launch a medicine on the market, it must submit clinical data that ensure the quality, safety and efficacy of the medicine to a drug agency. If so, the firm gets marketing approval. Part of the drug development process, clinical data are costly investments for firms: clinical trials enrolling hundreds, even thousands of patients are organised to evaluate the quality, safety and efficacy of a drug. For generic makers, such investments are not required. They only have to assert the bioequivalence of the drug they submit and can rely on the clinical data previously produced[7]. Thus, saving resources on clinical trials, generic makers market their products at lower price.

Concerning the **disclosure of clinical data**, through FTAs, USA works on two directions: protecting as long as possible those data from utilisation by third parties (generic makers) and limited as far as possible the data submitted by applicants. First, whereas the TRIPs agreement only recommends the protection of such data from *"unfair commercial use"* (Article 39-3), the FTAs simply prescribe their protection for at least 5 years. Precisely, *"If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of (a) safety and efficacy data or (b) evidence of prior approval of product in another territory that requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at* ***least five years for pharmaceutical*** *and ten years for agricultural chemical products* ***from the date of approval in the Party's territory****"* (Article 15-10, paragraph 1a). Thus, generic makers who would like to launch a copy of a drug in a country "A" will not be able to use the clinical data initially submitted. They will have to wait for the end of the data exclusivity period in country "A" or they will have to proceed to new clinical trials and produce their own clinical data. In the latter case, additional costs will be generated and higher prices will be charged to patients. More debatable, the principle of new clinical trials for medicines already approved and used in another country raises ethical considerations (Abbott, 2006)[8]. At the end, the protection of data grants market exclusivity to the firm which initially submits the clinical data and may delay the entry of more affordable generic drugs in developing countries[9].

Further, in the CAFTA-DR-USA FTA, another provision states that *"If a party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety and efficacy of a product that was previously approved in another country, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in another territory or (2) information concerning safety and efficacy that was previously submitted to obtain marketing approval in another territory for* ***a least five years for pharmaceutical products*** *and ten years for agricultural chemical products* ***from the date approval was granted in the Party to the person who received authorization in the other territory****"* (Article 15-10, paragraph 1b). Additionally, the trade agreement lays down that *"a party may require that the person*

[7] The drug must have the same chemical activity within the body compared to the original drug.

[8] NGOs complain about the non-ethical dimension of this provision. During the clinical trials, numbers of patients infected for instance by HIV/AIDS may be prescribed a placebo while the quality, efficiency and safety of an ARV have been already checked in a developed country during previous clinical trials.

[9] During the Uruguay round, some developed countries plaid for the protection of data and failed to obtain it. Finally, through FTAs, USA succeeds in implementing provisions favourable to data protection and market exclusivity.

providing the information in the other territory seek approval in the Party within five years after obtaining marketing approval in the other territory" (Article 15-10, paragraph b). Thus, a firm will adopt the following strategy: it will not ask for data exclusivity in the country "A" for the reason that its data exclusivity and so its market exclusivity are already ensured by data protection in country "B". Five years later, the firm will then ask for data protection in country "A" as allowed legally and five–years of data protection will be granted in country "A".

All put together these provisions may grant data protection and market exclusivity to a firm for ten years in country "A". Or to put it differently, ten years may go by before generic makers will be allowed to use clinical data and launch a copy of a medicine at low cost. More problematic, situations may arise where a medicine goes off-patent but market exclusivity is still granted since data protection is not over in country "A" (Abbott, 2006).

Beside, the Morocco-USA FTA sets up that new clinical information will be protected for *"at least three years from the date of approval in the Party"* (Article 15-10, paragraph 2b). This requirement may help firms to extend again and again the protection of clinical data, for new uses of a product for instance, and obtain longer market exclusivity thanks to incremental developments made around the product.

Concerning the disclosure of information related to an invention, efforts are made to reduce as much as possible the information disclosed. The Morocco-USA FTA prescribes that *"each Party shall provide that the disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date"* (Article 15-9, paragraph 10). Following the seminal paper of Arrow (1962), IPRs were justified by the need to promote innovation and social welfare. As information was defined as a public good, under-investments in innovation were likely to occur threatening at the end social welfare. Later, Hatch-Waxman Act extended patent term in exchange for a timely entry of generic drugs as soon as patents expired; the condition being a large disclosure of information necessary to ensure a large diffusion of innovation and accessibility to it, especially among generic makers ready to launch copies of medicines that are about to go off-patents. Beyond these social considerations, the non-disclosure of information represents a significant issue and a crucial way, among others, to preclude generic competition by ensuring a limited access to information about chemical entities. And due to limited resources devoted to review the application for patents and marketing approvals in developing countries, regulatory authorities may have difficulties to evaluate the sufficiency and the clearness of the information submitted. In fact, they may be inclined to rely on the patent or the marketing approval granted in developed countries instead of proceeding to a review of the data submitted.

As discussed above, developing countries may resort to **PI** to deal with a national emergency or an anticompetitive practice (prohibitive price or insufficient supply of the domestic market for instance). This possibility is related to the **exhaustion** principle that prevails. The Morocco-USA FTA suggests that efforts will be made through bilateral and regional agreements to impose a restrictive exhaustion principle, which rejects PI. Therefore, a national or a regional exhaustion regime may respectively be implemented whenever possible in a bilateral or a regional agreement. The Morocco-USA FTA lays down that *"each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner* ***shall not be limited by the sale or distribution of that product outside its territory****"* (article 15-9, paragraph 4). Accordingly, as a national exhaustion principle is adopted and nothing in the TRIPs agreement forbids such provision, Morocco has actually renounced to a legitimate capability to import cheaper drugs from foreigner countries in order to deal with an emergency or an anticompetitive practice. At the end, population may suffer from prohibitive prices.

Regarding the ability for developing countries to issue a **CL** for the same motives, the complexity and the uncertainty created by the provisions implemented in FTAs may seriously undermine the practical resort to CL. In the Morocco-USA FTA, *"party shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent* ***during the term of that patent****, unless by consent or with the acquiescence of the patent owner"* (Article 15-10, paragraph 4a). On one side, TRIPs flexibilities provide that patents can be override and a CL issued in circumstances of national emergency for example. On the other side, FTAs may prevent the marketing approval of drugs, even under a CL: *"the party shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved used* ***during the term of that patent****, unless consent or acquiescence of the patent owner"* (Article 15;10, paragraph 2b, CAFTA-USA FTA). In other words, the patent term and so the protection of market exclusivity may prevail, even in particular

circumstances. Further, since the objectives and the principles of FTAs remain unclear and references to flexibilities, exceptions or safeguards are basically missing, a public health sensitive interpretation of FTAs is thus hardly bearable. At the end, these conflicting provisions may bring about endless discussions and disputes in WTO and national courts about the provision to be adopted. As a result, generic entry may be deferred and more affordable drugs impeded.

At the end, many provisions in FTAs may severely undermine the recourse to TRIPs flexibilities, obstruct the practical supply of generic drugs and ultimately damage drugs accessibility. As means to grant market exclusivity, patent and data protection may preserve monopolistic positions, defer competition and alter drug accessibility in developing countries. Nevertheless, numbers of bilateral or regional FTAs are already signed or under negotiations. Still, no one shall neglect the way provisions under TRIPs agreement may damage drug accessibility in developing countries.

4. Competition and drug accessibility in developing countries: some Indian and Thai evidence

At this point of analysis, precisions have been made about international agreements, their potential promises and threats. Concerning the promises, under TRIPs agreement, flexibilities provided aim at enabling developing countries to promote public health and drug accessibility. Adversely, some "open" provisions may be used to extend market exclusivity and defer the launch of generic drugs. Similarly, under bilateral or regional FTAs, some provisions constitute serious impediments to competition and drug accessibility through the promotion of market exclusivity in developing countries. Going beyond factual elements, evidence from India or Thailand will be here exposed to state how international arrangements dealing with trade and IPRs lessen in practice drug accessibility in southern countries. But first let see the institutional factors that may support drug accessibility.

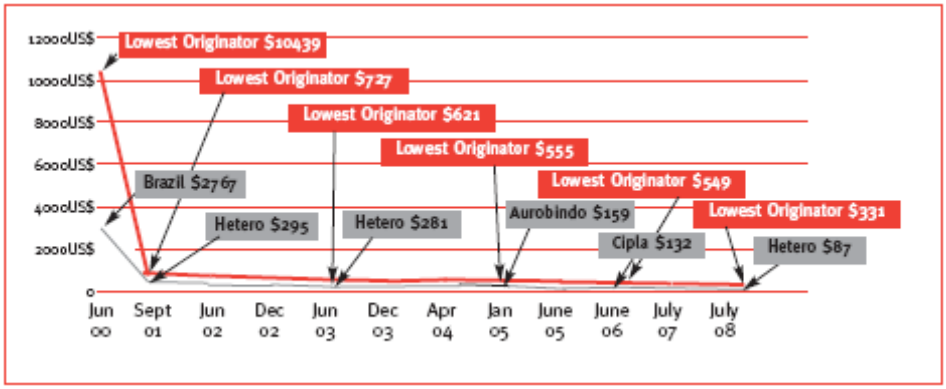
4.1. The global effect of a favourable Indian IPRs regime on the price of anti-AIDS drugs

ARVs production started in India in 1991. At that time, Cipla wisely started the manufacturing of the less costly ARVs, whose active substance content was low and manufacturing process was less complex. A decade later, five Indian companies (Cipla, Ranbaxy, Hetero, Aurodindo and Cadila) were involved in the ARVs production and more than a fifteen ARVs, including bi-therapies and tri-therapies, were marketed in the world (Guennif, 2004).

The entry of these actors on the market brought the cost of treatment crashing down. For example, the price of a therapy, combining three ARVs recommended by the WHO as a first-line regimen for naive patient in developing countries, decreased drastically. The sharp decline started with Cipla announcement in February 2001 that it would sell its triple therapy in the form of a cocktail at $350 per year per patient to non-governmental organisations (NGOs) (MSF, 2005)[10]. At that time, a tri-therapy cost 931 USD per year and per patient with princeps. From March 2001, the price of tri-therapy with princeps fell to 727 USD. Moreover, competition between Indian generic makers triggered a new decline in prices. Two months after Cipla's announcement, Hetero joined the competition and declared its intention to sell a cocktail at 347 USD to NGOs. Few months later, Ranbaxy raised the stakes by fixing the price of its cocktail at 295 USD for NGOs. In a recent report, MSF (2008) stated that prices were still decreasing. In 2003, Hetero was selling its tri-therapy at 152 USD per patient per year against 562 USD with princeps. In 2008, the same firm was supplying the treatment at 87 USD per patient and per year while the princeps combinaison is sold at 331 USD. Thus, *"generic competition has shown to be the most effective means of lowering medicines price"* (MSF, 2005).

[10] A cocktail is a treatment made of three ARVs that are present in a single pill to be taken 2 or 3 times a day. This so-called fixed-dose combination brings down the number of pills to be taken every day, improves significantly patient compliance and helps to prevent resistance (WHO, 2003).

The effects of generic competition



Source: MSF, 2008.
The fall in price of first-line therapy made of three antiretrovirals: Stavudine, Lamivudine and Nevirapine.

As stated in a previous work (Guennif, 2004), the core of this powerful competitive environment favourable to price reduction and drug accessibility improvement, relies in a consistent IPRs regime. In 1970, India relaxed its IPRs regime. Before this date, under a strong IPRs regime, patents were granted for both process and product in the pharmaceutical sector. As a result, the domestic pharmaceutical industry was nascent and India was heavily dependant on external supplies of medicines marketed at prohibitive prices (Mittal, 1993, Keayla, 1995, Watal, 2001, Ramana, 2002, Lalitha, 2002).

After 1970, India relaxed its IPRs regime mainly by providing patents only for process, by introducing a working patent provision and by setting a drug price control order. Within two decades, the results of this new institutional arrangement were conclusive: a fragmented domestic pharmaceutical industry made largely of thousand small units arose, the production of raw material and formulation drastically increased. Exports in the sector were such that the balance of trade was positive at the end of the 80s. Thus self-sufficiency was achieved and prices fell down. In conclusion, by making its IPRs regime more flexible, India encouraged the growth of a pharmaceutical industry and improved accessibility to drugs. And later, this high-performance industry succeeded in pushing ARVs prices down and improving accessibility in developing countries hit by HIV/AIDS epidemic.

Yet, as a WTO member, since 2005 India is step by step amending its patent law to make it TRIPs compliance. At this point, one may legitimately wonder how a new IPRs system, which basically means a new reinforcement of the Indian patent law, would improve drug accessibility (and support the future course of the Indian pharmaceutical industry). In particular, WHO has changed lately its recommendations concerning anti-AIDS treatments in its 2006 report. From now on, medicines like Emtricitabine (FTC) and Tenofovir (TDF) are part of the first-line regimens recommended by the WHO. FTC and TDF were both patented after 1995 and patents will expired respectively in 2015 and 2018. As medicines patented after 1995 in a WTO member's territory, these medicines are patentable in developing countries provided that the transitional period enables it. In India, the transitional period expired in 2005, so firms can apply for a patent. If a patent is granted, Indian manufactures will be unable to produce copies at low cost and supply public health authorities, NGOs and patients in their own territory and in developing countries. The stakes are hug since these drugs are part of fixed-dose combinations that enhances patients' observance and reduce resistance. Thus, FTC and TDF may not only be unaffordable in India and other developing countries, but most of all fixed-dose combinations made of one or both medicines will be out of reach for patients in the South.

Nevertheless, the Indian patent law opts for a limitation of patent scope by restraining the patentability criteria. New uses of a previously known drug are not patentable in India. Additionally, the Indian patent law provides for a pre-grant opposition: people can oppose a patent application filed by a firm. Due to these two provisions, for instance Gleevec, a medicine used to treat leukaemia and marketed by Novartis, was denied a patent in 2005. The Patent Controllers state that Gleevec was not a new drug but a new use of a previously known drug. Presently, Novartis is challenging the decision. Similarly, numbers of NGOs oppose the patent application filed by the firm Gilead on TDF on the same ground. Doing so, NGOs are willing to prevent impediments to access to this essential drug. Earlier, an opposition was made to GlaxoSmithKline's patent application on Combivir, an anti-AIDS bi-

therapy. Since then, Gilead announced it was negotiating voluntary licenses with Indian manufacturers to make TDF within the next year … after obtaining a patent in India.

At the end, not involved in any US FTAs and aware of its obligation as member of the WTO to amend its patent law in a way consistent with TRIPs agreement, India is showing a strong political will. It is currently exploring any flexibility provided by the TRIPs agreement to promote public health and drug accessibility. Here the preservation of competition and the presence of a powerful domestic industry should not be underestimated, factors that may be seriously undermined by missing or open provisions found in TRIPs agreement and/or stringent provisions elected in USA FTAs.

4.2. Thailand experience: socio-economic development under strong IPRs regime

In the 90s, due to international pressure and TRIPs agreement, Thailand implemented a strong IPRs regime whose impacts are still questionable (Guennif & Mfuka, 2003). Whereas technology transfers remains diffuse till now, the negative effects on accessibility and availability of medicines are readily perceptible.

Between 1979 and 1992, a period in which patents were only granted for process in Thailand, a generic version reached the market 1 to 2 years after the marketing of princeps. Following the modifications of its IPRs regime in 1992 and henceforth the granting of patent for both process and product for 20 years in the pharmaceutical sector, generic versions of patented products were available at least 5 years after the filing of the patent application, and 5 to 6 years later when this concerns a product under the Safety monitoring program (SMP) (Kwa, 2001)[11].

Furthermore, Thailand experienced the greatest difficulties in ensuring the supply of medicines at affordable prices. "The ddI affair" illustrates perfectly these difficulties. The Government Pharmaceutical Organization (GPO) is a Thai public unit, which manufactures the drugs supplied to public hospitals. It managed to develop a generic version of the anti-AIDS treatment ddI whose patent dates back to 1987 and which was marketing by the American firm, Bristol-Myers & Squibb (BMS) at prohibitive price. In 1992, the year when the new TPA came into force, BMS patented an improved formulation of ddI and asked for market exclusivity, by demanding that the product be placed under SMP[12]. It obtained a temporary monopoly and sold the drug at $2,5 per tablet in a country where the daily minimum wage averaged $3.84. GPO had to stop its manufacturing programme aimed at supplying a generic version at lower price. Thus, the ARV remained unaffordable for most patients living with HIV/AIDS (Guennif & Mfuka, 2003).

Far from abandoning, in 1997, GPO filed a request for a CL, provided by the 1992 Thai Patent Act (and later by the TRIPs agreement). Under USA pressure[13], the government gave up and put an end to the procedure for the issue of a CL. GPO had to produce a new ddI formulation (ddI) in powder form, so as not to infringe the patent obtained at that moment by BMS for its improved formulation. Since then, AIDS activists sued BMS in 2001 and asked for the revocation of the patent for lack of *"significant inventive steps or novelty"* so that GPO could produce tablets, more convenient for patients and less expensive (cf. table below). Since then, BMS patent was not invalided but its scope reduced so that GPO could produce tablet larger than 100mg dosage form (Oxfam, 2004). The generic was marketed at half price of the original drug. At the end, under the pressure of the civil society, BMS gave up its patent. But as indicated earlier, a US FTA is presently under discussion.

[11] The SMP was established in 1992 under USA pressure. It made it possible to grant "exclusive marketing rights" (EMR). Officially, the SMP aimed at improving the quality of newly marketed products. Unofficially, it allowed companies to get protection for products that had never been patented in the country. It permits multinationals to obtain a temporary 3-year monopoly for products patented and marketed elsewhere before 1992. However, once it came within the purview of Special 301, Thailand once again amended its TPA in 1993, extending the EMR to 5 years. Most of all, during the period where the Thai Food and Drug Administration was controlling drug quality, no generic version could be marketed.

[12] The modification of the formulation consisted simply in the addition of an antacid.

[13] Use of the "Special 301" once again.

Comparison of princeps and generic prices in Thailand (in USD, 2001)			
Medicine	Princeps price	Generic price	Decrease in %
Fluconazole (200mg caps)	6.20	0.26	95,8
Stavudine (40mg caps)	2.60	0.10	96
Zidovudine (AZT) (100mg caps)	0,50	0.15	70
Didanosine (ddI) (100mg tab/170mg powder)	1.20	0.62	48

Source: Oxfam, 2001 and GPO, 2001.

Considering public health issues, these facts permit legitimately to address the potential effects of the USA FTAs where patentability criteria are broaden, data protection introduced, PI forbidden and CL limited. Whereas exceptions to the patent holder's rights are provided by the TRIPs agreement, like Thailand pressured by commercial threats or due to FTAs stringent provisions, which create moreover complexity and uncertainty, developing countries may be legally unable to resort to generic supply to reduce drastically medicine prices and may face practical difficulties when resorting to CL to sustain drug accessibility.

5. Discussion

Under TRIPs agreement, developing countries members of the WTO are required to implement a constraining IPRs regime where flexibilities are provided for the protection of public health and the support of drug accessibility. As partners further of FTAs, these countries are committed to more stringent IPRs regime and narrow flexibilities, devoted largely to the promotion of market exclusivity at the expense of competition and affordability.

Following these considerations, developing countries have to show a strong political will to stand international pressure which is aimed at imposing them stringent agreements. For instance, to be able to follow the Indian example, they need to limit the scope of patent in order to resort to the useful effect of competition on price. More difficult, following the Brazilian example, who use the compulsory licence as a credible threat to cut the price of medicines, suppose the existence of pharmaceutical manufacturing capabilities in the territory. This requirement is all the more vivid when efforts are made to impede the resort to the possibility for developing countries to proceed to importation under a CL. All the regulatory requirements are such that the procedure is difficult to achieve in the end. Countries need to declare the national urgency, plan the quantity of medicine needed, ask the producer to label the drugs so as to prevent their parallel exports towards more lucrative markets.

Besides, international organisations may be more involved in scrutinizing bilateral and regional agreements in order to ensure that those are not inconsistent with national constitutions (for instance the USA Constitution) or international settlements. Otherwise, the promotion of public health and drug accessibility may rely for most part on the strong involvement of the civil society as indicate examples in South-Africa, India or Thailand.

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