TRIPS Plus Agreements and Issues in Access to Medicines in Developing Countries

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Abstract

Harmonisation of intellectual property rights among the members of WTO has in the recent years seen informed debates on access to medicines. Though flexibilities exist in the WTO Agreement to safeguard public health priorities, such as parallel imports and compulsory licensing yet the use of these flexibilities depend on various factors including the country's developmental status and the capacity of the industry in these countries. Importantly in recent years the regional and bilateral trade agreements signed between developing and developed countries also influence the flexibilities available. While the developing countries are lured to such agreements because of the opening up of trade and trade concessions, yet, the conditions of such trade especially those binding the intellectual property rights of the goods concerning the USA are stricter and broader and thereby become more powerful than the WTO Agreement itself governing the countries. Particularly, concerns have been raised about the patentability criteria and data exclusivity that have the potential to extend the monopoly status and thereby delay the entry of generic drugs. Such practices would lead to delay in the entry of generic drugs in the market, thereby extending the monopoly power of the patented products affecting the access to medicines. This paper discusses a few of these aspects.

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1 Introduction

`Health for all' is becoming a distant dream for developing countries, especially those with growing number of population affected by HIV/AIDS or other life style diseases for which there are only few medicines and virtually no alternatives exist. Access to medicines in these countries is a problem due to various reasons. While lack of purchasing power of the people and lack of health cover are one side of the issue, international free trade agreements (FTA) governing these countries also play a role in impeding the access to medicines particularly those that are newly invented. In this paper, we discuss the impact of harmonisation of intellectual property rights governing the new innovations in the pharmaceutical sector and the TRIPS Plus agreements that countries are subjected to through the regional or bilateral agreements. The structure of the paper is as follows. In section 2 following this brief introduction, the objectives, principles and flexibilities of the TRIPS agreement are presented. Section 3 discusses the experience of Thailand in utilising the compulsory license, followed by a discussion on the content of a few FTAs in Section 4. Section 5 presents the conclusion.

2 Flexibilities Provided by the TRIPS Agreement

The WTO categorically states that the objective of the TRIPS agreement is to implement international minimum standards for the protection of intellectual property (Boulet and Velasquez 1999; Raizada & Sayed, 2002). 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

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are free to adopt a more stringent regime than the one required by the TRIPS agreement (Article 1). 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. In fact, WTO rules, which govern technical barriers to trade applied for reasons of protecting human health, are covered by either the Agreement on Technical Barriers to Trade (TBT Agreement) or the Agreement on the Application of Sanitary and Phytosanitary measures (SPS Agreement). Under both these agreements, health is considered a legitimate objective for restricting trade (WHO, WTO 2002). 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. Patents may be circumvented in particular circumstances

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 *"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/ in case of the prohibitive prices or inadequate quantities made available, a country can issue a compulsory licence (CL). CL would be the route

followed where there is no possibility of 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 at lower price and/or greater quantity. The Agreement acknowledges that States have full discretion to define situations that qualify as national emergency.

According to the TRIPS agreement, a patent owner has the right to manufacture, use, and offer for sale, sell or import the product (Article 28a). The patent owner also has the authority to transfer these rights through licensing contracts (Article 28b). The right to import is governed by the principle of 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 circulation of goods in a country. If the patent owner accepts the marketing of the 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 the product for example in the European Union (EU), regional exhaustion would limit the product's circulation within the EU. But 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 the marketing of the product in any country, international exhaustion authorises its export to any other country.

In case of international exhaustion, parallel import (PI) is also legally correct. For instance, country "A" can purchase a drug from a country "B" if the price of the drug is lower in that country. In case of regional exhaustion, countries "A" and "B" must belong to the same region like the EU, the African Regional Industrial Property Organization (ARIPO) for East Africa and so on. Also, the principle of PI is a regulatory measure that makes it possible to fight against anti-competitive and discriminatory practices, 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 means 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.

3 The Doha Declaration

Given the difficulties and pressures encountered by developing countries in making effective use of flexibilities provided by the TRIPS agreement, because of the part of 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. An additional flexibility has been introduced: the possibility for members to import medicines under CL. Thus, a country like Tanzania at the

time of any national health emergency 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 the national emergency. Strict conditions were set out: regarding predetermined production volume, unequivocal identification of products, 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 still persists. 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 et al 1987; Scherer, 1998; Cohen et al 2000; Crampes, 2000). On the other side, technology transfers may be promoted and provide developing countries with new technical and therapeutic innovations (Mansfield, 1994, Saggi, 2000; Lall, 2003; Maskus, 2004; Correa, 2001a & 2001b and 2005; Maskus & Reichman, 2005; Gallagher, 2005). 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, 2001; NIHCM, 2002).

4 Thailand Experience

In the 1990s, due to international pressure, Thailand implemented a strong IPRs regime whose impacts are still debatable (Guennif and Mfuka, 2003). Whereas technology transfers issues remain unclear 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 within one or two years after the marketing of the patented product. 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).

Further, Thailand experienced severe difficulties in ensuring the supply of medicines at affordable prices. The didanosine (DDL) episode detailed below illustrates these difficulties. The Government Pharmacaceutical Organisation (GPO) is a Thai public unit which manufactures the drugs supplied to public hospitals. GPO developed a generic version of the anti-AIDS treatment DDL whose patent dates back to 1987 and which was marketed by the American firm Bristor-Myers and Squibb (BMS) at prohibitive price. In 1992, the year when the new Thailand Patent Act came in to force, BMS patented an improved formulation of DDL (the modification consisted simply an addition of an antacid) and asked for market exclusivity by demanding that the product be placed under SMP. 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 this anti retroviral (ARV) remained unaffordable for most patients living with HIV/AIDS, (Guennif and Mfuka, 2003).

In 1997, GPO filed a request for a CL, provided by the 1992 Thai Patent Act and later by the TRIPS Agreement. Under the pressure of the USA, the government gave up and put an end to the procedure for the issue of a CL. GPO had to produce a new DDL formulation 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 (Table 1). Though BMS patent was not invalidated since then, yet its scope has been reduced, so that GPO could not 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 mentioned elsewhere a US FTA is presently under discussion.

While animated debates govern the progressive implementation of TRIPS agreements in developing countries and several 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, number of USA FTAs[1] are being signed which undermine severely the capability of developing countries to benefit from TRIPSs flexibilities. Basically, the USA has very high level of IPR accorded to its innovations and thus tries to enforce on other countries particularly the trading partners, these high standards of IPRs popularly called as TRIPS plus measures through regional and bilateral free trade agreements. The countries joining the agreement are lured with the access to the huge US market in exchange for accepting higher intellectual property standards dictated by the USA. A few of these are discussed in the following paragraphs.

Table 1: Comparison of Branded and Generic Prices of Selected Drugs in Thailand (in USD, 2001)

Medicine	Branded Drugs Price	Generic Price	Decrease in %
Fluconazole (200mg caps)	6.20	0.26	96
Stavudine (40mg caps)	2.60	0.10	96
Ziduvudine (AZT) 100mg caps)	0.50	0.15	70
Didanosine (DDL) 100mg tab/170mg powder	1.20	0.62	48

Source: Oxfam 2004

5 Free Trade Agreements: Accessibility of Drugs under Higher Standards

For the past five years, numerous FTAs have been signed and others are about to be signed between developed and developing countries as presented in Table 2. This table shows that USA is leading negotiations with developing countries through bilateral and regional FTAs with the purpose of implementing FTAs on a larger geographical scheme. For instance, the bilateral and the 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 vain, in order to uphold a regional agreement with the Association of South-East Asian Nations (ASEAN), US is 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,

[1] Though the European Union, countries of European Free Trade Associations and Japan have signed FTAs, they do not impact the public health principles as much as the US FTAs do.

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 to develop a network of bilateral FTAs with ASEAN countries.

Table 2: Bilateral and Regional Trade Agreements Signed by the US

Country	Year
Jordan	2000
Singapore	2003
Chile	2003
Australia, Bahrain, Morocco	2004
Oman, Columbia, Peru	2006
CAFTA	2003
NAFTA	1993
Under discussion: Thailand, UAE, Malaysia, Korea, Southern African Customs Union, Andean countries, Middle East Trade Area	

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

5.1 Objectives and Purposes of FTA

Every FTA contains a chapter on IPRs[2]. But unlike the TRIPS Agreement, this chapter does not clearly spell out the objectives and purposes of these agreements. 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.

In some bilateral or regional agreements (CAFTA-DR USA FTA, Chile-USA FTA for instance), initial provisions are set up and objectives are defined. The

[2] 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's commercial pressure. Finally, this mechanism leads to the conclusion of FTAs between USA and developing countries during the 2000s.

objectives of this Agreement, as elaborated more specifically through its principles and rules including national treatment, most favoured nation (MFN) 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 a 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 means 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 on the peremptory position adopted towards IPR, implicitly or explicitly as in the Chile-USA FTA, where it states that *"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 means 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 the States to interpret the content of this agreement in the light of public health promotion. In addition, 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"*. Like the 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.

5.2 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, 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.

5.2.1 Criteria of Patentability

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.

Besides, going beyond the prescription of the TRIPS agreement, FTAs 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 firms to extend the scope of protection attached to a product by simply declaring new medical indications. Such interpretations of 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. The obvious consequence of such provisions is the delay in the launch of generic medicines and keep prices out of reach for public health authorities, non-governmental organisations (NGOs) and patients in developing countries.

5.2.2 Patent Territory

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 that was developed and patented for instance only in USA in 1999, it will be considered as a new one and be eligible for patentability in Morocco because it was not patented in Morocco till today. 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 offer 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 patented 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 contradiction arising from TRIPS agreement and FTAs may be such that, a firm may be 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 necessary to challenge and invalidate patent claims.

Finally, where a limited interpretation of the patentability criteria may ease the prevention of ever greening strategy and favour the launch of more affordable generic drugs in developing countries, the Morocco-USA FTA reveals the strategy 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 delaying the launch of competitive generic drugs in developing countries with ultimately a negative impact on accessibility.

5.2.3 Patent Duration

The effective patent duration may be undeniably reduced due to regulatory requirements such as the time taken to review the clinical data, which reduces the effective exploitation of a patent. This evidence gave rise in the 1980s to an extension of the patent duration in USA under the Hatch-Waxman Act (1984) 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, 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.

5.2.4 Disclosure of Clinical Data

When a firm wants to launch a medicine in the market, it must submit clinical data that support the quality, safety and efficacy of the medicine to the drug approval agency. Generating clinical data which is part of the drug development

process, are costly investments for firms: Clinical trials call for enrolling volunteers and organising hundreds, even thousands of patients on whom the drug would be administered to evaluate the quality, safety and efficacy of a drug and the data are submitted to the drug approval agency. Generic drug producers do not undertake this process. They only have to assert the bioequivalence of the drug they submit by resorting to the clinical data previously produced[3]. Thus, it saves resources for the generic makers and help them to market their products at lower price.

Concerning the disclosure of clinical data, through FTAs, USA works on two directions: protecting those data as long as possible from utilisation by third parties (generic makers) and limit 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).At the end, grant of data exclusivity to the firm, which initially submits the clinical data might delay the entry of more affordable generic drugs in developing countries[4].

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*

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

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 at 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 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).

Besides, 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 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 the information disclosed as much as possible. 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 social welfare. Later, Hatch-Waxman Act (1984) 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 Parallel Imports 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 the 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, the user 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 override and a CL issued in circumstances of national emergency. 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 approval 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 hence access to 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 accessibility to drugs. As grant of 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 negotiation. Among the developing countries, India is showing a strong political will by not signing any FTA with the US and still fulfilling its obligation as member of the WTO in a way consistent with TRIPS agreement a path which might be difficult for other countries to follow.

6 Conclusion

Under TRIPS agreement, developing countries as members of the WTO are required to implement a constraining IPRs regime, though flexibilities are provided for the protection of public health and the support of drug accessibility. However, 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, which restricts the accessibility to drugs. The discussion showed that through the FTAs, the data exclusivity is effectively enforced preventing the entry of generics, which would affect the access to medicines in the developing countries and also restrict price competition. The developing countries by signing such trade agreements loose out on their flexibility particularly the health aspects. Hence, it is essential that international organisations may be more involved in scrutinizing bilateral and regional agreements in order to ensure that those are not inconsistent with national constitutions or international trade settlements. Otherwise, the process of globalisation while opening the trade gates will close the door of `health for all'.

References

Abbott F. M. (2006). “Intellectual property provisions of bilateral and regional trade agreements in light of US Federal law”, *International Centre for Trade and Sustainable development*, Issue Paper no 12.

Arrow K.J. (1962). “Economic Welfare and the Allocation of Resources for Invention”, in Nelson R. (ed.), *The Rate and Direction of Inventive Activity*, Princeton University Press, pp. 609-25.

Boulet P. & Velasquez G. (1999). *Mondialisation et accès aux médicaments: les implications des Accords ADPIC/OMC*, Organisation Mondiale de la Santé.

Cohen W., Nelson R.R., Walsh J.P. (2000). “Protecting their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (Or Not)”, *WBER Working Paper Series*, no 7552.

Correa C. M. (2001a). “TRIPS, Development and Public Health”, *The Journal of World Intellectual Property*, Geneva, 3 April.

Correa C. M. (2001b). Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries, *TWA Trade and Development Series*, no 13.

Correa C. M. (2005). “The TRIPS Agreement and Transfer of Technology”, in Gallagher K. P. (eds), *Putting development first*, Zed Books.

Crampes, C., (2000). "La Recherche et la Protection des Innovations dans le Secteur Pharmaceutique", *International Economic Law Review*, 14 (1).

Demsetz, H. (1967). “Toward a Theory of Property Right”, *American Economic Review*, May.

Grabowsky H. G. (2002). “Patents, Innovation and Access to New Pharmaceuticals”, *Journal of International Economic Law*, 5 (4), December, pp. 849-860.

Guennif S. & Mfuka C. (2003). “Impact of Intellectual Property Rights on AIDS Public Health Policy in Thailand”, in Moatti & alii (eds), *Economics of Aids and access to HIV/AIDS care in developing countries. Issues and challenges*, ANRS, Collection Sciences Sociales et Sida.

Kwa A. (2001). “Dying For ‘Free Trade’ / Dying at the Hands of ‘Free Trade’: The Law of the Jungle Institutionalised”, *Focus on the Global South*, July.

Lall S. (2003). “Indicators of the Relative Importance of IPRs in Developing Countries”, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue paper no 3, June.

Levin R., Klevorick A., Nelson R.R. & Winter S. (1987). “Appropriating the Returns from Industrial Research and Development”, Brookings Papers on Economic Activity: Microeconomics.

Lichtenberg F. R. (2001). “Are the Benefits of Newer Drugs Worth their Costs? Evidence from the 1996 MEPS”, *20 Heath Affairs*, September/October, 21.

Mansfield (1994). Intellectual Property Protection, Direct Investment and Technology Transfer. Germany, Japan and the United States. *International finance corporation*, Discussion paper 27.

Mansfield E. (1986). “Patents and *Innovation*: an Empirical Study”, *Management Science*, 32 (2), February.

Maskus K. E. (2004). Encouraging International Technology Transfer”, *UNCTAD-ICTSD Project on IPRs and Sustainable Development*, Issue Paper no 7, May.

National Institute for Health Care Management (NICHM, 2002), “Changing Patterns of Pharmaceutical Innovation”, National Institute for Health Care Management, *Research report*, May.

Oxfam (2004). “Free Trade Agreement between the USA and Thailand Threatens Access to HIV/AIDS Treatment”, *Oxfam Briefing Note*, July.

Raizada B. K. & Sayed J. (2002). “IPR and Drugs and the Pharmaceutical Industry-concerns for Developing Countries”, in Dasgupta & Bibek (eds), *Salvaging the WTO’s future: Doha and beyond*, New Delhi, Konark, pp. 275-289.

Saggi K. (2000). “Trade, Foreign Direct Investment and International Technology Transfer. A Survey”, *The World Bank Development Research Group*, Policy Research Working Paper, 2349, May.

Scherer, F. M., (1998). “The Patent System and Innovation in Pharmaceuticals“, Harvard University, December.

WHO and WTO (2002). WTO Agreements and Public Health, a Joint study by the WHO and the WTO Secretariat, accessed on line from www.wto.org.

WTO (2001). "Declaration on the TRIPS Agreement and Public Health", Doha WTO Ministerial 2001, 14th of November 2001, World Trade Organization, www.wto.org.