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

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Harmonization of intellectual property rights among WTO members in the recent years has seen debates on access to medicines. Though flexibilities exist in the WTO Agreement to safeguard public health priorities, such as, parallel imports, compulsory licensing, yet the capacity to utilize these flexibilities depends on various factors including country’s developmental status and capacity of the industry in these countries. However, in the recent past, USA has been signing regional and bilateral trade agreements with developing countries. While developing countries are lured to such agreements because of the opening up of trade and trade concessions, however, conditions of such trade especially those binding the intellectual property rights of the goods concerning USA are stricter and broader and thereby become more powerful than the WTO Agreement governing the countries. Particularly, concerns have been raised about patentability criteria, data exclusivity with potential to extend monopoly status of the newly introduced drugs and delay the entry of generic drugs, which would obviously keep the prices beyond the reach of developing countries thereby making access to drugs difficult. A few of these aspects are discussed in this paper.

Keywords: TRIPS, TRIPS Plus, FTAs, access to medicines, data protection, parallel imports, compulsory licence

‘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. Access to medicines in these countries is a problem due to various reasons. While lack of purchasing ability of the people and health cover are one side of the issue, international free trade agreements (FTAs) governing countries also play an important role in impeding access to medicines, particularly, newly invented drugs. Impact and harmonization of intellectual property rights governing new innovations in pharmaceutical sector and the TRIPS Plus Agreements through regional or bilateral agreements among developing countries are discussed in this paper.

Flexibilities Provided by the TRIPS Agreement

The objective of the TRIPS Agreement is to implement international minimum standards for the protection of intellectual property. The agreement does not set-up a single and universal IPR system, members have to respect these minimum standards through 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). WTO acknowledges the need for members to meet objectives regarding development and public health. Accordingly, protection of patents has to fall within a national space in which governments are responsible for meeting these objectives.

Thus, 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 IPR. In fact, WTO rules which govern
technical barriers to trade applied for reasons of protecting human health are covered by either 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.\textsuperscript{3,4} TRIPS Agreement intends to implement an adequate protection of IPR that fits with the public health priorities of developing countries and dissemination of innovation in the world, they provide flexibilities. 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. 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 (voluntary transfer of rights against royalties negotiated between actors). A CL can be used by a public organization or a private firm. A country may authorize a government agency or a private firm to produce a drug to deal with national emergency and supply the generic version of medicine at lower price and/or in 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 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 in a region, exhaustion authorizes its export to any other country. In case of international exhaustion, parallel import (PI) is also legally correct. 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 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 and discriminatory practices and promote public health. There are animated debates, the principle members should adopt. On 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 at higher price.

The Doha Declaration: Public Health must Prevail over IPR

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 IPR 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 IPR 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 IPR (Paragraph 5d) and to settle the scope of the practical resort to PI. An additional flexibility has 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 and adequate remuneration to the patent owner as provided by the TRIPS Agreement (Article 31h).

Yet, the issue of innovation dissemination in the world and especially technology transfers to developing countries still persists. Possibly, implementation of a global minimum legislative framework for the protection of IPR ensures on one side, firms to recover the resources invested in the development of new medicines. On the other side, technology transfers may be promoted and provide developing countries with new technical and therapeutic innovations. As a consequence, a strong IPR regime is considered to uphold innovation and favour the rising of social welfare through the supply of new drugs.

Thailand Experience

In the ‘90s, due to international pressure, Thailand implemented a strong IPR regime whose impacts are still debatable. Whereas technology transfers issues remain unclear till now, the negative effects on accessibility and availability of medicines are readily perceptible. Between 1979-1992, a period in which patents were only granted for process in Thailand, a generic version reached the market within one or two years after marketing of the patented product. Following modifications of its IPR regime in 1992 and henceforth 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 filing of patent application and 5 to 6 years later when this concerns a product under the Safety Monitoring Program (SMP).

Further, Thailand experienced the greatest difficulties in ensuring supply of medicines at affordable prices. The DDL episode detailed below illustrates these difficulties. The Government Pharmaceutical Organization (GPO) is a Thai public unit which manufactures 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, Bristol-Myers and Squibb (BMS) at prohibitive price. In 1992, when new Thailand Patent Act came in to force, BMS patented an improved formulation of DDL (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 the country whereas the daily minimum wage averaged $3.84. GPO had to stop its manufacturing programme as its aim to supply generic version at lower price failed. Thus, ARV remained unaffordable for most patients living with HIV/AIDS.

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 USA, the government gave up and put an end to issuing of 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 revocation of the patent for lack of ‘significant inventive steps or novelty’, so that GPO could produce more convenient and less expensive tablets for patients (Table 1). Though BMS patent was not invalidated, yet its scope has been reduced, so that GPO could not produce tablet larger than 100 mg.
Table 1—Comparison of brand and generic prices of selected drugs in Thailand (in USD, 2001).

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Branded drugs price</th>
<th>Generic price</th>
<th>Decrease in %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole (200 mg caps)</td>
<td>6.20</td>
<td>0.26</td>
<td>95.8</td>
</tr>
<tr>
<td>Stavudine (40 mg caps)</td>
<td>2.60</td>
<td>0.10</td>
<td>96.0</td>
</tr>
<tr>
<td>Ziduvudine (AZT) 100 mg caps</td>
<td>0.50</td>
<td>0.15</td>
<td>70.0</td>
</tr>
<tr>
<td>Didanosine (DDL) 100 mg tab/170 mg powder</td>
<td>1.20</td>
<td>0.62</td>
<td>48.0</td>
</tr>
</tbody>
</table>


dosage form. 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.

While animated debates govern the progressive implementation of TRIPS Agreements in developing countries and several concerns are expressed about the way these countries 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 USA. For the past five years, far from the logic of multilateralism followed by WTO, a number of USA FTAs are being signed which undermine severely the capability of developing countries to benefit from TRIPS flexibilities.

Basically, 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 IPR popularly called TRIPS Plus measures through regional and bilateral free trade agreements. The countries joining the agreement are lured with access to the huge US market in exchange for accepting higher intellectual property standards dictated by USA.

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 (Table 2). Data in the 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, bilateral and 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 is expanding the number of FTAs signed and actually negotiate 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 USA. In order to achieve this large regional agreement, USA intends 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 signing trade agreements with USA on bilateral and/or regional basis; the list given above is not exhaustive.

Objectives and Purposes of FTA

Every FTA contains a chapter on IPR. 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 objectives of this Agreement, as elaborated more
specifically through its principals and rules including national treatment, most favoured 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 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 IPR 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 IPR. 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 IPR on industrial development and socio-economic welfare in southern countries, the protection of IPR as an efficient means to promote trade and sustainable development is postulated in USA FTAs.

Considering the fact that 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 ‘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 IPR 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.

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, protection of clinical data, CL and PI. CAFTA-DR-USA FTA and the Morocco-USA FTA, the latter being defined as the higher level of IPR 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.

Criteria of Patentability

Following the TRIPS Agreement, the Morocco-USA FTA admits the need for non-patentability criteria. Whereas 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.

FTAs favour a broad interpretation of the patentability criteria. 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). 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 ever greening of patent in developing countries. Even though the product is not really new, it can be granted numerous patents for successive incremental innovations. The 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 organizations (NGOs) and patients in developing countries.
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, will be considered as a new one and 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.

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. 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 greenling strategy and favour 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.

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 80s to an extension of the patent duration in USA under the Hatch-Waxman Act and in other developed countries. 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, 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.

Disclosure of Clinical Data

When a firm wants to launch a medicine on 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 organizing hundreds, even thousands of patients on whom the drug would be administered to evaluate the quality, safety and efficacy of 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. 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 the data from utilization by third parties (generic makers) and limit the data submitted by applicants. Though, the TRIPS Agreement only recommends 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. At the end, granting market exclusivity to the firm, which initially submits the clinical data, may delay the entry of more affordable generic drugs in developing countries.

Further, in the CAFTA-DR-USA FTA, another provision states that ‘a 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 (i) evidence of prior marketing approval in another territory or (ii) 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’.

These provisions may grant data protection and market exclusivity to a firm for ten years in country ‘A’. Or 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’.

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 disclosure 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). As per the seminal paper of Arrow (1962), IPR 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 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, 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.

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, population may suffer from prohibitive prices.

Regarding ability for developing countries to issue a CL for the same motives, complexity and 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 may be 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 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. 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. 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.

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 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. Among the developing countries, India is showing a strong political will by not signing any FTA with US and still fulfilling its obligation as member of WTO in a way consistent with TRIPS Agreement, a path which might be difficult for other countries to follow.

**Conclusion**

Under TRIPS Agreement, developing countries as members of the WTO are required to implement a constraining IPR 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 IPR 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 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 organizations may be more involved in scrutinizing bilateral and regional agreements in order to ensure the consistency with national constitutions (for instance, the USA Constitution) or international settlements. Otherwise, the process of globalization while opening the trade gates will close the door of ‘health for all’.

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References


27. Oxfam, Free trade agreement between the USA and Thailand threatens access to HIV/AIDS treatment, Oxfam Briefing Note, July 2004.

28. 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.

29. The drug must have the same chemical activity within the body compared to the original drug.

30. 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.

31. 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.