Tripping up TRIPS debates IP and health in bilateral agreements

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Abstract: Access to medicine is at the forefront of multilateral debates on patent law. This paper argues that bilateralism allows the USA to circumvent these debates and to set new international standards. Recently-concluded US Free Trade Agreements (FTAs) impose more stringent conditions than the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) requires. Although these 'TRIPs-plus provisions' are not technically incompatible with the Doha Declaration on Public Health, they can be considered as additional barriers for the entry of generic medicines.

Keywords: USA; bilateral; free trade agreements; health; TRIPS-plus; legal transplant; access to medicine; Doha declaration.

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1 Introduction

Most analysts agree that international patent negotiations take place in a context of asymmetrical power and interests between developed and developing countries (Maskus, 2000). Critical theory of international relations proved to be significant in the understanding of the dynamics of this specific type of negotiation. It predicts that the institutionalisation of unequal norms increases material capabilities of the most powerful actors but, in turn, decreases their legitimacy in front of social movements. To avoid a regime revolution, they must "offer some measure or prospect of satisfaction to the less powerful" (Cox, 1987, p.7). Therefore, in order to compensate these concessions, most powerful actors tend to institutionalise new unequal norms in other forums, not yet challenged by social movements.

Braithwaite and Drahos (2000) have proven the validity of this theoretical framework with their empirical analysis of the history of patent negotiations. They found that developed countries counter the resistance of developing countries by applying the strategy of 'forum shifting', which consists of moving the negotiating agenda from one organisation to another. In the 1970s, when developing countries dominated the debate on technology transfer at the United Nations conference on trade and development (UNCTAD), developed countries successfully reoriented the discussion towards the less political and more technical World Intellectual Property Organization (WIPO). In the 1980s, when developing countries called for a revision of the *Paris Convention for the Protection of Industrial Property*, some developed countries shifted the forum to the General Agreement on Tariffs and Trade (GATT).

In 1994, the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was perceived as the 'new frontier' of the patent regime. Many developing countries believed that it "would represent the end of the road and the last multilateral effort to regulate internationally the issue of IPRs" (El-Said, 2005). While critical theory suggests that an asymmetrical regime is unlikely to stagnate, no other multilateral organisation devoted to patent law has been created in the last decade.

This paper argues that developed countries have shifted the 'new frontier' of IP lawmaking outside of the multilateral sphere. During the past decade, the European Union, the European Free Trade Association, the USA and Switzerland, among others, signed many bilateral agreements that provide standards that go beyond the TRIPS agreement, namely the so-called 'TRIPS-plus agreements'. Most of these bilateral agreements were signed with middle-income countries that are sufficiently developed to produce generic drugs locally but that do not have enough bargaining power to counter bilateral pressure. The threat of trade sanctions and, most of all, the prospect of a privileged access to European and American markets convinced these middle-income countries to sign the TRIPS-plus agreements.

I will confine my argument to the free trade agreements (FTAs) signed by the USA. While other countries have also signed TRIPS-plus agreements, the USA has been the most active country on the bilateral front over the past three years. In 2002, the US congress enacted the trade promotion authority stating that any

> "agreement governing intellectual property rights that are entered into by the USA [must] reflect a standard of protection similar to that found in US law." (Trade Act of 2002, Section 2102)

Since then, the Bush administration has signed FTAs with Jordan, Singapore, Chile, Central American countries, the Dominican Republic, Australia, Morocco and Bahrain. Other FTAs are currently under negotiation with Panama, the Andean countries and the Southern African Customs Union.

It has been previously argued that developing countries succeeded in creating a linkage between the biodiversity regime and the patent regime and that the US circumvents these debates through bilateral agreements that provide higher standards on the patentability of plants and animals (Morin, 2004). This paper argues that bilateralism also allows the USA to bypass TRIPs' debates on access to medicine and to set higher standards for pharmaceuticals protection. To verify this hypothesis, selected patent provisions of recently concluded US FTAs are compared with those of the TRIPs agreement.

Recent US free trade agreements	
Agreement between the USA and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, signed on October 24, 2000. (JFTA)	
USA	Singapore Free Trade Agreement, signed on May 6, 2003 (SFTA)
USA	Chile Free Trade Agreement, signed on June 6, 2003 (CFTA)
USA	Central American and Dominican Republic Free Trade Agreement, sign on December 17, 2003 (CAFTA)
USA	Australia Free Trade Agreement, signed on May 18, 2004 (AFTA)
USA	Morocco Free Trade Agreement, signed on March 2, 2004 (MFTA)
USA	Bahrain Free Trade Agreement, signed on September 14, 2004 (BFTA)

Most provisions included in US FTAs are TRIPS-*equivalent*, that is to say, literally meaning they are duplicated from the TRIPS Agreement. However, some are TRIPS-plus provisions. Among the latter, they prescribe the patentability of second therapeutic uses of known medicine (Section 3), provide a stronger protection for data submitted to regulatory authorities (Section 4), extend the term of protection (Section 5), narrow the exceptions to the rights conferred (Section 6), add conditions on the use of compulsory licences (Section 7), proscribe the international exhaustion doctrine (Section 8), and restrict the grounds for revocation (Section 9). Primarily, in order to understand the legal and political significance of these TRIPS-plus provisions, one needs to look at multilateral debates on access to medicines (Section 2).

2 From multilateral debates to bilateral agreements

Bilateral agreements "reflect a reaction to the growing resistance that US initiatives encounter in the WTO" (Correa, 2004). While the industry and developed countries were the key actors leading the negotiation of the TRIPS agreement, NGOs and developing countries took a more active role in the post-TRIPS period (Helfer, 2004). As the UK's Commission on Intellectual Property Rights (2002a) observes, NGOs have played "an important role in highlighting and analysing issues of concern to developing countries". Similarly, Adrian Otten (CIPR, 2002b), Director of WTO's IP division, commented on the palpable change in the balance of power within the TRIPS Council:

> "I have been with the WTO and the GATT for more than 25 years and we have seen an increasing number of influential developing countries or blocks of developing countries become members and active participants."

Indeed, developing countries and NGOs underlined the significance of taking into account health issues when defining the appropriate level of protection. While there are provisions in TRIPS that allow countries to balance patent protection against public health objectives, these remain open to interpretation. This uncertain legal environment can dissuade developing countries to take advantage of these provisions.

This argument seemed especially relevant in the light of actions taken against a number of countries using compulsory licensing. In 1997, the USA threatened to enforce sanctions on Thai exports if Thailand did not drop its plan to use compulsory licensing provisions. In 1998, 40 pharmaceutical manufacturers brought suit against South Africa's

law on compulsory licensing. In 2000, the USA filed a claim under the WTO dispute settlement mechanism against Brazil for its use of compulsory licences.

In the light of these actions, a broad transnational coalition was formed, including: NGOs, some academics, the generic pharmaceutical industry, countries facing health crises, countries with large producers of generic drugs and the World Health Organization. The coalition attributed the problem of access to medicines, in part, to patent protection. As Sell and Prakash (2004) argue, the paradigm 'patents = free trade + investment = economic growth' was reformulated by 'generics = lower prices = life saved'. Pharmaceutical patents quickly became the symbol of the fight against the HIV/AIDS pandemic.

With the normative and institutional support of this coalition, developing countries clearly expressed that health issues were a deal-breaker for a new trade round. Indeed, the launch of the Doha round of negotiations was made possible in 2002 partly because WTO members reached a side agreement on public health. The *Doha Declaration on Public Health* specifically stated "the TRIPS Agreement does not and should not prevent members from taking measures to protect public health". Accordingly, WTO members affirm that

> "it can and should be interpreted and implemented in a manner supportive of the WTO members' right to protect public health and, in particular, to promote access to medicines for all" (para. 4).

A year later, WTO members went one step further. They agreed on a solution to the problem, left unresolved by the Doha Declaration, of countries with insufficient manufacturing capacities to make effective use of compulsory licensing. The Decision of August 30th, 2003 defined the conditions under which a country can use a compulsory licence to allow the production and export of generic drugs for the supply of another country.

Public health advocates welcomed these substantial changes as an 'important achievement' (Hoen, 2002). However, the reaction from the industry was less enthusiastic. The Pharmaceutical Research and Manufacturers of America recently acknowledged that the balance of power at the WTO no longer serves its interests:

> "PhRMA recognises that the current impasse in the Doha Development Round negotiations as well as in the deliberations in the TRIPS Council call into question the current value of the WTO as a venue for improving the worldwide protection of intellectual property. Free Trade Agreements thus provide a logical approach to gaining improved intellectual property protection." Pharmaceutical Research and Manufacturers of America (2004)

These claims echoed loud in the office of the US Trade Representative (USTR). Indeed, the US forum shifted from the WTO to bilateral FTAs where developing countries are isolated from the institutional support of their coalition and from the normative support of transnational NGOs (Drahos, 2002). Following, the US took advantage of the asymmetry of power to introduce TRIPS-plus provisions, such as, the patentability of new uses of known medicines.

3 Patentability of new uses of known medicines

All FTAs duplicate the first sentence of Article 27(1) of the TRIPS agreement: 'patents shall be available for any inventions, whether products or processes, in all fields of technology'. According to this statement, there would be at least two kinds of patentable inventions: product inventions and processes inventions.

However, the TRIPS agreement leaves unclear the question of whether a new use of a known product qualifies as a patentable invention. One could consider that the patentability of new uses is included in the patentability of processes, such as in US law (Kantor, 2005). One could also interpret Article 27(1) to mean that WTO members have the freedom to determine if a new use of a known product is patentable. Article 27(3)(b) is more precise regarding the patenting of new uses for medical purposes: "Members may also exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals". Thus, it is safe to think that a WTO member can exclude from patentability a new use of a substance known to cure cancer but subsequently found effective for the treatment of HIV/AIDS.

The FTAs concluded with Australia, Morocco and Bahrain do not allow such flexibility. The Australian FTA states "patents shall be available for any new uses or methods of using a known product" (AFTA, art. 17.9.1). The FTAs, signed with Morocco and Bahrain, go one step further and specify that the patentability of new uses of known product includes those "for the treatment of humans and animals" (MFTA, Art 15.9.2; BFTA, Art 14.8.2).

This new provision will likely serve as a model for subsequent FTAs. Given that the USTR seeks for consistency, once a new rule is incorporated in an FTA, it is usually maintained in subsequent FTAs. Thus, it is safe to assume that the USA will try to use the Australian, Moroccan and Bahraini precedents as leverage to convince Andean countries to change their current law, such as, to allow the patentability of second therapeutic uses for known pharmaceutical products (Andean Court of Justice, 2000).

4 Far-reaching protection of undisclosed data

Before commercialising a new pharmaceutical product, a company must first obtain a marketing approval from a regulatory authority, such as, Food and Drug Administration (FDA) or the European Agency for Evaluation of Medicinal Products. To get this approval, the company may have to conduct certain tests to assess the safety and efficacy of its product and submit the results to a regulatory authority. Since clinical tests require vast financial resources and extensive time, some experts argue that these data are a valuable investment that must be protected from disclosure to other potential applicants. Others argue that the entry of generic drugs should be facilitated by allowing secondary entrants to rely on data submitted by a first applicant.

Somewhere between these two viewpoints, Article 39(3) of the TRIPS agreement establishes a minimum international standard for the protection of marketing approval data.

> Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

This provision leaves considerable room for interpretation. A WTO member could consider that his obligation only applies to a limited range of data. For example, he could choose to limit his protection on data that involves a *considerable effort* in terms of financial investment. The type of protection that is conferred also leaves room for different interpretations. A protection against unfair commercial use does not necessarily prohibit a third party from submitting a marketing approval application for that data (Correa, 2004; UNCTAD-ICTSD, 2005).

FTAs signed with Singapore, Chile, Australia, Morocco and Bahrain provide a more specific and far-reaching protection for data submitted to regulatory authorities (SFTA, Art. 16.8; CFTA, Art. 17.10; CAFTA, Art. 15.10; AFTA, Art. 17.10; MFTA, Art. 15.10; BFTA, Art. 14.9). The undisclosed data to be protected are not only those that involve a considerable effort, but also include all information concerning the safety or efficacy of a product that contains a new chemical entity. Contradictory to the TRIPS approach of unfair competition law, FTAs grant applicants exclusive rights on their data for a minimum protection period of five years from the date of approval (ten years for agricultural chemical products). During this period, other applicants who seek marketing approval for a similar product cannot rely on these data, even if they were submitted to a foreign regulatory authority.

In addition, FTAs establish a link between the drug registration and the patent system. They do so by conferring two additional rights to patent owners:

- patent owners shall be notified of the identity of any third party applying for a marketing approval on a patented product
- patent owners shall give their consent for the issue of any marketing approval during the term of their patent.

According to a report from the US Federal Trade Commission (2002), such a link, without additional safeguards, is vulnerable to abuse from brand-name companies who can prevent the availability of more generic drugs (Federal Trade Commission, 2001, i).

Even when there is no patent on the product submitted for marketing approval, the protection of undisclosed data can have similar economic consequences. In most cases, the effective commercial term of a patent will extend beyond the term of protection provided by data exclusivity. However, in some cases, a patent may not be issued or the development period may be so long that the patent has expired. The protection of undisclosed data would then function as a substitute for patent protection, *de facto*, excluding competitors until they obtain their own data or until the end of the five year protection period (Pugatch, 2004).

Another crucial issue is the relationship between data exclusivity and compulsory licensing. It is unclear whether compulsory licences also apply to the data submitted to the regulatory authority. If ruled not to apply to this data, these licences would be ineffective in all cases where marketing approval is still subject to the patent owner's consent.

Given the major advantages that this implies for brand-name companies, FTA provisions on data exclusivity represent a significant achievement for the USA. The following example, taking place in Guatemala, illustrates this fact (IPWatch, 2005). In December 2004, a few months after the CAFTA negotiations were finished, Guatemala changed its law to allow secondary entrants to rely on data submitted by a first applicant before the end of the five year period. US officials reacted by saying that the new law put into question Guatemala's commitment to implement CAFTA and warned that the latter may not be sent to Congress for ratification until Guatemala undo its law. In January 2005, the Guatemalan government then introduced a new bill that would protect undisclosed data for a period of five years.

In Guatemala and in many other countries that signed an FTA with the USA, the regulatory authorities in charge of marketing approvals will become the watchdog of rights conferred by a patent. As a result, marketing approval procedures may well become increasingly complicated, as well as, lengthier for generic firms. However, as the next section will show, FTAs palliate this side effect for brand-name drug products by providing a compensation for unreasonable delays.

5 Protection of an effective patent term

Article 33 of the TRIPS Agreement provides that "the term of protection available shall not end before the expiration of a period of 20 years". Since this period is counted from the filing date, it guarantees only a nominal term of protection. The effective term of protection, defined as the length of time for which a product can effectively be marketed with the benefit of exclusive patent rights, can be substantially reduced by a number of administrative procedures. Two of these administrative procedures are the patent examination process and the marketing approval process.

Concerning the patent examination process, article 62(2) of the TRIPS agreement explains that the procedure shall permit the granting of a patent within a reasonable period of time in order to avoid unwarranted curtailment of the protection period. However, the TRIPS Agreement does not specify what is meant by a 'reasonable period of time' nor does it delineate how patent holders should be compensated for unwarranted curtailment.

At the time of negotiating the TRIPS agreement, this problem of unwarranted curtailment was not really relevant for US law since the US traditionally calculated the period of protection from the date of granting rather than from the date of filing. However, the USA had to change its laws to comply with the TRIPS nominal period of protection. To guarantee an effective period of protection of 17 years from the date of granting, the *Patent Term Guarantee Act* was enacted in 1999. The Act declares that the term of a patent can be extended when the USPTO fails to issue a patent within three years after the actual filing date (35 USC 154).

From the US industry point of view, a similar guarantee of an effective term should exist everywhere: "In some countries, political interference by the health ministry […], administrative delays and backlogs are the primary reason for delays in granting patents" (IFAC, 2003). Thus, only a few months after the *Patent Term Guarantee Act* had come into force in the USA, its essence was duplicated in US FTAs. Most of them state that "each Party, at the request of the Patent owner, shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent" (SFTA,

Art. 16.7.7; CFTA, Art. 17.9.6; CAFTA, Art. 15.9.5; AFTA, Art. 17.9.8; MFTA, Art. 15.9.7; BFTA, Art. 14.8.6). To avoid any ambiguity, the USA defined the notion of unreasonable delay, stating

> "An unreasonable delay shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made, whichever is later." (In the case of the CFTA and CAFTA, these delays were extended to five years and three years).

The second administrative procedure that can reduce the effective patent term is the marketing approval process. In the USA, where *Food and Drug Administration* procedures are particularly rigorous, these delays can be particularly long. Consequently, Congress enacted the *Hatch-Waxman Act* in 1984, allowing a patent owner to apply for an extension of his patent for a period corresponding to one-half of the clinical testing time plus all of the approval time, up to a maximum of five years (35 US 156).

Once again, US FTA duplicated US law

> "With respect to any pharmaceutical product that is subject to a patent, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process."

However, the notion of unreasonable curtailment is left undefined. (JFTA, Art. 4.23; SFTA, Art. 16.8.4; CFTA, Art. 17.10.2; CAFTA, Art. 15.9.6; AFTA, Art. 17.9.8; MFTA, Art. 15.10.3; BFTA, Art. 14.8.6).

By protecting an effective term of protection beyond what the TRIPS require, US FTAs seem to serve as vehicles for the legal transplantation of US law into foreign countries. Arguably, this one-size-fits-all approach is not always suitable for countries facing major health crises. For this reason, among others, Henry A. Waxman, co-sponsor of the US act that introduced an extended term of protection to compensate FDA procedures, is now opposed to US FTAs:

> Like most good legislation, the Hatch-Waxman compromise was carefully designed for a specific situation, in a specific regulatory system. But our success here does not mean it is appropriate for other countries. That is why I am greatly alarmed by its inclusion in Free Trade Agreements […]. Many of our trading partners face vastly different challenges and circumstances than we do here in the USA. (Waxman, 2003)

It should be pointed out that none of the FTAs have incorporated the *Hatch-Waxman Act* in its entirety. While the Act protected the effective patent term, it also simplified the marketing approval process. However, as we will see in the next section, none of the FTAs duplicated this latter aspect of the *Hatch-Waxman Act*.

6 Restrictions on the authorised exceptions

A patent confers exclusive rights on making, using, offering for sale, selling and importing an invention without the authorisation of the patent holder. However, every patent regime provides some exception to these exclusive rights, such as, the use of the invention for teaching and research or the preparation of medicines for certain prescriptions. Most of these exceptions are covered by Article 30 of the TRIPS

Agreement. The paper does not list the specific exceptions that are authorised, but rather defines three general conditions for their admissibility:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.

The TRIPS agreement does not exclude any specific exception as long as it fulfils the requirements of Article 30. Most US FTAs duplicate this provision. However, they add a provision that can restrict its potential use:

> If a Party permits a third person to use the subject matter of a subsisting patent solely to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires […]. (JFTA, Art. 4.19; SFTA, Art. 16.7.5; CFTA, Art. 17.9.4; CAFTA, Art. 15.9.5; AFTA, Art. 17.9.6; MFTA, Art. 15.9.5; BFTA, Art. 14.8.5)

This provision essentially reflects the report of the panel in the dispute *Canada–Patent Protection of Pharmaceutical Products* (Roffe, 2004). In 2000, a panel found that the regulatory exemption (sometimes called the 'bolar exception'), which permits competitors to manufacture samples of the patented product for the purpose of seeking marketing approval, fell within the general conditions of Article 30. It also concluded that the stockpiling exemption, which permitted competitors to manufacture and stockpile a patented product for sale after its expiration, constituted a 'substantial curtailment' of the rights of patent owners and, therefore, did not fall within the terms of Article 30. By integrating this ruling in its FTAs, the US made sure that it can keep its regulatory exemption (35 USC 271) and that other countries cannot follow the Canadian example and maintain a stockpiling exception.

While this FTA provision reflects a WTO panel report, it still represents an additional restriction on US partners compare to their WTO obligations. A panel report does not apply to countries other than that of the complaining party. If another panel or the appellate body was to examine the stockpiling exemption again, it may decide to take into account the Doha Declaration on public health (which was adopted two years after the *report Canada–Patent Protection of Pharmaceutical Products*) and arrive at a different interpretation of Article 30. Although this is unlikely to happen, it cannot be excluded.

In addition, US FTAs provide a second restriction on the use of a general exception:

> "[…] and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party." (JFTA, Art. 4.19; SFTA, Art. 16.7.5; CFTA, Art. 17.9.4; CAFTA, Art. 15.9.5; AFTA, Art. 17.9.6; MFTA, Art. 15.9.5; BFTA, Art. 14.8.5)

This restriction on exporting without the consent of the patent owner seems limited to products initially produced to support an application for marketing approval. If this interpretation is right, a signatory country could rely on another provision of the FTA to allow the export of generic medicines produced for purposes other than meeting marketing approval requirements (Veroneau, 2004).

However, for a group of four congressmen, this provision preclude signatory countries

> "from exporting generic versions of patented pharmaceutical products for any reason other than use in obtaining marketing approval because that is the only exception noted." (Levin et al., 2004)

If this interpretation is correct, it could restrict the number of potential solutions to the problem of countries with insufficient capacities in the pharmaceutical sector to make effective use of compulsory licensing. A group of developing countries suggested that Article 30 of TRIPS should be interpreted in order to authorise third parties to make, sell and export pharmaceutical products without the consent of the patent holder to address the problem of countries with insufficient industrial capacities (Council, 2002). Since FTAs provide that "if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party", it is possible, though unlikely, that they prohibit such interpretation of Article 30 and its FTAs equivalent.

To address the problem of countries with insufficient capacities to make effective use of compulsory licensing, FTAs signatories might have to use the mechanism provided in the decision adopted by the WTO General Council on August 30 (WTO, 2003). This decision allows WTO members, under certain conditions, to export pharmaceutical products made under compulsory licences and predominantly intended for the supply of the domestic market. However, as the next section will show, not all FTAs signatories will actually be able to benefit from this decision.

7 Additional restrictions on the use of compulsory licences

A compulsory licence is an authorisation given by a government allowing a third party to use a patented invention without the consent of the patent holder. Article 31 of the TRIPS agreement prescribes the general conditions under which a WTO member can issue a compulsory licence. These conditions are numerous and restrictive. They include the patent holder's right to receive an adequate remuneration and the availability of a judicial mechanism to review the validity of any decision relating to compulsory licences. Nevertheless, as the Doha Declaration on Public Health explicitly recognised, WTO members remain free "to determine the grounds upon which such licences are granted".

Yet, three of the recent US FTAs restrict the grounds upon which a compulsory licence can be granted. The first of these FTAs is the one signed with Jordan, specifying a restrictive list of legitimate grounds:

> Neither Party shall permit the use of the subject matter of a patent without the authorisation of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirement, provided that importation shall constitute working. (JFTA, 4.20)

FTAs signed with Singapore and Australia go even further (SFTA, Art. 16.7.6, AFTA, Art. 19.9.7). Consistent with US law and practices, they specify that if a party uses compulsory licences to remedy an anti-competitive practice, they should recognise that a patent does not necessarily confer market power. In addition, these two FTAs prohibit the use of compulsory licences on the grounds of failure to meet working requirements (as opposed to the Paris Convention, which specifically authorises this condition). Finally, the Singaporean and Australian FTAs provide that if a Party uses a compulsory licence in the case of a national emergency, the Party "may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use". This additional restriction protects the data submitted for the marketing approval of the product. Thus, in some cases, the effective use of a compulsory licence to market generic products would be undermined by the exclusivity, which the patent owner has on these data.

On the other hand, FTAs signed with Chile, Central American countries, Bahrain and Morocco do not include any specific provisions on compulsory licences. For these countries, compulsory licensing is authorised as long as it fulfils the requirements of TRIPS Article 31. A side letter even explicitly states that the IP chapter does not prevent the effective application of the General Council's August 30, 2003 Decision on compulsory licences for exportation to countries with insufficient industrial capacities.

Since these FTAs, signed with developing countries, do not provide additional requirements for compulsory licences, one could argue that they demonstrate the US deference for the Doha Declaration on Public Health. However, the Doha declaration recognises that every WTO member, i.e., not only developing countries, has the right to determine the grounds upon which compulsory licences could be granted. The August 30, 2003 Decision is actually intended for countries, such as Singapore and Australia, that have sufficient industrial capacities to produce and export generic product to other countries. If the Australian or Singaporean governments want to issue compulsory licences to supply to less developed countries, they will have to negotiate with the USA on a special relaxation of the rules as the Canadian government has done. Indeed, before the Canadian legislation on compulsory licences to improve access to medicines in developing countries came into force, the Canadian government signed a memorandum of understanding with the USA, agreeing that the provisions of NAFTA would not be applied to block the legislation. Nevertheless, the USA did not duplicate this memorandum of understanding in the FTAs that it later concluded with Australia.

8 Prohibition of the international exhaustion doctrine

During the TRIPS negotiations, the USA, among other countries, wanted to enforce the principle of national exhaustion. Developing countries, on the other hand, wanted to protect the practice of parallel imports to safeguard the principle of international exhaustion. The result was somewhat ambiguous:

> "For the purposes of dispute settlement under this Agreement, […] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

The Doha Declaration on TRIPS and Public Health left out any doubt, stating:

> "The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge."

The negotiation of bilateral treaties, therefore, is laden with opportunities for the USA to enforce its notion of national exhaustion. As such, bilateral treaties concluded with Morocco and Australia prohibit the application of a full principle of international exhaustion, requiring 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 a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least, where the patentee has placed restriction on importation by contract or other means (AFTA, Art. 17.9.4, MFTA, Art. 15.9.4).

This approach reflects US case law under which the rights of a patent holder are exhausted when the patented product is first sold anywhere in the world provided the patent holder did not restrict subsequent movement of the product by contract. Since a patent holder can still place restriction on parallel imports, the approach cannot be considered as a full application of the international exhaustion doctrine.

To date, every bilateral treaty that prohibits the principle of international exhaustion has been signed with countries that already give greater importance to national exhaustion. Conversely, since CAFTA does not explicitly prohibit the doctrine of international exhaustion, Central American countries can maintain their current law and practice regarding parallel imports.

It is nevertheless interesting to note that the enforcement of provisions prohibiting the use of international exhaustion has spurred a domestic debate in the USA. In view of the high cost of pharmaceuticals in the USA, the Senate is currently reviewing a bill that would introduce the international exhaustion doctrine into US law. The proposed Act states,

> "It shall not be an act of infringement to use, offer to sell, or sell within the USA or to import into the USA any patented invention […] that was first sold abroad by or under authority of the owner or licensee of such patent." (S.2328)

This debate over international exhaustion in the US points to the fact that the US is, in itself, not immune to the impact of the increasing rule-based environment it is creating. Challenging how the Executive is pursuing its agenda and its impact on the country's ability to set national policy, David Dreier, a member of Congress, argued:

> We need to set our national policy on the critical issues first, before trying to engage in setting international standards […]. If our trade negotiators with Australia are moving the drug policy debate in one direction or the other, the tail will be wagging the dog on some of the most important policy decision we face (Dreier, 2003).

The USTR has tried to reassure congressmen by publishing a document called "Questions and Answers about Pharmaceuticals". In this document, the USTR expressed a curious opinion by arguing that Congress could enact a law that breaches its international commitments regarding international exhaustion: "Even if a dispute settlement panel found the USA acted inconsistently with the FTA, it could not require Congress to amend the law" (USTR, 2004). Considering that the USA is doing everything it can to convince

developing countries to fully implement the TRIPS agreement, this point of view is quite astonishing.

9 Restrictions on the grounds for revocation

During the TRIPS negotiation, the issue concerning the grounds that can justify a revocation of a patent was highly controversial (Gervais, 2003). The final version of TRIPS Article 32 circumvents these controversies and does not address directly the issue of the grounds for revocation: "An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available". Most analysts interpret the TRIPS as leaving to the WTO members the discretion to determine the ground for revocation. Accordingly, WTO members would have the authority to revoke a patent on grounds of public interest, including for compliance with the public health law and for abuses that might result from the exercise of the exclusive rights.

In this context, FTAs represent a new opportunity for the USA to restrict the basis of revocation. Indeed, most FTAs include commitments on revocation that go beyond the TRIPS agreement:

> Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent. A Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking a patent or holding a patent unenforceable. (SFTA, Art. 16.7.4; CFTA, Art. 17.9.5; CAFTA, Art. 15.9.4; AFTA, Art. 17.9.5; MFTA, Art. 15.9.5; BFTA, Art. 14.8.4)

These grounds reflect US law where a patent can be revoked on grounds that would have justified the refusal of its grant and where, under the 'clear hands' doctrine, a patent might be unenforceable for a basis of fraud, misrepresentation or inequitable conduct. However, while the notions of "fraud, misrepresentation or inequitable conduct" can be broadly defined, these FTAs do not allow the revocation on any ground pertaining to other public interest. They do not authorise, as the Convention of Paris does, revocation in cases where the compulsory licensing grant is not sufficient to prevent the failure to work.

The introduction of this new provision in bilateral FTAs may offer some support for US's multilateral objectives. Indeed, under WIPO negotiations of the Substantive Patent Law Treaty, the grounds for revocation were once again negotiated multilaterally.[1] Although these negotiations have been recently suspended, the US strategically built an alliance through its FTAs that can be instrumental to support the restriction of the grounds for revocation in subsequent multilateral negotiations. As the IP negotiation history has shown, bilateralism could be an exit line when the multilateral road is obstructed, as well as, an entry line for a subsequent multilateral highway.

10 Concluding remarks

As summarised in Table 1, this paper demonstrated a number of important features of FTAs, namely:

- the patentability of new uses of known medicines
- the protection of undisclosed data
- the extended term of protection to compensate administrative procedures
- the prohibition of some exceptions
- the definition of circumstances for compulsory licensing
- the proscription of the international exhaustion doctrine
- and the restriction of the grounds for revocation.

FTAs clearly allow the USA to go beyond the TRIPS agreement. This paper demonstrated that some FTAs: prescribe the patentability of new uses of known medicines, strengthen the protection of undisclosed data, extend the term of protection to compensate administrative procedures, prohibit some exceptions to the conferred rights, define circumstances for compulsory licensing, proscribe the doctrine of international exhaustion, and restrict the ground for revocation. All of these TRIPS-plus provisions are additional barriers to the entry of generic medicines in FTAs signatories' market.

Table 1 Selected TRIP-plus provisions related to health issues

	TRIPS (*1994*)	*JFTA* (*2000*)	*SFTA* (*2003*)	*CFTA* (*2003*)	*CAFTA* (*2003*)	*AFTA* (*2004*)	*MFTA* (*2004*)	*BFTA* (*2004*)
New use of a known medicine shall be patentable	–	–	–	–	–	√	√	√
Patent owners shall give their consent for the issue of any marketing approval	–	–	√	√	√	√	√	√
The term of a patent must be extended to compensate marketing approval process	–	√	√	√	√	√	√	√
Generic medicines can only be made and exported for purposes of marketing approval	–	√	√	√	√	√	√	√
Compulsory licences are not authorised except under specific circumstances	–	√	√	–	–	√	–	–
The exclusive right to prevent importation shall not be limited by sale outside the territory	–	–	–	–	–	√	√	–
The ground for revocation is explicitly restricted	–	√	√	√	√	√	√	√

Since FTAs include TRIPS-plus provisions, many believe that they are inconsistent with the Doha Declaration. Among them, several members of Congress argued that, in a letter to President Bush,

> "provisions in [bilateral] agreements or under consideration for inclusion violate the requirement in Section 2101(b)(4)(C) of the Trade Promotion Authority Act of 2002 to uphold the 2001 WTO Declaration on Public Health." (Solis et al., 2004)

Furthermore, French President Chirac expressed in no uncertain terms that forcing some countries to abandon the Doha Declaration on Public Health in favour of bilateral negotiations constitutes immoral blackmail (Chirac, 2004).

The US Trade Representative, Robert Zoellick, was quick to respond to Chirac's bold assertion. In an interview with the Financial Times he retorted with defiance, exclaiming

> "I guess my response to France would be that I wish they would quit trying to undermine the rest of the world economy with agricultural exports and to divert attention with issues like this." (Dyer et al., 2004)

A diversion which he deems to be unfounded in view of his belief that FTAs do not contradict the Doha Declaration. From Zoellick's point of view,

> "FTAs not only do not conflict with the objectives expressed in the Doha Declaration, but reinforce those objectives and facilitate efforts to address public health problems." (Veroneau, 2004)

The flexibilities guaranteed by the Doha Declaration can be legitimately used to enhance, rather than curtail, patent protection norms. Giving the example of the US agreement with Jordan to substantiate his view, Zoellick claims that Jordan has effectively used its agreement with the USA as a gateway to develop its pharmaceutical industry, thus enhancing access to medicines for Jordanians. As such, the US government firmly believes that the protection of public health is compatible with the adoption of ever-increasing patent protection norms in the pharmaceutical industry.

In my view, although FTAs are legally compatible with the Doha Declaration on Public Health, they contravene to its spirit. The Doha Declaration is a political declaration that aims to preserve a flexible interpretation of TRIPS' minimum standards. It does not in any way establish a legal ceiling against the extension of IP standards. WTO members remain free to lay down rules that go beyond the minimum standards of the TRIPS agreement. That being said, the Doha Declaration was clearly adopted with a view to preserve the flexibility of developing countries to maintain a minimal protection (Abbott, 2004). If a WTO member wishes to raise its patent standards, the decision should originate from a domestic decision process and not be prescribed by a foreign actor, be it a transnational firm through a private contract, an international organisation through a technical assistance program, or a foreign country through a bilateral treaty. Given that mutual trust is a key condition for the conclusion of the Doha Round, respecting the spirit of the Doha Declaration should remain a priority of developed countries.

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Note

[1]These negotiations have been recently suspended, due to opposition by developing countries.