
The impact of FTAs on public health policies and TRIPS flexibilities

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Abstract: This paper, after providing a brief historical overview of the ways international agreements deal with public health-related IPRs, analyses the TRIPS-plus trend in Free Trade Agreements (FTAs) and its impact on access-to-medicines policies. It focuses on FTAs concluded by the USA and the Member states of the European Free Trade Association (EFTA) with a number of developing countries and their provisions on patents and test data protection. New obligations in this field go well beyond the TRIPS minimum standards and may seriously affect access in developing countries to affordable generic pharmaceutical products.

Keywords: intellectual property rights and public health; Free Trade Agreements (FTAs); TRIPS-plus obligations; access to medicines; patent rights; protection of pharmaceutical test data; generic medicines.

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1 Introduction

The impact of patents on public health policies, in particular with respect to access to medicines, has been one of the most debated WTO issues in recent years. With the adoption of the Doha Declaration on the TRIPS Agreement and Public Health¹ and the General Council Decision for the implementation of paragraph 6 of that Declaration,² the focus of the discussion has started to shift away from the multilateral level to the regional and bilateral arena, where a number of post-TRIPS Free Trade Agreements (FTAs) have been signed. As far as substance is concerned, these FTAs have added to traditional patent rights another form of protection that is relevant in the context of access to medicines: exclusive rights in pharmaceutical test data submitted to regulatory authorities in the course of marketing approval procedures.

Prominent actors have voiced the concern that provisions on intellectual property rights (IPRs) in FTAs that go beyond the TRIPS minimum standards ('TRIPS-plus') have a serious impact on countries' public health policies. As expressed by Paul Hunt, UN Special Rapporteur on the Right to Health:

"I am deeply concerned that the US-Peru trade agreement will water-down internationally agreed health safeguards, leading to higher prices for essential drugs that millions of Peruvians will find unaffordable." (Bridges Weekly Trade News Digest, 2004)³

With respect to the FTA between the USA and Morocco, Nobel Prize laureate Joseph Stiglitz observed:

"The new agreement, many Moroccans fear, will make generic drugs needed in the fight against AIDS even less accessible in their country than they are in the United States." (Stiglitz, 2004; Oxfam, 2004)⁴

In a forceful manner, a report for US Rep. Henry A. Waxman has concluded:

"In 2001, the United States joined the international community in adopting the Doha Declaration, which recognized that trade agreements should not impede the efforts of developing countries to obtain essential drugs at affordable prices. Since then, the Bush Administration has negotiated multiple trade agreements with developing countries, including the CAFTA agreement now pending before Congress. Contrary to the principles of the Doha Declaration, the Administration has used these trade agreements to restrict the access of developing countries to low-cost generic drugs. By delaying generic drug approvals, extending patent terms, limiting compulsory licensing, prohibiting parallel importation, and otherwise restricting countries' efforts to improve access to affordable drugs, the trade agreements undermine the safeguards

outlined in the Doha Declaration. These agreements may offer advantages to multinational pharmaceutical companies, but they do so at a serious cost to public health in the developing nations.” (United States House of Representatives, 2005, p.13)

Thus, the widely-shared concern is that developing countries by signing TRIPS-plus FTAs risk losing the very flexibilities they are granted through the TRIPS Agreement, the Doha Declaration and its implementing decision.

This paper, after providing a brief historical overview of the ways international agreements deal with public health-related IPRs, analyses the TRIPS-plus trend in FTAs and its impact on access-to-medicines policies. The Annexure provides a comparative overview of the main FTAs analysed in this paper.

2 The issue of patent rights and public health under the Paris Convention and the TRIPS Agreement

Patent rights potentially restrict access to pharmaceutical products, due to their exclusive nature. This was one of the reasons why a number of today’s developed countries for quite some time excluded pharmaceutical products from patentability (Roffe et al., 2005; UNCTAD-ICTSD, 2003).⁵ In addition, the first international treaty for the protection of industrial property, the Paris Convention, left countries considerable freedom in the design of their health policies. Any state party was free to exclude entire areas of technology or certain products or processes from patentability. The Convention also leaves every party the discretion to draft its own patentability criteria, and to make the failure to work a patent locally a ground for the issue of a compulsory licence.⁶

The TRIPS Agreement brought about a number of important changes in the area of patent law (UNCTAD-ICTSD, 2005).⁷ First of all, it introduced the obligation to make patents available in all fields of technology, and for both products and processes.⁸ This makes it impossible for WTO Members other than least-developed countries (LDCs, see below) to keep pharmaceutical products excluded from patentability. TRIPS also obligates Members to make available patents without discrimination as to the place of invention, the field of technology or whether the products are imported or produced locally.⁹ The latter raises questions on the flexibility countries have today on establishing ‘local working’ requirements for patents (providing compulsory licensing or revocation of the patent if the protected product is not produced locally but imported) (UNCTAD-ICTSD, 2005).¹⁰

On the other hand, the TRIPS Agreement still leaves WTO Members considerable discretion for the design of their national patent laws. In particular, the following features are relevant in the access to medicines context. The TRIPS Agreement:

- Leaves Members the freedom to define strict criteria of patentability. This is an important tool in preserving a large public domain for follow-on research and the promotion of competing products to help maintain prices at modest levels.
- Contains no obligation to make patents available for new uses of known products (‘second uses’). This may be a way of avoiding ‘ever greening’ of patents by seeking an additional full patent term for the same product.
- Contains no obligation to prohibit price controls on patented products.

- Authorises the control of IPR abuses through competition laws and policies, in particular in licensing agreements.¹¹
- Allows for exceptions, under certain conditions, to the exclusive rights conferred by a patent.¹² One relevant exception in the public health field is the early working ('Bolar') exception.
- Allows Members to freely determine the substantive grounds for the issuance of compulsory licences.¹³
- Authorises Members to determine their own system of IPR exhaustion (national, regional, or international). Through an international exhaustion regime, developing countries may facilitate parallel imports of low-priced drugs from abroad.¹⁴
- With respect to the protection of pharmaceutical test data submitted to regulatory authorities for marketing approval purposes, leaves it up to each Member to provide protection through exclusive or non-exclusive rights (i.e., through rules on unfair competition) (UNCTAD-ICTSD, 2005).¹⁵ There is an important difference between these two approaches, which is discussed below.
- Authorises LDC Members to benefit from extendable transition periods for the implementation of the TRIPS minimum standards (1 July 2013 in general; 1 January 2016 for the application of patent rights and rules on the protection of undisclosed information in the area of pharmaceutical products).¹⁶

The TRIPS flexibilities were reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health, stating that

“In this [public health/access to medicines] connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”¹⁷

The WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health¹⁸ even extended the TRIPS flexibilities in regard of compulsory licensing: in essence, that Decision waives the exporting country's obligation under Article 31(f), TRIPS Agreement, to use drugs produced under compulsory licence predominantly for the supply of its own, domestic market.¹⁹ In respect of the importing Member, the Decision waives the obligation under Article 31(h), TRIPS Agreement, to pay an adequate remuneration to the patent holder, where remuneration for the same product has already been paid in the exporting Member.²⁰ A number of WTO Members such as Canada, the EU, India, Norway, the Netherlands and Switzerland have passed domestic legislation to implement the Decision or are in the phase of doing so (Abbott, 2005).²¹

3 The trend toward TRIPS-plus in FTAs

In recent years, all four major economic players, i.e., the European Union (EU), Japan, the USA, and the countries of the European Free Trade Association (EFTA) have been active in the negotiation of FTAs (Abbott, 2004b).²² In the EU's FTAs, there are a number of TRIPS-plus obligations, but these are less relevant to the public health context, covering mainly the protection of plant varieties and biotechnological inventions (CUTS,

2004)²³ or geographical indications (Vivas-Eugui and Spennemann, 2006).²⁴ As to the Japanese FTAs, they usually include only vague references to IPR protection, either under the investment chapter,²⁵ or in an independent chapter on IPRs.²⁶ The EFTA states have concluded three FTAs that are relevant in the present context, i.e., with Chile (2003), Lebanon (2004) and Tunisia (2004). Each of these agreements contains an annex on IP protection, providing, *inter alia*, provisions in the area of patents and undisclosed information.

Since 2001, the USA has signed a considerable number of FTAs, in particular with developing countries. To provide a brief overview (Fink and Reichenmiller, 2005),²⁷ those FTAs include agreements with Vietnam,²⁸ Australia; Bahrain; the Parties to the Dominican Republic – Central American Free Trade Agreement (DR-CAFTA, comprising Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua); Chile; Morocco; Oman; Peru; and Singapore. Finally, current negotiations on FTAs include Colombia and Ecuador, Thailand, Panama, the Southern African Customs Union (SACU), the United Arab Emirates, and the Free Trade Area of the Americas (FTAA).²⁹

This paper will focus on the US FTAs, which in general contain full chapters on IPR protection with detailed substantive provisions on all types of IPRs.³⁰ Where appropriate, reference will also be made to the relevant EFTA free trade agreements.³¹

All of the signed US FTAs include provisions on patents and data protection that go beyond the minimum standards established by the TRIPS Agreement (see below) (Timmermans, 2005; El-Said, 2005).³² During the Uruguay Round negotiations, the USA had to accept compromises, in particular with respect to data protection, where this country proposed a regime of exclusive protection (as opposed to the final outcome under TRIPS, see above) (UNCTAD-ICTSD, 2005).³³ For major trading powers like the USA, the EU or Japan, bilateral or regional negotiations of FTAs with developing countries represent a welcome opportunity to achieve what was not possible to negotiate successfully at the multilateral level. However, there is only limited scope for coalitions between like-minded developing countries in regional or bilateral negotiations, respectively, to resist upward pressure on IPRs obligations.

From a developing country perspective, it is important that an FTA contains a large number of other issue chapters, which in exchange for higher protection of IPRs might offer to developing countries market access to their developed country counterparts, facilitating their overall integration into the global economy and thus contributing to the reduction of poverty (Roffe, 2004).³⁴ Thus, the conclusion of FTAs is often perceived by developing country societies as a major political and economic achievement, while the impact of increased IPR standards on domestic health policies does not immediately become obvious.

4 Analysis of the health-related provisions in FTAs and their impact

The following section will describe and analyse health-related TRIPS-plus provisions in US and EFTA FTAs in the areas of patents and test data protection.

4.1 *TRIPS-plus in the area of patent law*

4.1.1 *Patent term extensions*

Under Article 33, TRIPS Agreement, the minimum term of patent protection is 20 years from the filing date. However, the period during which the patentee may actually take advantage of his monopoly rights may be affected in two ways. First, the patent grant may take several years, thus reducing the effective term of protection. Second, in order to market a patented pharmaceutical product, the right holder still needs the marketing approval by the responsible regulatory authority, which may also reduce the effective term during which the patentee may benefit from his monopoly rights. For that reason, all of the above, signed US FTAs as well as the EFTA – Chile FTA require an extension of the patent term in case the regulatory approval process delays the marketing of the patented product or process (Roffe, 2004).³⁵ With the exception of the Jordan FTA, all of the above, signed US agreements additionally require an extension of the patent term in case of ‘unreasonable’ delays occurring in the patent grant procedure. The number of years required for such delay to be ‘unreasonable’ varies with the respective FTA (Roffe, 2004).³⁶ The EFTA FTAs do not contain a comparable provision.

4.1.2 *Patentability of second uses*

As opposed to the TRIPS Agreement, the US FTAs with Australia, Bahrain and Morocco require parties to make available patents for new uses of known products. This provides patent holders with the opportunity to ‘ever green’ existing patents, adding another full term of protection on the already patented pharmaceutical product.

4.1.3 *Patentability criteria*

As opposed to the TRIPS Agreement, the DR-CAFTA contains a definition of what constitutes ‘industrial application’, referring to the US law concept of ‘utility’ (Roffe, 2004).³⁷ This prevents parties from adopting narrower definitions, like the concept of ‘industrial applicability’ as applied in European countries. The difference may be considerable. As opposed to the concept of ‘industrial applicability’, the ‘utility’ approach permits the patentability of business models and purely experimental inventions that do not produce any technical effects and cannot be made or used in an industry. This may result in the patenting of research tools needed for the development of competing products (UNCTAD-ICTSD, 2005).³⁸

4.1.4 *Compulsory licences*

As opposed to the TRIPS Agreement, the US FTAs with Australia, Jordan, Singapore and Vietnam limit the grounds for the use of compulsory licences to cases of anti-trust remedies, public non-commercial use, national emergencies or other circumstances of extreme urgency.³⁹ On the other hand, the same agreements contain no definition of the above terms, leaving it to the parties to define, for instance, what constitutes a case of ‘national emergency’. The EFTA FTAs with Tunisia and Lebanon for the grants of compulsory licences refer to the conditions laid down in Article 31, TRIPS Agreement.⁴⁰ Only the FTA EFTA – Chile expressly refers to the terms of the Doha Declaration on TRIPS and Public Health.⁴¹

4.1.5 Parallel imports

Under the US FTAs with Australia, Morocco and Singapore, the patent owner is authorised to prevent parallel imports through the use of contract or other means.⁴² From a technical point of view, such authorisation does not amount to a general exclusion of international patent right exhaustion. It is important to distinguish between intellectual property rights on the one hand, and the law of contract, on the other hand. The concept of IPR exhaustion only affects the existence of a particular IPR, but does not limit the discretion of the parties to a sales contract to exclude certain countries from the geographical area where the purchaser of a patented product may resell that item.⁴³ In the above FTAs, the parties keep in theory the freedom to maintain or introduce international patent right exhaustion. In case the purchaser of a patented product does not agree on a territorial restriction for the resale of the products, he preserves his right to resell them anywhere in the world in parallel to the patent holder. However, it is unusual that through a treaty there is such an attempt to induce private parties to prevent parallel imports. The US House of Representatives report to Rep. Henry Waxman warns on this trend:

“... making this policy permanent in trade agreement prevents countries that do not currently restrict parallel importation from reconsidering their national policies. Even in the USA there is great support for a form of parallel importation: both the house and the Senate have measures that would allow the importation of lower-priced patented drugs from Canada. The trade agreement language would make it difficult for the USA or other nations with current restrictions on importation to revisit their national policies.”

4.1.6 Early working exception

The TRIPS Agreement in Article 30 authorises Members to provide, under certain circumstances, limited exceptions to exclusive patent rights. One of these exceptions, as endorsed by a WTO panel⁴⁴ and available in many domestic laws (UNCTAD-ICTSD, 2005),⁴⁵ is the authorisation of third party competitors to use patented subject matter to generate information required to support an application for marketing approval of a pharmaceutical or agricultural chemical product (‘Bolar exemption’). The purpose of this exception is to accelerate market entry of generic competitors after the expiry of the respective pharmaceutical or agrochemical patent. As marketing approval may be time consuming, the generic producer is accorded the possibility to produce and submit for approval the patented substance during the patent term, to assure regulatory approval is available by the end of the patent term. Otherwise, delays in approving competing products would amount to a *de facto* extension of the exclusivity period accorded by the patent.

An early working exemption is provided in all of the US FTAs under scrutiny. However, the Bahrain FTA and DR-CAFTA contain a particularity in this respect. Both agreements authorise early working of patented material for the purpose of meeting approval requirements to market the product ‘once the patent expires’.⁴⁶ This proviso has been interpreted as limiting generic drugs approvals to the time after the expiry of the patent, thus ignoring the approval requirement for medicines produced under compulsory licence for export under the Decision on the Implementation of Paragraph 6 (Abbott, 2004a).⁴⁷ It could be argued, however, that in the public health context, the authorisation of third parties to produce the patented drug under compulsory licence

equals the expiry of a patent, as in both cases the patentee loses his monopoly position. Such interpretation would be in line with the requirement for WTO Members to implement the TRIPS Agreement in a manner supportive of Members' right to promote public health⁴⁸ and Members' right to issue compulsory licences.⁴⁹ A provision in an FTA that denies the effectiveness of marketing approvals in cases of compulsory licensing would negate these agreed rights and would therefore be 'contrary to the letter and spirit' of paragraph 4 of the Doha Declaration (Abbott, 2004a).⁵⁰

4.2 *TRIPS-plus in the area of data protection*

4.2.1 *Extension of the obligations provided under Article 39, TRIPS Agreement*

As to the protection of test data submitted to regulatory authorities in the context of marketing approval procedures (concerning the safety and efficacy of pharmaceutical and agricultural chemical products containing new chemical entities, so-called 'regulated products'), the TRIPS Agreement in Article 39.3 leaves Members the discretion whether such data should be protected through exclusive rights or through a system of unfair competition rules (UNCTAD-ICTSD, 2005).⁵¹ Under the latter, the data originator may prevent third party competitors from submitting the same test data for marketing approval, provided the third party has obtained the data by dishonest commercial means. On the other hand, and contrary to an exclusive rights regime, unfair competition rules do not prevent the regulatory authorities themselves to rely on the original data to assess submissions by third party competitors relating to similar products (UNCTAD-ICTSD, 2005; Meitinger, 2005).⁵² This considerably facilitates the market entry by competitors, as they are not obliged to repeat the same clinical and toxicological tests as already undertaken by the data originator. Such tests are time consuming and expensive, and often represent insurmountable barriers for the market entry of small producers of generic pharmaceutical products.

The USA – Jordan FTA reproduces the TRIPS standards for the protection of test data, mandating protection against 'unfair commercial use'.⁵³ All of the other US FTAs examined here, however, introduce a regime of exclusive rights in the test data, providing that once a company has submitted original data on a pharmaceutical product, regulatory authorities shall not permit competing producers to rely on these data for a period of five years from the date of marketing approval in that Party (ten years in case of agricultural chemical products).⁵⁴ This provision effectively requires generic producers to come up with their own test data, which very often is not economically feasible. It thus provides the data originator with a period of exclusivity. It is important to note that this exclusivity applies to *non-patented* pharmaceutical or agrochemical products, thus creating a new form of monopoly not required by TRIPS (Abbott, 2004a).⁵⁵ Such exclusivity on test data was actually proposed by the USA during the Uruguay Round negotiations of the TRIPS Agreement, but not accepted by other delegations (UNCTAD-ICTSD, 2005).⁵⁶ In this sense, the FTAs fulfil important complementary functions in US intellectual property policy. As far as the EFTA free trade agreements are concerned, the treaties with Tunisia and Lebanon show some particularity: data exclusivity and non-reliance are waived where the data originator is 'adequately compensated'.⁵⁷ While both the Chile and Tunisia FTAs provide for a five-year exclusivity, the Lebanon FTA requires parties to adopt a minimum period of protection of six years.

As to the scope of the obligation to provide for exclusive rights in test data, the examined FTAs vary. The USA – Chile FTA refers to ‘undisclosed information’,⁵⁸ reproducing the TRIPS standard. The US DR-CAFTA (‘undisclosed data’, Chapter 15, Article 15.10.1(a)) as well as the Australia and Jordan FTAs (‘undisclosed test or other data’, Chapter 17, Article 17.10.1(a), and Article 4, paragraph 22, respectively) use similar language, which seems to indicate that the obligation for regulatory authorities not to use such information or data as grounds for marketing approvals does not apply in case the information/data has become public (Correa, 2004; Roffe, 2004).⁵⁹ By contrast, the US FTAs with Singapore (Chapter 16, Article 16.8.1) and Morocco (Chapter 15, Article 15.10.1) refer more broadly to ‘information’, implying that reliance on original data is precluded even where the information has become public.

While Article 39.3, TRIPS Agreement applies to ‘new chemical entities’, the FTAs in this respect do not follow a uniform approach. While exclusive protection under the USA – Singapore FTA is not limited to products containing new chemical entities, the USA – Australia FTA refers to ‘new products’, without however defining novelty in the sense of inventiveness, but as products containing no “chemical entity that has been previously approved for marketing in the Party” (Roffe, 2004).⁶⁰ Likewise, the USA – Chile FTA applies only in cases of ‘new chemical entities’.⁶¹

On top of the five-year exclusivity period as described above, the FTAs with Bahrain and Morocco require parties to accord another three years of data exclusivity for ‘new clinical information’, such as previously unapproved uses of approved products.⁶² This provision may be seen as helping data originators ‘evergreen’ their exclusive rights by preventing the market entry of generic competitors. Data originators might claim overlaps of usages between the generic products and their own, newly approved uses, even where the generics are only intended to cover old uses (which is possible after the expiry of the original five-year period of exclusivity). Legal proceedings to dismiss such claims and to distinguish between old and new uses are likely to create further delay for market entry of generic competitors (Abbott, 2004a; Mellouk, 2005).⁶³

Some FTAs extend the exclusive protection of test data beyond the national territories of the parties involved. Usually regulatory authorities may base their own marketing approvals on the grant by foreign authorities of marketing approvals for the same or similar products in other countries. Under the USA – Singapore FTA, such recognition of foreign marketing approvals is made dependent on the consent of the data originator in the other country.⁶⁴ Without his consent, domestic approvals based on foreign approvals may only be granted at least five years after a pharmaceutical product has been approved for the data originator in the foreign country or domestically.⁶⁵ Thus, the data originator is protected in a party to the FTA even where he has received marketing approval only in a foreign country not party to the FTA.

However, this does not prevent domestic regulatory authorities to examine test data originally submitted to foreign authorities. The USA – Singapore FTA only prevents *automatic recognition* of foreign approval decisions. It does not hinder domestic authorities to *independently examine* submissions by generic producers that are based on data submitted earlier by data originators abroad, including in one of the Parties to the FTA. The provisions on exclusivity as described above (as contained in all of the examined FTAs, except the Jordan FTA) only prevent reliance by regulatory authorities on original data submitted in the *domestic* context, but do not apply to data originally submitted *abroad*. In this respect, the USA – Singapore FTA still leaves a possibility for

domestic regulatory authorities to facilitate market entry of generics through reliance on foreign original data.

This possibility, however, has been shut down in the more recent FTAs with Australia, Bahrain and the DR-CAFTA countries. These agreements not only prevent recognition of foreign marketing approval decisions, but expressly prohibit reliance by domestic regulatory authorities on “the safety or efficacy information submitted in support of the prior marketing approval in the other territory, for at least five years for pharmaceutical products ... from the date of marketing approval of the new product in the Party”.⁶⁶ Thus, the data originator may prevent reliance on his test data previously submitted *abroad*, but the five-year term of exclusivity is counted only from the date the data originator is granted marketing approval for the *domestic* market. It is not clear from the above provisions whether reliance by domestic authorities on the originator's data is possible during the period *between* the submission of the data abroad and a subsequent grant to the data originator of domestic marketing approval. Some consider the above provisions to prevent such reliance, effectively providing the data originator with the possibility to keep the market of a Party without supply of the product in question until he chooses to seek domestic marketing approval.⁶⁷ Under the DR-CAFTA FTA, the data originator is required to limit this "waiting period" by seeking domestic marketing approval within five years after obtaining the approval abroad.⁶⁸ Neither the Australia nor the Bahrain FTA contains a comparable limitation. In the literature, deep concerns have been expressed about the possibility for the data originator to fully utilise the five-year waiting period under the DR-CAFTA FTA before enjoying the five-year exclusivity period for pharmaceutical products, thus enjoying an actual ten-year period of exclusivity.⁶⁹

4.2.2 *Linkage between regulatory procedures and patent rights*

While the above observations concern non-patented pharmaceutical and agrochemical products, most of the FTAs under examination also contain a provision that is likely to have an important impact with respect to patented pharmaceutical and agrochemical products. With the exceptions of the USA – Vietnam and USA – Jordan FTAs, all of the examined agreements establish a link between the regulatory approval procedure and the patent right covering the respective product. For instance, Chapter 15, Article 15.10.3 of CAFTA provides:

“3. Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the Party or in another territory, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval of a product during the term of a patent identified as claiming the product or its approved use, it shall provide that the patent owner be informed of such request and the identity of any such other person.”

In other words, the decision by regulatory authorities to grant marketing approval is made dependent on the will of the patent holder (paragraph (a), as quoted above), thus linking the separate realms of safety regulations and patent law. Thereby, the term of data protection is effectively extended to the full term of a patent, which is not required under TRIPS (Abbott, 2004a; Roffe, 2004).⁷⁰ The EFTA FTAs do not contain comparable provisions.

Next to the difficulties created for regulatory authorities to determine the validity of patents, this provision has been interpreted as possibly precluding governments' possibilities to use compulsory licensing as a means of making available low-priced pharmaceutical products (Abbott, 2004a).⁷¹ Since marketing approval is independent of patent law, the third party authorised to produce a patented product under compulsory licence would arguably depend on the patentee's consent or acquiescence for the actual marketing of the product (UNCTAD-ICTSD, 2005).⁷²

4.3 The impact of the MFN principle

According to Article 4 of the TRIPS Agreement,

“With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members.”

In the context of FTAs, this means that TRIPS-plus provisions as analysed above will have to be granted by the parties to the respective FTAs to nationals from all other WTO Members (Vivas-Eugui, 2003; Roffe, 2004).⁷³ While the meaning of advantage, favour, privilege or immunity in the area of IPRs is not entirely clear (Roffe, 2004 ; UNCTAD-ICTSD, 2005),⁷⁴ it seems that the above TRIPS-plus obligations fall under these terms, as they enhance the IP right holders' legal position.

4.4 The 'side letters' or 'understandings'

Being aware of public concern about the impact of FTAs on countries' abilities to promote enhanced access to medicines, the parties in the cases of the US FTAs with Bahrain, the DR-CAFTA countries and Morocco agreed on 'side letters' or 'understandings'. According to these documents, the IP standards as contained in the respective FTAs do not affect the parties' ability to protect public health.

For instance, the USA and Morocco exchanged letters in June 2004 indicating that:

“The obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.

In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the 'TRIPS/health solution'), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.

With respect to the aforementioned matters, if an amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights enters into force with respect to the parties and a party's application of a measure in conformity with that amendment violates Chapter Fifteen of the Free Trade Agreement, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment."⁷⁵

Responding to requests from the US Congress, a letter by the General Counsel of USTR stated with respect to the USA-Morocco FTA that:

"... if circumstances ever arise in which a drug is produced under a compulsory licence, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the FTA would not stand in the way."⁷⁶

The legal value of these side letters in the interpretation and application of the FTA provisions on IPRs has been questioned by international legal scholars (Correa, 2004; Abbott, 2004a).⁷⁷ In addition, USTR seems to be of the view that the side letters do not create any kind of exemption allowing parties to the FTAs to ignore their obligations contained in the respective IP chapters (Fink and Reichenmiller, 2005).⁷⁸ Thus, these instruments may not necessarily be considered as fully responding to public concerns as described at the beginning of this paper.

4.5 Final observations

The paper has reviewed recent trends in the area of intellectual property protection and their impact on public health policies, in particular with respect to access to medicines. The Doha Declaration on the TRIPS Agreement and Public Health of 2001 signalled an important political manifestation of the international community by reaffirming that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health". According to the Ministerial Declaration,

"the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health, and in particular, to promote access to medicines for all."

One worrisome recent development has been the shift of the discussion away from the multilateral level to the regional and bilateral arena, where a number of post-TRIPS Free Trade Agreements (FTAs) have been signed. The FTAs have strengthened the position of large drug companies at the expense of risking the flexibilities recognised in the TRIPS Agreement, as confirmed by the Doha Ministerial Declaration.

For developing countries the great challenge is how to respect international commitments in terms of protecting legitimate rights of innovators while promoting access to medicines for all. In this respect, developing countries should preserve and be encouraged to fully use the flexibilities of the system. The least developed countries should make full use of the transitional periods that in the case of pharmaceutical products has been extended until January 1, 2016. In the case of those that have not signed FTAs they should resort to the use of public policy instruments such as compulsory licensing. With respect to countries entering into free trade agreements, they should ensure that the flexibilities in TRIPS are not further jeopardised. Finally, for those countries having entered into TRIPS-plus commitments an attempt should be made to explore further existing flexibilities as well as innovative forms of implementing their

new obligations including full use of compulsory licensing regimes, exhaustion of property rights and the use of competition policy as a form of preventing the abuse of intellectual property rights by rights holders.

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Notes

¹WT/MIN(01)/DEC/W/2 of 14 November 2001.

²WT/L/540 of 2 September 2003.

³United Nations Press Release of 5 July 2004. See also Bridges Weekly Trade News Digest (2004). Similar concerns have been expressed with respect to agreements being promoted by EFTA. In June 2005, NGOs from both Thailand and the EFTA countries submitted a request to the UN Special Rapporteur on the Right to Health, urging him to warn the EFTA states not to restrict access to affordable generic medicines in Thailand through a future FTA with that country. The request on behalf of the EFTA NGOs is available at http://www.evb.ch/index.cfm?page_id=3647. The authors are grateful to Davinia Ovet of 3D for pointing this out.

⁴Stiglitz (2004). Similar points have been raised by civil society organisations such as Oxfam in the context of the FTA negotiations between Thailand and the USA:

“Oxfam shares the concerns of Thai NGOs that a Free Trade Agreement with the USA, containing unnecessarily high intellectual property standards, will seriously undermine future access to affordable medicines in Thailand.”
(Oxfam, 2004)

⁵See UNCTAD-ICTSD (2003) pp.33, 34. Accordingly (fn.37), the patentability of pharmaceutical products was introduced as late as 1960 in France, 1968 in Germany, 1977 in Switzerland, 1978 in Italy and Sweden, and 1992 in Spain. For an historical overview of the development of the international patent system, see Roffe *et al.* (2005).

⁶For the latter, see Article 5, paras 2 and 4, of the Paris Convention.

⁷For a detailed analysis, see UNCTAD-ICTSD (2005) in particular Chapter 17.

⁸See Article 27.1, TRIPS Agreement.

⁹Article 27.1, TRIPS Agreement.

¹⁰See UNCTAD-ICTSD (2005) Chapter 25: Patents: Non-voluntary Uses (Compulsory Licenses).

¹¹See Articles 8.2, 40, TRIPS Agreement.

¹²See Article 30, TRIPS Agreement.

¹³See Article 31, TRIPS Agreement.

¹⁴In this context, see the Report by the Commission on Intellectual Property Rights, recommending that:

“Developing countries should not eliminate potential sources of low cost imports, from other developing or developed countries. In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee’s rights have been exhausted in the foreign country. Since TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.”
(Commission on Intellectual Property Rights, 2002, p.42)

¹⁵See Article 39.3, TRIPS Agreement. According to another view, this article does not leave Members the discretion to choose, but obligates them to provide for exclusive rights in the test data. For a discussion, see UNCTAD-ICTSD (2005) Chapter 28, Section 3.

¹⁶See Decision of the Council for TRIPS of 29 November 2005, IP/C/40 (‘Extension of the Transition Period under Article 66.2 for Least-Developed Country Members’); and paragraph 7 of the Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W/2.

¹⁷See paragraph 4 *in fine* of the Declaration on the TRIPS Agreement and Public Health.

¹⁸WTO document WT/L/540 of 2 September 2003. On 6 December 2005, the WTO General Council decided to permanently amend the TRIPS Agreement, based on the 30 August 2003 Decision. The new Article 31*bis*, which is essentially identical with the 30 August Decision, will enter into force once ratified by two thirds of all WTO Members. Until then, the 30 August Decision will remain in force.

¹⁹See paragraph 2 of the Decision, and Article 31*bis*, paragraph 1 of the TRIPS Agreement.

²⁰See paragraph 3, second sentence of the Decision, and Article 31*bis*, paragraph 2 of the TRIPS Agreement.

²¹See Abbott (2005).

²²See Abbott (2004b).

²³Such as, for instance, the 2000 Cotonou Agreement with the ACP countries, or the 2002 Agreement with Lebanon (for some analysis of the EU FTAs, see CUTS (2004)).

²⁴Such as, for example, the 2002 Agreements with Chile on trade in wine and spirits, or the 1997 Agreement with Mexico on the mutual recognition and protection of designations for spirit drinks. For a detailed analysis of the EU and US FTA provisions on GIs, see Vivas-Eugui and Spennemann (2006).

²⁵Such as, for instance, the 2004 Agreement with Mexico for the Strengthening of Economic Partnership, referring to IPRs as a form of investment.

²⁶Such as, for example, the 2002 Agreement with Singapore for A New Age of Economic Partnership. Chapter 10 on IPRs includes no substantive provisions but is limited to provisions on cooperation and formalities.

²⁷See Fink and Reichenmiller (2005).

²⁸In technical terms, the USA-Vietnam bilateral agreement is not a free trade agreement, but a bilateral trade agreement seeking to establish normal trade relations under US trade law. See Fink and Reichenmiller (2005) p.10, fn.2.

²⁹This paper in its analysis will be limited to those FTAs that have already been signed.

³⁰All US FTAs are available at <http://www.ustr.gov/Trade_Agreements/Section_Index.html>.

³¹All EFTA FTAs are available at <<http://secretariat.efta.int>>.

³²For an analysis of the TRIPS-plus standards in the three Arab FTAs (Bahrain, Jordan and Morocco) and their implications, see El-Said (2005). For a particular focus on the interface between trade, IPRs and marketing approval issues under recent FTAs and their negative impact on efforts to enhance access to medicines, see Timmermans (2005).

³³For more details on the negotiating history of the relevant provisions on data protection and patents, see UNCTAD-ICTSD (2005).

³⁴Chile, for instance, has been actively pursuing the conclusion of bilateral agreements on market access and trade liberalisation. This policy has reportedly contributed to the reduction of the poverty rate from 47% in 1989 to 20% in 2003 (see Roffe, 2004).

³⁵The USA-Chile FTA, for instance, does not specify the limits of such compensatory extension. See Roffe (2004) p.26. The EFTA FTAs with Lebanon and Tunisia do not include any reference to compensatory extension.

³⁶In the case of the Chile FTA, a delay is ‘unreasonable’ either if the patent is issued after more than five years from the date of filing; or three years after a request for examination of the application has been made, whichever is later (Article 17.9). In the cases of Australia and Singapore, these time lines are four and two years, respectively, while CAFTA is identical to the Chile FTA (Roffe, 2004, p.23).

³⁷See Roffe (2004) p.20.

³⁸See UNCTAD-ICTSD (2005) p.361, also stating that in 2001, the US Patent and Trademark Office’s Utility Examination Guidelines were modified, thus possibly resulting in an exclusion from patentability of a number of research tools.

³⁹See, e.g., Article 4, paragraph 20 of the USA – Jordan FTA.

⁴⁰See Annex V, Article 3(b) of the Lebanon FTA and Annex V, Article 3(b) of the Tunisia FTA.

⁴¹See Annex XII, Article 3(c).

⁴²See, e.g., Chapter 15, Article 15.9.4 of the USA – Morocco FTA, and Chapter 17, Article 17.9.4 of the USA – Australia FTA.

⁴³For the distinction between IPRs and contract law, see European Court of Justice (ECJ), *Zino Davidoff SA v A&G Imports, Ltd*, Case No. C-414/99. According to the ECJ, the exclusion of international trademark exhaustion under EC law does not prevent a trademark holder to expressly consent to the importation by a third party of trademarked products sold for the first time outside the European Economic Area (EEA).

⁴⁴See *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R of 17 March 2000. For a detailed analysis and criticism of this decision, see Garrison (2006).

⁴⁵For an overview, see UNCTAD-ICTSD (2005) Chapter 23 (p.443 *et seq.*).

⁴⁶See Chapter 15, Article 15.9.5 of CAFTA, and Chapter 14, Article 14.8.5 of the USA – Bahrain FTA. The other US FTAs do not include a comparable qualification.

⁴⁷See Abbott (2004a) p.4, 5.

⁴⁸See paragraph 4 of the Doha Declaration on TRIPS and Public Health.

⁴⁹See paragraph 5 (b) of the Doha Declaration on TRIPS and Public Health.

⁵⁰See Abbott (2004a) p.12.

⁵¹For an analysis of Article 39, TRIPS Agreement, see UNCTAD-ICTSD (2005).

⁵²See UNCTAD-ICTSD (2005) p.531. In this context, see Meitingner (2005). This author argues that free reliance on original test data through second comers would be unfair. In order to be TRIPS-compliant, second comers relying on original data should compensate the first applicants. On the other hand, this author considers a regime of data exclusivity as TRIPS-compliant, but not mandatory.

- ⁵³See Article 4, paragraph 22 of the USA – Jordan FTA.
- ⁵⁴See, e.g., Chapter 15, Article 15.10.1(a) of CAFTA, and Chapter 15, Article 15.10.1 of the USA – Morocco FTA.
- ⁵⁵See Abbott (2004a) p.7. The same author observes that such exclusivity renders illegal the registration of generic drugs for public non-commercial use (p.6).
- ⁵⁶See UNCTAD-ICTSD (2005) Chapter 28 (Undisclosed Information), Section 2.2 (Negotiating history), pp.523–526.
- ⁵⁷See Annex V, Article 4 of the Tunisia FTA and Annex V, Article 4 of the Lebanon FTA. The Chile FTA does not include a comparable exception to its regime of data exclusivity.
- ⁵⁸See Chapter 17, Article 17.10.1 of the USA – Chile FTA.
- ⁵⁹See Roffe (2004) p.26. For a particularity under the DR-CAFTA in this respect, see Correa (2004), p.10.
- ⁶⁰See Chapter 16, Article 16.8.1 of the USA – Singapore FTA, and Chapter 17.10.1(d) of the USA – Australia FTA. The latter contains a separate provision on agrochemical products, extending protection to ‘certain new uses of the same product’, see Article 10.10.1(b). See also Roffe (2004) Box 8, p.25.
- ⁶¹See Chapter 17, Article 17.10.1.
- ⁶²See Chapter 15, Article 15.10.2 of the USA – Morocco FTA and Chapter 14, Article 14.9.2 of the USA – Bahrain FTA.
- ⁶³See Abbott (2004a) p.11 and see also Mellouk (2005).
- ⁶⁴See Chapter 16, Article 16.8.2.
- ⁶⁵For agrochemical products, the period is ten years.
- ⁶⁶See Chapter 14, Article 14.9.1(b)(i) of the USA – Bahrain FTA. Similar language can be found in Chapter 15, Article 15.10.1(b) of CAFTA and Chapter 17, Article 17.10.1(c) of the USA – Australia FTA.
- ⁶⁷See Correa (2004) pp.8, 9, and Abbott (2004a) pp. 6, 7.
- ⁶⁸Article 15.10.1(b), second sentence.
- ⁶⁹See Correa (2004) p.9 and Abbott (2004a) p.7.
- ⁷⁰Abbott (2004a) p.8. Roffe (2004) p.26, observes that under the USA – Chile FTA, the link between marketing approval and the consent of the patent holder is less explicit and, unlike CAFTA, does not include references to marketing approvals in other countries.
- ⁷¹Abbott (2004a) p.8.
- ⁷²See UNCTAD-ICTSD (2005) Chapter 28, p.537.
- ⁷³On the proliferation of TRIPS-plus standards through the MFN principle, see Roffe (2004) p.18, as well as Vivas-Eugui (2003) pp.5, 6.
- ⁷⁴See UNCTAD-ICTSD (2005) p.78 (referring to possible cases where a country grants more extensive IPR *exceptions* to the nationals of some countries, but not to others). See also Roffe (2004) p.18.
- ⁷⁵Similar language is employed in an “Understanding regarding certain public health measures” concluded between the signatories of CAFTA on August 5, 2004 and in an exchange of letters between the USA and Bahrain.
- ⁷⁶See the letter from USTR General Counsel John K. Veroneau to Congressman Levin dated July 19, 2004, available at *Inside US Trade*.
- ⁷⁷See Correa (2004) p.12 and Abbott (2004a) p.11.
- ⁷⁸See Fink and Reichenmiller (2005) p.3, referring to personal communications by USTR staff.
- ⁷⁹This overview is essentially based on Fink and Reichenmiller (2005) Table 2, p.5.

Annexure: Overview of TRIPS-plus standards concerning protection of patents and pharmaceutical test data in selected FTAs⁷⁹

	USA-Vietnam	USA-Jordan	USA-Singapore	USA-Chile	USA-Morocco	USA-Australia	USA-DR-CAFTA	USA-Bahrain	EFTA FTAs
Patent term extensions	Extension mandatory where delays caused by regulatory approval process	Extension mandatory where delays caused by regulatory approval process	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Extension where delays caused by regulatory approval process. In addition, mandatory extension where delay in patent grant exceeds four years from filing date (five years for USA-Chile) or two years after request for examination (three years for USA-Chile)	Chile FTA: where delay caused by regulatory approval process
Patentability of second uses	No specific reference	No specific reference	Requirement to provide patents for new uses of known products	Requirement to provide patents for new uses of known products	Requirement to provide patents for new uses of known products	Requirement to provide patents for new uses of known products	No specific reference	Requirement to provide patents for new uses of known products	No specific reference
Compulsory licenses	Limited to national emergencies, for public non-commercial use and as antitrust remedies	Limited to national emergencies, for public non-commercial use and as antitrust remedies	TRIPS standards apply	TRIPS standards apply	TRIPS standards apply	Limited to national emergencies, for public non-commercial use and as antitrust remedies	TRIPS standards apply	TRIPS standards apply	TRIPS standards apply
Parallel imports	No provision on IPRs exhaustion	TRIPS standards apply	Express authorisation to prevent parallel imports through contractual arrangements	TRIPS standards apply	Express authorisation to prevent parallel imports through contractual arrangements	Express authorisation to prevent parallel imports through contractual arrangements	TRIPS standards apply	TRIPS standards apply	TRIPS standards apply

Annexure: Overview of TRIPS-plus standards concerning protection of patents and pharmaceutical test data in selected FTAs⁷⁹ (continued)

	USA-Vietnam	USA-Jordan	USA-Singapore	USA-Chile	USA-Morocco	USA-Australia	USA-DR-CAFTA	USA-Bahrain	EFTA FTAs
Test data protection for pharmaceutical products	Data exclusivity, normally for not less than five years	TRIPS standards apply. In addition, length of protection should be the same as in originator's country	Data exclusivity for five years. In addition, where reliance on foreign marketing approvals, data exclusivity applies automatically in domestic context	Data exclusivity for five years	Data exclusivity for five years. Additional three years in case of 'new clinical information'	Data exclusivity for five years. In addition, data exclusivity applies in all FTA Parties, once obtained in another (non-FTA) territory. USA-Bahrain: additional three-year data exclusivity for 'new clinical information' (equally on cross-border applications)	Data exclusivity for five years. In addition, data exclusivity applies in all FTA Parties, once obtained in another (non-FTA) territory. USA-Bahrain: additional three-year data exclusivity for 'new clinical information' (equally on cross-border applications)	Data exclusivity for five years (Chile and Tunisia), six years (Lebanon). Exclusivity waived where data originator adequately compensated (Tunisia and Lebanon)	Data exclusivity for five years (Chile and Tunisia), six years (Lebanon). Exclusivity waived where data originator adequately compensated (Tunisia and Lebanon)
Linkage between regulatory procedures and patent rights	No linkage	No linkage. But patentee to be notified if marketing approval is sought during patent term	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	Marketing approval during patent term dependent on authorisation by patent holder. In addition, patent holder to be notified of the identity of the generic producer requesting marketing approval	No linkage
Side letters on public health	No	No	No	No	Yes	No	Yes	Yes	No