Oxfam Briefing Note

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Undermining access to medicines: Comparison of five US FTAs

A technical note

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The US government is using bilateral and regional free-trade agreements (FTAs) to impose unnecessarily stringent intellectual property standards on developing countries that go beyond even the damaging requirements of World Trade Organisation (WTO) rules. These new higher standards favour the short-term commercial interests of US pharmaceutical companies, at the expense of public health in developing countries.

Recent FTAs negotiated by the US include US-Chile (2003), US-Jordan (2000), US-Morocco (2004), US-Singapore (2003), and the US-Central America Free Trade Agreement (CAFTA–2004) [1] that includes the Dominican Republic. The US is also negotiating numerous new FTAs with other developing countries including the Free Trade Area of the Americas [2] (FTAA deadline 2005), Andean countries, Thailand, Panama, Bahrain and Southern African countries, with others under consideration.

In the following table, Oxfam has analysed a selection of key US FTAs. Our analysis shows that the provisions in these agreements go far beyond the obligations required by the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The table shows how these new "TRIPS-plus" obligations in the FTAs close off the public health safeguards available to WTO members under TRIPs and will restrict access to affordable medicines in developing countries. The negotiation of TRIPS-plus patent rules also contravenes the WTO Doha Declaration on TRIPS and Public Health and the US administration's trade negotiating mandate that instructs the USTR to respect the Doha Declaration in all FTA negotiations. A "side letter" on public health

accompanies CAFTA; it states that CAFTA provisions should not prevent the Parties from taking necessary measures to protect public health or from implementing WTO decisions on TRIPS. But the letter has interpretive value only and will not change the binding TRIPS-plus provisions in the text, which require the Parties to introduce measures that will limit availability of affordable medicines.

The Doha Declaration was signed in November 2001 by all WTO members including the US. It confirmed the primacy of public health over patents, and reaffirmed the rights of countries to use all the public interest safeguards in TRIPS, including, inter alia, compulsory licensing and parallel importation [3], to promote 'access to medicines for all'. This was followed by a decision by the WTO in August 30th 2003 to lift TRIPS restrictions on compulsory licensing for export of generic medicines to countries that lack the capacity to manufacture them themselves. Oxfam believes the following provisions in US FTAs will threaten implementation of the Doha Declaration and the WTO August 30th 2003 decision, and restrict developing countries' access to affordable medicines:

- New requirements for governments to extend patent protection beyond the 20 year period required under TRIPS. Extending this monopoly period will further delay the introduction of affordable generic medicines.
- New restrictions of the grounds for compulsory licensing, which could limit government's ability to promote competition by generic producers in order to increase access to medicines.
- New provisions giving patent holders the means to block parallel importation. This will limit governments' ability to shop around for patented medicines placed on foreign markets at lower prices.
- New provisions preventing generic companies from using clinical trial data generated by brand name companies to obtain marketing approval. This could delay or prevent generic competition even in the absence of patent barriers and even if a compulsory license is issued.
- New provisions preventing national drug registration authorities from registering generic versions of drugs until after the patent expires. This could undermine the use of compulsory licenses and prevent or delay access to affordable generic versions of new medicines.

The US government appears determined to prevent developing countries from getting access to cheaper generic versions of patented medicines. A key part of this strategy is to ratchet up global patent standards through various mechanisms, including unilateral pressure on countries, bilateral trade and intellectual property agreements, and multilateral standard setting. What the US has been unable to obtain at the WTO where it is faced with recently-formed assertive blocs of developing countries, it is seeking to achieve through bilateral trade agreements and pressure on individual countries – frequently poor countries that have little ability to negotiate or resist. Each newly ratified agreement is then used as a template or model for future bilateral and multilateral agreements. Under the Most Favoured Nation provision in TRIPS, once countries agree to higher patent standards in a free-trade agreement with the US, they may have to automatically apply them to patent holders from other WTO members. If enforced, this would allow other rich countries such as the EU to free-ride on the US strategy.

Oxfam believes the US strategy is undermining the credibility of multilateral decision-making. Countries should not have to expend huge amounts of time and political capital to gain consensus at the WTO, and then have these efforts undermined by a US

strategy that depends on unequal negotiating power to pick off developing countries one by one.

Oxfam urges:

- the USA to refrain from imposing TRIPS-plus standards in bilateral and regional trade agreements with developing countries
- the EU, other rich countries and developing countries to collectively call for an end to this practice at international forums such as the WTO and WHO
- developing countries to say no to negotiating intellectual property standards in FTAs.
- the international community to continue monitoring the health impacts of global patent rules with a view to giving developing countries greater freedom to decide the appropriate length and scope of patent protection for medicines based on their public health needs.

Footnotes:

[1] CAFTA has been signed by the parties but not ratified yet.

[2] The Free Trade Area of the Americas is being negotiated between all countries of the Western Hemisphere except Cuba. The provisions in this document are from the third version of the negotiating text made public in 2003. Because the text is still under negotiation, proposed language is in brackets except where the text has already been agreed (in which case it appears without brackets).

[3] The FTAs negotiated by the US restrict or eliminate the public health safeguards in the TRIPS Agreement, such as compulsory licensing and parallel importation. Compulsory license provides a vital tool for governments to override patents when prices are too high or supply limited to authorise production or import of affordable generic versions of patented medicines. Parallel importation allows governments to shop around in other countries for cheaper patented medicines.

1. Policy Issue: Relationship to TRIPS and the "Doha Declaration"

The Doha Declaration was unanimously agreed by WTO members – including the United States - in November 2001. It affirms the right of all WTO members to use the safeguards and flexibilities in TRIPS to promote "access to medicines for all" and constitutes a commitment to favour public health over patent rights. The US Congress subsequently enshrined the Doha Declaration in the mandate granted to the US Trade Representative for negotiating FTAs; the Trade Act of 2002 instructs the USTR to respect the Declaration in all trade negotiations. But none of the FTAs reference the Doha Declaration. Instead, the USTR has consistently violated its mandate by negotiating TRIPS-plus provisions in FTAs – including with developing countries - which limit and restrict the public health safeguards in TRIPS and delay or prevent the introduction of affordable generics. All of the bilateral and regional FTAs are TRIPS-plus. The impact will be diminished availability of cheap generic versions of expensive patented medicines which will further reduce access to medicines, in direct contrast to the Doha aims. To assuage concerns about FTA patent provisions, USTR has negotiated "side letters" on public health to accompany CAFTA and the recently negotiated FTA with Morocco. But the side letters, which state that the FTAs should not prevent the Parties from taking measures to promote access to medicines or to implement WTO decisions regarding the TRIPS Agreement, have interpretive value only. They do not change the binding TRIPS-plus provisions in the text, which require countries to enact measures that reduce availability of generics. Rather than accepting USTR assurances that side letters will protect their capacity to promote access to medicines, developing countries should reject FTAs that contain TRIPS-plus patent rules.

Agreement	Provision	Text	Comments
TRIPS (Annex 1C) 1995		The Declaration is used to interpret TRIPS, and it led to agreement to modify Article 31 of the TRIPS Agreement this year. Paragraph 4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this 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." Paragraph 6: "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General	The "Doha Declaration on the TRIPS Agreement and Public Health" was adopted unanimously by all WTO members in November 2001, at the Fourth Ministerial in Doha, Qatar. It has interpretive value vis-à-vis the provisions in the TRIPS Agreement, as it was the result of unanimous agreement by all signatories. It recognizes the right of all WTO members to use the TRIPS flexibilities and safeguards to promote public health, without fear of retaliation. Paragraph 6 of the Declaration contains a commitment to resolve the dilemma of WTO members that are too poor to afford expensive patented medicines but cannot manufacture their own drugs; a solution to this problem was agreed in August 2003, which WTO members are transforming into an amendment of the TRIPS Agreement. The Declaration also granted LDCs an extended transition period for TRIPS compliance (until at least 2016). The Declaration represents a commitment to prioritise public health over patent rights, in recognition of the linkage between patent rights and high prices for new technologies and products, notably medicines. It was enshrined in the mandate given by the US Congress to the US Trade Representative when negotiating free trade agreements; USTR is instructed by Congress to respect the Doha Declaration in all FTA negotiations.

		Council before the end of 2002."	
NAFTA * [1](1994)		NAFTA preceded the Declaration. NAFTA is TRIPS-plus.	NAFTA was passed before the Doha Declaration was adopted, but its patent provisions are "TRIPS -plus" in that it limits or restricts the TRIPS public health flexibilities and safeguards. The following are TRIPS-plus provisions in NAFTA: no public interest objectives and principles, provides for extension of the patent term, provides for protection of test data.
Chile * (2003)		The text does not mention the Declaration. The Chile FTA is TRIPS-plus.	The IP chapter of this FTA is "TRIPS-plus" in many ways. It undermines the Doha Declaration by eliminating or restricting the public health safeguards in TRIPS. In negotiation this TRIPS-plus IP chapter, the USTR violated its mandate to "respect the Declaration on TRIPS and Public Health." TRIPS-plus provisions in Chile FTA: no public interest objectives and principles, provides for extension of the patent term, limits grounds for revoking a patent, prevents registration of generics at any point during the entire patent term, provides for test data protection,.
Singapore * (2003)		The text does not mention the Declaration. The Singapore FTA is TRIPS-plus.	The IP chapter of this Agreement undermines the Doha Declaration, eliminating or restricting the public health safeguards in TRIPS. Provisions in the Singapore FTA that are TRIPS-plus: no public interest objectives and principles, provides for extension of the patent term (linking same to extension of the patent abroad), limits grounds for revoking a patent, provides patent holders with means to block parallel importation, provides for test data protection, prevents registration of generics relying on originator test data during the entire patent term, limits grounds for using compulsory licensing.
CAFTA * (2004)		No mention of the Declaration although a "side letter" on public health indicates that CAFTA should not prevent the Parties from taking necessary measures to protect public health, or implementing agreements reached on access to medicines at the WTO. CAFTA is TRIPS-plus.	The IP chapter of CAFTA undermines the Doha Declaration, eliminating or restricting the public health safeguards in TRIPS. By negotiating the TRIPS-plus patent provisions in CAFTA, the USTR violated its mandate under Trade Promotion Authority to "respect the Declaration on the TRIPS Agreement and Public Health." Provisions in CAFTA that are TRIPS-plus: no public interest objectives and principles, provides for extension of the patent term, prevents registration of generics relying on originator test data during the entire patent term, provides for test data protection. The side letter on public health has only interpretive value and does not actually modify the patent rules contained in the agreement to enable countries to protect public health. Its vague language upholding countries' right to promote access to medicines will not offset the binding TRIPS-plus provisions in the text, which require the Parties to introduce measures that will reduce access to affordable medicines.
FTAA * [2] (Deadline for completion January 2005)		The text does not mention the Declaration. Many of the bracketed provisions in the FTAA negotiating text are TRIPS-plus.	The IP chapter of the FTAA violates the Doha Declaration, by eliminating or restricting the public health safeguards in TRIPS. The proposed FTAA zone encompasses many poor countries, including on LDC (Haiti). The Doha Declaration provides LDCs with an extended transition period - until at least 2016 - before they must comply with the TRIPS Agreement. Under the FTAA, Haiti would be required to comply with TRIPS-plus provisions well before that. Provisions in the FTAA negotiating text that are TRIPS-plus: provides for patent extension (linking same to extension abroad), provides for test data protection, limits grounds for using compulsory licensing, prevents registration of generics during the patent term.

[1] An asterisk indicates that the FTA or provision is TRIPS-plus, meaning that it restricts or eliminates the flexibilities in the TRIPS Agreement.

2. Policy Issue: Patent Term

Intellectual property laws are meant to reflect a balance between the rights of the inventor and broader public interests, for example in having access to new products. The period of monopoly granted to a patent holder by a patent is intended to enable the company to earn enough to recuperate research costs and other investments; the twenty year global patent protection provided by TRIPS already grants an unnecessarily long period of time to enable an innovator company to profit from its invention and recuperate investment costs. Extending the monopoly – as FTA provisions would do – favors the patent holder and delays the availability of cheaper generic versions of patented products. In the case of medicines, this creates unnecessary suffering or death particularly for patients too poor to afford expensive patented drugs.

Agreement	Provision	Text	Comments
TRIPS	Article 32	"The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date."	The harmonization of the patent term among WTO members under TRIPS at 20 years reflected a significant extension of the patent term in international law. This period was agreed by WTO members as adequate for recuperation of the inventor's R&D and other investment costs. TRIPS does not require extension of the patent term beyond twenty years for any reason.
NAFTA *	Section 1709, Article 12 and Section 1709, Article 8	"Each party shall provide a term of protection for patents of at least 20 years from the date of filing or 17 years from the date of grant. A Party may extend the term of patent protection, in appropriate cases, to compensate for delays caused by regulatory approval processes."	The Parties "may" - not must - extend the term of the patent to compensate for delays in granting regulatory approval. Section 1709, Article 8 sets the parameters for revoking a patent..
Chile *	Not specified, but impacted by Article 17.9 (6), Article 17.10 (2), and Article 17.9 (5)	Article 17.9 (6): "Each party shall provide for the adjustment of the term of a patent, at the request of the patent owner, to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall be understood to include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays." Article 17.10 (2): "...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."	The patent term is not specified but since the FTA builds on the provisions in TRIPS, it is presumably twenty years. This FTA contains provisions that would extend the patent monopoly beyond twenty years and are therefore TRIPS-plus. Per Article 17.9 (6), Parties must provide for the adjustment of the patent term, upon request by the patent holder, to compensate for delays in issuing the patent. Under Article 17.10 (2), they must extend the patent term to compensate for delays in granting regulatory approval. In TRIPS there is no such requirement and under NAFTA, Parties can decide whether to provide for extension of the patent to compensate for delays in granting regulatory approval only. Article 17.9 (5) limits the grounds on which a patent can be revoked.

Singapore *	Not specified but impacted by Article 16.7 (7), Article 16.8 (4a), Article 16.7 (8)	Article 16.7(7): "Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than four years from the date of filing of the application with the Party, or two years after a request for examination of the application has been made, whichever is later, provided that periods attributable to actions of the patent applicant need not be included in the determination of such delays." Article 16.8 (4): "With respect to any pharmaceutical product that is subject to a patent: (a) 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." Article 16.7 (8): "Where a Party provides for the grant of a patent on the basis of an examination of the invention conducted in another country, that Party, at the request of the patent owner, may extend the term of a patent for up to five years to compensate for the unreasonable delay that may occur in the issuance of the patent granted by such other country where that country has extended the patent term based on such delay."	The patent term is never specified, but is presumably twenty years since this chapter builds on TRIPS. This FTA contains many provisions that would extend the patent monopoly beyond twenty years and is therefore TRIPS-plus. The patent term must be extended by the parties, in response to a request by the patent holder, when there has been a delay in granting the patent. Further, Article 16.7 (8) states that when another country has granted a patent for a product, then one of the Parties (US or Singapore) grants a patent based on examination / granting of the patent in the other country, if the first country experienced delay in granting the patent and therefore extended the patent term (by up to five years), the Party may also extend the patent term. Under Article 16.8 (4) the patent term must also be extended to compensate for delays in granting regulatory approval. Article 16.7 (4) severely curtails the grounds on which a patent can be revoked, and states that opposition proceedings to a patent application cannot be made public prior to the granting of a patent, which would prevent interested parties from feeding into the process prior to the granting of a patent and rendering it more difficult to revoke an improperly granted patent.
CAFTA *	Not specified but impacted by Article 15.9 (6), Article 15.10 (2), and Article 15.9 (8)	Article 15.9 (6): "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. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays." Article 15.10 (2): "With respect to any pharmaceutical product that is subject to a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process." Article 15.9 (8): "Each Party shall provide patent applicants with at least one opportunity to submit amendments, corrections, and observations."	The patent term is never specified but is presumably twenty years since this chapter builds on TRIPS. The patent term must be extended under Article 15.9 (6), at the request of a patent owner, for unreasonable delays that occur in granting the patent. Under Article 15.10 (2) the Parties must also extend the patent term to compensate the patent holder for delays in granting marketing approval, although the parameters of this are not clearly defined. These provisions are TRIPS-plus

FTAA *	Section B.2.e, Article 9 and Section B.2.j, Article 1	There is one bracketed provision under Article 9 that sets the patent period at twenty years, to reflect TRIPS. Other TRIPS-plus proposed language is also included under this article: (9.2): "Each Party, at the request of the patent owner, shall extend the term of a patent to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall at least include a delay in the issuance of the 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, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays." (9.3) "Where a Party provides for the grant of a patent on the basis of a patent granted in another country, that Party, at the request of the patent owner, shall extend the term of the patent granted under such procedure by a period equal to the period of the extension, if any, provided in respect of the patent granted by such other country." (1.4): "Where a product is subject to a system of marketing approval pursuant to paragraphs 1.2 or 1.3 and is also subject to a patent in the Party: (a) the Party shall not approve an application to market a product on the basis of information in an earlier marketing approval for the same product where that application has been filed by a party other than the recipient of the original marketing approval or with his consent, and shall not otherwise authorize a third party to market the same product, prior to the expiration of the patent, and (b) the Party shall not alter the term of protection specified in paragraphs 1.2 and 1.3 in the event that the patent expires on a date earlier than the end of the term of such protection, (c) In addition, if the product is subject to a patent in one Party as well as in another Party, the second Party shall extend the term of the patent within its territory to expire no earlier than the date of expiration of the patent in the first Party."	The minimum patent term is defined at twenty years in two bracketed provisions, one of which references TRIPS, although subsequent language provides for extension of the patent term and is therefore TRIPS-plus. Language proposed in Section B.2.e, Article 9.2 would require countries to extend the patent term beyond twenty years, at the request of the patent holder, to compensate for delays in granting the patent. Article 9.2 would also require the extension of a patent granted in one country based on the granting of a patent in a second country, if that second country had for any reason extended the patent period for that product. In this case, the extension would be equal to the extension in the second country. This provision also appears in Section B.2.j, Article 1.4 (c) under the “undisclosed information” section. There is another patent extension requirement set forth under Section B.2.e, Article 5.4; this article requires that the Parties extend the patent term to confer a period of marketing exclusivity in cases where the granting of the patent precedes the granting of marketing approval. The goal under all of these proposed provisions, which are reflective of provisions found in other FTAs negotiated by the United States, is to extend the patent term beyond twenty years. Article 1.4 (c) would require that one Party extend the patent for a product to match the length of the patent for that same product in another Party, unnecessarily extending the patent monopoly in the first Party.

3. Policy Issue: Compulsory Licensing

Compulsory licensing is a key public health safeguard in the TRIPS Agreement. This important tool, whereby a government temporarily overrides a patent in the public interest and authorizes the production of cheap generic versions of a patented product, is a feature of all intellectual property systems. It is an essential way of helping balance the rights of inventors and the broader public interest. FTAs negotiated by the United States restrict recourse to this policy tool, through language restricting grounds on which compulsory licensing can be used, restricting marketing approval for generics, and providing for data exclusivity for either a few years or the entire duration of the patent. The Doha Declaration affirmed countries' right to use compulsory licensing - and to determine for themselves the circumstances warranting this action - so any restrictions or limitations on it violate the 2001 commitment by all WTO members to respect countries' right to use the safeguards in TRIPS and to prioritize public health over patent rights.

Agreement	Provision	Text	Comments
TRIPS	Article 31	"Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; (d) such use shall be non-exclusive; (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances; ... (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; ..."	Article 31 sets forth the procedure that countries must follow when using compulsory licensing, a process by which the government temporarily overrides a patent in the public interest. Countries are able, under the TRIPS Agreement, to determine for themselves the circumstances under which they use compulsory licensing - for example, when confronted with a "public health problem." There is no restriction of compulsory licensing to emergencies or epidemics. When using compulsory licensing, governments must first attempt to obtain a license from the patent holder within a reasonable time and on reasonable terms (but this requirement can be waived when the country is facing a national emergency or in the case of public, non-commercial use). Suppliers of the product under the compulsory license may include government entities or parties authorized by the government to sell on the commercial market. Article 31 limits the export of generics produced under compulsory license (the quantities produced must be "predominantly" for the domestic market); Article 31 (f) will be amended per the "paragraph 6" solution agreed by WTO members in August 2003. Governments do not have to negotiate with the patent holder before issuing a compulsory license to remedy anti-competitive behaviour.

Doha Declaration	Paragraphs 5.b and 5.c	Paragraph 5.b: “Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” Paragraph 5.c: “Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV / AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”	The Doha Declaration affirmed the right of WTO members to use compulsory licensing, and to determine for themselves the grounds for its use.
NAFTA *	Section 1709, Article 10	"Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: (a) authorization of such use shall be considered on its individual merits; (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly; (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; (d) such use shall be non-exclusive; (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances; (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; ..."	NAFTA reflects the TRIPS Article 31 guidelines for use of compulsory licensing, but then limits its use during the first five years following product registration due to TRIPS-plus data exclusivity provisions. The required five year period of test data protection would make it impossible to use compulsory licensing during this period. (See section on Data Exlusiivity) This is because generic companies, when seeking regulatory approval, typically rely on the safety and efficacy data submitted for the originator product. They demonstrate only “bio-equivalence,” which means that their generic version of the drug is identical to the originator drug and that it reacts the same way in the body. By relying on originator data, they avoid having to replicate the costly and time-consuming data. During a period of "non-reliance" on originator data - also called "test data protection" or “data exclusivity” - generics producers would be unable to gain marketing approval without replicating the tests. In an emergency situation repeating these tests would be impossible, due to time constraints. Compulsory licensing during this five year period is therefore not viable, as no alternate suppliers would be able to enter the market.
Chile *	Not specified but impacted by Article 17.9 (4), Article 17.10	No provision specifically governs the use of compulsory licensing although its use is limited by other provisions of the FTA.	TRIPS standards can be assumed to apply, in the absence of a provision outlining alternate guidelines for using compulsory licensing. However, TRIPS-plus provisions mandating the protection of test data and provisions preventing generics companies from obtaining marketing approval at any point during the patent term would prevent the Parties from using compulsory licensing, as no generics producers would be able to enter the market even in the absence of patent barriers.

Singapore *	Article 16.7 (6)	"Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the competition laws of the Party; (b) in the case of public, non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that: (i) such use is limited to use by the government or third parties authorized by the government, (ii) the patent owner is provided with reasonable and entire compensation for such use and manufacture, and (iii) the Party shall not require the patent owner to transfer undisclosed information or technical know-how related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph. Where a Party's law allows for such use pursuant to subparagraphs (a) and (b), the Party shall respect the provisions of Article 31 of the TRIPS Agreement."	This Article, which sets forth the parameters for using compulsory licensing under this FTA, are TRIPS-plus even though it references TRIPS Article 31. Use of compulsory licensing is limited to: remedy anti-competitive behaviour, public non-commercial use, and national emergencies. TRIPS contains no such limitations on use of compulsory licensing, instead leaving it to WTO members to determine when its use is appropriate or necessary. This provision also sets a new, higher standard of compensation when compulsory licensing is used -"reasonable and entire" rather than "adequate" - and the Parties cannot require the transfer of test data or know-how in connection with production under the compulsory license. The compulsory licensing language in this FTA is TRIPS-plus and is made worse by other sections of the agreement. Provisions mandating the protection of test data and provisions preventing generics companies from obtaining marketing approval at any point during the patent term would prevent the Parties from using compulsory licensing, as no generics producers would be able to enter the market even in the absence of patent barriers.
CAFTA *	Not specified but impacted by Article 15.10 (3), Article 15.10 (1)	No provision specifically governs the use of compulsory licensing although its use is limited by other provisions in this FTA.	TRIPS standards can be assumed to apply, in the absence of a provision outlining alternate guidelines for using compulsory licensing. However, TRIPS-plus provisions mandating the protection of test data and provisions preventing generics companies from obtaining marketing approval at any point during the patent term would prevent the Parties from using compulsory licensing, as no generics producers would be able to enter the market even in the absence of patent barriers.
FTAA *	Section B.2.e, Article 6	This article contains a variety of proposed provisions governing use of compulsory licensing, including language reflective of TRIPS Article 31. The proposals include the following very TRIPS-plus provision (6.1) which reflects language seen in other FTAs negotiated by the United States: "Where a Party permits the use of the subject matter of a patent without the authorization of a patent owner by the Government of the Party or by a private entity acting on behalf of the Government of the Party, such authorization shall comply with the following conditions: (a) The authorization shall be granted only for public non-commercial purposes or in situations of a declared national emergency or other situation of extreme urgency, (b) The authorization shall be limited to the making, using, or importing of the patented invention soley to satisfy the requirements of the Government use, and shall not entitle a private party acting on behalf of the Government to sell products produced pursuant to such authorization to a party other than the Government, or to export the product outside the territory of the Party, (c) the patent owner shall be provided with reasonable and entire compensation for such use and manufacture, (d) no Party shall require the patent owner to transfer undisclosed information or technical know how related to a patented invention that has been subjected to involuntary use authorization. No Party shall grant authorizations to third parties to use the subject matter of the patent without the consent of the patent owner ... unless to remedy a practice determined after judicial or administrative process to be anti-competitive..."	This proposed language governing compulsory licensing is TRIPS-plus in that it would limit use of compulsory licensing to remedy anti-competitive behaviour, to national emergencies, and to public non-commercial use. TRIPS contains none of these limitations, instead allowing countries to determine for themselves the grounds on which to issue a compulsory license. Further, this provision would restrict the export of generics produced under compulsory license, which would prevent countries such as the United States, Mexico, Canada, Brazil, Argentina, and other countries in the hemisphere with pharmaceutical manufacturing capacity from exporting generics under the August 2003 "paragraph 6" solution agreed at the WTO.

4. Policy Issue: Parallel Importation

Parallel importation refers to the importation of a patented product that has been placed on markets both abroad and domestically but is sold more cheaply elsewhere. It can be an important tool for developing countries to save money by importing patented drugs approved for domestic sale from other countries where they may sold at a lower price. Parallel importation is possible when patent rights have been "exhausted," meaning that once a patented product is placed on a market anywhere in the world, the patent holders' control over what can be done with that product has ended. TRIPS allows each WTO member to decide for itself whether patent rights have been exhausted under its laws once the drug is introduced anywhere in the world. Restriction of this right can limit access to affordably-priced medicines.

Agreement	Provision	Text	Comments
TRIPS	Article 6	"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."	The TRIPS Agreement allows countries to determine their own rules on parallel importation.
Doha Declaration		Paragraph 4: "... we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." Paragraph 5c: ‘’ … 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, subject to the MFN and national treatment provisions of Articles 3 and 4.”	The Doha Declaration affirmed the rights of governments to determine their own rules on parallel importation.
NAFTA		The text does not mention exhaustion or parallel importation.	The absence of language on this issue means that TRIPS standards should prevail. Parties should ensure that use of parallel importation is provided for under their national laws.
Chile		The text does not mention exhaustion or parallel importation.	As above.
Singapore	Article 16.7 (2)	"Each party shall provide a cause of action to prevent or redress the procurement of a patented pharmaceutical product, without the authorization of the patent holder, by a party who knows or has reason to know that such product is or has been distributed in breach of a contract between the right holder and a licensee, regardless of whether such breach occurs in or outside its territory. Each Party shall provide that in such a cause of action, notice shall constitute constructive knowledge."	This article is TRIPS-plus as it limits parallel importation by requiring that the US and Singapore provide patent holders with the means to block the importation of patented drugs into the US or Singapore when same is done in violation of a distribution agreement abroad (anywhere in the world). Patent holders could restrict all distribution agreements territorially in view of blocking parallel importation into either the US or Singapore under this provision.
CAFTA *		The text does not mention exhaustion or parallel importation.	As Chile above.
FTAA *	Section B.2.e, Article 4	"This Chapter shall not affect the authority of each Party to determine the conditions under which the exhaustion of rights related to products legitimately introduced in the market by, or with the authorization of, the right holder shall apply. However, each Party undertakes to review its domestic legislation within a period not exceeding five years after the entry into force of this Agreement, in order to adopt, at a minimum, the principle of regional exhaustion in regard to all Parties."	The proposed language on parallel importation partially reflects TRIPS language, allowing each country to determine its own rules on exhaustion / parallel importation. But then it moves beyond this and becomes TRIPS-plus, obliging countries to set up regional exhaustion under their laws within five years. This would allow parallel importation within the FTAA zone, while keeping the world market segmented. But countries would undoubtedly be pressured by the United States to set up national exhaustion, which would prevent use of parallel importation.

5. Policy Issue: Data Exclusivity

The data exclusivity provisions in the FTAs negotiated by the United States are all TRIPS-plus, providing five to ten years of "non-reliance" on originator test data. This means that for the first five to ten years following registration of a drug, even in the absence of patent barriers, government regulatory authorities cannot rely on originator test data to approve a bio-equivalent generic product. The implications for use of compulsory licensing within this period are clear: if no generic suppliers can obtain marketing approval without repeating time-consuming and costly tests on their product (which would be impossible during an emergency situation due to time constraints), then compulsory licensing is rendered useless. Some FTAs, notably CAFTA, link data exclusivity with patent protection so as to prevent generics producers from obtaining marketing approval at any time during the patent period, even when a compulsory license is issued, and even in preparation to enter the market upon patent expiry, both of which are allowed under TRIPS. These CAFTA provisions would effectively prevent use of compulsory licensing during the entire patent term and clearly contravene the Doha Declaration, setting a standard of patent protection that favors patent owners while totally disregarding broader public interests such as public health and access to affordable drugs.

Agreement	Provision	Text	Comments
TRIPS	Article 39.3	"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize 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."	The TRIPS Agreement does not detail how WTO members must fulfil their obligation to protect test data from "unfair commercial use." This is left to countries themselves to determine. Protection is provided to test data for "pharmaceutical products that utilize new chemical entities."
NAFTA *	Section 1711, Articles 5, 6, and 7	"(5) If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use. (6) Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies. (7) Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. "	NAFTA reflects the TRIPS language on protecting test data submitted in connection with marketing approval from "unfair commercial use," for products using a "new chemical entity." But Article 6 specifies that Parties must provide test data protection for a "reasonable time", defined as at least five years, which is TRIPS-plus. For situations in which a Party grants regulatory approval to a product, relying on approval granted in another Party, the period of test data protection begins at the time of the first approval relied upon (per Article 7).

Chile *	Article 17.10 (1)	"If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public."	This provision is TRIPS-plus as it mandates five years of test data protection for pharmaceutical products that use a "new chemical entity." It provides for disclosure of the test data by government authorities if necessary for the public interest, but not reliance on it for purposes of granting regulatory approval. During the period of test data "non-reliance" it would not be possible for the Parties to use compulsory licensing, as generics companies would be unable to obtain marketing approval unless they repeated the time-consuming and costly safety and efficacy tests for the product. Most would choose to not enter the market rather than repeat the testing, especially if the market in question were small. And in an emergency situation, it would be impossible to repeat the tests, due to time constraints.
Singapore *	Article 16.8 (1), (2), and (3)	"(1.) If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the marketing approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. (2.) If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product or ten years from the date of approval for an agricultural chemical product in the territory of the Party or in the other country, whichever is later. (3.) Where a product is subject to a system of marketing approval pursuant to paragraph 1 or 2 and is also subject to a patent in the territory of that Party, the Party shall not alter the term of the protection that is provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of such protection."	This provision is TRIPS-plus as it mandates five years of test data protection for "pharmaceutical products," rather than "new chemical entities" as in previous FTAs. During the period of test data "non-reliance" it would not be possible for the Parties to use compulsory licensing, as generics companies would be unable to obtain marketing approval unless they repeated the time-consuming and costly safety and efficacy tests for the product. Most would choose to not enter the market rather than repeat the testing, especially if the market in question were small. And in an emergency situation, it would be impossible to repeat the tests, due to time constraints. This FTA contains test data provisions exceeding those in Chile, NAFTA, and TRIPS. Protection is provided not only to test data submitted to regulatory authorities in the US and Singapore, but also to test data submitted to regulatory authorities elsewhere; this is designed to prevent generic companies from using originator test data submitted abroad to skirt domestic test data protection. Protection is provided for five years, starting from the time of approval either abroad or in the Party, whichever is later. Under Article 16.8 (3), test data protection may even last longer than patent protection, blocking generic competition even in the absence of patent barriers.

CAFTA *	Article 15.10 (1) and (3)	Article 15.10 (1): "(a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed test data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party. (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety and efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) prior marketing approval in another territory or (2) information concerning safety and efficacy that was previously submitted to obtain marketing approval in another territory for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party to the person who received authorization in the other territory. In order to receive protection under this subparagraph (b), a Party may require that the person providing the information in the other territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory. (c) For purposes of this Article, a new product is one that does not contain a chemical entity that has been previously approved in the Party." Article 15.10 (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…"	Article 15.10 (1) is TRIPS-plus as it requires parties are to provide not only five years of non-reliance on test data when granting marketing approval to generic products, but they must also refrain from granting marketing approval based on prior marketing approval given to the originator product. This enhances the standard of protection to originator products. The Parties may disclose information submitted to them when necessary to protect the public. Test data protection is provided to "new pharmaceutical products" that use "chemical entities not previously approved in the Party"; this is in contrast to "pharmaceutical products that utilize new chemical entities" which is the language in previous FTAs except Singapore. The FTA specifies that the Parties must protect any data disclosed by government entities, after having been submitted to them in view of obtaining regulatory approval, from "unfair commercial use." This is reflective of TRIPS even though overall the test data provisions in CAFTA are very TRIPS-plus. CAFTA provisions on test data are extremely TRIPS-plus, offering up to ten years of protection to originator drugs from generic competition, even in the absence of patent protection and even if a compulsory license is issued. Under Article 15.10, the Parties must protect test data submitted to regulatory authorities anywhere in the world for five years; generics producers may not use evidence of registration of the originator drug in another country to prove safety and efficacy of their generic version. The company which owns the original test data then has five years in which to apply for regulatory approval in the CAFTA country (during which time its test data submitted to regulatory authorities elsewhere enjoys protection and CAFTA country regulatory authorities are bound by an obligation of non-reliance). Once it obtains marketing approval in the CAFTA country for that product, the five year period of protection for test data submitted domestically begins. Depending on how the originator company times its market entry, this could result in ten years of test data protection. This is the most extreme test data provision seen to date in an FTA. In addition, test data protection is incorporated into the marketing approval provisions (Article 15.10 (3)) which prevent regulatory authorities in the Parties from granting marketing approval to generics companies relying on originator test data for the entire duration of the patent term, unless they obtain the consent of the patent owner. This means that even if a compulsory license is issued, generics companies would not be able to supply the market unless they repeated the time-consuming and costly safety and efficacy testing for their product. Most companies would choose to simply not enter the market in question, especially if it is a small market. And in an emergency situation, it would be impossible to repeat the tests, due to time constraints.

FTAA *	Section B.2.j, Article 1	Under Article 1 there are four proposed provisions governing the protection of test data, one of which reflects TRIPS language. The other three, reproduced below, are TRIPS-plus: (1.2) "If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, such Party shall not permit third parties not having the consent of the party providing the information to market the same or similar product on the basis of the approval granted to the party submitting such information for a period of at least five years form the date of approval." (1.3): "If a Party provides a means of granting approval to market products specified in paragraph 1.2 on the basis of the grant of an approval for marketing of the same or a similar product in another Party, the Party shall defer the date of any such approval to third parties not having the consent of that party providing the information in the other Party for a period of at least five years from the date of approval in the Party or the date of approval in the other Party, whichever is later." (1.4): "Where a product is subject to a system of marketing approval pursuant to paragraphs 1.2 or 1.3 and is also subject to a patent in the Party: (a) the Party shall not approve an application to market a product on the basis of information in an earlier marketing approval for the same product where that application has been filed by a party other than the recipient of the original marketing approval or with his consent, and shall not otherwise authorize a third party to market the same product, prior to the expiration of the patent, and (b) the Party shall not alter the term of protection specified in paragraphs 1.2 and 1.3 in the event that the patent expires on a date earlier than the end of the term of such protection, (c) In addition, if the product is subject to a patent in one Party as well as in another Party, the second Party shall extend the term of the patent within its territory to expire no earlier than the date of expiration of the patent in the first Party."	Provisions governing test data are hidden in the back of the Agreement under Section B.2.j ("undisclosed information"), rather than being included in the patents section of the intellectual property chapter. Test data protection is provided to data related to "pharmaceutical products", not necessarily "new" products or ones utilizing "new chemical entities." Proposed Articles 1.2-1.4 are TRIPS-plus providing five years of non-reliance on test data for purposes of granting marketing approval, also preventing regulatory authorities from granting marketing approval to generics based on marketing approval for the originator product. This proposed language would provide up to ten years of non-reliance on test data / prior marketing approval in the FTAA zone, which would render compulsory licensing nearly impossible anywhere for the first ten years following registration of a product. This language is less stringent than the test data protection offered under CAFTA; under that FTA, a company could obtain five years of test data protection in connection with marketing approval obtained anywhere in the world, followed by a subsequent five year period following registration of the product in a CAFTA country. This proposed language in the FTAA provides up to ten years of protection, depending on how the originator company times market entry, but only in connection with marketing approvals in the FTAA zone. Further, Article 1.4 (a) would prevent governments from granting marketing approval to generics producers relying on originator test data for the entire duration of the patent term unless they obtain the consent of the owner of the data. This would prevent countries from using compulsory licensing during the entire patent term, since generics suppliers would be unable to obtain marketing approval even in the absence of a patent barrier. Article 1.4 (b) clarifies that test data protection could block generic competition even if a compulsory license were issued or in the absence of any patent barriers (for example if the patent expired prior to the expiration of the data exclusivity period, data exclusivity could still block generic competition to the originator product). Finally, Article 1.4 (c) would require that one Party extend the patent for a product to match the length of the patent for that same product in another Party, unnecessarily extending the patent monopoly in the first Party.

6. Policy Issue: Linkage between Patent and Regulatory Approval

Recent FTAs contain new TRIPS-Plus provisions which link patent status to the granting of regulatory approval extend the patent monopoly. This inappropriately involves regulatory approval agencies, whose focus should be on safety concerns, in the enforcement of patents. Under TRIPS, a generics company could "register" its product or "obtain marketing approval" (meaning approval to enter the market, following a determination that the product is safe and effective) before patent expiry enabling them to enter the market as soon as the patent barrier is gone. The new measures in US FTAs effectively extend the patent monopoly by the time it takes for them to get approval following patent expiry. Moreover, new provisions that prevent the granting of marketing approval for generics during the entire patent period would prevent countries from using compulsory licensing, as no suppliers of the product under the compulsory license would be able to enter the market. Extending the inventor's monopoly beyond this period by undermining safeguards such as compulsory licensing and preventing generics competitors from preparing to enter the market upon patent expiry inappropriately favors innovators, at the expense of the public, and contravenes the Doha Declaration. Further, this type of provision has been abused in the US context, where pharmaceutical companies have used frivolous infringement lawsuits to stall the granting of marketing approval for generic competitors. Such behaviour is under investigation by the FCC, and US lawmakers have publicly called for not exporting this troubled system to other countries via FTAs.

Agreement	Provision	Text	Comments
TRIPS		The text does not link patent status to regulatory approval.	The TRIPS Agreement contains no linkage. Healthcare advocates have argued that this separation is appropriate, given the different goals of regulatory authorities (safety of medicines) and patent authorities (enforcement of IP).
NAFTA		The text does not link patent status to regulatory approval.	As above.
Chile *	Section 17.10	Article 17.10 (2): "With respect to pharmaceutical products that are subject to a patent, each Party shall: (a) 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; (b) make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent; and (c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner."	TRIPS-plus provisions governing regulatory approval, set forth under Article 17.10, would de facto extend the period of patent monopoly. Article 17.10 (2.c) would prevent generics producers from obtaining marketing approval at any time during the patent period - even if a compulsory license were issued. In this and other FTAs, non-reliance on test data is used to block compulsory licensing for five to ten years. This FTA extends the period in which there is no generic competition to the originator product: without the consent of the patent owner generics producers cannot obtain marketing approval during the entire patent term even if they generate their own safety and efficacy data. Also, this provision would delay the approval of generic drugs until patent expiry, which would de facto extend the patent monopoly by the period it would then take for the generic to obtain approval and actually enter the market.
Singapore *	Article 16.8 (4)	Article 16.8 (4): "With respect to any pharmaceutical product that is subject to a patent: (a) 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; (b) the Party shall provide that the patent owner be notified of the identity of any third party requesting marketing approval effective during the term of the patent; and (c) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner."	TRIPS-plus provisions governing regulatory approval, set forth under Article 16.8 (4.c), would de facto extend the period of patent monopoly. Article 16.8 (4) would also prevent generics producers from obtaining marketing approval at any time during the patent period - even if a compulsory license were issued. In this and other FTAs, non-reliance on test data is used to block compulsory licensing for five to ten years. This FTA extends the period in which there is no generic competition to the originator product: without consent of the patent owner generics producers cannot obtain marketing approval during the entire patent term even if they generate their own safety and efficacy data. Also, this provision would delay the approval of generic drugs until patent expiry, which would de facto extend the patent monopoly by the period it would then take for the generic to obtain approval and actually enter the market.

CAFTA *	Article 15.10 (3)	Article 15.10 (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 identity of any such other person." Article 15.9 (3): "Each Party 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 account of the legitimate interests of third parties."	TRIPS-plus provisions governing regulatory approval, set forth under Article 15.10, would de facto extend the period of patent monopoly. Article 15.10 (3.b) requires governments to notify the patent owner when a generic company applies for marketing approval during the patent term, including in preparation to enter the market upon patent expiry. This provision is more "TRIPS-plus" than previous FTAs, notably Chile and Singapore, which require governments to notify the patent owner when a generics producer sought to obtain marketing approval "effective during the patent term" (marketing a generic product during the patent term would constitute a violation of the patent unless done under compulsory license). Article 15.10 (3.a) would prevent generics producers from obtaining marketing approval while relying on originator test data at any time during the patent period - even if a compulsory license were issued. The language actually goes beyond other FTAs, obligating the Parties to prevent generics producers from “marketing” their products at any time during the patent period, rather than obligating Parties to prevent them from obtaining “marketing approval.” Also, this provision would delay the approval of generic drugs until patent expiry. This would de facto extend the patent monopoly by the period it would then take for the generic to obtain approval and actually enter the market.

FTAA *	Section B.2.e, Article 5 and Section B.2.j, Article 1	There are a variety of proposed provisions reflective of TRIPS Article 30, in addition to proposed language outlining Bolar exceptions. For example, **Section B.2.e, Article 5.4**: "Where a Party permits the use of a patented invention to generate information required by a regulatory authority to obtain approval to market a product, such Party shall limit such use to acts reasonably performed to generate information to demonstrate that a product is scientifically equivalent to a previously approved product, provided however that: (a) where the grant of the patent precedes the approval for marketing of the product subject to the patent, the Party shall extend the term of the patent by a period sufficient to confer a reasonable term of exclusivity, (b) any product produced under this authority shall not be commercially used, sold, or offered for sale in the Party or exported outside the territory of the Party except as reasonably performed for obtaining marketing approval, and (c) the patent owner shall be provided notice of the identity of any entity that includes data generated under this authority in an application for marketing approval based on the previously approved product that seeks the authority to market the product prior to expiration of the patent." Under **Section B.2.j, Article 1** there are four proposed provisions governing the protection of test data, one of which reflects TRIPS language. The other three, reproduced below, are TRIPS-plus: (1.2) "If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, such Party shall not permit third parties not having the consent of the party providing the information to market the same or similar product on the basis of the approval granted to the party submitting such information for a period of at least five years form the date of approval." (1.3): "If a Party provides a means of granting approval to market products specified in paragraph 1.2 on the basis of the grant of an approval for marketing of the same or a similar product in another Party, the Party shall defer the date of any such approval to third parties not having the consent of that party providing the information in the other Party for a period of at least five years from the date of approval in the Party or the date of approval in the other Party, whichever is later." (1.4): "Where a product is subject to a system of marketing approval pursuant to paragraphs 1.2 or 1.3 and is also subject to a patent in the Party: (a) the Party shall not approve an application to market a product on the basis of information in an earlier marketing approval for the same product where that application has been filed by a party other than the recipient of the original marketing approval or with his consent, and shall not otherwise authorize a third party to market the same product, prior to the expiration of the patent, and (b) the Party shall not alter the term of protection specified in paragraphs 1.2 and 1.3 in the event that the patent expires on a date earlier than the end of the term of such protection, (c) In addition, if the product is subject to a patent in one Party as well as in another Party, the second Party shall extend the term of the patent within its territory to expire no earlier than the date of expiration of the patent in the first Party."	Linkage between the granting of regulatory approval and patent status is provided for under provisions relating to limited exceptions to patent rights and the protection of test data. The proposed language is TRIPS-plus and would block generic companies from obtaining marketing approval at any point during the patent term, even if a compulsory license were issued or as part of preparing to enter the market upon patent expiry.

7. Policy Issue: Exceptions to Rights Conferred

Provisions providing for limited exceptions to patent rights provide important flexibility to countries seeking to balance patent protections with policies in the broader public interest. For example, when the "paragraph 6" problem was under discussion at the WTO, developing countries argued that Article 30 should serve as the legal basis for generics producing countries to export affordable drugs to poor countries without their own manufacturing capacity. When coupled with more specific language in FTA intellectual property chapters, language reflective of TRIPS Article 30 still provides legal cover for policies in the public interest – but it may be offset by more restrictive provisions elsewhere in the text that spell out TRIPS-plus obligations. One important policy that countries have enacted under TRIPS Article 30 is the "Bolar provision," a limited exception to patent rights that enables companies seeking to develop a generic product then obtain marketing approval (to enter the market upon patent expiry) to use, produce, or copy patented materials for this purpose during the patent term. In the absence of a Bolar provision, such use of patented materials would be unlawful until expiry.

Agreement	Provision	Text	Comments
TRIPS	Article 30	"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably … prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."	Article 30 provides flexibility for governments to set up Bolar provisions or other limited exceptions to patent rights. There is no express reference to third party use of a patented invention for marketing approval purposes prior to patent expiry (for example production of the product for sale upon patent expiry). However, a WTO panel ruled that this clause permits limited production prior to patent expiry, but no stockpiling.
NAFTA	Section 1790, Article 6	"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably… prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."	The text reflects TRIPS Article 30 language.
Chile	Article 17.9 (3), Article 17.9 (4)	"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably… prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Article 17.9 (4): "If a Party permits the use by a third party of the subject matter of a subsisting patent to support an application for marketing approval or sanitary permit of a pharmaceutical product, the Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of the Party other than for purposes related to meeting requirements for marketing approval of the sanitary permit, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for issuing marketing approval or sanitary permits in the exporting Party."	This text reflects TRIPS Article 30. Article 17.9 (4) provides for a Bolar provision, enabling generic companies to use patented products in connection with preparing their own products for marketing approval upon patent expiry domestically or abroad.

Singapore	Article 16.7 (3), Article 16.7 (5)	"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably… prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Article 16.7 (5): "If a Party permits the use by a third party of the subject matter of a subsisting patent 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 meeting requirements for marketing approval, and if the Party permits exportation, the products shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party."	The text reflects TRIPS Article 30 language. Article 16.7 (5) provides for a Bolar provision, enabling generic companies to use patented products in connection with obtaining approval to enter the market upon patent expiry, whether domestically or abroad.
CAFTA	Article 15.9 (3), Article 15.10 (5)	Article 15.9 (3): "Each Party 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 account of the legitimate interests of third parties." Article 15.10 (5): "Consistent with paragraph 3, if a Party permits a third party to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical 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, and if a 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."	The text reflects TRIPS Article 30 language. Article 15.10 (5) provides for a Bolar provision, enabling generic companies to use patented products in connection with preparing their own products for marketing approval upon patent expiry domestically or abroad.
FTAA *	Section B.2.e, Article 5	There are a variety of proposed provisions reflective of TRIPS Article 30, in addition to proposed language outlining Bolar exceptions. For example: (5.4) "Where a Party permits the use of a patented invention to generate information required by a regulatory authority to obtain approval to market a product, such Party shall limit such use to acts reasonably performed to generate information to demonstrate that a product is scientifically equivalent to a previously approved product, provided however that: (a) where the grant of the patent precedes the approval for marketing of the product subject to the patent, the Party shall extend the term of the patent by a period sufficient to confer a reasonable term of exclusivity, (b) any product produced under this authority shall not be commercially used, sold, or offered for sale in the Party or exported outside the territory of the Party except as reasonably performed for obtaining marketing approval, and (c) the patent owner shall be provided notice of the identity of any entity that includes data generated under this authority in an application for marketing approval based on the previously approved product that seeks the authority to market the product prior to expiration of the patent."	Section B.2.e, Article 5.4 provides for a Bolar provision. But the provision is more restrictive than the flexible Article 30 language in TRIPS (which has served as the legal cover for Bolar provisions in many WTO members). This same provision requires the extension of the patent term in cases where granting of the patent precedes the granting of marketing approval. It also would require that governments notify patent owners of the identity of generic producers apply for marketing approval, relying on originator test data, during the patent term. This type of provision has been abused in the US context by pharmaceutical companies and is under investigation. The latter two elements are TRIPS- plus.

8. Policy Issue: Objectives and Principles

The objectives and principles of international agreements are used when interpreting the provisions of an agreement. The inclusion of language referencing the public interest and development in TRIPS sends an important signal that private intellectual property rights should also serve public interests such as technology transfer, and that they should be balanced by the right of the government to act in the public interest. All FTA negotiating parties belong to the WTO and are therefore signatories of TRIPS, and all adopted the Doha Declaration which affirms the importance of interpreting TRIPS in light of its principles and objectives, so public interest principles and objectives should be included in FTAs.

Agreement	Provision	Text	Comments
TRIPS	Article 7 (Objectives)	"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."	The public interest language in the principles and objectives, although not binding, sends an important signal that private intellectual property rights should be balanced by the right of governments to act in the public interest.
	Article 8 (Principles)	"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."	
Doha Declaration	Paragraph 5.a, Paragraph 4	Paragraph 5.a: "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles." Paragraph 4: "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this 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."	The Doha Agreement affirmed that the TRIPS Agreement can and should be interpreted in the public interest, and that members have the right to use all of the safeguards and flexibilities in the Agreement without fear of challenge.
NAFTA		There is no reference to public health or development objectives.	In the absence of TRIPS objectives and principles, there is less basis for a public interest interpretation of this agreement.
Chile		There is no reference to public health or development objectives.	As above.
Singapore		There is no reference to public health or development objectives.	As above.
CAFTA		There is no reference to public health or development objectives.	As above.
FTAA	Section A, Article 2 (Objectives)	"The protection and enforcement of intellectual property rights covered in this Chapter should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in the Americas, to the mutual advantage of producers and users of technological knowledge, with a view to fostering social and economic welfare and a balance of rights and obligations."	This text reflects TRIPS language on the balance between the interests of patent owners and the broader public good. It is in brackets, indicating lack of consensus.

	Section A, Article 3 (Principles)	(3.1): "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."	This language reflects TRIPS Article 8 and is followed by a bracketed provision regarding the prevention of abuse of intellectual property rights. Language referencing the Doha Declaration was formerly in the bracketed negotiating text, but it no longer appears in the most recent version.

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