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BILATERALISM IN INTELLECTUAL PROPERTY: DEFEATING THE WTO SYSTEM FOR ACCESS TO MEDICINES

Carlos M. Correa[†]

I. Introduction

The adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)[1] was regarded by developing countries as the end of a process of substantial strengthening of intellectual property rights (IPRs) protection. They expected that, having consented to high IPRs standards, they would be protected from unilateral actions and further demands of increased levels of protection by rich countries. They were wrong, however. Shortly after the conclusion of the Uruguay Round, the European Union and the United States continued to use various means to put pressure on developing countries not only to implement the TRIPS Agreement, but to obtain "TRIPS-plus" protection, that is, levels of protection beyond the minimum standards required by the TRIPS Agreement. Thus, the United States did not dismantle its controversial Special Section 301 of the Trade Act,[2] which empowers the United States Trade Representative ("USTR") to initiate cases and retaliate even against countries compliant with the TRIPS standards.[3] Threatening the removal of trade preferences or cutting development aid became common practice. These pressures—epitomized by the case brought against South Africa[4]—

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[1] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 1197 (1994).

[2] A WTO panel examined, in a case initiated by the EC and their Member States, the consistency with WTO obligations of the authorization given to the U.S. government to retaliate under several provisions (such as "Special 301") of the U.S. Trade and Tariff Act of 1984 (19 U.S.C § 2114c(2)(A)). The panel did not find – based on a commitment by the U.S. government not to apply sanctions without WTO authorization – a violation of WTO obligations. *See* WTO Panel Report on United States – Section 301-310 of the Trade Act of 1974, WT/DS152/R (Dec. 22, 1999).

[3] *See* the "Special 301" section of the U.S. Trade and Tariff Act of 1984. 19 U.S.C. § 2114c(2)(A)(1984).

[4] *See* MARIE BYSTRÖM & PETER EINARSSON, TRIPS – CONSEQUENCES FOR DEVELOPING COUNTRIES: IMPLICATIONS FOR SWEDISH DEVELOPMENT COOPERATION 36, 37 (2001), *at* http://www.grain.org/docs/sida-trips-2001-en.pdf (a consultancy report to the Swedish International Development Cooperation Agency).

raised significant criticism from academic[5] and non-governmental organizations[6] and developing countries, which eventually led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration")[7] by the WTO Doha Ministerial Conference. The Doha Declaration confirmed the flexibilities that the TRIPS Agreement left Member countries to implement various obligations at the national level.

The strategy to seek higher standards of IPRs through unilateral pressures has been supplemented by an apparently less coactive, but perhaps more effective, approach. TRIPS-plus obligations are extracted in exchange for trade concessions made in the context of free trade agreements. The European Communities practiced this approach in a number of agreements entered with, among others, South Africa (1999), Tunisia (1998), and the Palestinian Authority (1997), which required the latter to ensure adequate and effective protection of intellectual property rights "in conformity with the highest international standards." The United States—which has become "the principal architect of the global regulatory ratchet for intellectual property"[8]—has concluded the negotiation of free trade agreements (FTAs) including IPRs specific rules, with Jordan, Singapore, Morocco, Chile and the Central American countries.[9] Trade

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[5] *See, e.g.* PETER DRAHOS, DEVELOPING COUNTRIES AND INTERNATIONAL INTELLECTUAL PROPERTY STANDARD-SETTING 14-18 (2002), *at* http://www.iprcommission.org/papers/pdfs/study_papers/sp8_drahos_study.pdf (a study prepared for the United Kingdom Commission on Intellectual Property Rights.

[6] *See, e.g.*, SUSAN SELL, PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS (2003).

[7] Fourth Doha Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/W/2 (Nov. 14, 2001) [hereinafter *Declaration on TRIPS and Public Health*].

[8] Peter Drahos, *Expanding Intellectual Property's Empire: The Role of FTAs*, GRAIN (2003), *at* http://www.grain.org/rights/tripsplus.cfm?id=28.

[9] The United States also applies Trade and Investment Framework Agreements ("TIFAs") in order to promote the establishment of legal protections for investors, enhancement of intellectual property protection, changes in customs procedures, and transparency in government and commercial regulations. There are TIFAs in place in a number of countries, including Bahrain, Egypt, Tunisia, Algeria, Saudi Arabia, Kuwait, and Yemen. *See generally* U.S. Trade Representative, *Middle East Free Trade Initiative: U.S. Regional Plan to Spur Economic Growth* (Mar. 2, 2004), *available at* http://www.ustr.gov/Document_Library/Fact_Sheets/2004/Middle_East_Free_Trade_Initiative_U.S._Regional_Plan_to_Spur_Economic_Growth.html; United States Department of State, *Trade and Investment Framework Agreements*, *available at* http://www.state.gov/e/eb/tpp/c10333.htm; *See, e.g.* Agreement Concerning the Development of Trade and Investment Relations, June 18, 2002, U.S.-Bahr., *available at* http://www.ustr.gov/assets/Trade_Agreements/Regional/MEFTA/asset_upload_file168_3538.pdf.

negotiations in course include the Southern African Customs Union,[10] Thailand,[11] and three Andean countries (Ecuador, Peru, and Colombia).

FTAs would seem to have a strategic rather than an immediate commercial objective for the United States. They reflect a reaction to the growing resistance that United States initiatives encounter in the WTO. Bilateral dealings permit the United States to obtain[12] what it cannot easily get multilaterally: "Presumably, US leverage is also greater in bilateral or plurilateral negotiations than in larger forums where other major economic powers are present."[13] However, bilateral agreements reinforce the multilateral process as well, as the FTAs oblige partners to adhere to IPRs international conventions of U.S. choice, including UPOV (1991) and the recent WIPO Copyright Treaty and Performances and Phonogram Treaty (1996). European FTAs also oblige their partners to adhere to a number of international conventions.[14]

Interestingly, the countries involved in bilateral negotiations with the United States account for a minor share of U.S. exports.[15] FTAs are attractive to governments of developing countries as they may gain political credit for greater access (generally for agricultural products, raw materials, and low value added manufactures) to the large U.S. market. The less tangible but equally or more important effects on development policies appear as matters of secondary concern. Whatever the commercial gains of FTAs in the short and long term for such countries may be, the dramatic increase in the level of protection of IPRs is likely to have a direct and

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[10] The Southern African Customs Union includes Botswana, Lesotho, Namibia, South Africa, and Swaziland.

[11] Press Release, Office of the U.S. Trade Rep., USTR Notifies Congress of Intent to Initiate Free Trade Agreement Negotiations with Thailand (Feb. 12, 2004) *available at* http://www.usa.or.th/relation/rel021204.htm.

[12] *Hearing to Review U.S. Trade Policy Objectives and Initiatives Before the Subcommittee on Trade of the House Comm. on Ways and Means*, 105th Cong. 22 (Mar. 18, 1997) (statement of Ambassador Charlene Barshefsky, U.S. Trade Representative), *available at* http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=105_house_hearings&docid=f:51072.pdf (stating that "we recognize that certain problems can only be addressed effectively, and with a degree of specificity, on a bilateral basis."). *See* Jean-Frédéric Morin, *Le droit international des brevets: entre le multilatéralisme et le bilatéralisme américain*, 34 *Études Internationales* 537 (2003), *available at* http://www.iisd.ca/whats_new/us_bilateral_IPR.pdf.

[13] Richard E. Feinberg, *The Political Economy of United States' Free Trade Arrangements*, 26 WORLD. ECON. 1019, 1036 (2003).

[14] *See, e.g.*, Free Trade Agreement, *opened for signature* Nov. 27, 2000, Ice.-Liech.-Nor.-Switz.-Mex., *at* http://www.sice.org/Trade/mexefta/mexefta1.asp.

[15] For instance, Morocco accounts for .04 percent of U.S. exports and all Central American countries account for 1.44 percent of U.S. exports. *See* Feinberg, *supra* note 13, at 1035.

significant impact on the capacity to design and implement development policies, particularly in the area of public health.

This paper elaborates on the bilateralism in IPRs standard setting, using as an example the substantial elevation of IPRs standards in the Central American Free Trade Agreement ("CAFTA")[16] in relation to pharmaceutical test data (Article 39.3 of the TRIPS Agreement) and the new requirement (not present in the TRIPS Agreement) linking patent protection to the registration of a pharmaceutical product. Though not extensively treated by the literature, these issues are of key importance to determine the degree of competition in the pharmaceutical market, especially in countries that have introduced product patent protection only recently. Enhanced protection of pharmaceuticals, as obtained by the United States in CAFTA, may substantially limit competition and restrain access to medicines, in direct contradiction with the objectives of the Doha Declaration.

II. The TRIPS Standard on Data Protection

Article 39.3 of the TRIPS Agreement requires Members to protect test data submitted for the marketing approval of pharmaceuticals and chemical products for agriculture. Such data normally relate to the results of tests about quality, safety, and efficacy of new compounds. Test data must be protected if national authorities require its submission. Thus, if they rely on an approval granted in a foreign country, the obligation does not apply. In addition, Article 39.3 does not require protection be given to data that are already publicly available, but to secret data. Protection is mandated only for new chemical entities. Members have considerable discretion in defining this concept, which excludes second indications, new formulations, or dosage forms. Finally, in order to grant protection, national regulatory authorities may request the applicant to prove that the information for which protection is sought is the result of significant investment.

In addition, Article 39.3 requires countries to protect test data against "unfair commercial use." Protection is to be conferred against dishonest commercial practices. A practice expressly required or permitted by the law may not be deemed dishonest. Granting marketing approval to a second entrant, based on the similarity with a previously approved product, is not a proscribed "use" under Article 39.3.

Test data must be protected under the discipline of unfair competition, as established in the Paris Convention for the Protection of Industrial

[16] Free Trade Agreement, Aug. 5, 2004, Dom. Rep.-Central America-U.S., *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/DR-CAFTA/DR-CAFTA_Final_Texts/Section_Index.html.

Property (Article 10bis)[17] and the TRIPS Agreement (Article 39.1). Under such discipline, *no exclusive rights are granted*, but only the right to take legal action against whomever has obtained a commercial advantage by means of a dishonest practice. Obtaining a commercial advantage, as such, is not condemnable under unfair competition rules.[18] Legal protection only arises when dishonest conduct has been used for that purpose.

A. Controversies on Interpretation

Despite the fact that Article 39.3 does not provide for the granting of exclusive rights, governments of some developed countries have argued—responding to strong industry lobbying—that protection of test data can only be ensured if a minimum period (e.g. five years) of exclusivity is granted. The manufacturer that developed test data, it is held, has invested heavily, and deserves a fair return on investment. Where patent law fails to provide protection (for example, because the patent on an active component is to expire shortly, or because a product is based on a combination of known substances used in a novel manner), unless data exclusivity is granted, competitors would face no barrier to producing and registering an exact copy of the product.

But this argument leads to the protection of investment as such, and not of a creative or inventive outcome—the very purpose of intellectual property rights. Furthermore, Article 39.3 does not mention at all an obligation to grant exclusivity for test data. The granting of exclusivity constitutes a drastic derogation to the principle of free competition, which cannot be inferred from a text that does not provide for it.[19]

The issue of data protection is especially relevant for off-patent products as well as for products, such as biological, that are often difficult to patent. In cases where the product is patented, the patent holder can, in principle, exclude any commercial competition during the lifetime of the patent—a period of exclusion which will generally run longer than that afforded by data protections.

Data protection rules are particularly problematic for developing countries that until recently did not provide patent protection for pharmaceuticals and/or chemical products for agriculture,[20] like in the case

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[17] Paris Convention for the Protection of Industrial Property, *opened for signature* Mar. 20, 1883, art. 10bis, *at* http://www.wipo.int/clea/docs/en/wo/wo020en.htm.

[18] *See, e.g.*, ANSELM KAMPERMAN SANDERS, UNFAIR COMPETITION LAW: THE PROTECTION OF INTELLECTUAL AND INDUSTRIAL CREATIVITY (1997).

[19] *See* CARLOS M. CORREA, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS; IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 50, (2002) *at* http://www.southcentre.org/publications/protection/toc.htm.

[20] *See, e.g.*, Brook K. Baker, *The Drug Registration Battlefield: U.S. Trade Policy Erects New, Nearly Impenetrable Barriers to Lower-Cost Generic Medicines of Assured Quality,*

of most Latin American countries. Data exclusivity, if granted, may become a substitute for patent protection for many products and nullify, in practice, their right to keep in the public domain products for which patents were not recognized under pre-TRIPS legislation.

B. National Experiences

The protection of test data was circumscribed to a few countries until recently. The United States, Japan, and the European Communities pioneered it, based on a *sui generis* system ("data exclusivity"). This system applies to disclosed and undisclosed data as well[21] and prevents third parties from using the test data or relying on them in order to seek marketing approval without the originator's consent. The exclusivity, however, does not prevent a third party from developing its own data on the same product. Under U.S. pressure, several countries have adopted this approach (e.g. Australia) or have assumed obligations (e.g. Chile) to do so under bilateral agreements. In Brazil, data exclusivity has been adopted only in relation to veterinary and agricultural products (not for pharmaceuticals), for a period of ten years for products consisting of new chemical entities, and of five years for other products (Law No. 10.603 (17.12.03)).

In the Andean Community, a TRIPS-plus standard was adopted by Decision 344 ("Common Regime on Industrial Property") in 1993, but repealed in September 2000 by Decision 486.[22] Under this Decision, the Andean Community's countries must protect test data against unfair commercial use without providing for exclusivity, in line with the TRIPS standard. However, data exclusivity was recognized in Colombia for pharmaceuticals in 2002 (Decree No. 2085).[23]

HEALTH GAP REPORT (Health Global Access Project, New York, N.Y.), Feb. 16, 2004, *available at* http://www.cptech.org/ip/health/dataexcl/baker02162004.html; *see Article 39.3 of the TRIPS Agreement: Its Genesis and Present Context,* COMPLETED PROJECT (Indian Institute of Foreign Trade, New Delhi, India), July 2003, *available at* http://www.iift.edu/iift/wto/ptoj_completed.asp.

[21] In fact, national health authorities such as the U.S. Food and Drug Administration generally publish clinical trials and submit analytical data for marketing approval. *See* U.S. FOOD AND DRUG ADMINISTRATION, BASIC QUESTIONS AND ANSWERS ABOUT CLINICAL TRIALS, *available at* http://www.fda.gov/oashi/clinicaltrials/clintrialdoc.html.

[22] Decision 486: Common Intellectual Property Regime, *entered into effect* Dec. 1, 2000, Andean Community, *available at* http://www.sice.oas.org/trade/junac/decisiones/DEC486e.asp#notet.

[23] *Ultimas Normas, Servicio de Salud Colombia,* Sept. 19, 2002, *available at* http://www.saludcolombia.com/actual/htmlnormas/Dec2085_02.htm.

The U.S. government initiated a case under WTO rules complaining about Argentina's alleged failure to appropriately protect test data. The dispute was settled at the consultation stage after two years of discussions.[24] Argentina did not accept the U.S. claim, maintained its law, and did not grant data exclusivity. No further action has been taken by the United States against Argentina, or any other country that does not recognize data exclusivity in the framework of the WTO. However, the USTR has listed, under the Special Section 301 of the Trade Act, a large number of countries that, according to USTR, do not confer adequate (that is, exclusive) protection for test data.

In sum, although the establishment of exclusive protection for test data is not required under the TRIPS Agreement,[25] it has been provided for in developed countries and in bilateral or regional agreements involving some developing countries. Such exclusivity operates like a substitute for patent protection, thereby detracting from the public domain products that should be freely available. The implications of this issue for public health and agricultural production are significant.

III. TRIPS-plus in CAFTA

CAFTA was negotiated by the four Central American countries (Costa Rica, El Salvador, Guatemala, Nicaragua), and the Dominican Republic will join this agreement. These countries are among the poorest in the Americas, however, CAFTA has elevated the standards of intellectual property protection as if they were in the ranks of the richest and most developed countries. While CAFTA extends to Central America U.S. law and practice, as mentioned below, it also introduces standards that exceed current levels of protection in the United States.

A. Data Exclusivity

CAFTA significantly departs from the TRIPS Agreement in many areas, particularly in those of interest to the pharmaceutical industry. Thus, it obliges to extend the term of patent protection to compensate for delays in patent examination and in the marketing approval of pharmaceutical products. It also establishes a *sui generis* regime of "data exclusivity" for the protection of test data submitted for registration of pharmaceuticals. According to Article 15.10.1 (a) of CAFTA:

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[24] *See* Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, June 20, 2002, IP/D/18/Add.1, IP/D/22/Add.1, *available at* www.wto.org.

[25] Lucas R. Arrivillaga, *An International Standard of Protection for Test Data Submitted to Authorities to Obtain Marketing Authorization for Drugs–TRIPS Article 39.3*, 6 J. WORLD INTELL. PROP. 139,143 (2003).

> If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed 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) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.[26]

Thus, if the original medicine is approved in a Central American country, no approval to a generic company can be given during the following five years from the date of approval of the original medicine in that country, whether using the data submitted by the originator company or relying on such approval. Despite the fact that, applications for registration can languish for years,[27] and that the company that originated the data has no obligation to file for marketing approval within a limited deadline, the five years period will be counted from the date of approval in the country where the application was made.

CAFTA contemplates the situation in which a country allows registration of a drug on the basis of the marketing approval obtained in another country. Some developing countries have followed this model, which squarely puts them outside the scope of Article 39.3 of the TRIPS Agreement. Article 15.10.1 (b) of CAFTA provides the following:

> 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 or 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) evidence of prior marketing approval in the other territory, or (2) information concerning safety or 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's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.[28]

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[26] Free Trade Agreement, *supra* note 16, art. 15.10.1(a).

[27] *See, e.g.*, Baker, *supra* note 20.

[28] Free Trade Agreement, *supra* note 16, art. 15.10.1(b).

This paragraph prevents both the use of test data submitted to a foreign authority as well as relying on the prior approval in a foreign country. The five-year protection runs from the date of approval of the medicine by the originator in the Party. A Party *may* require that the originator seek approval within five years after obtaining marketing approval in the other territory. If this requirement was established, the originator would enjoy a full ten years period of protection during which no other party would be able to use, without his consent, directly or indirectly, the relevant test data.

Due to poor wording, some questions arise in relation to this provision, notably whether or not a competitor could request marketing approval during the first five year period, in the absence of an application by the originator, whether the national authority could approve the competitor's product and if so, whether this authorization could subsist or would have to be revoked when the originator finally obtains marketing approval in the Party. This provision seems to give the originator company, by law, a lead-time of at least five years over its competitors. Although the five year period is counted from the date of the originator's approval, it is difficult to interpret that before that date it would be possible for national authorities to grant marketing approval to a third party without the consent of the originator company. If this interpretation were correct, the net effect on public health, as elaborated below, would be most disturbing.

1. New Chemical Entities

Member countries are bound to grant protection under Article 39.3 to chemical entities that are "new," that is, molecules that were not previously incorporated into a product approved for marketing in any country. CAFTA, however, obliges the Parties to apply the concept of "new chemical entities" with a broader meaning than required under the TRIPS Agreement, not surprisingly in a manner that significantly favours the interests of U.S. pharmaceutical companies. According to Article 15.10(1)(c) "new chemical entities" includes entities "not previously approved" in the Party granting approval, without any time limit. Thus, a chemical entity previously approved at any time in a foreign country will continue to be "new" for a CAFTA Party until it is registered there, even if this happens many years after its first marketing approval in the world.

In a footnote to the same Article it is clarified that "[w]here a Party, on the date it implemented the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use that conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1."[29] Although apparently benefiting *any* Party, this exception will allow the United States

[29] *Id.* at art. 15.10.1(a) n.15.

to keep a period of three years, as provided for in its national law, for products not involving new chemical entities, while imposing five years to Central American countries.

2. Undisclosed Data

Legal creativity has reached surprising levels with the CAFTA. One of the important limitations to the scope of Article 39.3 is that it only applies to *undisclosed* information. As mentioned, the test data required for approval are normally published; however, not surprisingly, a major objective of the U.S. pharmaceutical industry has been to extend the prohibition to use tests data even if publicly available. This objective has been attained in a peculiar way.

According to Article 15.10.1 (d) "no Party may consider information accessible within the public domain as undisclosed data" for the purposes of this paragraph only, that is, in relation to the disclosure of data "where necessary to protect the public."[30] But "if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article."[31] Instead of clearly spelling the elements of a *sui generis* regime for disclosed and undisclosed test data, the CAFTA has engendered a new legal fiction: information freely available to the public (for instance published in the web page of the U.S. Food and Drug Administration) is deemed "undisclosed."

B. Linkage

The United States has obtained another objective actively pursued by its pharmaceutical industry: the CAFTA links drug registration to patent status. There is no provision of this kind in the TRIPS Agreement. It was, however, included, in other bilateral agreements negotiated by the United States, such as the FTA with Chile. Article 15.10.2 of the CAFTA provides:

> 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 territory of a Party or in another country, that Party:

[30] *Id.* at art. 15.10.1(d).

[31] *Id.*

> (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and
>
> (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.[32]

The patent-registration linkage ignores that patents are private rights, as stated in the Preamble of the TRIPS Agreement, and that, whether a given product infringes or not, a patent is a legal matter entirely separate from the technical issues concerning safety and efficacy of drugs. Health authorities have no knowledge or experience whatsoever to assess the claims of a patent. As discussed elsewhere,[33] patents in pharmaceuticals cover a wide range of subject matter, and can be used (or abused) to deter generic competition.[34] New chemical entities—the development of which shows a declining trend since the 1990's—account for a small fraction[35] of the thousands of patents obtained every year around known drugs, including those in the public domain. Patents in this field cover,[36] for instance:

a) Pharmaceutical formulations;[37]

b) Combinations of known products;[38]

c) Optical isomers;[39]

f) Active metabolites;[40]

h) Salts of known substances;[41]

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[32] *Id.* at art. 15.10.2.

[33] *See, e.g.*, CARLOS M. CORREA, TRENDS IN DRUG PATENTING (2001).

[34] *See* Lara J. Glasgow , *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*. 41 IDEA 227, 234-235 (2001).

[35] In 2002, for instance, only thirty "new chemical entities" were developed. *See* IMS Health, *New Product Focus* (Dec. 2002).

[36] *See, e.g.*, Attila Mándi, *Protection and Challenge of Pharmaceutical Patents*, 1 J. Generic Med. 1 (2003).

[37] That is, a particular form given to an active ingredient for administration to the patient, for instance, micronized particles.

[38] They often consist of the simple mixture of known drugs (e.g. aspirin, carisoprodol, and codeine phosphate).

[39] Many chemical compounds present a molecular structure comprising two mirror forms. Frequently, after the mixture ("racemic" mixture) of both forms has been patented, an application is made for a patent for the most active isomer.

[40] For example, after terfenadine had been on sale for several years, a patent was obtained for the relevant active metabolite.

i) Variants of known manufacturing processes;[42]

j) Polymorphs.[43]

All these types of patents refer to a *product*.[44] Unfortunately, there is no wording in the CAFTA indicating that the linkage would only operate when the second applicant intends to commercialize the product as patented, or that the linkage only applies with regard to patents claiming an *active ingredient*,[45] but a limitation of this type may be established in the implementing national legislation. Should, under the vague formulation of the CAFTA ("a patent claiming the product"), marketing approval be denied if there were, for instance, a patent over a particular salt of a drug that is in the public domain? If so, the linkage would widely and unduly exclude generic competition until all patents around a product expire.

The patent-registration linkage goes beyond the standards applied in developed countries. In Europe, for instance, there is complete independence between intellectual property protection and registration. Health authorities have no legal capacity to look into IPRs issues and deny approval to an application that conforms to the relevant technical standards, even if there were an infringement of IPRs. This is simply not their business. In the United States,[46] the Food and Drug Administration must inform patent owners who registered patents in the so called "Orange Book" about the existence of a third party's application on the same drug, but it is the patent owner who needs to act before the courts if he wants to interfere with the application procedures of a non licensed third party.

The linkage system is clearly a TRIPS-plus obligation. It creates a new exclusive right (the right to prevent marketing approval of a pharmaceutical product) non-existent under Article 28 of the TRIPS

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[41] For example, hydrates, anhydrates and solvates of the same drug.

[42] For example, processes that shorten the number of steps necessary to obtain a product.

[43] Polymorphs are different forms of crystallization of the same drug, *see, e.g.*, SmithKline Beecham Corp. v. Apotex Corp., 247 F. Supp. 2d 1011, 1016-1017 (N.D. Ill. 2003) *aff'd* 365 F.3d 1306 (Fed. Cir. 2004).

[44] CAFTA also seems to oblige Central American countries to grant *use* patents, an obligation absent in the TRIPS Agreement. See the reference to "approved use" in the Free Trade Agreement, *supra* note 16, art. 15.10.3(a).

[45] *See, e.g.*, "Decreto por el que se reforma el Reglamento de Insumos para la Salud y el Reglamento de la Ley de la Propiedad Industrial" [Decree reforming the Regulation of the Health Supplies and the Regulation of the Law of Industrial Property], Diario Oficial de la Federacion, 19 de septiembre de 2003, 106-107, *available at* http://www.gobernacion.gob.mx/dof/2003/septiembre/dof_19-09-2003.pdf (limiting the linkage to patents on "la sustancia o ingrediente activo" [the active substance or ingredient], thereby narrowing down the linkage's restriction on competition).

[46] *See generally*, U.S. FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (July 2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Agreement and national patent laws. It also creates a presumption of validity of pharmaceutical product patents which health authorities are neither empowered nor have the capacity to challenge. In numerous cases, however, patents—often deliberately acquired to block genuine competition—are invalidated by administrative authorities or courts.[47] The United States Federal Trade Commission has held in a recent report that, the circumstances under which a patent is granted "suggest that an overly strong presumption of a patent's validity is inappropriate" and that it "does not seem sensible to treat an issued patent as though it had met some higher standard of patentability."[48] This is why courts in the United States and Europe take a very cautious approach towards the granting of injunctions in patent cases.[49]

IV. Implications

There is a clear contradiction between the protectionism of the pharmaceutical industry's interests enshrined in the CAFTA and the international efforts made to ensure the availability of drugs, including in countries without capacity for manufacturing pharmaceuticals. The concerns raised about the implications of the TRIPS Agreement on public health were reflected in the adoption, upon the initiative of developing countries, of the "Doha Declaration on the TRIPS Agreement and Public Health,"[50] at the Fourth WTO Ministerial Conference (November 9-14, 2001). The Doha Declaration recognized the "gravity" of the public health problems afflicting many developing and least developed countries ("LDCs"), especially—but not limited to—those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics, and recognized that the TRIPS 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.[51]

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[47] *Id.*

[48] U.S. FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 8, 10 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf.

[49] *See, e.g.*, Joseph Strauss, *Reversal of the Burden of Proof, the Principle of "Fair and Equitable Procedures" and Preliminary Injunctions Under the TRIPS Agreement*, 3 J. WORLD INTELL. PROP. 807, 822 (2000); J. Reichman & M. Zinnani, *Las medidas precautorias en el derecho estadounidense: el justo balance entre las partes*, 8 JURISPRUDENCIA ARGENTINA 15-21 (2002).

[50] *Declaration on TRIPS and Public Health*, *supra* note 7.

[51] *Id.* at para. 4.

The Declaration also instructed the Council for TRIPS to address a delicate issue: how can Members lacking or with insufficient manufacturing capacities make effective use of compulsory licensing.[52] Manufacturing capacities in pharmaceuticals are distributed very unevenly in the world. Not many countries have the capacity to produce both active ingredients and formulations, and very few countries maintain significant research and development capabilities.

A controversial agreement to implement paragraph 6 was reached by the WTO General Council, after a significant diplomatic battle, on August 30, 2003.[53] The agreed "solution" is based on a compromise developed by the Chair of the TRIPS Council[54] and on a "Statement by the Chair" proposed by the United States as a condition to accept the deal. Though subject to cumbersome conditions—intended to protect the large pharmaceutical companies—the Decision provides a mechanism for the export/import of patented pharmaceutical products under compulsory licenses.

The implications for public health of the CAFTA provisions are significant. "Data exclusivity" does not provide exclusionary rights like a patent, but creates an effective barrier to generics competition. Even where a product were off-patent, no marketing approval can be granted to a generic manufacturer unless (a) he develops the full set of test data necessary to obtain approval, or (b) the terms of data exclusivity have expired. The first option is costly, time-consuming, and raises serious economic and ethical concerns. Duplicating existing tests is not only a social waste; it is also ethically questionable as it entails unnecessary animal suffering and risks for humans. The second option has a high social cost, as patients are deprived from access to affordable drugs.

The data exclusivity and the patent-registration linkage can make illusory the granting of compulsory licenses and non-commercial government use, as prospective compulsory licensees are unlikely to have sufficient incentives to replicate test data, and governments cannot normally wait until a new set of test data has been developed. The TRIPS-plus provisions on pharmaceutical products contained in the CAFTA not only contradict the spirit and express objective of the Doha Declaration, they are likely to effectively prevent the use of the system established by the Council's Decision, as generic companies will be unable to obtain

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[52] *Id.* at para. 6.

[53] Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405 (Aug. 28, 2003).

[54] *See* Statement of the Chairman of the Council for TRIPS, JOB(02)/217 (Dec. 16, 2002), *available at* http://commerce.nic.in/wtotrips3.htm.

marketing approval during the period of data exclusivity or the patent life, without the authorization of the patent holder.[55]

V. Conclusion

The United States seems to have strategically opted for bilateralism as the main route to support U.S. industry in its relentless campaign to increase the levels of IP protection worldwide. This bilateralism, of course, operates in a context of deep asymmetries. It is quite obvious that there is no Central American pharmaceutical industry able to benefit in any manner from the protection that the United States is bound to confer in its territory under Article 15.10 of the CAFTA, and that it is the Central American people, particularly the poor, who will pay the costs created by this new protectionist framework.

The CAFTA also raises questions about how bilateral the U.S. bilateralism actually is. As mentioned, the absolute and automatic patent-registration linkage seems to go beyond U.S. law. Also, Article 15.10 may ban, in practice, the use of patented inventions for compulsory licensing and governmental non-commercial purposes. By creating through bilateral negotiations standards of protection higher than those applied domestically, the powerful U.S. pharmaceutical industry may be able to force an amendment of U.S. domestic law in ways simpler and less costly that through lobbying in Congress.

However, it is still to be seen whether the United States will fully implement these new standards. It has been active, for instance, in utilizing compulsory licenses to remedy anti-competitive practices and non-commercial government use.[56] Would the government or courts accept that the interests of a pharmaceutical company prevails over public interest if the supply of a drug were needed in an emergency, like in an "anthrax"

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[55] Moreover, CAFTA (Article 15.9.5) recognizes a "Bolar provision" that seems to limit the possibility of exporting pharmaceutical products, except for those complying with marketing approval requirements in a foreign country. If this interpretation were correct and this provision applied effectively in the United States, generics companies in the United States (as well as those located in Central America) would be unable to export drugs under the WTO decision.

[56] *See, e.g.*, Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, WORKING PAPER (South Centre's Develop. and Equity Series, Geneva, Switz.), 1999, *available at http://www.southcentre.org/publications /complicence/toc.htm*; Jerome Reichman & Catherine Hasenzahl, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS, and an Overview of the Practice in Canada and the USA*, *in* UNCTAD-ICTSD INTELLECTUAL PROPERTY RIGHTS & SUSTAINABLE DEVELOPMENT SERIES (2003), *available at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl. pdf.

case?[57] While Central American countries will likely be under significant pressure to apply the new treaty rules, the United States may find ways to soften or neutralize their impact. The incomplete implementation of the Berne Convention with regard to moral rights, and the reluctance to amend the copyright law despite the adverse decision in *United States–Section 110(5) of the US Copyright Act*,[58] suggest that a great deal of resistance to implement bilateral commitments inconsistent with current U.S. law may arise.

Central American governments expect considerable commercial benefits from the CAFTA's implementation in terms of access to the U.S. market. Whether such benefits will materialize or not is uncertain. However, such countries have accepted to severely limit generic competition in pharmaceuticals through TRIPS-plus data exclusivity and patent-registration linkage systems. These provisions will make it more difficult to ensure access to drugs to all, and will deter the development of a competitive generic industry in the region. In particular, Central American countries will be prevented, in practice, from using the system for access to drugs established by the WTO Decision of August 30th, 2003.

The CAFTA denies the right of developing countries to use to the fullest extent possible the flexibilities allowed by the TRIPS Agreement to protect public health. The serious public health problems identified by the "Doha Declaration on the TRIPS Agreement and Public Health" can only aggravate in countries subject to TRIPS-plus (and even U.S.-law plus) standards like those contained in the CAFTA and similar FTAs. A few U.S. pharmaceutical companies will increase their benefits only marginally (given the small size of the Central American pharmaceutical market), but a large number of people may be deprived from medical treatment. What is a minor benefit for pharmaceutical companies may be a major loss for poor countries. The world can only become a more difficult place to live in if countries with a major responsibility towards global welfare continue, in shaping intellectual property rules, to give priority to narrow commercial interests rather than to improving the lives of people and development prospects around the world.

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[57] *See, e.g.*, South Centre, *AIDS and Anthrax: Strange Bedfellows?*, 38 S. LETTER 38, 38-39 (2001), *available at* http://www.southcentre.org/southletter/sl38/sL38.pdf.

[58] *See* WTO Panel Report on United States – Section 110(5) of the US Copyright Act,WT/DS160/R (June 15, 2000) *available at* 2000 WL 816081.