The "Good Old Days" of TRIPS: The U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection

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Intellectual property rights carry significant implications for world health. In 1994, the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) placed pharmaceuticals among the forms of technology that constitute patentable subject matter.[1] Over the past ten years, non-governmental organizations, governments, and international institutions have increasingly acknowledged that this mandated inclusion influences the availability of new drugs, at least within the member nations of the World Trade Organization (WTO).[2]

The nature of this effect, however, remains open to debate. Whether pharmaceutical patents provide financial incentives that support private research and development, as the industry attests, or allow monopoly pricing and production that hinder the ability of poor nations to address health crises, such patents have become an unavoidable feature of global medicine. The TRIPS-driven harmonization of intellectual property protection across borders is likely to continue into the foreseeable future.

Although negotiations regarding the expansion of patent rights for pharmaceuticals have been highly contested—with conflicts frequently

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1. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, LEGAL INSTRUMENTS–RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement] (establishing that patents are available in all fields of technology), *available at* http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm.

2. *See generally* Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT'L L.J. 481 (2002) (offering a political perspective on the TRIPS Agreement and its implementation).

arising between developed and developing countries[3]—the TRIPS Agreement represents the result of extensive multilateral discussion. For example, while the TRIPS Agreement requires a twenty-year minimum patent term,[4] it allows countries to offer "limited exceptions to the exclusive rights conferred by a patent" and includes provisions for compulsory licensing of patented inventions under limited circumstances.[5] In the years since the TRIPS Agreement entered into force, this discussion has continued, resulting in new statements on pharmaceutical patents and public health issues in the 2001 Doha WTO *Ministerial Declaration*,[6] the concurrent *Declaration on the TRIPS Agreement and Public Health*,[7] and, most recently, in an implementation agreement regarding the compulsory licensing of patented pharmaceutical products.[8] WTO member nations have also agreed to extend the transition period for least-developed countries to comply with those elements of the TRIPS Agreement related to the protection of pharmaceuticals.[9] However imperfect these compromises, and whatever their eventual effect on global health, the new agreements are intended to address the concerns of developing and least-developed member nations. In this sense, the ongoing TRIPS process represents a victory of collective bargaining power.

Recent U.S. bilateral and regional free trade agreements (FTAs), by contrast, do not offer trading partners an equivalent opportunity to influence either the text or the implementation of intellectual property

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3. *Id.*

4. TRIPS Agreement, *supra* note 1, at art. 33.

5. *Id.* at art. 30-31.

6. World Trade Org., Doha WTO Ministerial 2001, *Ministerial Declaration*, WT/MIN(01)/DEC/1 (Nov. 20, 2001), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm.

7. World Trade Org., Doha WTO Ministerial 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter *TRIPS Public Health Declaration*], *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. The TRIPS Public Health Declaration affirms that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to secure access to medicines for all." *Id.* at para. 4.

8. World Trade Org., General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. The agreement describes the acceptable circumstances for compulsory licensing and for the export and import of such goods.

9. *TRIPS Public Health Declaration*, *supra* note 7, at para. 7.

provisions. The Office of the United States Trade Representative (USTR) is engaged in a systematic effort to increase international intellectual property protection, one country at a time.[10] This effort is not limited to the global consensus ostensibly embodied in the TRIPS Agreement, but extends to additional protections in areas such as digital rights management and the establishment of criminal sanctions for infringement.[11] Most significantly from a public health perspective, the USTR seeks to supplant ambiguous provisions in TRIPS with concrete substantive minima in FTAs for the protection of regulatory test data, or the otherwise undisclosed scientific studies submitted to regulatory agencies in the process of seeking approval to market pharmaceuticals.[12] The legal status of this test data is of paramount importance to the manufacturers of generic pharmaceutical products, who reference the existence of brand-name pharmaceutical test data in order to obtain post-patent marketing approval for their own, less expensive versions of the same drugs. This indirect reliance, in turn, affects the price of generic pharmaceuticals and the degree of public access to these medicines. Although the United States has engaged in ongoing consultations with Argentina on this intellectual property and public health matter under the aegis of the WTO Dispute Settlement Understanding, it has thus far declined to submit the question of what constitutes adequate test data protection under TRIPS to a WTO panel,[13] preferring instead to enshrine

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10. *See* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2003 SPECIAL 301 REPORT (May 1, 2003), http://www.ustr.gov/reports/2003/fullreport.pdf.

11. *Id.*

12. *See id.*; North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 605 (1993) [herinafter NAFTA Agreement], *available at* http://www.ustr.gov/regions/whemisphere/nafta.shtml; United States - Singapore Free Trade Agreement, May 6, 2003, 42 I.L.M. 1026 (2003) [hereinafter Singapore FTA], *available at* http://www.ustr.gov/new/fta/Singapore/final.htm; United States - Chile Free Trade Agreement, June 6, 2003, 42 I.L.M. 1026 (2003) [hereinafter Chile FTA], *available at* http://www.ustr.gov/new/fta/Chile/text/index.htm; Central American Free Trade Agreement, Jan. 28, 2004, (draft text) [hereinafter CAFTA Agreement], *available at* http://www.ustr.gov/new/fta/Cafta/text/index.htm; and United States - Morocco Free Trade Agreement, Mar. 31, 2004 (draft text) [hereinafter Morocco FTA], *available at* http://www.ustr.gov/new/fta/Morocco/text/index.htm.

13. World Trade Org. Dispute Settlement Body, *Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WT/DS171/3, *Argentina - Certain Measures on the Protection of Patents and Test Data*, WT/DS196/4 (June 20, 2002); Office of the United States Trade Representative, *Dispute Settlement Update* (Mar. 9, 2004),

its favored interpretation in various bilateral and regional FTAs.

This brief Case Study describes the treatment of pharmaceutical regulatory test data under both TRIPS and recent U.S. FTAs and argues that there has been an increasing elaboration of protective legal structures in the latter. While individual countries may perceive benefit in expanding their protection of test data, such public health analysis should not take place under the pressure of free trade negotiations.[14] The TRIPS Agreement and its implementation may be far from ideal, but its transparent, multilateral approach to intellectual property harmonization offers technology-importing nations greater influence over evolving issues like pharmaceutical test data protection than the often unequal free trade negotiation process.

UNDERSTANDING TEST DATA PROVISIONS

TRIPS ARTICLE 39.3

The first step in understanding the contested international treatment of pharmaceutical test data is to analyze the relevant provision of the TRIPS Agreement. Protection for pharmaceutical test data in TRIPS is cast as an extension of the provisions regarding "unfair competition" found in Article 10*bis* of the Paris Convention for the Protection of Industrial Property.[15] Under this general rubric, Article 39 of TRIPS provides for the protection of "undisclosed information" or trade secrets. The provision regarding test data, Article 39.3, is the result of a compromise among

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available at http://www.ustr.gov/enforcement/update.pdf [hereinafter Dispute Settlement Update].

The WTO Dispute Settlement Body can interpret TRIPS provisions but is not authorized to expand protection, and it has avoided the temptation to fill gaps in the Agreement. J.H. Reichman, *The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT'L L. 441, 446-49 (2000).

14. Even in the United States the expanded protection of test data is a relatively recent development, driven largely by the perceived inadequacy of the patent system to provide financial incentives for the development of certain pharmaceuticals with limited markets. The United States first attempted to address this issue in 1982 with the passage of the Orphan Drug Act, 21 U.S.C. §360cc (2004).

15. Paris Convention for the Protection of Industrial Property, art. 10*bis*. The TRIPS Agreement refers directly to the Paris Convention, which was established in 1883 for the protection of non-literary or artistic intellectual property and is the earliest direct precursor to TRIPS.

differing submissions from several participating nations.[16] The final version reads as follows:

> 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.[17]

Among the several undefined terms in Article 39.3, the issues of what constitutes a "new chemical entity" and how to define the limits of "unfair commercial use" appear to be the most pressing.[18]

TRIPS requires that member nations provide test data protection only for "new chemical entities," which at a minimum should exclude substances that have previously received regulatory approval. In the pharmaceutical context, this provision would arguably not require protection for new combinations, dosages, applications, or formulations of existing drugs, even if they required submission of additional test data to gain marketing approval.[19] This limitation, even if assumed, does not clarify whether "new" indicates novelty in the patent sense or merely a fresh submission for marketing approval, either in the member state or worldwide. Under the most restrictive (and least likely) interpretation, a new chemical entity would have to represent a novel patentable invention, and only such products would be entitled to test data protection. An interpretation more consistent with the intent of the countries that originally sought the test data provision would require protection for all previously undisclosed, first-time marketing approval submissions, whether or not the chemical entity were eligible for patent protection.[20] Further

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16. *See* JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 197-99 (2000); G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L. L. & BUS. 1, 5-20 (2003).

17. TRIPS Agreement, *supra* note 1, art. 39.3.

18. *See* WATAL, *supra* note 16, at 203-06; Skillington & Solovy, *supra* note 16, at 25-28, 29-35; Carlos M. Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L. L. 69, 74-75, 76-79 (2002).

19. Correa, *supra* note 18, at 75.

20. *See id.* at 74-75.

evidence that TRIPS Article 39.3 is unclear as to the definition of "new" includes recent U.S. FTAs that either eliminate the modifier entirely or include separate provisions for new and pre-existing chemical products.[21] Under the TRIPS Agreement, then, member states are free to adapt their understanding of the category of "new chemical entities" to suit national health care policy.

Much of the discussion of "unfair commercial use" under Article 39.3 involves the question of whether third parties can rely on protected undisclosed test data to obtain marketing approval for their own products. In particular, a company seeking to market a generic drug can avoid vast, inefficient expenditures of time and money if it is able to simply submit evidence of bioequivalence (equal potency and availability to the body) with a previously approved chemical entity in order to support its own application. In this case, the government entity that required submission of the original test data has not disclosed it to the third party or even necessarily made "use" of the test data, much less unfair commercial use. Instead, it may be argued that the government has merely affirmed the interchangeability of the two compounds in a manner consistent with public health concerns regarding access to medicines.[22] This narrow interpretation of what constitutes unfair commercial use in the context of pharmaceutical test data is controversial. Whether or not a health agency actually consults data on safety and efficacy before approving an equivalent drug or merely remains aware that such data exists, a later application submitted without independent test data could not meet government standards without the existence of the original test data. The third party applicant thus derives commercial advantage from a regulatory process that makes use of undisclosed test data, arguably an unfair benefit. National health policies seek to balance this alleged unfairness with the public benefits of a robust generics industry.

Early versions of Article 39.3 contained a specific requirement that would have precluded third parties from relying on undisclosed test data to facilitate the approval of competing products for a "reasonable" period of time.[23] Some commentators have argued that temporal exclusivity provisions are the only way to ensure protection against unfair commercial use consistent with the TRIPS Agreement.[24] Given that TRIPS Article 39.3

21. *See infra* notes 29-49 and accompanying text.

22. Correa, *supra* note 18, at 80 (discussing Bayer v. Canada (Attorney General), [1999] 1 F.C. 553).

23. WATAL, *supra* note 16, at 197-99; Skillington & Solovy, *supra* note 16, at 5-20.

24. *See, e.g.*, Skillington & Solovy, *supra* note 16, at 33.

is silent with respect to the type of substantive minima required for other areas of intellectual property protection, it is unclear that member states could be forced to provide specific periods of absolute test data protection. Aside from ongoing consultations with Argentina,[25] the United States's preferred method of limiting third party reliance on pharmaceutical test data is the inclusion of multi-year periods of exclusive use in its free trade agreements.[26] Apparent flexibility in the interpretation of TRIPS is thus curtailed by the greater obligations required by parallel instruments.

U.S. Free Trade Agreements

The extent to which the United States was forced to compromise on the issue of pharmaceutical and agricultural chemical test data protection in the TRIPS Agreement is apparent from both historical accounts of the original TRIPS negotiation process[27] and the more extensive protection mandated by bilateral and multilateral FTAs. Representative examples of FTAs with more extensive intellectual property provisions than TRIPS include the North American Free Trade Agreement (NAFTA), enacted shortly before the TRIPS Agreement, and recent agreements or proposed agreements with Singapore, Chile, Central American nations, and Morocco. The progression from NAFTA, which includes test data provisions that the United States tried and failed to incorporate into TRIPS, to the most recent agreements illustrates the increasingly protectionist objectives of the USTR. The newest FTAs attempt not only to close the loopholes of TRIPS with respect to test data protection, but also to extend the term of patent protection for pharmaceutical products in order to account for the period of regulatory review.[28]

The NAFTA Agreement, like TRIPS, treats test data as a form of trade secret, focusing initially on nondisclosure and then, if disclosure occurs, on the prevention of unfair commercial use.[29] Protection is limited to agricultural and chemical products containing "new chemical entities," although as in TRIPS there is no effort to define "new."[30] With regard to the reliance of generics companies on protected data to obtain marketing approval, NAFTA requires exclusivity for a "reasonable period," defined as

25. Dispute Settlement Update, *supra* note 13.
26. *See infra* notes 28-49 and accompanying text.
27. *See* Sell, *supra* note 3.
28. *See infra* notes 38-42 and accompanying text.
29. NAFTA Agreement, *supra* note 12, at art. 1711(5).
30. *Id.*

"normally" at least five years and conditioned upon both the nature of the data and the effort and expenditure required to produce it.[31] Should a third party attempt to rely on test data submitted in another NAFTA country, the exclusivity period runs from the date of the first marketing approval cited.[32] However, NAFTA provisions specifically authorize "abbreviated approval procedures" for competing products following the exclusivity period, effectively limiting claims of unfair commercial use.[33] Despite U.S. efforts, TRIPS includes no such temporal exclusivity requirement. There is no distinction in either NAFTA or TRIPS between pharmaceutical and chemical products.

In contrast to NAFTA, concluded a decade earlier, the United States - Singapore Free Trade Agreement (Singapore FTA) does not invoke trade secret protection for test data. Instead, Singapore and subsequent FTAs include special provisions for "certain regulated products," such as pharmaceuticals.[34] The Singapore FTA provides that "information regarding the safety and efficacy of a pharmaceutical or agricultural chemical product" shall be excluded from third party reliance in marketing approval for five and ten years, respectively.[35] There is no mention of the effort expended in producing the "information," nor is there a requirement that the products be "new." The flexible five-year presumption in NAFTA is transformed in the Singapore FTA into fixed periods of five years for pharmaceuticals and ten for agricultural chemicals,[36] a shift reflected in subsequent U.S. FTAs.

In addition, several provisions in the Singapore FTA effectively lengthen the terms of test data protection and pharmaceutical patent protection. Unlike NAFTA, the period during which test data submitted in another country cannot be used for marketing approval without consent runs not from the date of the foreign approval, but from the later of the foreign approval date or the domestic approval date for the original product.[37] Additional efforts to lengthen the effective term of protection for pharmaceutical and agricultural chemicals under the Singapore FTA include the requirement that the exclusivity period for data pertaining to patented products be allowed to continue past expiration of the patent

31. *Id.* at art. 1711(6).
32. *Id.* at art. 1711(7).
33. *Id.* at art. 1711(6).
34. Singapore FTA, *supra* note 12, at art. 16.8.
35. *Id.* at art. 16.8(1).
36. *Id.*
37. *Id.* at art. 16.8(2).

term, should the patent expire before the end of the exclusivity period.[38] The Singapore FTA also introduces a provision, for pharmaceuticals only, for patent term extensions to compensate for "unreasonable curtailment of the patent term as a result of the marketing approval process."[39] Finally, pharmaceutical patent holders are entitled to notification of the identity of "any third party requesting market approval effective during the term of the patent," as well as assurance that such marketing approval will not be granted during the patent term without consent.[40] These pharmaceutical patent extensions, which appear in neither NAFTA nor TRIPS, are included in later FTAs as well.[41]

The draft United States - Chile Free Trade Agreement (Chile FTA), Central American Free Trade Agreement (CAFTA), and United States - Morocco Free Trade Agreement (Morocco FTA) each continue to refine the definition of a "new" pharmaceutical or agricultural chemical product and how to measure the duration of test data protection. The Chile FTA and CAFTA define "new" products as those that have not been previously approved,[42] rather than new or novel in the patent sense; CAFTA also specifies that the products not have received marketing approval in the individual member country.[43] With respect to third party marketing approval on the basis of previously submitted test data, both the Chile FTA and CAFTA echo the Singapore FTA's exclusivity periods of five years for pharmaceuticals and ten for agricultural chemicals.[44] In addition, CAFTA provides that the exclusivity period shall run from the date that the original applicant received marketing approval in the individual CAFTA member country—rather than in any foreign country—although CAFTA members may condition this term of protection on the original applicant seeking approval in the member country within five years of the foreign application.[45]

The Morocco FTA goes beyond earlier agreements by protecting, in addition to the basic category of regulatory test data for new pharmaceutical and agricultural chemical products, a separate body of new

38. *Id.* at art. 16.8(3).

39. *Id.* at art. 16.8(4)(a).

40. *Id.* at art. 16.8(4)(b-c).

41. CAFTA refers to this grant as "restoration" rather than "extension" of the patent term. CAFTA, *supra* note 12, at art. 15.10.

42. Chile FTA, *supra* note 9, at art. 17.10(1); CAFTA, *supra* note 9, at art. 15.10(1)(c).

43. CAFTA, *supra* note 9, at art. 15.10(1)(c).

44. Chile FTA, *supra* note 9, at art. 17.10(1); CAFTA, *supra* note 9, at art. 15.10(1)(a).

45. CAFTA, *supra* note 9, at art. 15.10(1)(b).

clinical information required for the approval of (not necessarily new) pharmaceutical products, other than information related to bioequivalency.[46] Like the Singapore and Chile FTAs and CAFTA, the Morocco FTA grants exclusivity periods for pharmaceutical and agricultural products of five and ten years, respectively, measured in this case from the date of original approval within the contracting country.[47] For new clinical information, which might pertain to previously reviewed or approved pharmaceuticals, the period of protection is limited to three years.[48] In addition, protection of new clinical information is conditioned upon the requirement that its origination involve "considerable effort."[49] Although the language regarding effort echoes NAFTA and TRIPS, the division between new products and new clinical information indicates the development of an additional category of protected information that could affect the availability of existing pharmaceutical chemicals approved for new applications.

CONCLUSION

From the early suggestion in NAFTA that original applicants should enjoy a "reasonable period" of exclusivity with respect to reliance on pharmaceutical test data to standardized periods of protection and expansive definition of what constitutes a "new" product, the mechanism of free trade agreements has allowed the United States to establish international levels of protection far beyond the original, deliberately ambiguous TRIPS consensus on trade secrets. While some countries may enjoy benefits similar to those that the United States identified in creating its own domestic protections for test data,[50] others may not yet have reached the stage at which incentives to invest in the creation of clinical data for new drug approval outweigh the need to facilitate marketing of competing versions on an expedited basis. The serial free trade negotiation process, particularly between nations with unequal bargaining power, is an unlikely forum for development of comprehensive, balanced policies on health care. It is, however, an opportunity for the United States to advance elements of intellectual property protection that exceed worldwide norms. This apparent divide-and-conquer strategy on the part of

46. Morocco FTA, *supra* note 9, at art. 15.10(1-2).

47. *Id.* at art. 15.10(1).

48. *Id.* at art. 15.10(2).

49. *Id.*

50. *See* Skillington & Solovy, *supra* note 16, at 8-11.

the United States circumvents the multilateral nature of TRIPS negotiations, decreases opportunities for the flexible interpretation of TRIPS by member nations, effectively lengthens the terms of pharmaceutical patents, and threatens to create a de facto global standard that may adversely affect the development of generic pharmaceutical production capacity. Although the TRIPS regime represents a global compromise that required many nations to increase intellectual property protections only with great reluctance, recent U.S. FTAs make TRIPS look like the good old days.