STUDIES ON TRADE AND INTEGRATION IN THE AMERICAS

Patent and Test Data Provisions of Recent Bilateral Trade Agreements (FTAs) Negotiated by Countries in the Western Hemisphere: An Overview of U.S. Legal Standards

John R. Thomas

A Publication of the
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The series **Studies on Trade and Integration in the Americas** addresses issues of importance to trade, economic integration, growth and competitiveness in the Western Hemisphere. The reports are prepared by the staff of the Trade Section or under its supervision and do not necessarily reflect the opinions of the OAS Member states. An electronic version of this document is available on the Internet site of the Department of Trade and Tourism (DTT) at www.oas.org/sedi/trade

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PREFACE

Countries in the Americas face a wide range of challenges as they are currently negotiating and implementing trade agreements at the multilateral, regional and bilateral levels. In addition to the Doha Development Agenda, regional and bilateral trade negotiations and integration efforts are proceeding apace in the Western Hemisphere and beyond. Several new trade agreements have been signed in the last few years and countries are now in the process of implementing those agreements. All these initiatives confront governments of the region, especially smaller economies, with a number of capacity building challenges as they strive to take full advantage of the new market access opportunities that these agreements bring about.

The OAS General Secretariat, through the Trade Section of the Department of Trade and Tourism (DTT), plays an active role in the area of trade capacity-building (TCB). In response to requests for assistance from member States, the OAS carries out programs and initiatives designed to strengthen the capacities of countries to take advantage of the opportunities and manage the challenges arising from trade agreements and integration processes. OAS sponsored programs have benefited more than 2500 government officials, small and medium enterprises (SMEs) and representatives from civil society in OAS member states over the last four years.

Some of the flagship programs aim to hone the institutional capacities of the public agencies responsible for designing and managing trade policies. Taking advantage of the valuable experience in the administration of trade agreements existing in countries in the Americas, the OAS provides support in the design, programming and execution of horizontal cooperation initiatives under the "Program on Best Practices in the Administration of Trade Agreements" initiated in 2004 with the support of the Mexican Secretariat of Economy. Under this and other similar programs, participating countries share their expertise and best practices with other countries in Latin American and the Caribbean through flexible networks dealing with specific trade issues (such as sanitary and phytosanitary measures, investment, intellectual property, services and dispute settlement) to facilitate the exchange of best practices, institutionalize dialogue, promote mutual learning and trade cooperation in the Americas.

In the area of intellectual property these OAS programs have included a number of national and regional capacity building activities in key issues such as patents, trademarks, geographical indications, copyright and related rights, flexibilities in international agreements related to public health, environmental aspects of IPR protection, and approaches and mechanisms to benefit from IPR systems. These OAS activities take into account the growing number, depth, differences and complexity of intellectual property regimes in trade agreements by providing countries in the Americas with opportunities to learn from each other and share practices, creative solutions and resources developed by their institutions and officials in the process of implementation and administration of these rules.

Provisions and commitments related to intellectual property included in trade agreements touch upon a number of regulatory areas (such as trade, intellectual property, investment,

customs, agriculture, health, culture, environment, indigenous rights and so forth). Agreements also require accession to international IP treaties, assessment of new rules and their intended and unintended consequences. In dealing with these provisions, governments in the Americas have developed valuable experiences and know-how on drafting legislation, institutional modernization and consultation mechanisms with stakeholders. These experiences involve the synchronized implementation of multilateral, regional and bilateral arrangements; a strategy to undertake commitments following a timetable included in trade agreements while facing an evolving regulatory and technological landscape. Furthermore, countries in the Americas, especially smaller economies, face the challenges to adapt the provisions of trade agreements to their legal, economic and social conditions to develop regimes that are balanced and provide the incentives to promote creativity, innovation and tangible economic benefits.

Capacity building is essential to facilitate this process of adapting legislation, administrative procedures, institutional infrastructure and public policy to the requirements of increased integration with their trading partners. A recurring request from officials in OAS member states relates to information, resources and documents that can facilitate the understanding of the nature, scope and implications of intellectual property provisions in trade agreements. One of the areas where information is particularly in demand concerns standards of patent and test data. These issues have been a source of analysis and controversy during negotiations and in the process of implementation of recent trade deals. In this context the Secretariat has asked Professor John R. Thomas to prepare a paper focusing on patent and test data provisions of recent Bilateral Free Trade Agreements (FTAs) negotiated by countries in the Western Hemisphere. In particular, Prof. Thomas provides the reader with a detailed description of the rules on patents and test data included in recent trade agreements from the perspective of U.S. domestic law. Statutes, court decisions, administrative rules and practices developed in the United States have served as inspiration and background to several IPR provisions incorporated in international trade agreements. The information and insight provided by Prof. Thomas seek to shed light on these two areas and offer government officials, private sector and civil society with one more source of information as they undertake the delicate effort of implementing and administering intellectual property rules.

The DTT welcomes comments from readers on this and other studies, and hopes to contribute to fostering the dialogue on trade, economic integration and competitiveness-related issues in the Hemisphere. The views expressed in the Trade and Integration Studies series are the authors' own and should not be attributed to the General Secretariat of the OAS or any OAS Member State.

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INTRODUCTION

This paper considers the provisions relating to patents, as well as the intellectual property aspects of pharmaceuticals and test data, of the following international agreements:

- Chile-US Free Trade Agreement
- CAFTA-DR-US Free Trade Agreement
- Colombia-US Trade Promotion Agreement*
- Panama-US Trade Promotion Agreement*
- Peru-US Trade Promotion Agreement

These agreements are collectively referred to as the "Western Hemisphere Trade Agreements."

The core of the paper reviews the requirements of these international agreements and then considers related provisions of U.S. law. The analysis of each article is structured in a format similar to annotated law reports (i.e., explaining and discussing the state of the law by providing references to statutes, case law, executive agency rules or secondary sources as relevant).

A. GENERAL INTELLECTUAL PROPERTY PROVISIONS

1. Other International Agreements

The Western Hemisphere Trade Agreements require that each signatory join the Patent Cooperation Treaty, International Convention for the Protection of New Plant Varieties (UPOV Convention),[1] and in most instances the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.[2] The United States has acceded to each of these international agreements.[3]

* Agreements Pending Ratification before the U.S. Congress

[1]This provision appears in Article 15.1.5(a) of the CAFTA-DR-US FTA, Article 17.1.3(a) of the Chile-US FTA, Article 16.1.3(c) of the Colombia-US TPA, Article 15.1.3(a) of the Panama-US TPA, and Article 16.1.3(c) of the Peru-US TPA.

[2]This provision appears in Article 15.1.3(b) of the CAFTA-DR-US FTA, Article 16.1.2(b) of the Colombia-US TPA, Article 15.1.2(e) of the Panama-US TPA, and Article 16.1.2(b) of the Peru-US TPA. The Chile-US FTA does not require ratification of the Budapest Treaty.

[3]Information regarding the signatories to each of these international agreements may be found at the WIPO web site, www.wipo.int.

The Western Hemisphere Trade Agreements require that each signatory make all reasonable efforts to ratify or accede to the Patent Law Treaty (PLT) concluded through the World Intellectual Property Organization (WIPO).[4] The United States has acceded to the PLT.[5]

The Western Hemisphere Trade Agreements also require their signatories to confirm existing rights and responsibilities under the WTO TRIPS Agreement, as well as intellectual property agreements concluded under the auspices of WIPO.[6]

B. PATENTS

2. Patentable Subject Matter

The Western Hemisphere Trade Agreements repeat the requirement of TRIPS Agreement Article 27 that patents be available for inventions in all fields of technology, providing that the invention is new, involves an inventive step, and is capable of industrial application.[7] With the exception of the Chile-US FTA, the Western Hemisphere Trade Agreements also confirm that nothing within these agreements shall be construed to prevent signatory states from excluding inventions from patentability as allowed by Articles 27.2 and 27.3 of the TRIPS Agreement.[8]

The U.S. Patent Act allows patents to issue on any useful process, composition of matter, manufacture, or machine that is novel and would not have been obvious to a person of ordinary skill in the art at the time the invention was made.[9]

3. Patent Protection for Plants

The Western Hemisphere Trade Agreements require their signatories undertake all reasonable efforts to make patent protection available for plants.[10] The United States specifically

[4]This provision appears in Article 15.1.6(a) of the CAFTA-DR-US FTA, Article 17.1.4(a) of the Chile-US FTA, Article 16.1.4(a) of the Colombia-US TPA, Article 15.1.4(a) of the Panama-US TPA, and Article 16.1.4(c) of the Peru-US TPA.

[5]A list of PLT signatory states may be found at http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=4.

[6]This provision appears in Article 15.1.7 of the CAFTA-DR-US FTA, Article 17.1.5 of the Chile-US FTA, Article 16.1.6 of the Colombia-US TPA, Article 15.1.5 of the Panama-US TPA, and Article 16.1.6 of the Peru-US TPA.

[7]This provision appears in Article 15.9.1 of the CAFTA-DR-US FTA, Article 17.9.1 of the Chile-US FTA, Article 16.9.1 of the Colombia-US TPA, Article 15.9.1 of the Panama-US TPA, and Article 16.9.1 of the Peru-US TPA.

[8]This provision appears in Article 15.9.2 of the CAFTA-DR-US FTA, Article 16.9.2 of the Colombia-US TPA, Article 15.9.2 of the Panama-US TPA, and Article 16.9.2 of the Peru-US TPA.

[9]35 U.S.C. §§ 101, 102, 103 (2006).

[10]This provision appears in Article 15.9.2 of the CAFTA-DR-US FTA, Article 17.9.2 of the Chile-US FTA, Article 16.9.2 of the Colombia-US TPA, Article 15.9.2 of the Panama-US TPA, and Article 16.9.2 of the Peru-US TPA.

provides for both plant patents[11] and for plant variety protection certificates.[12] In addition, the U.S. Supreme Court has held that plants may be the subject of a utility patent–that is to say, the usual sort of patent granted for new technologies.[13]

The Western Hemisphere Trade Agreements also require that any signatory that provides patent protection for plants or animals at the date of the Agreement shall maintain such protection.[14] As noted previously, the United States grants utility patents for plants,[15] and it also does so for animals.[16]

4. Exceptions to Rights Conferred

The Western Hemisphere Trade Agreements repeat the language of Article 30 of the TRIPS Agreement, which allows signatories to permit minor exceptions to the exclusive rights conferred by a patent.[17] U.S. patent law currently provides for a small number of exceptions that the United States would likely justify as permissible under Article 30. These exceptions include a limited experimental use privilege[18] and an exception for aircraft, vessels or other vehicles that visit the United States on a temporary basis.[19]

5. Grounds for Patent Revocation

The Western Hemisphere Trade Agreements require each signatory to agree that the grounds to revoke or nullify a patent will be limited to those that would have justified a refusal to grant a patent in the first instance.[20] Section 282 of the U.S. Patent Act stipulates that invalidity

[11] 35 U.S.C. §§ 161-164 (2006).

[12] 7 U.S.C. § 2321 *et seq.*

[13] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).

[14] This provision appears in Article 15.9.2 of the CAFTA-DR-US FTA, Article 17.9.2 of the Chile-US FTA, Article 16.9.2 of the Colombia-US TPA, Article 15.9.2 of the Panama-US TPA, and Article 16.9.2 of the Peru-US TPA.

[15] *Id.*

[16] *See* U.S. Department of Commerce, U.S. Patent and Trademark Office, Manual of Patent Examining Procedure (8th ed. 2006) ("whether or not an invention embraces living matter is irrelevant to the issue of patentability."). For an example of a U.S. patent claiming a nonhuman transgenic animal, see U.S. Patent No. 7,238,851 (July 3, 2007).

[17] This provision appears in Article 15.9.3 of the CAFTA-DR-US FTA, Article 17.9.3 of the Chile-US FTA, Article 16.9.3 of the Colombia-US TPA, Article 15.9.3 of the Panama-US TPA, and Article 16.9.3 of the Peru-US TPA.

[18] 35 U.S.C. § 271(e)(1) (2006).

[19] 35 U.S.C. § 272 (2006).

[20] This provision appears in Article 15.9.4 of the CAFTA-DR-US FTA, Article 17.9.5 of the Chile-US FTA, Article 16.9.4 of the Colombia-US TPA, Article 15.9.4 of the Panama-US TPA, and Article 16.9.4 of the Peru-US TPA.

arguments addressed to issued patents are identical to the standards that govern the initial patenting decision.

The Western Hemisphere Trade Agreements further allow each signatory to provide that fraud, misrepresentation, or inequitable conduct may also form the basis for holding a patent unenforceable.[21] In the United States, a patent may be held to be unenforceable if the court concludes that the applicant intentionally misrepresented material facts to the U.S. Patent Office. This doctrine has not yet been codified into the Patent Act, but it is well-established in the case law.[22]

6. The Experimental Use ("Bolar") Exception

The Western Hemisphere Trade Agreements include a complex provision relating to the generic pharmaceutical and agricultural chemical industry. With this provision, the signatories recognized that the signatories may allow generic firms to use subject matter patented by another for purposes of pursuing their own applications for marketing approval. In such case, however, the signatory generally may not allow the generic product to be marketed until after the patent expires.[23]

The United States implements this provision through an express statutory provision exempting from infringement acts done "solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[24] The U.S. Patent Act further allows patent holders to bring charges of infringement against generic firms at such time they either market their products,[25] or, in the case of pharmaceuticals, when they file applications for marketing approval.[26]

7. Patent and Marketing Approval Backlog

The Trade Promotion Agreements between the United States and Colombia, Panama, and Peru respectively, each require that signatories make best efforts to process applications

[21]This provision appears in Article 15.9.4 of the CAFTA-DR-US FTA, Article 17.9.5 of the Chile-US FTA, Article 16.9.4 of the Colombia-US TPA, Article 15.9.4 of the Panama-US TPA, and Article 16.9.4 of the Peru-US TPA.

[22]*See, e.g.,* Eli Lilly and Co. v. Zenith Goldline Pharmaceuticals, Inc., 471 F.3d 1369 (Fed. Cir. 2006).

[23]This provision appears in Article 15.9.5 of the CAFTA-DR-US FTA, Article 17.9.4 of the Chile-US FTA, Article 16.9.5 of the Colombia-US TPA, Article 15.9.5 of the Panama-US TPA, and Article 16.9.5 of the Peru-US TPA.

[24]35 U.S.C. § 271(e)(1) (2006).

[25]35 U.S.C. § 271(a) (2006).

[26]35 U.S.C. § 271(e)(2) (2006).

expeditiously in order to avoid unreasonable delays. The parties are required to cooperate and assist each other to achieve these objectives.[27]

In the United States, the Patent and Trademark Office (USPTO), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) are charged with performing their obligations to review applications in a seasonable manner.[28]

8. Patent Term Restoration

The Western Hemisphere Trade Agreements require their signatories to extend the terms of patent due to delays encountered at the Patent Office during the process of patent procurement.[29] Under current law, the 20-year patent term commences upon the application's filing date. The applicant obtains no enforceable rights until such time the patent issues, however. As a result, lengthy administrative delays at the Patent Office could severely prejudice a patent's term. The U.S. patent statute currently calls for a day-per-day extension of patent term in certain circumstances where the U.S. Patent Office does not meet specified statutory deadlines.[30] Among the more notable deadlines imposed under the patent term extension statute is the guarantee of an initial review of the application within 14 months of the filing date.[31] The U.S. statute also guarantees no more than a three-year overall pendency; failure to meet this deadline results in a day-per-day term extension.[32]

The CAFTA-DR-US FTA and Chile-US FTA further require their signatories to extend patent term if the patent proprietor has encountered delays in obtaining an award of marketing

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[27]This provision appears in Article 16.9.6(a) of the Colombia-US TPA, Article 15.9.6(a) of the Panama-US TPA, and Article 16.9.6(a) of the Peru-US TPA.

[28]*See* ENVIRONMENTAL PROTECTION AGENCY, ANNUAL REPORT FY 2006 (available at http://www.epa.gov/oppfead1/annual/2006/06annual-rpt.pdf) (noting extensive efforts to meet legislative review directives in a timely manner); UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION AND RESEARCH, REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS (2005) (http://www.fda.gov/cder/reports /rtn/2005/rtn2005.PDF) (noting goal to review drug applications promptly); UNITED STATES PATENT AND TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT, FISCAL YEAR 2006, at 4 (available at http://www.uspto.gov/web /offices/com/annual/2006/2006annualreport.pdf) (discussing efforts to reduce the backlog of patent applications).

[29]This provision appears in Article 15.9.6(a) of the CAFTA-DR-US FTA, Article 17.9.6 of the Chile-US FTA, Article 16.9.6(b) of the Colombia-US TPA, Article 15.9.6(b) of the Panama-US TPA, and Article 16.9.6(b) of the Peru-US TPA.

The Trade Promotion Agreements between the United States and Colombia, Panama, and Peru respectively each provide that this obligation extends only optionally to patents on pharmaceutical products. These three international agreements further stipulate that an unreasonable delay includes a delay of at least five years between a patent's filing and issuance date, or three years between the request for examination and issuance date, whichever is later.

[30]35 U.S.C. § 154(b) (2006).

[31]35 U.S.C. § 154(b)(1)(A) (2006).

[32]35 U.S.C. § 154(b)(1)(B) (2006).

approval from the food and drug authorities.[33] Under the Trade Promotion Agreements between the United States and Colombia, Panama, and Peru respectively, such term extension is optional.[34] These provisions account for the situation where a pharmaceutical firm has obtained a patent covering its new product, the food and drug authorities may not have yet granted that firm permission to sell that product. In such circumstances the 20-year patent term continues to run, but the patent owner cannot sell the patented product.

The U.S. Patent Act includes a provision that compensate patent owners for a portion of the time spent before the U.S. Food and Drug Administration (FDA) in pursuit of marketing approval.[35] This complex statute that sets the period of extension has been described as "among the most unwieldy statutes in the federal code."[36] In a nutshell, a U.S. patent proprietor who wishes to obtain the term extension must submit an application to the U.S. Patent and Trademark Office (USPTO). That application must be filed prior to the expiration of that patent, and within 60 days of receiving marketing approval. Only one patent can be extended upon an approval for marketing–in the event more than one patent covers the product, the proprietor must choose one.

The period of extension is set to one-half of the testing phase (the time between the filing of the "Investigational New Drug Application," or IND, and the filing of the "New Drug Application," or NDA), plus a day-per-day extension of the time between the filing of the NDA at the FDA and the date the FDA approves the NDA. Any period that the applicant did not act with due diligence is subtracted from the time period for which extension is claimed. The maximum period of extension is subject to two caps: (1) five years of total patent term extension, or (2) a total effective patent term after the extension of not more than 14 years. The scope of rights during the period of extension is generally limited to the use the FDA approved for the product.

9. Grace Period

The parties to the Western Hemisphere Trade Agreements agree that public disclosures will not prejudice patent rights if such disclosures were derived from the patent applicant, and such disclosures occurred within 12 months prior to the date of filing of the application.[37] The U.S. Patent Act provides a one-year "grace period" to all patent applicants in keeping with this requirement.[38] This period benefits individual inventors, small firms, university professors, and

[33]This provision appears in Article 15.9.6(b) of the CAFTA-DR-US FTA and Article 17.10.2 of the Chile-US FTA.

[34]This provision appears in Article 16.9.6(c) of the Colombia-US TPA, Article 15.9.6(c) of the Panama-US TPA, and Article 16.9.6(c) of the Peru-US TPA.

[35]35 U.S.C. § 156 (2006).

[36]JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 285 (2005).

[37]This provision appears in Article 15.9.7 of the CAFTA-DR-US FTA, Article 17.9.7 of the Chile-US FTA, Article 16.9.7 of the Colombia-US TPA, Article 15.9.7 of the Panama-US TPA, and Article 16.9.7 of the Peru-US TPA.

[38]35 U.S.C. § 102(b) (2006).

other entities who may disclose their technologies to the public before deciding to seek patent protection.

10. Amendments

Each of the Western Hemisphere Trade Agreements, with the exception of the Chile-US FTA, provide that all patent applicants will have at least one opportunity to amend or correct their applications.[39] These international agreements further stipulate that these changes must not introduce new matter into the disclosure of the invention. The U.S. Patent Act provides applicants with the ability to amend their applications after filing,[40] subject to the rule that no new matter should be introduced.[41]

11. Sufficiently Clear and Complete Disclosure

Each of the Western Hemisphere Trade Agreements, with the exception of the Chile-US FTA, provides that a patent's disclosure is satisfactory if it allows a person skilled in the art, as of its filing date, to carry out the invention without undue experimentation.[42] This language is consistent with governing U.S. law regarding the enablement requirement.[43] Paragraph 9 further provides that each signatory may require patent applicants to disclose the best mode for carrying out the invention. The United States currently imposes a best mode requirement.[44]

12. Invention Sufficiently Supported by Disclosure

Each of the Western Hemisphere Trade Agreements, with the exception of the Chile-US FTA, provides that a claimed invention is sufficiently supported by its disclosure if the disclosure reasonably conveys to a skilled artisan that the applicant was in possession of the claimed invention as of its filing date.[45] This language articulates the "written description" requirement currently

[39]This provision appears in Article 15.9.8 of the CAFTA-DR-US FTA, Article 16.9.8 of the Colombia-US TPA, Article 15.9.8 of the Panama-US TPA, and Article 16.9.8 of the Peru-US TPA.

[40]35 U.S.C. § 132 (2006).

[41]*Id.*

[42]This provision appears in Article 15.9.9 of the CAFTA-DR-US FTA, Article 16.9.9 of the Colombia-US TPA, Article 15.9.9 of the Panama-US TPA, and Article 16.9.9 of the Peru-US TPA.

[43]35 U.S.C. § 112 (2006).

[44]*Id.*

[45]This provision appears in Article 15.9.10 of the CAFTA-DR-US FTA, Article 16.9.10 of the Colombia-US TPA, Article 15.9.10 of the Panama-US TPA, and Article 16.9.10 of the Peru-US TPA.

applied by U.S. courts.[46] This requirement ensures that a patent applicant does not amend its application to include technology that it had not invented at the time it filed the application.

13. Industrial Application

Each of the Western Hemisphere Trade Agreements, with the exception of the Chile-US FTA, provides that a claimed invention satisfies the industrial application requirement if it has a specific, substantial, and credible utility.[47] This language is identical to the governing U.S. law.[48] This requirement ensures that patents pertain to technologies from which the public may derive an immediate benefit, rather than a speculative benefit that may require the work of additional individuals to realize.

C. TEST DATA/MEASURES RELATED TO CERTAIN REGULATED PRODUCTS

14. Ten-Year Data Protection for New Agricultural Chemical Products

Each of the Western Hemisphere Trade Agreements imposes an obligation upon signatory states that require sponsors of new agricultural chemical products to submit safety and efficacy data in order to market their products. This obligation consists of preventing third parties, without the consent of the product's sponsor, to market a product on the basis of the submitted information, or the fact that marketing approval was granted to the sponsor, for a period of ten years.[49] In this context, the term "new" means a product that does not contain a chemical entity that has been previously approved in that signatory state.[50]

In the United States, the Federal Insecticide, Fungicide, and Rotendicide Act (FIFRA) provides for a ten-year period of "exclusive use" by the registrant of data submitted in support of an

[46] *See* Monsanto Co. v. Scruggs, 459 F.3d 1328 (Fed. Cir. 2006).

[47] This provision appears in Article 15.9.11 of the CAFTA-DR-US FTA, Article 16.9.11 of the Colombia-US TPA, Article 15.9.11 of the Panama-US TPA, and Article 16.9.11 of the Peru-US TPA.

[48] *See* In re Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

[49] This provision appears in Article 15.10.1(a) of the CAFTA-DR-US FTA, Article 17.10.1 of the Chile-US FTA, Article 16.10.1(a) of the Colombia-US TPA, Article 15.10.1(a) of the Panama-US TPA, and Article 16.10.1(a) of the Peru-US TPA.

[50] This provision appears in Article 15.10.1(c) of the CAFTA-DR-US FTA, Article 17.10.1 of the Chile-US FTA, Article 16.10.1(c) of the Colombia-US TPA, Article 15.10.1(c) of the Panama-US TPA, and Article 16.10.1(c) of the Peru-US TPA.

application for marketing approval.[51] This ten-year period of data protection applies to products that were initially registered with the Environmental Protection Agency (EPA) after 1978.[52]

15. Approval by Reference for New Agricultural Chemical Products

Certain of the Western Hemisphere Trade Agreements also address the situation where the signatory state allows or requires the sponsor to submit evidence of the safety or efficacy of a new agricultural chemical product that was previously approved in another territory, including the grant of prior marketing approval in that other territory. In such circumstances, the signatory pledges not to allow third parties, without the consent of the product's sponsor, to market a product on the basis of the submitted information, or the fact that marketing approval was granted to the sponsor, for a period of ten years. In order to receive protection under this provision, the signatory state may require that the sponsor to seek marketing approval within that signatory state within five years of obtaining marketing approval in that other territory.[53]

The United States does not allow approval of regulated pharmaceutical products solely by reference to other nations. Although U.S. Environmental Protection Agency (EPA) commonly accepts safety and efficacy data that were developed outside of its territory, that agency ultimately will reach its own conclusions regarding the compliance of a particular product with U.S. standards.[54] As a result, there is no corresponding provision in U.S. law on this point.

16. Five-Year Data Protection for New Pharmaceutical Products

Certain of the Western Hemisphere Trade Agreements also address new pharmaceutical products. As with agricultural products, the term "new" means a product that does not contain a chemical entity that has been previously approved in that signatory state. With respect to the Western Hemisphere Trade Agreements between the United States, on one hand, and the CAFTA member nations and the Dominican Republic, on the other, each signatory is obliged to deny third parties, without the consent of the product's sponsor, to market a product on the basis of the submitted information, or the fact that marketing approval was granted to the sponsor. This obligation extends for a period of five years.[55]

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[51] 7 U.S.C. § 136a(c)(1)(F)(I) (2006).

[52] *Id.*

[53] This provision appears in Article 15.10.1(b) of the CAFTA-DR-US FTA, Article 16.10.1(b) of the Colombia-US TPA, Article 15.10.1(b) of the Panama-US TPA, and Article 16.10.1(b) of the Peru-US TPA.

[54] 7 U.S.C. § 136a(c)(5) (2006).

[55] This provision appears in Article 15.10.1(a) of the CAFTA-DR-US FTA and Article 17.10.1 of the Chile-US FTA.

With respect to Peru, Colombia, and Panama, the period of data protection for pharmaceutical products is deemed a "reasonable period," which "shall normally mean five years," taking into account the nature of the data and the expenditures require to produce them.[56]

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, provides a five-year period of data protection for pharmaceutical products that qualify as new chemical entities.[57] A pharmaceutical is considered to be a "new chemical entity" (NCE) if that product's active ingredient has not previously been approved for marketing.[58] The statute expressly stipulates that a drug does not qualify as an NCE if it contains the salt or ester of a previously approved active ingredient.[59] During the five-year period of NCE exclusivity, the U.S. Food and Drug Administration (FDA) may not accept applications to market generic drugs that rely upon the test data generated by its sponsor.[60]

17. Approval by Reference for New Pharmaceutical Products

The CAFTA-DR-US FTA also addresses the situation where the signatory state allows or requires the sponsor to submit evidence of the safety or efficacy of a new agricultural chemical product that was previously approved in another territory, including the grant of prior marketing approval in that other territory. In such circumstances, the signatory pledges not to allow third parties, without the consent of the product's sponsor, to market a product on the basis of the submitted information, or the fact that marketing approval was granted to the sponsor, for a period of five years. In order to receive protection under this provision, the signatory state may require that the sponsor to seek marketing approval within that signatory state within five years of obtaining marketing approval in that other territory.[61]

The United States does not allow approval of regulated pharmaceutical products solely by reference to other nations. Although U.S. Food and Drug Administration (FDA) commonly accepts safety and efficacy data that were developed outside of its territory, that agency ultimately will reach its own conclusions regarding the compliance of a particular product with U.S. standards.[62] As a result, there is no corresponding provision in U.S. law on this point.

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[56]This provision appears in Article 16.10.2(b) of the Colombia-US TPA, Article 15.10.2(b) of the Panama-US TPA, and Article 16.10.2(b) of the Peru-US TPA.

[57]21 U.S.C. § 355(c)(3)(E)(ii) (2006); 21 U.S.C. § 355(j)(5)(F)(ii) (2006).

[58]21 C.F.R. § 314.108(a) (2007).

[59]21 U.S.C. § 355(j)(5)(F) (2006).

[60]*Id.*

[61]This provision appears in Article 15.10.1(b) of the CAFTA-DR-US FTA.

[62]21 U.S.C. § 355(d) (2006).

18. Protection Against Disclosure

Each of the Western Hemisphere Trade Agreements includes provisions obliging signatories states to protect from disclosure proprietary test data that firms submit to the government in order to obtain marketing approval, although the precise terms of these provisions differ. The CAFTA-DR-US and Chile-US FTAs require protection against disclosure of test data concerning pharmaceutical and agricultural products that qualify as new chemical entities, except where necessary to protect the public.[63] The Panama-US FTA also imposes this obligation, but with respect to agricultural chemicals only.[64]

With respect to the Trade Promotion Agreements between the United States and Peru, Colombia, and Panama, each signatory agrees to protect pharmaceutical test data where the data involves a new chemical entity and required considerable effort to originate, except where the disclosure is necessary to protect the public interest or unless steps are taken to ensure that the data are protected against unfair commercial use.[65]

In the United States, the Food and Drug Administration (FDA) does not disclose information pertaining to pharmaceuticals that is incorporated within proprietary data packages.[66] The U.S. Federal Insecticide, Fungicide, and Rotendicide Act (FIFRA) includes complex provisions concerning the maintenance of data pertaining to agricultural chemicals.[67] Under FIFRA, applicants for marketing approval may identify data that they believe are trade secrets. If the Environmental Protection Agency (EPA) agrees that this information is proprietary, then that agency must withhold those data from public disclosure. FIFRA also includes both exceptions to this nondisclosure rule, and then further exceptions to these exceptions. The statute explains:

> All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. . . . This paragraph does not authorize the disclosure of any information that–

[63] This provision appears in Article 15.10.1(d) of the CAFTA-DR-US FTA, Article 16.10.1(d) of the Chile-US FTA.

[64] This provision appears in Article 15.10.1(d) of the Panama-US TPA.

[65] This provision appears in Article 16.10.2(a) of the Colombia-US TPA, Article 15.10.2(a) of the Panama-US TPA, and Article 16.10.2(a) of the Peru-US TPA.

[66] 21 U.S.C. § 331(j) (2006). *See* 39 Fed. Reg. 44601, at 44611-12 (Dec. 24, 1974) ("current statutory prohibitions prevent disclosure of useful information contained in the agency's files, and particularly, data relating to the safety and effectiveness of drugs."); 42 Fed. Reg. 3094, 3106 (Jan. 14, 1977) (explaining that the U.S. Food and Drug Administration has treated data from clinical trials as a trade secret since 1938).

[67] 7 U.S.C. § 136h (2006).

(A) discloses manufacturing or quality control processes,

(B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.[68]

19. The TRIPS Agreement and Public Health

The Trade Promotion Agreements between the United States and Peru, Colombia, and Panama, respectively, each allow a signatory to take measures to protect public health in accordance with the Declaration on the TRIPS Agreement and Public Health, any waivers to TRIPS Agreement obligations granted by the WTO, and any amendment of the TRIPS Agreement.[69]

20. Linkage

The term "linkage" generally refers to a connection between patent dispute resolution proceedings and the award of marketing approval by a country's food and drug authority. The Western Hemisphere Trade Agreements impose certain obligations upon their signatories regarding patent disputes that may arise during the marketing approval process for pharmaceuticals.

The Chile-US FTA requires its signatories both (1) to prevent third parties from marketing a product that would infringe a patent on a product or its approved use during the term of the patent as part of its marketing approval procedures, and (2) to inform the patent holder of the third party's marketing request.[70] The CAFTA-DR-US FTA imposes similar obligations, but they apply only when a party relies upon test data submitted by the original sponsor of a pharmaceutical product in support of its own application for marketing approval.[71]

The Trade Promotion Agreements between the United States and Peru, Colombia, and Panama, respectively, each require that requires their signatories, when a party relies upon test data submitted by the original sponsor of a pharmaceutical product in support of its own application for marketing approval, both to provide for expeditious procedures and effective remedies with respect to pharmaceutical patent disputes, a transparent system to provide notice to a patent holder that

[68]7 U.S.C. § 136h(d)(1) (2006).

[69]This provision appears in Article 16.10.2(e) of the Colombia-US TPA, Article 15.10.2(e) of the Panama-US TPA, and Article 16.10.2(e) of the Peru-US TPA.

[70]This provision appears in Article 17.10.2 of the Chile-US FTA.

[71]This provision appears in Article 15.10.2 of the CAFTA-DR-US FTA.

another person seeks to cover an approved pharmaceutical, and sufficient time and opportunity for a patent holder to seek remedies for infringement prior to the marketing of an allegedly infringing product. These international agreements further state that a signatory *may* implement these obligations by (1) to preventing third parties from marketing a product that would infringe a patent on a product or its approved use during the term of the patent as part of its marketing approval procedures and (2) informing the patent holder of the third party's marketing request; provided that the party also provides (1) an expeditious procedure through which pharmaceutical patents can be challenged and (2) effective rewards for successful patent challenges. This latter requirement may be met by providing a period of marketing exclusivity to the first applicant to successfully challenge the validity or applicability of the patent.[72]

The Trade Promotion Agreements between the United States and Peru, Colombia, and Panama further provide that a term of marketing exclusivity is not affected if a relevant patent expires before the end of the period of marketing exclusivity.[73]

The U.S. system of "linkage" is complex. In short, brand-name firms that obtain marketing approval from the U.S. Food and Drug Administration (FDA) are required to list pertinent patents that it believes would be infringed if a generic drug were marketed prior to the expiration of those patents.[74] The FDA then lists those patents in one of its publications, *Approved Drug Products with Therapeutic Equivalence Evaluations*, a text that is more commonly known as the "Orange Book."[75]

Firms that wish to market generic drugs, and rely upon the test data developed by the brand-name firm, are required to state their views with respect to each identified patent. In particular, they must file either a so-called "section viii" statement or a patent certification.[76] Section viii statements are appropriate when the Orange Book-listed patent claims a method of use for which the applicant is not seeking approval. Alternatively, the generic applicant must provide one of four certifications:

(1) the brand-name firm has not filed any patent information with respect to that drug;

(2) the patent has already expired;

(3) the generic firm agrees not to market its product until the patent expires; or

(4) the patent is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the generic drug application is submitted.[77]

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[72]This provision appears in Article 16.10.4 of the Colombia-US TPA, Article 15.10.4 of the Panama-US TPA, and Article 16.10.4 of the Peru-US TPA.

[73]This provision appears in Article 16.10.5 of the Colombia-US TPA, Article 15.10.5 of the Panama-US TPA, and Article 16.10.5 of the Peru-US TPA.

[74]21 U.S.C. § 355(c)(2) (2006).

[75]Food and Drug Administration, Electronic Orange Book (available at http:/www.fda.gov/cder/ob/).

[76]21 U.S.C. § 355(j)(2)(A)(viii) (2006).

[77]21 U.S.C. § 355(j)(2)(A)(vii) (2006).

These statements are respectively termed paragraph I, II, III, and IV certifications. A generic drug application including a paragraph I or II certification may be approved immediately, after all applicable regulatory requirements are met.[78] A generic firm that files a paragraph III certification cannot obtain FDA approval prior to the stipulated date of patent expiration.[79]

Under the U.S. Patent Act, the filing of a paragraph IV certification constitutes an act of patent infringement.[80] In addition, the generic firm filing a paragraph IV certification must notify the patent owner. The patent owner may, within 45 days of receiving such notice, commence a patent infringement suit against the generic applicant. If the patent owner does bring suit, then the FDA must suspend approval of the generic application until one of the following times:

> (1) the date of the court's decision that the paragraph IV certified patent is either invalid or not infringed;
>
> (2) the date the paragraph IV certified patent expires, if the court finds the patent would be infringed by the proposed generic product; or
>
> (3) 30 months from the date the patent owner received notice of the paragraph IV certification.[81]

This "30-month stay" is intended to give the parties time to resolve their patent dispute before the generic product enters the market. At the close of the 30-month period, should the litigation not yet be resolved, the patent proprietor may move the court to issue a preliminary injunction preventing marketing of the generic drug until the lawsuit is concluded.

In the United States, the food and drug laws provide prospective manufacturers of generic pharmaceuticals with a reward for challenging patents associated with an approved pharmaceutical. That reward consists of a 180-day period of marketing exclusivity awarded to the first generic applicant to file a paragraph IV certification.[82] Congress intended that during this 180-day period, the brand-name and generic drugs would compete in a duopoly market. At the close of this period, other generic manufacturers may receive FDA marketing approval.[83]

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[78] 21 U.S.C. § 355(j)(5)(B)(i) (2006).

[79] 21 U.S.C. § 355(j)(5)(B)(ii) (2006).

[80] 35 U.S.C. § 271(e)(2) (2006).

[81] 21 U.S.C. § 355(j)(5)(B)(iii) (2006).

[82] 21 U.S.C. § 355(j)(B)(iv) (2006).

[83] *See* JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 354-55 (2005).

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The Organization of American States

The Organization of American States (OAS) is the world's oldest regional organization, dating back to the First International Conference of American States, held in Washington, D.C., from October 1889 to April 1890. The establishment of the International Union of American Republics was approved at that meeting on April 14, 1890. The OAS Charter was signed in Bogotá in 1948 and entered into force in December 1951. Subsequently, the Charter was amended by the Protocol of Buenos Aires, signed in 1967, which entered into force in February 1970; by the Protocol of Cartagena de Indias, signed in 1985, which entered into force in November 1988; by the Protocol of Managua, signed in 1993, which entered into force in January 29, 1996; and by the Protocol of Washington, signed in 1992, which entered into force on September 25, 1997. The OAS currently has 35 Member States. In addition, the Organization has granted Permanent Observer status to 57 States, as well as to the Holy See and the European Union.

The basic purposes of the OAS are as follows: to strengthen peace and security in the Hemisphere; to promote and consolidate representative democracy, with due respect for the principle of non-intervention; to prevent possible causes of difficulties and to ensure the pacific settlement of disputes that may arise among the Member States; to provide for common action on the part of those States in the event of aggression; to seek the solution of political, juridical and economic problems that may arise among them; to promote, by cooperative action, their economic, social and cultural development, and to achieve an effective limitation of conventional weapons that will make it possible to devote the largest amount of resources to the economic and social development of the Member States.

MEMBER STATES: Antigua and Barbuda, Argentina, The Bahamas *(Commonwealth of)*, Barbados, Belize, Bolivia, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Dominica *(Commonwealth of)*, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, St. Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname, Trinidad and Tobago, United States, Uruguay and Venezuela.

PERMANENT OBSERVERS: Algeria, Angola, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, China, Croatia, Cyprus, Czech Republic, Denmark, Egypt, Equatorial Guinea, Estonia, European Union, Finland, France, Georgia, Germany, Ghana, Greece, Holy See, Hungary, India, Ireland, Israel, Italy, Japan, Kazakhstan, Korea, Latvia, Lebanon, Luxembourg, Morocco, Netherlands, Nigeria, Norway, Pakistan, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Serbia and Montenegro, Slovakia, Slovenia, Spain, Sri Lanka, Sweden, Switzerland, Thailand, Tunisia, Turkey, Ukraine, The United Kingdom of Great Britain and Northern Ireland, and Yemen.

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