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Intellectual Property and the Free Trade Agreements: Innovation Policy Issues

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Intellectual Property and the Free Trade Agreements: Innovation Policy Issues

Summary

The United States has recently entered into a number of Free Trade Agreements, or FTAs, with Australia, Chile, Singapore, and other trading partners. Negotiations are currently ongoing with respect to the establishment of additional FTAs. In keeping with a congressional directive established in the Bipartisan Trade Promotion Act of 2002, P.L. 107-210, one objective of forming the FTAs is to establish "a standard of [intellectual property] protection similar to that found in United States law." As a result, most of the FTAs stipulate minimum levels of protection with respect to copyrights, data protection, patents, trademarks, and other forms of intellectual property. These standards relate to such provisions as the term of protection, scope of rights, and mechanisms by which these intellectual property rights are acquired and enforced.

The different FTAs vary in their comprehensiveness and level of detail. Each of these agreements has nonetheless been drafted in a manner that complies with current U.S. law. As a result, the effect of each FTA is to obligate signatories to such agreements to amend their intellectual property laws to match or resemble those of the United States.

The FTAs have been described as an effective mechanism for advancing U.S. interests in securing intellectual property protection. Increased levels of intellectual property protection with respect to computer software, music, motion pictures, and pharmaceuticals may promote a more favorable balance of trade for U.S. industry, decrease domestic prices for innovative goods and services, and serve other policy goals. The FTA framework has at times proven to be a more advantageous forum for achieving the intellectual property goals of the United States than multilateral settings.

Nonetheless, concerns have arisen over the intellectual property provisions of the FTAs. Some observers believe that certain FTA provisions may lock the United States into current intellectual property policies, inhibiting opportunities for future reform. Other commentators are concerned that under existing multilateral agreements, in particular those of the World Trade Organization, the intellectual property obligations found within one FTA may extend beyond that particular treaty partner. Finally, some observers perceive the FTAs to be an inappropriate and unfair vehicle for international intellectual property reforms due to the strong bargaining position of the United States. The scope of these potential consequences counsels continued congressional attention towards the FTAs that the United States has already formed, as well as those FTAs that are planned for the future.

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Intellectual Property and the Free Trade Agreements: Innovation Policy Issues

Congressional interest in the intellectual property laws, including patents, copyrights, and trademarks, has been reflected in recent Free Trade Agreements (FTAs) to which the United States is a signatory. Congress stated in the Bipartisan Trade Promotion Act of 2002[1] that an overall negotiating objective of such agreements was to encourage our treaty partners to agree to "a standard of [intellectual property] protection similar to that found in United States law."[2] In keeping with this mandate, the United States has entered into numerous FTAs that have required their signatories to conform to stipulated standards of intellectual property protection.[3] Because the FTAs are drafted in a manner that complies with current U.S. law, their effect is to obligate U.S. treaty partners to amend their intellectual property laws to match or resemble those of the United States.[4]

FTAs have been described as an effective mechanism for advancing U.S. interests in ensuring intellectual property protection.[5] Nonetheless, concerns have arisen over the intellectual property provisions of the FTAs. Some commentators have suggested that certain FTA provisions may lock the United States into current intellectual property policies, inhibiting opportunities for future reform.[6] Others are concerned that under existing multilateral agreements, in particular those of the World Trade Organization (WTO), the intellectual property obligations found within one FTA may extend beyond that particular treaty partner.[7] Finally, some observers

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[1] P.L. 107-210, 116 Stat. 993 (2002).

[2] 19 U.S.C. § 3802(b)(4)(A)(i)(II) (2004).

[3] See generally Free Trade Agreements: US Strategies and Priorities (Jeffery J. Schott, ed., 2004).

[4] See Russell J. Anderson, Jr., "Return of the Guilds: A Reflection on the Domestic and International Implications of *Eldred v. Ashcroft*," 12 *University of Baltimore Intellectual Property Law Journal* (2003), 49.

[5] See Peter K. Yu, "Currents and Crosscurrents in the International Intellectual Property Regime," 38 *Loyola of Los Angeles Law Review* (2004), 323.

[6] See Carlos M. Correa, "Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses," 26 *Michigan Journal of International Law* (2004), 331; CRS Report RL32375, *The U.S.-Australia Free Trade Agreement: Provisions and Implications*, by William H. Cooper.

[7] See Maria Julia Oliva, "Intellectual Property in the FTAA: Little Opportunity and Much Risk," 19 *American University International Law Review* (2003), 45.

perceive the FTAs to be an inappropriate and unfair vehicle for international intellectual property reforms.[8]

This report offers a broad overview of the intellectual property components of the FTAs. It begins by offering a brief introduction to the global intellectual property system. Next, this report considers the subject matter of the different free trade agreements themselves. It then reviews perceived concerns with respect to the free trade agreements and closes with concluding observations.

Intellectual Property Fundamentals

The term "intellectual property" refers to the subject matter of the laws that give rise to proprietary interests in creations of the mind. Significant legal intellectual property disciplines include copyright, which concerns artistic and literary works; patent, pertaining to pragmatic innovations; trademark, relating to commercial symbols; and data protection, concerning pharmaceutical and agricultural test data.[9] A brief review of each of these legal regimes, as they exist in the United States, will aid subsequent analysis.

Copyrights provide protection for original works of authorship. The types of creations addressed by copyright range from traditional works of art, including literature, music and visual art, to such modern forms of artistic expression as sound recordings, motion pictures and even computer software.[10] Copyright protection arises automatically, as soon as the work has been fixed in tangible form.[11] Authors may register their works with the U.S. Copyright Office, a component of the Library of Congress. If an author chooses to register his work, he obtains certain procedural and substantive advantages during copyright enforcement.[12] The copyright law affords authors the exclusive right to reproduce, adapt, and publicly distribute, perform, and display the protected work, subject to limitations such as the fair use privilege.[13] The term of copyright is ordinarily the life of the author plus 70 years.[14]

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[8] See, e.g., Frederick M. Abbott, "Intellectual Property Rights in Global Trade Framework: IP Trends in Developing Countries," 98 *American Society of International Law Proceedings* (2004), 95.

[9] See generally Roger E. Schechter and John R. Thomas, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS AND TRADEMARKS (2003).

[10] *Id.*

[11] *Id.*

[12] 17 U.S.C. § 408 — 412 (2004).

[13] 17 U.S.C. § 106, 107 — 122 (2004).

[14] 17 U.S.C. § 302 (2004).

Patents provide exclusive rights to inventors of new, useful and nonobvious inventions.[15] The patent law concerns hard technologies, including chemical, electrical and mechanical products and processes, as well as other pragmatic innovations in fields ranging from biotechnology to business methods.[16] An inventor may obtain a patent by filing a patent application with the United States Patent and Trademark Office (USPTO). Such an application must completely describe and precisely claim the invention.[17] Patents issued confer the right to exclude others from making, using, selling, offering to sell or importing into the United States the patented invention.[18] The term of a patent is ordinarily 20 years from the date the application was filed.[19]

Trademarks consist of any word or symbol used by a merchant to identify its goods or services, and to distinguish them from those of others.[20] To be subject to protection under the trademark laws, a mark must successfully distinguish the origins of its associated goods, and not be confusingly similar to marks used by others or merely describe the characteristics of those goods.[21] Trademark rights arise under state law as soon as the mark is used on goods in commerce.[22] However, trademarks may be registered with the USPTO, a step that affords significant substantive and procedural advantages.[23] Trademark law also protects the appearance of product packaging and, in some cases, the actual physical configuration of the goods, if these serve as brand identifiers. A trademark owner may prevent others from using any mark that creates a likelihood of confusion as to the source or sponsorship of the associated goods or services.[24] Trademark rights persist so long as the mark continues to be used and retains its distinctiveness.[25]

Another intellectual property right concerns the protection of pharmaceutical and agricultural chemical test data. Most national governments regulate the marketing of pharmaceuticals and agricultural chemicals in the interest of public health.[26] This oversight includes a required showing that these products are safe and effective before they can be distributed to the public. Such evidence is not generated by government laboratories, however. Rather, national governments require sponsors

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[15] 35 U.S.C. §§ 101, 102, 103 (2004).

[16] 35 U.S.C. § 101 (2004).

[17] 35 U.S.C. § 112 (2004).

[18] 35 U.S.C. § 271 (2004).

[19] 35 U.S.C. § 154(a)(2) (2004).

[20] See RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 9.

[21] *Id.*

[22] *Id.* at § 18.

[23] 17 U.S.C. § 1051 (2004).

[24] See RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 20.

[25] *Id.* at § 30.

[26] See CRS Report RL30989, *The U.S. Drug Approval Process: A Primer*, by Blanchard Randall IV.

of new drugs and agricultural chemicals to submit test data that evidence their safety and efficacy.[27]

Because the required test data may be very costly to generate, sponsors of new pharmaceuticals and agricultural chemicals often do not disclose test data to the public. Otherwise the sponsor's competitors could avoid the expenses of developing this data for themselves. Sponsors also desire government agencies that receive the test data to maintain the data in confidence.[28] In addition, brand-name pharmaceutical and agricultural chemical firms often seek to limit the ability of generic competitors to rely upon the data in order to obtain marketing approval of their own products, even if they cannot actually view the data themselves.[29]

In the United States, federal legislation limits the ability of generic competitors to reference data generated by the manufacturers of brand-name pharmaceuticals and agricultural chemicals. With respect to pharmaceuticals, these "marketing exclusivities" consist of a period of time during which the Food and Drug Administration (FDA) protects an approved drug protection from competing applications for marketing approval. Under the Hatch-Waxman Act,[30] drugs that qualify as a "new chemical entity"[31] may obtain five years of marketing exclusivity.[32] The Hatch-Waxman Act also provides for a three-year marketing exclusivity awarded to a drug sponsor that conducts new clinical studies upon a drug that does not qualify as a new chemical entity.[33] The Federal Insecticide, Fungicide, and Rodenticide Act of 1978,[34] also provides for data protection for agricultural chemicals under somewhat different certain terms and conditions.[35]

A number of rationales explain the intellectual property laws. Some legal experts assert that intellectual property laws are needed to encourage individuals to

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[27] See G. Lee Skillington & Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law and Business* (2003), 1.

[28] See James T. O'Reilly, "Implications of International Drug Approval Systems on Confidentiality of Business Secrets in the U.S. Pharmaceutical Industry," 53 *Food & Drug Law Journal* (1998), 123.

[29] See Adrian Zahl, "Pharmaceuticals and the Law: As Patent Laws Converge, Attention Shifts to 'Data Protection,'" 13 *Metropolitan Corporate Counsel* no. 2 at 24 (Feb. 2005).

[30] P.L. 98-417, 98 Stat. 1585 (1984).

[31] 21 U.S.C. §355(c)(3)(E)(ii) (2004) (with respect to §505(b)(2) applications); 21 U.S.C. §355(j)(5)(F)(ii) (2004) (with respect to ANDAs).

[32] Some authorities refer to this sort of exclusivity as new molecular entity, or NME exclusivity. See Gerald J. Mossinghoff, "Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process," 54 *Food & Drug Law Journal* (1999), 187.

[33] 21 U.S.C. §355(c)(3)(E)(iii)-(iv) (2004); 21 U.S.C. §355(j)(5)(F)(iii)-(iv) (2004).

[34] P.L. 95-396, 92 Stat. 819 (1978) (codified as amended at 7 U.S.C. §§136-136y (2004)).

[35] See Aaron Xavier Fellmeth, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement," 45 *Harvard International Law Journal* (2004), 443.

create new works of authorship, inventions, and other innovative subject matter. It is believed that absent a system of proprietary rights, free riders could readily exploit these works without having to bear the costs of creating them. Individuals would in turn possess diminished incentives to devote their efforts to being authors or inventors.[36] In addition, intellectual property rights are said to facilitate market mechanisms by creating discrete, well-defined property interests that decrease transaction costs and encourage commercial exchanges.[37]

On the other hand, intellectual property laws have been subject to criticism. Some assert that intellectual property rights are unnecessary due to market forces that already suffice to create an optimal level of creative activity. The desire to become famous, or to gain a lead time advantage over competitors, may well provide sufficient inducement to write or to invent without the need for further incentives.[38] In an era where information can be readily transmitted around the globe, the notion that an innovation can be an object of possession has also been challenged.[39]

Each of these contentions has a varying degree of persuasiveness. As of yet, however, no conclusive study has demonstrated that the social benefits of the intellectual property laws outweigh the costs. As a result, the justifications and criticisms of intellectual property remain open to challenge.[40]

The TRIPS Agreement

At present time, no unified legal regime governing intellectual property rights exists on an international basis. There is no global copyright, patent or trademark. Innovators must secure and enforce these rights within the particular jurisdiction where they desire protection.[41]

In addition, the varying national laws that establish intellectual property rights often differ in important respects. Such factors as the works subject to protection, the scope of rights, and the duration of protection are among the factors that may vary

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[36] See, e.g., Rebecca S. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 *University of Chicago Law Review* (1989), 1017.

[37] See, e.g., Henry H. Perritt, Jr., "Property and Innovation in the Global Information Infrastructure," 1996 *University of Chicago Legal Forum* (1996), 261.

[38] See Frederic M. Scherer & David Ross, *Industrial Market Structure and Economic Performance* (Rand McNally & Co., 3d ed. 1990).

[39] John Perry Barlow, "The Economy of Ideas," *Wired* 2.03 (March 1994).

[40] See Congressional Research Service Report for Congress, CRS Report RL31951, *Innovation, Intellectual Property, and Industry Standards*, by John R. Thomas.

[41] See, e.g., Opinion of the Comptroller General, 159 USPQ 298, 301 (1968) ("It is a fundamental concept that territorial limitations of sovereignty preclude a country from giving extraterritorial effect to its patent laws.").

widely in different jurisdictions.[42] Absent some obligation, a particular nation is not required to provide intellectual property rights that resemble those of the United States, or even to establish such laws at all.[43]

Since the nineteenth century, however, many nations in fact have committed to provide certain standards of intellectual property protection via bilateral and multilateral international agreements.[44] The most significant of these is the WTO Agreement on Trade — Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement.[45] Domestically, the Uruguay Round Agreements Act in 1995 made significant amendments to U.S. intellectual property laws in an effort to comply with the TRIPS Agreement.[46] As discussed below, the TRIPS Agreement required each WTO member state to provide minimum substantive standards of intellectual property protection and enforcement.

General Provisions

The TRIPS Agreement requires each WTO member state to observe the standards of "national treatment" and "most-favored-nation" with respect to its intellectual property laws.[47] Following the national treatment principle, WTO members agree to treat foreign inventors no worse than domestic inventors in their patent laws, so long as these foreign inventors are nationals of a WTO member state. It would be impermissible, for example, for the USPTO to charge nationals of a WTO member state a higher application fee than is required of U.S. citizens, or to provide a shorter patent term for such inventors than is granted to U.S. inventors. Under the most favored nation provision, with limited exceptions, any privilege granted to nationals of one WTO member state must also be afforded to nationals of all WTO member states.[48]

The TRIPS Agreement also requires each WTO member state to comply with certain provisions of earlier international agreements pertaining to intellectual

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[42] See Graeme W. Austin, "Valuing 'Domestic Self-Determination' in International Intellectual Property Jurisprudence," 77 *Chicago-Kent Law Review* (2002), 1155.

[43] See Evelyn Su, *The Winners and the Losers: The Agreement on Trade — Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries*, 23 HOUSTON JOURNAL OF INTERNATIONAL LAW 169 (2000).

[44] See Frederick Abbott *et al.*, *The International Intellectual Property System: Commentary and Materials* (1999).

[45] Agreement on Trade — Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994) ["TRIPS Agreement"].

[46] P.L. 103-465, 108 Stat. 4809 (1994).

[47] TRIPS Agreement, Art. 4.

[48] See Kevin J. Nowak, "Staying Within the Negotiated Framework: Abiding by the Non-Discrimination Clause of TRIPS Article 27," 26 *Michigan Journal of International Law* (2005), 899.

property.[49] These treaties include the Berne Convention,[50] which relates to copyrights; the Paris Convention,[51] which concerns patents and trademarks; and the Treaty on Intellectual Property in Respect of Integrated Circuits,[52] concerning semiconductor chip topography designs.

Copyrights

The TRIPS Agreement obligates each WTO member state to provide a term of copyright protection of no less than 50 years from the death of the author.[53] The TRIPS Agreement additionally requires WTO member states to protect computer programs as literary works.[54] Protection must also be accorded to data compilations that, by virtue of their selection or arrangement, constitute "intellectual creations."[55] The TRIPS Agreement also calls for "rental rights" — the right to authorize or prohibit the commercial rental to the public of a protected work of authorship — with respect to computer programs and cinematographic works.[56]

Patents

Following the TRIPS Agreement, each WTO member state agreed to allow patents to issue on inventions "in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[57] The TRIPS Agreement includes some exceptions to this broad principle, however. Certain methods of medical treatment, plants and animals other than microorganisms, and inventions that violate the "*ordre public* or morality" may be excluded from patentability at the option of the member state.[58]

WTO member states also agreed that patentees shall have the right to exclude others from making, using, offering for sale, selling, or importing the patented invention,[59] subject to limited exceptions.[60] The TRIPS Agreement further stipulates

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[49] TRIPS Agreement, Arts. 2, 9, 35.

[50] Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, 828 U.N.T.S. 221.

[51] Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 13 U.S.T. 1.

[52] May 26, 1989, I.L.M. 1477.

[53] TRIPS Agreement, Art. 12.

[54] *Id.* at Art. 10.

[55] *Id.*

[56] *Id.* at Art. 11.

[57] *Id.* at Art. 27(1).

[58] *Id.* at Art. 27(2).

[59] *Id.* at Art. 28.

[60] *Id.* at Art. 30.

that the term of patent protection available shall not end before the expiration of a period of 20 years counted from the filing date.[61]

The TRIPS Agreement places some limits upon the ability of WTO member states to award compulsory licenses for the use of another's patented invention.[62] Among the most detailed provisions of the TRIPS Agreement, Article 31 in part imposes the following restrictions upon the issuance of compulsory licenses:

- Each application for a compulsory license must be considered on its individual merits.
- The proposed user must have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and must demonstrate that such efforts have not been successful within a reasonable period of time. However, this requirement may be waived in the case of a national emergency or other circumstances of extreme urgency.
- The compulsory license must be revocable if and when its motivating circumstances cease to exist and are unlikely to recur.
- The patent owner must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.
- The legal validity of any decision relating to the authorization of such use shall be subject to judicial or other independent review.
- Any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use.

Many nations considered the last of the restrictions noted above — requiring that any compulsory license be authorized predominantly for local use — to be a burdensome standard. Some countries may lack the technological or financial capabilities to manufacture advanced products, including certain pharmaceuticals needed to combat AIDS or other epidemics. The WTO ministerial conference held in Doha, Qatar in 2001 recognized this concern when it issued a "Declaration on the TRIPS Agreement and Public Health."[63] The result was a 2003 decision of the WTO General Council that limited the domestic supply requirement with respect to

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[61] *Id.* at Art. 33.

[62] A "compulsory license" constitutes a statutorily created license that allows individuals to pay a royalty and use the invention without the patentee's permission. *Black's Law Dictionary* 938 (Bryan A. Gardner, ed., 8th ed. 2004).

[63] See CRS Report RS21609, *The WTO, Intellectual Property, and the Access to Medicines Controversy*, by Ian F. Fergusson.

pharmaceuticals needed to address public health problems.[64] Under the 2003 decision, any least developed country, as well as any other country that certifies it has insufficient manufacturing capabilities to manufacture a patented drug, may issue a compulsory license that allows for domestic public health needs to be satisfied through importation.[65] On December 6, 2005, WTO members agreed to incorporate the language of the 2003 decision directly within the TRIPS Agreement itself.[66]

Trademarks

The TRIPS Agreement provides that "[a]ny sign, or combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark." The TRIPS Agreement further requires that a trademark owner, with some exceptions,[67] "shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion."[68] Trademarks that have become well-known in a particular country are entitled to additional protection.[69]

Trademarks are subject to a minimum term of 7 years, which may be renewed indefinitely.[70] The TRIPS Agreement further stipulates that compulsory licensing of trademarks shall not be permitted.[71] Under this rule, legal requirements that foreign marks be used in conjunction with local marks are, as a general matter, prohibited.

Data Protection

The TRIPS Agreement requires each WTO member state to establish protections for pharmaceutical and agricultural chemical test data under certain conditions. Although this obligation is stated succinctly in Article 39.3 of the TRIPS Agreement, it has proven controversial. Article 39.3 specifically provides:

> 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

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[64] See http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[65] See also Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health," 99 *American Journal of International Law* 317 (2005).

[66] See World Trade Organization, "Members OK amendment to make health flexibility permanent," (Dec. 6, 2005) (available at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm).

[67] TRIPS Agreement, Art. 17.

[68] *Id.* at Art. 16.

[69] *Id.*

[70] *Id.* at Art. 18.

[71] *Id.* at Art. 21.

> 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.

Many commentators have observed that, in contrast to the more specific wordings of many other TRIPS Agreements provisions, Article 39.3 establishes broad parameters using vague language.[72] In particular, terms such as "new chemical entities," "considerable effort," and "unfair commercial use" receive no further definition within the TRIPS Agreement. As a result, the precise nature of the obligations Article 39.3 imposes upon WTO member states is not entirely clear.[73]

Other Intellectual Property Rights

The TRIPS Agreement also establishes minimum standards of substantive protection with respect to a number of other intellectual property rights. WTO member states must protect certain geographical indications, which are defined as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."[74] They must also protect industrial designs, which consist of a shape, configuration, pattern, or ornament applied to an article manufacture.[75] In addition, they must also provide a cause of action for the misappropriation of trade secrets.[76]

Enforcement

Along with other commitments made by WTO member states, TRIPS Agreement obligations are subject to enforcement through the WTO Dispute Settlement Body (DSB).[77] If one WTO member state believes that another member state is in violation of the TRIPS Agreement, the member states may enter into consultation through the DSB. If the member states cannot resolve their disagreement, the DSB will convene a panel to hear and resolve the dispute. Panel

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[72] See Lorna Brazell, *A world united? The US approach to the protection of regulatory data* (Jan. 12, 2005) (available at www.bilaterals.org).

[73] *Compare* G. Lee Skillington & Eric M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement," 24 *Northwestern Journal of International Law & Business* (2003), 1, *with* Carlos Maria Correa, "Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals," 3 *Chicago Journal of International Law* (2002), 69.

[74] TRIPS Agreement, Art. 22.1.

[75] *Black's Law Dictionary* 791 (Bryan A. Gardner, ed., 8th ed. 2004).

[76] TRIPS Agreement, Art. 39. A trade secret has been defined as a "formula, process, device, or other business information that is kept confidential to maintain an advantage over competitors." See James Pooley, *Trade Secrets* §1.01 (1998).

[77] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, WTO Agreement, Annex 2, Legal Instruments — Results of the Uruguay Round vol. 31, 33 I.L.M. 1226 (1994).

decisions are subject to review by the DSB Appellate Body. The WTO Agreement calls for compensatory trade measures in circumstances where the DSB finds a WTO member state to be in violation of the TRIPS Agreement, yet that member state does not amend its laws. If the parties are unable to agree upon mutually acceptable compensation, then the complaining state may impose limited trade sanctions, such as heightened tariff rates commensurate with the determined injury resulting from the offending practice, against the other member state.[78]

Effective Dates

The various patent portions of the TRIPS Agreement feature a variety of effective dates. These dates depend upon whether the WTO member state designates itself a developed, developing or least developed country. For WTO members other than developing and least developed countries, the compliance date for all requirements of the TRIPS Agreement was set to January 1, 1996.[79]

For signatory states designated as developing countries, the TRIPS Agreement set the general compliance date as January 1, 2000. However, there is one exception to this general date. If on January 1, 2000, a developing country did not extend patent protection to all areas of technology within the meaning of Article 27, that developing country may delay implementation of these provisions for an additional five years. Prior to the TRIPS Agreement, for example, many developing countries did not allow patents to issue on pharmaceuticals. The practical effect of this additional transition period was that developing countries did not need to allow patents concerning pharmaceuticals until January 1, 2005.

Least-developed countries are entitled to a lengthier transition period in implementing TRIPS Agreement obligations. Effective dates with respect to least-developed countries are found in the TRIPS Agreement itself, as well as the 2001 "Declaration on the TRIPS Agreement and Public Health" issued following the Doha Ministerial.[80] Following 2005 modifications to the text of the TRIPS Agreement, a least-developed country may delay implementing the TRIPS Agreement until July 1, 2013. A showing of hardship may qualify least-developed countries for further delays and other concessions.[81] The Doha Declaration further excuses least-developed country members from granting or enforcing patents on pharmaceuticals through January 1, 2016, without prejudice to their ability to seek other extensions of these transitions periods.

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[78] Mark Clough, "The WTO Dispute Settlement System — A Practitioner's Perspective," 24 *Fordham International Law Journal* (2000), 252.

[79] TRIPS Agreement, Art. 65.

[80] See supra notes 63-65 and accompanying text.

[81] TRIPS Agreement, Art. 66.

The TRIPS Agreement does not oblige its signatories to protect subject matter that fell into the public domain prior to the time its obligations became effective.[82] For example, suppose that a particular developing country (as compared to a developed or least-developed country) traditionally did not allow patents to issue on pharmaceuticals. If that developing country joined the WTO, it must amend its patent law to authorize pharmaceutical patents. The TRIPS Agreement requires only that patents be allowed on new products as of January 1, 2005, however, and does not mandate that patents be granted retroactively. As a result, within that developing country, patent protection need not be afforded to pharmaceuticals that were public available prior to January 1, 2005, even if those pharmaceuticals were patented elsewhere.

Debate on the TRIPS Agreement

The TRIPS Agreement has generated considerable controversy. Some commentators believe that the TRIPS Agreement has led to large transfers of wealth from poor countries to the developed world, and in particular to the United States.[83] Others have contended that the introduction of strong intellectual property rights protection into the developing world restricts sustainable development and perpetuates their dependence upon developed nations.[84] Still others believe that deleterious public health consequences will result from the TRIPS Agreement requirement that patents issue on pharmaceuticals.

Proponents of the TRIPS Agreement instead believe that the introduction of full-fledged intellectual property laws around the globe will provide needed incentives for investment and innovation.[85] Such efforts could promote solutions to problems that are particular to the developing world, including the provision of nutritional needs and cures for diseases not common in the developed world. Supporters also observe that the TRIPS Agreement was one component of a multi-faceted WTO agreement, and believe that the developing world obtained trade benefits in exchange for assuming obligations to protect intellectual property. Even after a decade of experience with the TRIPS Agreement, the exchange of views about possible reforms to the TRIPS Agreement continues at a brisk pace.

Intellectual Property and Free Trade Agreements

The TRIPS Agreement obligated each WTO member state to provide stated levels of intellectual property protection. Although commentators broadly agree that the TRIPS Agreement was a watershed event for international intellectual

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[82] TRIPS Agreement, Art. 70.

[83] Abbott, *supra* note 8.

[84] See A. Samuel Oddi, "TRIPS — Natural Rights and a 'Polite Form of Economic Imperialism,'" 29 *Vanderbilt Journal of Transnational Law* 415 (1996).

[85] See Jean Raymond Homere, "Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries," 27 *Columbia Journal of Law & the Arts* (2004), 277.

provision,[86] many of its obligations nonetheless fell short of the level of intellectual property rights available in the United States. For example, U.S. copyright law provides for a term of protection of the life of the author plus 70 years,[87] while a term of life plus 50 years is acceptable under the TRIPS Agreement.[88] U.S. patent law allows patent term to be extended in order to account for long delays in Patent Office acquisition procedures,[89] but the TRIPS Agreement does not require such a measure. The TRIPS Agreement allows WTO member states to disallow the registration of trademarks that are not visually perceivable[90] — an option that blocks protection for such commercial symbols as sounds and scents — but no such blanket restriction exists under U.S. law.

In enacting the Bipartisan Trade Promotion Act of 2002, Congress stated that an overall negotiating objective of such agreements was to encourage our treaty partners to agree to "a standard of [intellectual property] protection similar to that found in United States law."[91] In keeping with this mandate, the United States has entered into numerous FTAs that have required their signatories to provide higher levels of intellectual property protection than are required under the TRIPS Agreement.[92] With respect to the intellectual property laws, each of the FTAs stipulates standards that comply with current U.S. law. As a result, the United States need take no action in order to comply with those provisions of the FTA. In contrast, the U.S. treaty partner must often substantially amend its intellectual property laws in order to comply with the FTA.[93]

This report next offers an overview of these FTA "TRIPS-plus"[94] intellectual property obligations. It should be noted that the intellectual property provisions of most of these agreements are lengthy and detailed. Further, some of the FTAs impose more significant obligations than others.[95] As a result, if particular

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[86] See, e.g., Laurence R. Helfer, "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking," 29 *Yale Journal of International Law* (2004), 1.

[87] 17 U.S.C. § 302 (2004).

[88] TRIPS Agreement, Art. 12.

[89] 35 U.S.C. § 154(b) (2004).

[90] TRIPS Agreement, Art. 15.1.

[91] P.L. 107-210, 116 Stat. 993 (codified at 19 U.S.C. § 3802(b)(4)(A)(i)(II) (2004)).

[92] See Amy Kapczynski *et al.*, "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations," 20 *Berkeley Technology Law Journal* (2005), 1031.

[93] See Anderson, *supra* note 4.

[94] Because the FTAs include obligations that exceed those of the TRIPS Agreement, they are commonly referred to as "TRIPS-plus agreements." See Haochen Sun, "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health, 15 *European Journal of International Law* (2004), 146.

[95] See Frederick M. Abbott, "Toward a New Era of Objective Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism," 8 *Journal of*

(continued...)

information about an individual FTA is needed, that instrument should be consulted for a more detailed understanding of its contents.[96]

Copyrights

Several of the FTAs oblige their signatories to provide a copyright term equal to the life of the author plus 70 years, twenty years longer than the standard set by the TRIPS Agreement. Certain FTAs also include obligations that track those established domestically by the Digital Millennium Copyright Act (DMCA) of 1998.[97] In particular, FTA signatories agree to outlaw the circumvention of a technological copyright-control measure, subject to certain exceptions. Descrambling a scrambled work, decrypting an encrypted work, and bypassing a technological measure without the authority of the copyright owner are among the activities that would violate the DMCA. In addition, the FTAs also commonly require their signatories to prohibit the removal or alteration of "rights management information," which is in turn defined to mean electronic information that identifies a protected work and its author, as well as the terms and conditions of the use of the work.

Patents

Several FTAs require their signatories to provide a one-year "grace period" to patent applicants. Under these provisions, individuals are granted one year from the date they publicly disclose their inventions to decide whether to file a patent application or not.[98] FTAs also commonly require their signatories to accede to the Patent Cooperation Treaty,[99] an international agreement that expedites multinational patent acquisition procedures.[100]

Certain of the FTAs also call for patent term extension based upon administrative delays. The TRIPS Agreement obligates all WTO members to provide a patent term of twenty years from the date of filing.[101] However, patent applicants obtain no enforceable rights until such time as the patent actually issues. As a result, extensive Patent Office delays could substantially diminish the period of time in which the patent proprietor enjoys enforceable patent rights. Certain of the

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[95] (...continued)
International Economic Law (Mar. 2005), 77.

[96] The text of each of the FTAs is available at the web site of the United States Trade Representative, www.ustr.gov.

[97] P.L. 105-304, 112 Stat. 2860 (1998).

[98] *E.g.,* U.S.-Australia FTA, Art. 17.9(9).

[99] 28 U.S.T. 7645 (June 19, 1970).

[100] U.S.-Australia FTA, Art. 17.1(2).

[101] TRIPS Agreement, Art. 33.

FTAs therefore call for patent term extension in the event of "unreasonable delays in a Party's issuance of patents . . . ."[102]

Some FTAs also place additional conditions on the grant of compulsory licenses, beyond the requirements of the TRIPS Agreement. For example the Australia-U.S. FTA provides that a compulsory license may be issued only to remedy an antitrust violation or in cases of public non-commercial use, national emergency, or other circumstances of extreme urgency. In these latter instances, the FTA signatory must limit use of the patented invention to the government or a government-authorized entity and shall provide the patent proprietor with reasonable compensation. Further, the patent proprietor is not required to provide additional undisclosed information or technical know-how that is related to the patented invention.[103]

Trademarks

A number of the FTAs also pertain to the trademark law. They stipulate that a mark need not be visually perceptible in order to be registered as a mark, thereby allowing sounds and scents to serve as marks.[104] The FTAs also stipulate that licenses for trademarks need not be publicly registered to be valid,[105] and provide that disputes over Internet domain names should be resolved through recourse to the principles established in the Uniform Domain Name Dispute Resolution Policy.[106]

Data Protection

Certain FTAs require their signatories to provide five years of marketing exclusivity for pharmaceuticals that utilize new chemical entities. For example, Article 15.10:1(a) of the Dominican Republic-Central America-United States Free Trade Agreement provides:

> 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 the 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.[107]

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[102] *E.g.,* U.S.-Australia FTA, Art. 17.9(8)(a).

[103] *Id.* at Art. 17.9(7).

[104] *Id.* at Art. 17.2(2).

[105] *Id.* at Art. 17.2(10).

[106] *Id.* at Art. 17.3(1).

[107] U.S.-Chile FTA, Art. 17.10(1).

The term "new product" is generally defined as "one that does not contain a chemical entity that has been previously approved in the territory of the Party."[108]

Some of the FTAs additionally require their signatories to allow a three-year term of marketing exclusivity in various circumstances for pharmaceuticals that do not qualify as new products.[109] Among them is the Australia-United States Free Trade Agreement, which provides in part:

> With respect to pharmaceutical products, if a Party requires the submission of: (a) new clinical information (other than information related to bioequivalency) or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later.[110]

Other Provisions

The FTAs also address other intellectual property rights. For example, the U.S.-Australia FTA requires both signatories to provide certain levels of protection to "encrypted programme-carrying satellite signals."[111] In addition, the FTAs commonly call for minimal standards concerning litigation proceedings, remedies, and other intellectual property enforcement measures that exceed those of the TRIPS Agreement.[112] The FTAs also set out detailed procedures for the resolution of disputes over compliance with their provisions.[113]

Innovation Policy Issues

Observers have acknowledged that the FTAs have been an effective mechanism for advancing U.S. interests in intellectual property on the global stage.[114] Concerns have nonetheless arisen about the implications of the FTA intellectual property provisions. This report considers three of these concerns: potential lock-in effects, extent of FTA obligations, and the fairness of using FTAs as a mechanism for international intellectual property reforms.

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[108] See, e.g., DR-CAFTA Art. 15.10:1(c).

[109] See, e.g., U.S.-Bahrain FTA Art. 14.9(2)(a); U.S.-Jordan FTA Art. 22 n.10.

[110] U.S.-Australia FTA, Art. 17.10(2).

[111] *Id.* at Art. 17.7.

[112] U.S.-Australia FTA, Art. 17.11.

[113] See, e.g.., U.S.-Singapore FTA, Chapter 20.

[114] Yu, *supra* note 5.

U.S. Interests in the FTA Intellectual Property Provisions

The United States has for many years pursued a policy of encouraging our trading partners to expand legal protection for intellectual property.[115] Decreased levels of intellectual property piracy with respect to computer software, music, motion pictures, and pharmaceuticals may promote a more favorable balance of trade for U.S. industry. As Professor J. Thomas McCarthy, a member of the faculty of the University of San Francisco Law School, clearly stated: "We care because if no intellectual property protection exists regarding technical and entertainment information, then we have little to sell the rest of the world."[116]

Enhanced levels of intellectual property protection around the world may also serve other goals of the United States. For example, pharmaceuticals are often sold at higher prices in the United States than in other nations.[117] The previous unavailability of patent protection for innovative pharmaceuticals in some foreign jurisdictions is one factor that may have contributed to this price difference. The introduction of patent protection for pharmaceuticals in developing countries will potentially allow innovative drug companies to recover a portion of their R&D expenses in foreign jurisdictions. In turn, because U.S. consumers will no longer be responsible for funding such a large share of the R&D expenditures of innovative drug companies on a global basis, the price of medications may decrease in the United States. It is possible, however, that developing country markets may not prove sufficiently profitable such that prices would be reduced for U.S. consumers.[118]

In comparison with larger multilateral settings, FTAs may provide a more effective mechanism for advancing the intellectual property interests of the United States. USPTO officials have, for example, expressed frustration over slow progress in consultations over a proposed patent law harmonization treaty before the World Intellectual Property Organization (WIPO).[119] One recent USPTO news release has stated that recent events at WIPO raise "serious questions as to whether WIPO is even a viable forum for further meaningful patent discussions."[120] In contrast, the FTAs have already resulted in significant patent law reforms for many U.S. trading

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[115] See Peter Drahos, "Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach," 77 *Temple Law Review* (2004), 401.

[116] J. Thomas McCarthy, "Intellectual Property — America's Overlooked Export," 20 *University of Dayton Law Review* (1995), 809.

[117] See CRS Report RL32171, *Importation of Prescription Drugs Provisions in P.L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, by Susan Thaul and Donna U. Vogt.

[118] See Rahul Rajkumar, "The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health," 15 *Albany Law Journal of Science & Technology* (2005), 433.

[119] The WIPO is a specialized United Nations agency that serves as a forum for intellectual property. The WIPO website, www.wipo.int, provides more information about the agency.

[120] USPTO, "Patent Law Harmonization Talks Stall: Brazil, Argentina, India Oppose Compromise" (June 14, 2005), available at http://www.uspto.gov/main/homepagenews/bak2005jun14.htm.

partners. In addition, by establishing certain multinational intellectual property norms with the assistance of a number of trading partners, the United States may be better able to negotiate on a multilateral basis in the future.[121]

Potential Lock-In Effects

Although many observers have cited the merits of FTAs with respect to the intellectual property interests of the United States, others have expressed concerns about the effects or implications of these agreements. Some commentators have expressed concern that the FTAs may potentially introduce complications to U.S. law reform efforts, even in circumstances where modifications to domestic intellectual property rules are considered desirable in the future.[122] In particular, should the Congress later wish to make changes to its laws that are inconsistent with the terms of the FTAs, the United States would either have to renegotiate these agreements, or face the possibility of violating their terms. A potential example of this situation involves the importation of patented pharmaceuticals into the United States, a topic that the Singaporean, Australian, and Moroccan FTAs address. For example, Article 15.9, paragraph 4 of the United States — Morocco FTA provides:

> Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory. [Footnote 10: A Party may limit application of this paragraph to cases where the patent owner has placed restrictions on importation by contract or other means.]

This provision impacts, among other topics, a practice commonly termed "parallel importation"[123] or "reimportation."[124] Parallel imports are authentic products that are legitimately distributed abroad and then sold in the United States, without the permission of the authorized U.S. dealer. These goods are legitimate in that they are produced by the brand-name drug company or its authorized representative. In particular, parallel imports are not generic versions of a brand-name drug distributed by a different manufacturer, nor are they pirated copies that form part of the "black market." Because parallel imports disrupt the marketing arrangements established by the brand-name drug company, however, they are sometimes called "grey market goods."[125]

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[121] Drahos, *supra* note 114.

[122] Abbott, *supra* note 8.

[123] See, e.g., Warwick A. Rothnie, *Parallel Imports* (Sweet & Maxwell 1993); Simon Horner, *Parallel Imports* (Blackwell Science 1987).

[124] See Ivette P. Gomez, "Beyond the Neighborhood Drugstore: U.S. Regulation of Online Prescription Drug Sales by Foreign Businesses," 28 *Rutgers Computer & Technology Law Journal* (2002), 431.

[125] See, e.g., Seth E. Lipner, *The Legal and Economic Aspects of Gray Market Goods* (Quorum Books, Westport, Connecticut 1990).

Under current judicial precedent,[126] U.S. patents may be used to block imports of proprietary pharmaceuticals. The fact that the patent proprietor or its representative previously sold the drug outside the United States does not affect this analysis. This rule rejects a principle termed "international exhaustion," under which a sale of a drug anywhere in the world exhausts the U.S. patent. The FTAs that address this issue therefore comport with governing U.S. judicial opinions.

Proposed legislation before the 109th Congress would alter the current rules concerning the parallel importation of patented pharmaceuticals. The proposed Affordable Health Care Act (S. 16, Sen. Kennedy) would in part introduce the following provision into the patent statute:

> It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under section 804 of the Federal Food, Drug, and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent.[127]

If this bill, or a similar bill, were passed into law or enacted, the "international exhaustion" principle would apply to foreign sales of patented pharmaceuticals. In circumstances where the patent owner sold the patented pharmaceutical abroad, the patent owner would no longer be able to block imports of these products into the United States. This result appears to conflict with Article 15.9, paragraph 4 of the United States — Morocco FTA, as well as the counterpart provisions of the Singaporean and Australian FTAs.

Perhaps out of recognition of the impact of the FTAs on the parallel importation issue, Rep. Northrup introduced an amendment to the Departments of Commerce and Justice, Science, and Related Appropriations Act, 2006, P.L. 109-108. Section 631 of that bill provides:

> None of the funds made available in this Act may be used to include in any new bilateral or multilateral trade agreement the text of —
>
> (1) paragraph 2 of Article 16.7 of the United States-Singapore Free Trade Agreement;
>
> (2) paragraph 4 of Article 17.9 of the United States-Australia Free Trade Agreement; or
>
> (3) paragraph 4 of Article 15.9 of the United States-Morocco Free Trade Agreement.

This provision would apparently seek to prevent future FTAs from incorporating language rejecting an "international exhaustion" rule for pharmaceuticals. This provision does not address the existing Singaporean, Australian, and Moroccan FTAs, however. This episode suggests that compliance with the FTA intellectual property provisions may be an issue should Congress attempt to alter U.S. law in the future.

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[126] See *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368 (Fed. Cir. 2005); *Jazz Photo Corp. v. United States International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001).

[127] S. 16 at § 3(f).

Extent of Obligations

Most of the FTAs that the United States has joined are bilateral, although some current or contemplated FTAs extend to a limited set of trading partners. On its face, it would appear that U.S. obligations undertaken in a particular FTA would extend only to its fellow signatory or signatories. Commitments undertaken in the TRIPS Agreement may extend FTA obligations to a much broader range of U.S. trading partners, however. In particular, every WTO member may in fact be entitled to enjoy the benefits of the commitments made with a particular FTA due to the most-favored-nation obligation imposed by Article 4 of the TRIPS Agreement. That provision stipulates:

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

Although Article 4 of the TRIPS Agreement does provide four exceptions to this most-favored-nation obligation, none of these exceptions seems applicable to the FTAs.[128]

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[128] Article 4 of the TRIPS Agreement goes on to stipulate that:

> Exempted from this obligation [of most-favored nation treatment] are any advantage, favour, privilege or immunity accorded by a Member:
>
> (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;
>
> (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;
>
> (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;
>
> (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

As applied to the FTAs, these treaties do not appear to be general agreements concerning judicial assistance or law enforcement. They also do not appear to have been carried out under the auspices of the Berne or Rome Conventions, nor do they appear to be limited to the rights of performers, phonogram producers and broadcasting organizations. Finally, the three FTAs were completed after the WTO Agreement came into effect, rendering the final exception seemingly inapplicable.

In view of Article 4 of the TRIPS Agreement, some experts believe that a particular FTA may extend U.S. obligations not just to its partner or partners to that agreement, but to all WTO members as well.[129] Other commentators differ, however, stating that free trade agreements are exempted from most-favored-nation obligations due to certain provisions of the General Agreement on Tariffs and Trade.[130] One possible consequence of the breadth of FTA obligations is that other trading partners may be less willing to make concessions with respect to their intellectual property laws, given that they may already be entitled to the full scope of commitments that the United States made in existing FTAs.

Fairness Concerns

Some commentators have voiced the opinion that the intellectual property provisions of the FTAs are unfair to the smaller trading partners of the United States. As explained by trade attorney George Y. Gonzalez: "The process of 'bilateral' negotiation in a 'multilateral' world context favors the negotiating stance of the affluent developed states over the wealth-constrained developing states."[131] Under this view, access to the U.S. market for agricultural products, textiles, and other basic goods is extremely important to less wealthy nations. As a result, U.S. trading partners are readily willing to accede to the intellectual property proposals of the United States during the FTA negotiation process. Some observers have criticized the United States for allegedly taking advantage of its strong bargaining position and superior intellectual property expertise when it completes FTAs.[132]

It should be appreciated, however, that many observers believe that the adoption of robust intellectual property laws lies in the best interest of U.S. trading partners, including developing nations. Commentator Jean Raymond Homere has concluded, for example, that "developing countries with stronger [intellectual property] regimes are in a better position to attract knowledge-related foreign direct investments (FDI) flows."[133] The FTAs may also encourage greater innovation, as well as the exploitation of creative works, within jurisdictions that previously lacked strong intellectual property rights.[134] It may also be appreciated that any international

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[129] See Frederick M. Abbott, "The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health," 99 *American Journal of International Law* (2005), 317.

[130] See Judy Rein, "International Governance Through Trade Agreements: Patent Protection for Essential Medicines," 21 *Northwestern Journal of International Law and Business* (2001), 379 (stating that the Article XXIV "exception provided within the GATT, permitting customs unions and free trade areas, will probably be applied to World Trade Organization agreements.").

[131] George Y. Gonzalez, "An Analysis of the Legal Implications of the Intellectual Property Provisions of the North American Free Trade Agreement," 34 *Harvard International Law Journal* (1993), 305.

[132] See Oliva, *supra* note 7.

[133] See Homere, *supra* note 85.

[134] See Keith E. Maskus, "Intellectual Property Rights and Economic Development," 32 (continued...)

agreement necessarily involves an exchange of benefits and obligations among the signatory states, and that the partners to a particular FTA may be best situated to assess the advantages and disadvantages of entering into that agreement for themselves.

Concluding Observations

Congressional interest in the FTAs as a vehicle for advancing the intellectual property interests of the United States is fueled by a number of objectives. Among them are combating high levels of intellectual property piracy overseas, supporting research and development-based domestic industries, and establishing a more favorable balance of trade. Although the FTAs are believed to be an effective mechanism towards achieving these goals, concerns have arisen about both their fairness, as well as their consequences in terms of U.S. obligations towards other trading partners and their impact upon contemplated changes to domestic law. The scope of these potential consequences counsels continued congressional attention towards the FTAs that the United States has already formed, as well as those FTAs that are planned for the future.

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[134] (...continued)
Case Western Reserve Journal of International Law (2000), 471.