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The North-South Debate Regarding the Protection of Intellectual Property Rights

by

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THE NORTH-SOUTH DEBATE REGARDING THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

Alan S. Gutterman*

INTRODUCTION

The economic behavior of an individual is influenced, to a large extent, by the property rights that the state grants to the individual in the fruits of his or her labor.¹ At an aggregate level, since the performance of an economic group, such as a country, is the sum of the activities of its constituents,² it follows that any incentive created by a grant of individual property rights impacts positively on the level of wealth and distribution of income within the country as a whole.³ This positive relationship between property rights and economic activity has been explained as follows:

By defining the parameters for the use of scarce resources and assigning the associated rewards and costs, the prevailing system of property rights establishes incentives and time horizons for investment, production, and exchange. Since property rights define the behavioral norms for the assignment and use of resources, it is possible to predict how differences in property rights affect economic activity.⁴

In the past, references to property rights, at least in developing economic areas, were limited to land and other tangible assets.⁵ Today, however, state-created legal rights in knowledge, technology and innovation—generally referred to as “intellectual property” (IP)—are a

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1. Richard T. Rapp & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, 24 J. WORLD TRADE 75, 77 (Oct. 1990) (individuals expect property rights that a government grants will insure that these individuals are not deprived of value generated from their efforts).

2. *Id.*

3. *Id.*

4. Gary D. Libecap, *Property Rights in Economic History: Implications for Research*, 23 EXPLORATIONS IN ECONOMIC HISTORY 227 (1986) (analyzing evolution of property rights in the area of natural resources and cautioning that to utilize property rights as an indication of economic growth, one should consider factors such as transaction costs and political influences).

5. Rapp & Rozek, *supra* note 1, at 78 (explaining that by the post-modern industrialization period, intellectual property rights became a prominent focus of property rights).

focal point of debate around the world.⁶ The debate generally centers on how the granting of these IP rights, generally referred to as patents, copyrights, trademarks and trade secrets, affects the developed northern hemisphere countries and the developing southern hemisphere countries. Issues of particular importance include the use of IP rights as incentives for innovative activities in both developed and developing countries and the proper set of rules to invoke to protect the often divergent interests of the technology-rich, developed northern countries and the less prosperous, developing southern countries that typically must "import" technology to facilitate economic growth and development.

This article addresses certain of the key issues on the international scene relating to economic development, incentives for innovation, and the creation of property rights in new technologies. After briefly outlining and defining the IP rights typically recognized around the world, this article discusses perceived deficiencies in international IP protection which have been noted by U.S. firms. Next, this article summarizes recent multilateral and bilateral negotiations on the subject of IP rights and comments on their prospects for future success. Using the area of pharmaceuticals as an example, this article concludes with an analysis of the difficulties associated with any resolution of the IP debate, particularly in areas where the recognition of property rights may conflict with the general health and welfare of a society as a whole.⁷

I. LEGAL AND REGULATORY FRAMEWORK FOR DEFINING AND PROTECTING INTELLECTUAL PROPERTY

The global debate regarding the protection of IP rights converges in two distinct areas: (1) the scope of protectable subject matter, which is defined by statute and case law in each country; and (2) the enforcement of IP rights established by law. Indeed, observers in developed countries express growing concern over limitations that are increasingly imposed on legal rights in specified technical areas such as pharmaceuticals and com-

6. The potential breadth of the issue, at least in relation to economic development, can be appreciated by recognizing that patent rights in genetically engineered mice can be granted. Rohini Acharya, *Patenting of Biotechnology: GATT and the Erosion of the World's Biodiversity*, 25 J. WORLD TRADE 81, 85 (Dec. 1991). New advancements, particularly those developed through biotechnological research, threaten to displace traditional "trading goods" in the agricultural sector, thereby impeding the ability of agrarian countries to participate in the global trading order. In effect, farmers are being displaced from their potential innovative role in the agricultural field. *Id.*

7. For example, pharmaceutical products require substantial research and development expenditures, making return on investment an important consideration in deciding whether to proceed with any new product. However, for many developing countries, drugs and other pharmaceutical products are basic and essential goods that must be kept available even at the expense of private property rights. Julio Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures in Developing Countries*, 24 J. WORLD TRADE 81, 83 (Dec. 1990) (when developed countries have refused to issue patents, courts have inferred the reason to be that developed countries want to insure that there is competition within the market for these essential goods).

puter software. Moreover, these observers argue that the dwindling legal protections of IP rights are further undermined, if not wholly extinguished, by a persistent failure of local authorities to take the requisite steps to insure that violators are prosecuted.⁸

A. Purpose and Scope of IP Rights

A patent is an example of an IP right that is intended to provide an incentive to inventors to devote time and resources to developing new products and processes. In one sense, a patent operates as a reward in that it grants to an inventor certain legal rights against others who may seek to commercialize the results of the inventor's research without consent or approval.⁹ Without these legal rights, an inventor would have little incentive to engage in research, thereby discouraging the advancement of knowledge and technology.¹⁰

Presently, a patent right extends only to the border of the country in which the right has been granted. Thus, the holder of a U.S. patent can preclude others from using, making or selling the invention only in the United States¹¹ because protections in foreign countries may not be derived from a U.S. patent grant. If a foreign country has an established patent law regime that covers the subject matter of the invention, the inventor may be able to apply for a patent in that country and thereby preclude others from unauthorized use or sale of the invention in that market.¹² However, if the foreign country does not provide appropriate

8. *Id.* at 81.

9. Thomas Mesevage, *The Carrot and the Stick: Protecting U.S. Intellectual Property in Developing Countries*, 17 *RUTGERS COMPUTER & TECH. L.J.* 421, 446 (1991) (patent is considered a "just reward" for services inventor renders to society).

10. A United States patent holder generally has the right, during the term of the patent, to exclude others from making, using or selling the invention covered by the patent within the United States borders. 35 U.S.C.S. § 154 (Law. Co-op. Supp. 1992) (contents and terms of a U.S. patent). During this monopoly-like term, the patent holder may be able to recoup the costs incurred as a result of the development process. By licensing the right to make, use or sell the invention, the patent holder may recover some of the development expenses through royalties. *Id.* § 261 (ownership and assignments). In actuality, knowledge is advanced since, as a condition of the patent grant, the inventor must describe the invention in the patent application, which is published following the grant of the patent. *Id.* §§ 111, 112 (listing certain specifications required in patent applications and describing what such specifications entail). Publication allows others to discover or learn about the patented subject matter, even though they are precluded from practicing the invention until the patent has expired.

11. *Id.* § 154.

12. For an example of a treaty extending protection of industrial property or commercial establishments to non-nationals, see Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 25 Stat. 1372, T.S. No. 379, as revised by Act of Brussels, Dec. 14, 1900, 32 Stat. 1936, T.S. No. 411; Act of Washington, June 2, 1911, 37 Stat. 1645, T.S. No. 579; Act of Hague, Nov. 6, 1925, 47 Stat. 1789, T.S. No. 834; Act of London, June 2, 1934, 53 Stat. 1748, T.S. No. 941; Act of Lisbon, Oct. 31, 1958, 13 U.S.T. 1, T.I.A.S. No. 4931; Act of Stockholm, July 14, 1967, 21 U.S.T. 1583, 1629, 1631, T.I.A.S. No. 6923, 828 U.N.T.S. 305, 313 [hereinafter Paris Convention], reprinted in 2A J. BAXTER, *WORLD PATENT LAW AND PRACTICE* 3-22 (1989). A number of international conventions and treaties now allow inven-

patent protection, the inventor will be unable to prevent others in that country from using or selling the invention.¹³

In the world today, IP laws are far from uniform. This inconsistency reflects the fundamental schism that exists between developed and developing countries regarding both the benefits and perceived dangers of property rights in valuable technologies. An inventor in a developed country seeks strong IP protection to prevent those in developing countries from "free-riding" on his work and to establish additional markets through which to recover costs. On the other hand, the governments of many developing countries are reluctant to provide IP protection for foreign inventions, since such protection works as a disincentive to local innovators building their own research capabilities¹⁴ and, perhaps more importantly, allows foreign firms to exercise undue control over the availability and affordability of the protected items.¹⁵

B. *Legal Framework for Defining IP Rights*

In addition to patents, other forms of IP rights include trade secrets, copyrights, trademarks, and any form needed to protect knowledge or technology that does not fall neatly into a listed category.¹⁶ Covering a broad range of industries and information types, IP rights protect new and useful products and processes, valuable and relative secret business information, original intellectual works, and names and symbols utilized to identify and distinguish commercial goods.¹⁷

tors to obtain protection in various countries without burdensome application procedures. However, the utility of these conventions depends on the scope of protection actually available in the member states.

13. For example, a United States inventor obtains a patent for Product X in the United States. A patent for Product X is not available under the laws of Overseas Country. An industrial firm in Overseas Country subsequently obtains Product X, as well as the patent application covering the product which was published in the United States. The industrial firm in Overseas Country then uses the information to copy Product X and offer it for sale in Overseas Country. The United States inventor cannot prevent sale of Product X in Overseas Country, although it can seek an injunction of imports into the United States from Overseas Country. Since the "copying firm" does not have a patent covering Product X, the original inventor can enter the market in Overseas Country. However, the return on investment will be significantly decreased as a result of the local competition.

14. Mesevage, *supra* note 9, at 441 n.94.

15. Since developed countries dominate research and technology, it is the developed-country consumers who drive the inventions, rather than the needs of the developing countries. *Id.* at 441. If the granting of IP protections to inventors of developed nations decreases local innovation in developing countries, then one may assume that the developing countries possess research capacities. Namely, such an argument requires that the developing country have the potential to innovate with research and development infrastructures in place. However, since developing countries generally have little or no ability to generate new products which might compete with firms in developed countries, such an argument may be rebutted if the innovations which are allegedly discouraged could not feasibly be achieved.

16. *Id.* at 439.

17. See Paris Convention, *supra* note 12, art. 1(3), 21 U.S.T. 1630, 828 U.N.T.S. 311 ("Industrial property shall be understood in the broadest sense . . .").

1. Patents

A patent is the exclusive right granted by a government for an inventor to manufacture, use, or sell an invention within the national territory, for a certain number of years.¹⁸ Patents may be granted for new and useful products and manufacturing processes, as well as for methods of use of new or existing products.¹⁹ Some nations, including the United States, extend patent protection to designs and plants. Whoever makes, uses, or sells the patented invention within the granting jurisdiction without the consent of the patent holder infringes²⁰ the patent, and the holder may be entitled to various remedies, such as damages and injunctive relief.²¹ Unsuccessful efforts to harmonize patent laws worldwide have occurred in a variety of multilateral forums. Among the most common concerns raised by observers in developed countries are the following:²²

a. Patentability precluded by statute. Presently, a country may specify the statutory scope of IP rights by establishing its own definition of the types of products for which a patent may be granted. In many cases, a country will explicitly preclude patentability for specific products, such as chemicals and pharmaceuticals. The United States has urged that patent protection be made available for *all* products and processes that satisfy the criteria of novelty, utility and non-obviousness.²³

b. Patent term. The term or time period granted for patent protection varies by country. Often, the patent term in developing countries is much shorter than the patent term granted in major developed countries. Developing countries typically extend patent terms no longer than five years. The United States seeks a minimum term for patent protection of at least twenty years from the date that the patent application is filed.²⁴

c. Early lapse and compulsory licensing. In developing countries,

18. See 35 U.S.C.S. § 154 (Law. Co-op. Supp. 1992). See also RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 1420 (Stuart Berg Flexner ed., 2d ed. 1983).

19. See 35 U.S.C.S. § 154 (Law. Co-op. Supp. 1992) (contents and terms of patent). In other countries, governments may issue lesser forms of protection, such as utility models, petty patents, inventors' certificates, as well as patents of importation, patents of improvement, and certificates of addition. These lesser forms of patent protection generally coexist with regular patent protection and may be available when regular patent protection is denied or unobtainable. The Paris Convention, *supra* note 12, at art. 2-3, 21 U.S.T. 1631, 828 U.N.T.S. 313, provides for equal treatment toward nationals among member states with respect to patent rights and establishes certain filing priorities for patent applications. The Paris Convention has been supplemented in some respects by the Patent Cooperation Treaty, 35 U.S.C.S. §§ 200, 351, 361, 371 (Law. Co-op. 1981 & Supp. 1992).

20. For the U.S. statute that explains infringement, see 35 U.S.C.S. § 271 (Law. Co-op. 1981 & Supp. 1992).

21. *Id.* § 281.

22. Issues of concern are adapted from U.S. INT'L TRADE COMM'N, FOREIGN PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE EFFECT ON U.S. INDUSTRY AND TRADE, ITC Pub. No. 2065, 1-5, -6, 3-5, -6 (Feb. 1988) [hereinafter USITC STUDY] (on file with Wake Forest Law Review).

23. See Nogués, *supra* note 7, at 83.

24. *Id.*

patent rights are often subject to early termination because the patented invention or process has not been used, or "worked," in the country during a specified period.²⁵ Alternatively, failure to work an invention may result in the grant of a license to third parties at low royalty rates without the consent of the patent holder.²⁶ Compulsory licensing also becomes a problem when the state retains authority to license patented inventions to others in the name of the "public interest."²⁷ The United States has argued that compulsory licensing be limited to certain clearly defined situations.²⁸

d. Narrowed patent claims. Even in those cases where the apparent scope of patent protection is quite broad, administrative practices of the patent authority may force claims to be applied so narrowly that individuals seeking to can easily avoid claim coverage. As well, these individuals may obtain patents of their own by incorporating only slight variations on the invention without true innovation.²⁹

2. Trade secrets

A trade secret protects information, such as "a formula, pattern, compilation, program, device, method, technique, or process."³⁰ In order for such information to be classified as a trade secret, it must generate

25. "Working" requirements often mandate that the patented invention be used in the country within a specified period of time. Mere importation of the patented goods may not be sufficient to satisfy the working requirements, given the desire of the local country to provide incentives for the local manufacture of goods. Developed countries generally claim that the time periods are shorter than is realistic or that the required working is not commercially feasible in light of local resources. For examples of the working requirements of Brazil, Korea, Taiwan, and Thailand, see USITC STUDY, *supra* note 22, at app. E-16, -19, -22, -24. See also Paris Convention, *supra* note 12, art. 5(A)(2)-(A)(3), 21 U.S.T. 1630, 1636-37, 828 U.N.T.S. 305, 321 (providing that forfeiture of a patent may result if the granting of a compulsory license could not have prevented abuses--particularly the "failure to work").

26. For a discussion of work requirements, see USITC STUDY, *supra* note 22, at app. E-2, -16, -18, -19, -21, -22, -24 (working requirements for Brazil, Japan, Korea, Mexico, Taiwan, and Thailand); see generally Paris Convention, *supra* note 12, art. 5(A)(2), 21 U.S.T. 1630, 1636-37, 828 U.N.T.S. 305, 321 (1967).

27. USITC STUDY, *supra* note 22, at app. E-17, -18, -19, -21 (Brazil, Japan, Korea, and Mexico can issue compulsory licenses in the public interest); see generally Paris Convention, *supra* note 12, art. 5(A)(2), 21 U.S.T. 1630, 1637, 828 U.N.T.S. 305, 321 (1967).

28. See *House Panel Holds Oversight Hearing on Trade and Intellectual Property*, [May-Oct.] Pat. Trademark & Copyright J. (BNA) No. 940, at 318 (July 27, 1989) [hereinafter *Oversight Hearing*] (U.S. trade representative proposes that compulsory licenses be issued only in "extraordinary circumstances" such as national emergencies or antitrust violations).

29. USITC STUDY, *supra* note 22, at app. G-3 (Table G-2, Key 7) (U.S. firms report narrowed patent claims in several countries). A patent application consists of one or more "claims" for the invention that are intended to demonstrate its novelty and utility in relation to existing products and processes, or the "prior art." The breadth, and hence the value, of a patent is determined by the scope of the claims allowed by the patent examiner. For a discussion of patent application and specification, see 35 U.S.C.S. §§ 111, 112 (Law. Co-op. 1981 & Cum. Supp. 1992).

30. UNIF. TRADE SECRETS ACT § 1(4), 14 U.L.A. 437, 438 (1985 & West Cum. Supp. 1992).

“independent economic value” by not being generally known, and efforts to maintain its secrecy must be reasonable.³¹ Violations of trade secrets, referred to as “misappropriations,” include:

- Acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means;³²
- Disclosure or use of a trade secret of another without express or implied consent by a person who
 - (A) used improper means to acquire knowledge of the trade secret; or
 - (B) at the time of disclosure or use, knew or had reason to know that his knowledge of the trade secret was
 - (I) derived from or through a person who had utilized improper means to acquire it;
 - (II) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or
 - (III) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or
 - (C) before a material change of his position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.³³

Trade secret protection does not require any governmental filings or approvals and may well be more effective than a patent in certain areas. Trade secret protection is particularly important when the patent application process is delayed or “publication” of the protected subject matter, a required condition of the patent grant, will unduly harm the overall competitive value of the information.³⁴

Many countries do not recognize trade secret protection, and no international agreement exists with respect to the appropriate subject matter for such protection.³⁵ Even where some form of protection is granted,

31. A trade secret is information such as “a formula, pattern, compilation, program, device, method, technique, or process” which:

- (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and
- (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Id. § 1(4)(i)-(ii).

32. The Act defines improper means as “theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, or espionage through electronic or other means.” *Id.* § 1(1).

33. *Id.* § 1(2).

34. Publication of the patent application is required as a condition of the grant of the patent monopoly. Persons can use the information in the patent application to enhance their own understanding of the underlying technology and, possibly, to develop enhancements or improvements which fall outside of the scope of the original patent monopoly. For a discussion of patent application and specification, see 35 U.S.C.S. §§ 111, 112 (Law Co-op. 1981 & Cum. Supp. 1992).

35. For a listing of countries reported by U.S. firms as having no trade secret protection, see USITC STUDY, *supra* note 22, at app. G-5 (Table G-4, Key 1). See generally U.S. Proposal for Negotiations on Trade-Related Aspects of Intellectual Property Rights, [May-Oct.] Pat. Trademark & Copyright J. (BNA) No. 852, at 667 (Oct. 22, 1987) (proposal for

a country may limit the period of any obligation which the trade secret owner may impose upon the recipient to maintain the secret in confidence.³⁶ In other countries, trade secret protection is limited to persons in privity of contract with the owner of the secret. The owner has no right of action against a third party who acquires and uses the secret without authority or who induces a breach of any trade secret protection agreement.³⁷

3. Copyrights

Copyright protection is available to authors of original literary, dramatic, musical, artistic and other intellectual works.³⁸ For the specified term, the copyright owner has the exclusive right to:

- Reproduce the copyrighted work in copies or phonorecords.
- Prepare derivative works based upon the copyrighted work.
- Distribute copies or phonorecords of the copyrighted work to the public by sale or other transfer of ownership, or by rental, lease, or lending.
- Perform the copyrighted work publicly in the case of literary, musical, dramatic, and choreographic works, pantomimes, and motion pictures and audiovisual works.
- Display the copyrighted work publicly in the case of literary, musical, dramatic, and choreographic works, pantomimes, and pictorial, graphic, or sculptural works, including individual images of a motion picture or other audiovisual work.³⁹

Violations of the exclusive rights of the copyright owner are referred to as "infringement" or "piracy."

As a general rule, U.S. works are entitled to the same copyright protection in foreign countries as local law grants to the holders of copyrights in that country. However, this "protection" is often deemed inadequate because of deficiencies in the laws of those countries.⁴⁰ Among the most

international agreement encompassing trade secrets).

36. Restrictions on the duration of confidentiality agreements are generally imposed in the context of government review of trade secret licenses and technology transfer agreements. While the country may permit a patent holder to restrict the ability of a licensee to use the patent beyond the term of the license, assuming that the patent itself has not yet expired, a number of countries require that trade secrets, sometimes referred to as "know-how," be completely transferred to the licensee by the end of the term of the agreement. For example, see Resolution 22 of February 27, 1991: technology transfer regulations in Brazil require non-patented technology to be transferred, rather than licensed, to local companies as a condition for approval of a technology transfer arrangement. *INPI Issues New Rules on Technology Transfers*, 5 World Intell. Prop. Rep. (BNA) 199 (Aug. 1991).

37. In the United States, a trade secret owner can proceed against a third party who obtains the trade secret by improper means, even though no agreement exists between the trade secret owner and the third party which creates a direct obligation on the part of the third party to maintain the secrecy of the trade secret. For a discussion of disclosure through improper means, see *supra* note 32 and accompanying text.

38. 17 U.S.C.S. § 102(a) (Law. Co-op. 1978 & Cum. Supp. 1992).

39. *Id.* § 106.

40. USITC Study, *supra* note 22, at 4-15, -18 (results of questionnaire distributed to

common concerns are the following:⁴¹

a. Failure to protect new works and media forms. Although foreign copyright laws cover some types of works, they fail to cover other, newer works including sound recordings, computer programs, and other print or electronic compilations such as data bases.⁴² As well, foreign copyright laws do not encompass certain media such as videocassettes or computer programs in ROM, which embody new works.⁴³

b. Inadequate exclusive rights. Some foreign copyright laws grant only a portion of the exclusive rights enjoyed by U.S. authors.⁴⁴ For example, a copyright owner in a foreign country may be denied the exclusive right to cable retransmissions, public performance or display, or electronic distribution. Even when exclusive rights are granted, these rights may be subject to broad exceptions for public performances in hotels, film clips, and educational photocopying.⁴⁵

c. Compulsory licensing. As with patents, copyrights may be subject to onerous compulsory licensing provisions in some cases.⁴⁶

d. Term of protection. As with patents, in many developing countries the term of copyright protection is less than in the major developed countries.⁴⁷

U.S. firms surveying intellectual property protections abroad). For a summary of copyright protection offered by Brazil, Japan, Korea, Mexico, Taiwan, and Thailand, see *id.* at app. E-2, -15. See also *Administration's Statement on Protection of U.S. Intellectual Property Rights Abroad, Draft Bill Entitled "Intellectual Property Rights Improvement Act of 1986," and Section-By-Section Analysis of Draft Bill*, [Nov.-Apr.] Pat. Trademark & Copyright J. (BNA) No. 775, at 506 (Apr. 10, 1986) [hereinafter *Administration's Statement*] (expresses general concerns of U.S. regarding international protection of IP rights).

41. The common concerns are based on the USITC STUDY, *supra* note 22, at 3-2, -5 & app. E-2, -15.

42. For a general discussion of the failure to protect copyrighted works, see *U.S. Proposal on Trade-Related Aspects of Intellectual Property Rights*, [May-Oct.] Pat. Trademark & Copyright J. (BNA) No. 980, at 79, 80 (May 10, 1990) (U.S. proposal to protect works such as computer programs and databases).

43. For a summary of the scope of copyright protections, see USITC STUDY, *supra* note 22, at app. E-2, -15.

44. In responding to a questionnaire, U.S. firms most often cited Brazil and the Republic of Korea as providing inadequate exclusive rights for copyrights. *Id.* at app. G-2 (Table G-1, Key 3).

45. *Id.* at 3-2, -5. For example, there is disagreement in negotiations over trade-related IP rights (TRIPs) issues regarding whether performers or broadcasters should have the right to prohibit people from recording performances. *Uruguay Round Crashes to a Halt; TRIPs, Other Negotiations on Hold*, 5 World Intell. Prop. Rep. (BNA) 16, 19 (Jan. 1991).

46. For an overview of the United States' concern about compulsory licensing, see generally *Administration's Statement*, *supra* note 40, at 507. In fact, the European Community has accused the United States of discriminating against foreign inventions and reimposing "de facto compulsory licenses for defense-related products." *EC Officials Express Concern Over Unresolved TRIPs Issues*, 5 World Intell. Prop. Rep. (BNA) 215 (Aug. 1991).

47. Several U.S. firms responding to the questionnaire about the adequacy of copyright terms believe that terms are too short in lesser developed countries as compared to major developed countries. USITC STUDY, *supra* note 22, at app. G-3 (Table G-2, Key 3) (U.S. firms most often cite Brazil and Mexico, while no U.S. firms cite West Germany, Japan, or the United Kingdom).

4. Trademarks

A trademark is a "word, name, symbol or device, or any combination thereof," adopted and used by a merchant or manufacturer to identify his goods and to distinguish them from goods that may be manufactured or sold by others.⁴⁸ The owner of a trademark has a right of action against "counterfeiters," persons who use a representation or copy of a registered trademark or service mark without the owner's authorization.⁴⁹ The trademark owner may also prevent others from offering for sale, distribution, or advertising any goods or services using a copy or colorable imitation of a trademark or service mark which is so similar to the owner's mark that deception or confusion is likely to result.⁵⁰

Trademarks can operate as both a valuable source of goodwill and a key marketing tool in foreign markets. As such, U.S. firms have expressed concern regarding practices in some foreign countries that amount to "expropriation" of trademarks and service marks. Among the areas in which foreign laws have been found to be deficient are the following:⁵¹

a. *No protection of "well-known" marks.* Unregistered, but internationally "well-known," marks are often not protected against registration or use by unauthorized local parties.⁵²

b. *Narrow definitions of infringement.* Applications for use of a mark are often granted, usually to national companies, even though the mark is very similar to a preexisting mark of another company.⁵³

c. *Proof of use requirements.* Many countries require the owner of a trademark to present proof that the mark has actually been used as a condition for renewal of the registration. In many cases, "continuing commercial use" must be demonstrated within a perceived unduly short period,⁵⁴ particularly when use has actually been delayed or precluded by government action without a corresponding tolling period.⁵⁵ In addition, some countries only allow use by the owner, as distinguished from the owner's licensees or distributors, to be offered as proof of use.⁵⁶ This requirement substantially affects the form of local investment by the owner.

48. Lanham Act, 15 U.S.C. § 1127 (1988). See also BLACK'S LAW DICTIONARY 1493 (6th ed. 1990) (a trademark is a "distinctive mark of authenticity, through which the products of particular manufacturers or vendible commodities of particular merchants may be distinguished from those of others").

49. A service mark is a mark or device used to identify a service, such as transportation or insurance, offered to customers. For a comparable definition, see Lanham Act, 15 U.S.C. § 1127 (1988).

50. *Id.* § 1114(1)(a).

51. These deficiencies are based on results of the USITC STUDY, *supra* note 22, at 1-7.

52. In responding to the questionnaire, U.S. firms frequently cited several countries for offering no protection of "well-known" marks—Brazil, the Republic of Korea, Taiwan, Mexico, and Japan were cited most often. *Id.* at 1-7, 3-7, -8 & app. G-4 (Table G-3, Key 3).

53. *Id.* at 1-7, 3-7, -8.

54. *Id.* For a summary of countries cited by U.S. firms as having difficult, proof-of-use requirements, see *id.* at app. G-4 (Table G-3, Key 2).

55. *Id.* at 1-7.

56. *Id.*

d. Trademark licensing restrictions. Trademark license arrangements are often subject to unreasonable conditions by government authorities, including royalty restrictions, technology transfer limitation, or mandatory joint venture requirements.⁵⁷

e. Circumscribed usage or "linking." Some countries effectively diminish the value of a trademark by requiring the trademark to be used in a specified form or manner or used in conjunction with another trademark.⁵⁸

f. Compulsory licensing. Some countries have compulsory licensing provisions for trademarks and service marks. Although the United States has conceded the need, in certain instances, for compulsory licenses with respect to patents, it remains sharply opposed to any form of compulsory licensing in the trademark and servicemark area.⁵⁹

5. Other forms of intellectual property rights—semiconductor mask works and proprietary technical data

In the United States, the Semiconductor Chip Protection Act⁶⁰ affords protection for original mask works⁶¹ that are fixed in a semiconductor chip product⁶² by, or under the authority of, the owner of the mask work, which has been registered or commercially exploited anywhere in the world. The owner, or one authorized by the owner, retains the exclusive right (1) to reproduce the mask work by optical, electronic, or other means; (2) to import or distribute a semiconductor chip product which embodies the mask work; or (3) to cause another person to take either of these actions.⁶³ Nonetheless, the laws of many countries often expressly or effectively deny mask work protection. In such countries, *sui generis* protection is the only available—though usually ineffective—means of

57. *Id.* at 1-8, 3-7, -8. Brazil, Taiwan, Mexico, and the Republic of Korea were cited most often by U.S. firms as having unreasonable licensing requirements. *Id.* at 3-7, -8.

58. *Id.* Countries cited by U.S. firms for circumscribed usage or "linking" are Mexico, Brazil, the Republic of Korea, India, Venezuela, and Taiwan. *Id.*

59. *Id.* See also *Oversight Hearing*, *supra* note 28, at 318 (USTR proposes prohibiting compulsory licenses for trademarks).

60. 17 U.S.C.S. § 901 (Law. Co-op. Supp. 1992).

61. Section 901(a)(2) of the Semiconductor Chip Protection Act defines a "mask work" as a series of related images, however fixed or encoded—

(A) having or representing the predetermined, three-dimensional pattern of metallic, insulating, or semiconductor material present or removed from the layers of a semiconductor chip product; and

(B) in which series the relation of the images to one another is that each image has the pattern of the surface of one form of the semiconductor chip product.

Id. § 901(a)(2). Violations of rights in mask works are referred to as infringement or piracy. USITC STUDY, *supra* note 22, at 1-5.

62. A semiconductor chip product is "the final or intermediate form of any product (A) having two or more layers of metallic, insulating, or semiconductor material, deposited or otherwise placed on, or etched away or otherwise removed from, a piece of semiconductor material in accordance with a predetermined pattern; and (B) intended to perform electronic circuitry functions." 17 U.S.C. § 901(a)(1) (1984).

63. See USITC STUDY, *supra* note 22, at 1-5.

protection.

Proprietary technical data include any data or information submitted to a governmental agency for a regulatory review of new products, such as pharmaceutical and chemical products.⁶⁴ While the governmental body involved generally must maintain the confidentiality of proprietary technical data for a set period of time, many countries unreasonably limit the duration of protection from public disclosure.

C. Enforcement Procedures

The efficacy of any legal regime for the protection of IP rights depends upon the ability and willingness of local regulators and courts to enforce those rights. Many U.S. firms conducting business overseas have reported a consistent lack of cooperation from foreign authorities in the eradication of counterfeiting and infringement activities. The following inadequacies have been observed for each type of IP protection discussed above:

- No preliminary or final injunctive relief;
- Lack of seizure and impoundment relief;
- Lack of exclusion of infringing imports;
- Lack of compulsory court processes and discovery;⁶⁵
- Inadequate civil remedies, usually in monetary damages, which preclude effective deterrence;
- Inadequate fines or other criminal penalties;
- Unreasonably slow enforcement processes during which the illegal activity continues;
- Systematic discrimination against foreigners by enforcement officials;
- Inadequate training and resources for enforcement;⁶⁶
- Court decisions which have been widely recognized as biased against foreigners, and judiciaries which are not independent of local political influence;
- Officials who are, or are perceived as, likely to engage in bribery and other corrupt practices.⁶⁷

II. UNITED STATES PERCEPTIONS OF THE ADEQUACY OF FOREIGN IP PROTECTION

On March 12, 1987, at the request of the United States Trade Representative (USTR), the United States International Trade Commission (USITC) instituted an investigation to estimate, to the extent possible,

64. *Id.*

65. "Lack of discovery can exacerbate the enforcement of process patents, inasmuch as the burden of proof rests with a party, normally the plaintiff, who[sic] is not in position to determine facts that are solely within the control of the alleged infringer." *Id.* at 1-9.

66. In many cases, enforcement officials are so poorly trained and enforcement operations are so insufficiently funded that countries cannot meet even minimal levels of enforcement. *Id.*

67. These inadequacies were noted in the USITC STUDY, *supra* note 22, at 1-8, -9.

the impact on U.S. trade attributable to deficiencies in the protection of the IP rights of American firms provided by foreign countries.⁶⁸ In particular, the USITC attempted to evaluate the dollar value of sales lost to counterfeit and other infringing products imported into the United States and goods exported from the United States, as well as the lost tax revenues from both U.S. and foreign sources.⁶⁹ The USITC sought to identify the products, source countries, markets, and protection deficiencies that posed the most serious problems for U.S. firms.⁷⁰

The USITC surveyed 736 domestic companies, including each of the Fortune 500 companies, appropriate members of the American Business Conference, and smaller firms concentrated in industries known to depend on royalties or sales of goods protected by IP.⁷¹ Of those firms that responded, aggregate worldwide losses as a result of inadequate IP protection in 1986 were estimated to be \$23.8 billion, or 2.7% of sales affected by IP.⁷² Scientific and photographic goods reported the greatest losses, accounting for 21% of the total worldwide losses.⁷³ Other major industries which were significantly affected included computers and software (17%), electronics (10%), motor vehicles and parts (9%), entertainment (9%), and pharmaceuticals (8%).⁷⁴

A. Regime and Enforcement Inadequacies

The USITC study focused on the incidence rate of various inadequacies in foreign IP regimes and enforcement procedures. A number of general conclusions emerged from the data. First, most source countries, or countries which produce counterfeit and infringing goods, also provide markets for the counterfeited and infringing goods—whether produced in the country or imported.⁷⁵ Second, the countries most frequently cited for IP inadequacies also manufacture substantial quantities of the infringing goods.⁷⁶ Third, with the possible exception of audio or video piracy, newly industrialized countries produce a substantial proportion of infringing goods.⁷⁷

68. *Id.*

69. *Id.*

70. *Id.*

71. USITC STUDY, *supra* note 22, at 1-1. Foremost among these industries are computer software and hardware, motion picture, record and tape, fashion wearing apparel, toys, and sporting goods. *Id.* Questionnaires were also provided to 14 major trade associations to obtain responses on an industry basis and to solicit voluntary responses from their membership. Modified versions of the questionnaire were provided to the U.S. Chamber of Commerce. The U.S. Chamber of Commerce distributed these questionnaires to the American Chambers abroad to collect data on a country basis. *Id.*

72. *Id.* at 4-1, -2. For an illustrative estimate of losses for U.S. industry as a whole, see *id.* at app. H.

73. *Id.* at 4-1, -2.

74. *Id.*

75. *Id.* at 3-2.

76. *Id.*

77. *Id.*

1. *Patents*

One hundred and twenty-two U.S. companies cited a total of fifty-four countries for inadequate protection of patent rights.⁷⁸ Mexico, Brazil, Taiwan, Korea, and Japan were the countries most often reported.⁷⁹ Common deficiencies included no patent protection and unrealistic working requirements.⁸⁰ The most commonly observed remedy and enforcement deficiencies were unreasonably slow enforcement and politically-motivated court decisions.⁸¹

2. *Trade secrets*

Ninety-four U.S. companies reported deficiencies in trade secret protection for forty-seven countries.⁸² The most frequently reported countries were Mexico, Korea, Brazil, Taiwan, China, and Japan.⁸³ No protection against third parties was the most commonly cited deficiency.⁸⁴ Slow enforcement and inadequate civil and criminal penalties were the most often noted remedy and enforcement deficiencies.⁸⁵

3. *Copyrights*

Eighty-four U.S. companies cited inadequate protection of copyrights in a total of fifty-two countries.⁸⁶ The most frequently reported countries included Taiwan, Brazil, Korea, Indonesia and Argentina.⁸⁷ Lack of protection for American works in general, or for specific American works, and burdensome substantive or procedural formalities were the most often noted deficiencies.⁸⁸ Inadequate civil and criminal penalties were the most frequently observed remedy and enforcement deficiencies.⁸⁹

4. *Trademarks*

One hundred and thirty-three U.S. companies reported inadequate protection of trademark rights for sixty-six countries.⁹⁰ The countries most frequently cited were Mexico, Taiwan, Brazil, Korea, and Indonesia.⁹¹ Stringent licensing requirements and difficulty in demonstrating use for renewal were the most commonly observed deficiencies.⁹² Inadequate

78. *Id.* at 3-5.

79. *Id.* at 3-5, -6.

80. *Id.*

81. *Id.* at 3-5, -7, & Tables G-2, G-8.

82. *Id.* at 3-9.

83. *Id.* at 3-9, -10.

84. *Id.* at 3-9.

85. *Id.* at 3-9, -10 & Tables G-4, G-10.

86. *Id.* at 3-2.

87. *Id.* at 3-2, -3.

88. *Id.* at 3-3, -4.

89. *Id.* at 3-4, -5 & Tables G-1, G-7.

90. *Id.* at 3-7.

91. *Id.*

92. *Id.*

civil and criminal penalties, no preliminary or final injunctive relief, and limited training and resources for enforcement were the most commonly noted remedy and enforcement deficiencies.⁹³

5. *Other forms of intellectual property rights*

Inadequate protection of mask works was reported in twenty-six countries by fourteen U.S. companies.⁹⁴ Korea, West Germany, and Japan were most often cited.⁹⁵ However, companies reported only deficiencies of legal protection and inadequate *sui generis* coverage.⁹⁶ Inadequate civil and criminal penalties, no preliminary or final injunctive relief, lack of seizure and impoundment, and lack of exclusion of imports were the remedy and enforcement deficiencies noted.⁹⁷

B. *Secondary Barriers to Investment and Trade*

The USITC study also noted that other barriers to trade and investment may effectively diminish the value of any IP protection, either by curtailing potential sales, revenues, and profits, or by discouraging foreign innovators from entering the market.⁹⁸ Among the areas of concern cited by U.S. companies were: (1) quotas on imported goods; (2) discriminatory tax treatment; (3) restrictions on the establishment of local offices by foreign firms; (4) investment restrictions and local ownership requirements; and (5) price controls and embargoes.⁹⁹ As an example, one form of barrier which arises partly from inadequate local IP protection, is the prohibition on importation of "locally-produced" goods.¹⁰⁰ In many cases, local firms copy a foreign patented product to become a "local producer" and then petition the government to forbid the importation of goods manufactured by the foreign firm.¹⁰¹

The USITC study, as well as other industry-specific surveys completed in recent years, has served as a benchmark for official U.S. policies in multilateral and bilateral negotiations in the area of IP rights. In particular, countries such as Brazil and Taiwan, which are consistently identified by American firms as deficient in the IP area, have been the focus of intense efforts to improve existing legislation and practices.

93. *Id.* at 3-8 & Tables G-3, G-9.

94. *Id.* at 3-10.

95. *Id.*

96. *Id.*

97. *Id.* at 3-10, -11 & Tables G-5, G-11.

98. *Id.* at 3-12.

99. *Id.* at 3-12, -13.

100. *Id.* at 3-13.

101. *Id.* at 3-12. Pharmaceutical firms indicated that this was a common practice in the Republic of Korea. *Id.*

III. MULTILATERAL AND BILATERAL INITIATIVES RELATING TO INTERNATIONAL PROTECTION OF IP RIGHTS

The expansion of international trade over the past two decades has heightened the importance of IP matters in ongoing international trade and development discussions. Developed and developing countries often do not share the same objectives. Developed countries, with an existing stock of technological capabilities and a desire to penetrate new markets, generally seek enhanced protection for their technical assets in foreign markets. Developing countries, recognizing the need to gain access to these new technologies to pursue economic growth, competitiveness, and independence, do not always agree that stronger IP laws will accomplish those objectives.

Resolution of the "North-South" debate over international standards on Intellectual Property rights has been the goal of several multilateral negotiation efforts in recent years. For example, the World Intellectual Property Organization (WIPO) has attempted to harmonize the world's patent law regimes.¹⁰² As well, developed countries such as the United States, arguing that IP matters have become inseparable from trade issues, have pushed to resolve various issues under the auspices of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT).¹⁰³ Finally, the United States, under the auspices of the USTR, has engaged independently in a number of bilateral activities involving IP issues.¹⁰⁴

A. Patent Law Harmonization Efforts

Although the Paris Convention provides a general framework for patent law regimes, many countries believe that true harmonization can occur only after a comprehensive multilateral treaty covering the protection and patentability of inventions is completed. In recent years, the WIPO Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions (WIPO Committee)¹⁰⁵ has at-

102. Although the Paris Convention provides a basic framework for international patent laws and procedures to facilitate the filing of international patent applications in two or more member countries, it fails to impose standards on its members which the United States believes may be necessary for strong protection. See generally Paris Convention, *supra* note 12.

103. The Uruguay Round has been described by Arthur Dunkel, Director-General of the GATT, as "an effort to reorder the basis for economic relationships [among] countries." Harry B. Ensley, *Intellectual Property Rights in the GATT*, 15 *NEW MATTER* 1, 1 (1990). The Uruguay Round, the eighth round of negotiations in the 42-year history of the GATT, was unique in its intent to address the issue of "trade related aspects of intellectual property rights, including trade in counterfeit goods." *Id.*

104. In the United States, a primary reason for concern regarding the enforcement of worldwide IP rights is the recent change in the composition of U.S. export trade. It has been noted that "[t]he share of U.S. exports that rely heavily on intellectual property (IP) protection (chemicals, pharmaceuticals, computers, software, sound recordings, books, movies, and scientific equipment) has more than doubled" since the end of World War II to reach a level that exceeds one-quarter of total U.S. exports. *Id.* at 10.

105. *Report on Seventh Session of WIPO Committee Meeting on Harmonization*, 4

tempted to draft such a treaty. The WIPO Committee originally intended to submit a final draft of the treaty to a Diplomatic Conference for approval in 1991;¹⁰⁶ however, it is now unclear when, if ever, a treaty agreement can be reached.

While the United States has supported, in theory, the general concept of harmonizing international patent laws, discussions during the WIPO process have led to serious controversy within and outside the United States. One of the most hotly debated issues has been whether the United States should abandon its "first-to-invent" filing system in favor of a "first-to-file" procedure that is universally adopted outside of the United States. A second controversial issue involves the proposed required publication of pending patent applications within a given period of time after filing, even where the patent has not yet been issued. Each of these provisions raises significant legal questions for the United States, which has traditionally placed a high premium on the rights of inventors.¹⁰⁷

Moreover, participants in the WIPO process would require several additional and major changes in the U.S. patent system, including amendments that would:

- Eliminate from the grace period publications or public uses by third parties who did not derive from the applicant.
- Accord foreign applicants a one-year grace period from their foreign priority date.
- Make prior public use, sale, or disclosure in foreign countries part of the prior art.
- Eliminate secret commercial use by the inventor or non-public sale before the grace period as a basis for invalidating patents.
- Accord prior art status, for novelty but not for obviousness, to unpublished U.S. patent applications as of their foreign priority date or their U.S. filing date, whichever is earlier, provided such U.S. applications later become published.¹⁰⁸

In addition, the United States would be required to:

- (a) discontinue granting patents for plant and animal varieties and processes for their production, methods of medical treatment for humans or animals, and nuclear or fissionable material; (b) eliminate the requirement for disclosure of the best mode contemplated by the inventor of carrying out his invention, or at least eliminate such requirement from priority documents; and (c) provide for prior user

World Intell. Prop. Rep. (BNA) 14 (Jan. 1990) [hereinafter *Seventh Session of WIPO*].
106. *Id.*

107. 56 Fed. Reg. 22,702-02 (May 16, 1991). See also *Patent Harmonization: Is the U.S. Running Out of Time?*, 4 World Intell. Prop. Rep. (BNA) 19, 20 (Feb. 1990) [hereinafter *Patent Harmonization*]. However, the United States has agreed to permit publication of pending patent applications, provided that publication can be withheld for up to 24 months after filing.

108. *Report on Diplomatic Conference for Patent Harmonization Treaty*, 5 World Intell. Prop. Rep. (BNA) 213 (Aug. 1991) [hereinafter *Patent Harmonization Treaty*].

rights.¹⁰⁸

Many commentators believed such wholesale modifications to the U.S. patent system would be too high a price to pay for patent harmonization. However, a number of other observers voiced a more pragmatic view which recognized, not only the growing importance of European and Asian trading partners, but also the value of the technology generated and utilized in those regions.¹¹⁰ The supporters of this latter position advocated a so-called "balanced package" which would secure counter-vailing benefits in foreign countries as consideration for U.S. changes to its patent system.¹¹¹

In February of 1991, just months before the planned diplomatic conference, the United States proposed adding a first-to-invent option to the WIPO Treaty.¹¹² This proposal, included in a letter from the United States to the WIPO Director General Commissioner of Patents and Trademarks, Harry F. Manbeck, Jr., cited three factors that influenced the official view of the United States: (1) the United States private sector's failure to support a change to the first-to-file system; (2) the inability of other countries to adhere to the schedule set forth for the GATT negotiations; and (3) the unavailability of the Patent Treaty Organization's (PTO) then recently-formed Advisory Commission on Patent Law Reform's (PLR Commission) deliberation on the first-to-file system.¹¹³

Although the timing and content of the Manbeck letter caused concern among the conference organizers,¹¹⁴ the WIPO conference commenced on schedule. In response to the United States' proposal, however, the WIPO leadership decided to shorten the conference by a week in order to hold a second session in 1992 to formally consider the first-to-invent option.¹¹⁵

At the first session of the Diplomatic Conference, at The Hague in June of 1991,¹¹⁶ the lack of support for the United States first-to-invent

109. *Id.* at 214.

110. *Patent Harmonization, supra* note 107, at 19-21.

111. *See generally id.*; *Seventh Session of WIPO, supra* note 105.

112. *USPTO Proposes First-to-Invent Option in Harmonization Treaty*, 5 World Intell. Prop. Rep. (BNA) 93 (Apr. 1991).

113. *Id.*

114. *PTC Section Debates Patent Changes at American Bar Association Meeting*, 5 World Intell. Prop. Rep. (BNA) 280 (Oct. 1991) [hereinafter *PTC Section Debates*]. Some participants believed the United States had reneged on what was understood as a promise, under the 1987 resolution of the ABA's Patent, Trademark and Copyright Law section, to support the first-to-file system. *Id.*

115. *Patent Harmonization Treaty, supra* note 108, at 213.

116. The following attended the Conference: a delegation of more than 80 Member States of the WIPO, two special delegations from the African Intellectual Property Organization and the European Patent Organization, observer delegations from Costa Rica, India, Peru, Thailand, and Venezuela, several intergovernmental organizations (the United Nations, GATT, EC, and the Latin American Economic System), and 36 non-governmental organizations, including the American Bar Association. *Id.* For a summary of the reaction of the ABA's Section of Patent, Trademark and Copyright Law to recent WIPO developments, see *PTC Section Debates, supra* note 114, at 280-81.

proposal became apparent.¹¹⁷ Moreover, the demise of other elements of the so-called "balanced package" appeared to be preordained. For example, any proposals that included language for the broad interpretation or for the prompt and effective enforcement of patents met with substantial opposition.¹¹⁸ In addition, the U.S. proposal for invention patentability in *all* subject matters, and various provisions related to filing, search, and examination procedures, were sharply criticized.¹¹⁹

The debates at the initial session of the Diplomatic Conference appeared to undermine any realistic hope that the United States would accede to the WIPO Treaty. Commissioner Manbeck, commenting on the events of the Diplomatic Conference, noted that the United States found several problems with the proposed treaty. Manbeck stated that unless substantial improvement in the laws and practices of other countries was initiated, it was not realistic to believe that the United States would join in the treaty. Manbeck also noted that acceptance of the changes proposed to existing patent law would require a substantial lobbying effort among various interest groups. Manbeck further questioned whether U.S. interests would find any merit in compromising over domestic practices when other countries remained unwilling to consider new provisions designed to improve foreign patent laws.¹²⁰

Since Manbeck's comments, attitudes in the United States regarding the essential "first-to-file" issue have significantly changed. The influential Section of Patent, Trademark, and Copyright Law of the American Bar Association rescinded its prior opposition to the "first-to-file" position and went on record as favoring, in principle, an amendment to the U.S. patent laws. Such an amendment would provide that, except in cases of derivation, the first to file a patent application among rival applicants for the same invention is entitled to the patent, provided that the first-to-file procedure is part of a comprehensive patent harmonization treaty wherein other countries agree to changes in their patent systems that are sufficiently beneficial to U.S. applicants.¹²¹ In addition, the PLR Commission recommended adoption of first-to-file¹²² and Congress has been asked to consider appropriate amendments to the patent law with respect thereto.¹²³ Moreover, the United States has previously agreed to permit

117. *Patent Harmonization Treaty*, *supra* note 108, at 213. See also *Sharp Differences on U.S. Proposal Marked Paris Union's Special Session*, 5 *World Intell. Prop. Rep.* (BNA) 151-52 (June 1991).

118. *Patent Harmonization Treaty*, *supra* note 108, at 214.

119. *Id.*

120. For excerpts of Commissioner Manbeck's remarks, see *id.* With regard to IP interests, the United States remains disenchanted with the lack of meaningful enforcement tools within the WIPO and, as a result, has turned toward the GATT and bilateral negotiations as the preferred means for obtaining IP protections.

121. Resolution 102-8 was adopted at the 1992 ABA Annual Meeting in San Francisco. See *Chair's Letter* 11 *PTC Newsl.* 9 (Fall 1992).

122. *Id.* at 29.

123. *Patent Harmonization Bills Introduced in House, Senate*, 6 *World Intell. Prop. Rep.* (BNA) 136 (May 1992).

publication of pending patent applications, provided that publication can be withheld for up to twenty-four months after filing.¹²⁴ This proposal was incorporated into the WIPO Treaty draft.¹²⁵

Apart from the difficulties associated with obtaining approval from the United States, the WIPO discussions demonstrate some of the disparate objectives of developing countries. A block of developing countries, the "Group of 77," introduced two new articles for discussion in late 1990. These articles:

would impose an obligation on the owner of a patent to make a complete and clear disclosure, including best mode, of his invention, to provide information regarding corresponding foreign applications, to work the invention in the territory of the patent, to pay periodic fees, and to refrain from anticompetitive practices in respect to licenses and assignments.¹²⁶

These proposals provide a stark reminder of the mindset of developing countries concerning any IP negotiations—technology must be transferred to the developing countries in order to facilitate their economic growth and independence.

B. *The Uruguay Round: Trade-Related Aspects of IP Rights*

The WIPO efforts at patent harmonization took place in the context of broader discussions regarding the creation of an international IP regime. These discussions were conducted under the auspices of the GATT negotiations in the so-called "Uruguay Round." The focus on "Trade-Related Aspects of IP Rights" (TRIPs) was a novel topic of discussion within the GATT. In fact, the mere inclusion of the TRIPs topic proved to be a source of great discord between the participating developed and developing nations.¹²⁷

Beginning in the mid-1980's, the United States pharmaceutical industry, along with other industries similarly dependent upon IP protection, began to view the GATT as the most promising forum for obtaining international IP protection.¹²⁸ In particular, the GATT was viewed as preferable to the WIPO because it offered a dispute resolution mechanism that could be used for IP matters. Moreover, since the United States believed that most IP disputes involved trade, it argued that the

124. *Report on Eighth Session of WIPO Committee Meeting on Harmonization*, 4 *Intell. Prop. Rep.* (BNA) 186 (Aug. 1990) (*hereinafter* Report on Eighth Session).

125. *Id.*

126. *Eighth Session (Second Part) of Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions*, 9 *Pat. Trademark Copyright News* (BNA) 15 (Winter 1991). Most delegates objected to these articles due to their untimely submission and to a contradiction in terms within the agreements of the treaty. Subsequently, a decision was deferred to the Diplomatic Conference for consideration. *Id.* See also *Report on Eighth Session*, *supra* note 124, at 186.

127. *Patent Protection Abroad for U.S. Pharmaceuticals*, 5 *World Intell. Prop. Rep.* (BNA) 336, 338 (Dec. 1991).

128. *Id.*

GATT was the proper body to discuss these issues.¹²⁹

However, developing countries continued to favor the WIPO, where they remained numerically superior, as the lead organization in IP matters. A number of these developing countries, including India, Brazil and Mexico, registered their concerns about the TRIPs discussions and strongly encouraged the WIPO to develop a draft treaty on resolution of IP-related disputes.¹³⁰ Chile submitted a proposal to the TRIPs negotiations calling for a two-tiered mechanism under which the WIPO would rule on the IP segments of a specific dispute. Then, if the parties agreed, the trade-related aspects of the dispute would be arbitrated within the GATT. Unsurprisingly, this proposal was not well-received at the GATT.¹³¹

Various proposals were presented during the TRIPs discussions including, among other options: (1) that patents should be offered in all fields; (2) that the term of patent protection should extend for twenty years from the date the application is filed; (3) that compulsory licenses should be permitted only in extraordinary circumstances; and (4) that there should be a strong mechanism for resolving disputes in the IP area. However, the initial drafts of the proposed agreement raised a number of concerns:

- Countries would still be permitted to exclude various products from inclusion in the patentable subject matter.
- Compulsory licensing provisions remained too broad, were discriminatory as to subject matter, and not limited to local manufacture.
- Patents could be revoked for unspecified reasons.
- No clear decision was reached on patent terms.
- No decision was reached on transitional arrangements and discriminatory treatment regarding protection of existing IP rights and products.

The Uruguay Round discussions initially broke off in December of 1990 because of the inability of the United States and the European Community (EC) to reach agreement on the rules of trade in agriculture.¹³² As a consequence, the future of the TRIPs agreement became very much in doubt.¹³³ In addition to unresolved issues in the patent area, stalemate remained on a number of other issues, such as: (1) copyright protection that included moral rights currently denied by the United States; (2) the definite term for software protection; (3) the conditions for using a trademark; (4) the breadth of design protection; and (5) the EC's concern over special rules on geographical indications for the protection

129. *Id.*

130. *WIPO's Dispute Resolution Talks Highlight Other Conflicts With GATT*, 4 World Intell. Prop. Rep. (BNA) 78 (Apr. 1990).

131. *Id.*

132. *Uruguay Round Crashes to a Halt; TRIPs, Other Negotiations on Hold*, 5 World Intell. Prop. Rep. (BNA) 16 (Jan. 1991).

133. *Id.* at 17.

of wine.¹³⁴

In November of 1991, the Trade Negotiations Committee of the GATT Secretariat issued a status report on the TRIPs negotiations.¹³⁵ The report included the following comments on three categories of issues to be resolved:

First, decisions are required on some twenty key issues concerning the level and nature of the standards of protection of IP rights to be included in a TRIPs agreement. The main points for decision lie in the areas of copyright, geographical indications and patents, although there are some outstanding issues in other parts as well. In the patent area, for example, it remains to be decided to what extent it will be possible to agree that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced, as well as to determine the term of patent protection. In the area of geographical indications, it has to be decided whether additional protection should be available for wines and spirits, and the scope of and conditions on exceptions to such protection. In the area of copyright, outstanding issues include the nature of protection of computer programs and of rental rights.

A second category of decision that remains to be taken are those that will govern the timing of the economic impact of the results. This concerns not only the duration of the special transition periods that developing and least-developed countries will be entitled to, but also the extent to which the new obligations will apply to existing works, inventions and other subject matter as well as certain specific proposals regarding products whose marketing is subject to delay due to regulatory requirements. In regard to these matters, it is clear that participants are not only sensitive to the specific issues arising in regard to the phasing-in of TRIPs commitments, but also to how the timing of their economic impact with that of commitments that will be entered into in other areas of the Uruguay Round.

The third set of issues that have to be settled concerns the institutional framework for the international implementation of the results of the negotiations on TRIPs.¹³⁶

On December 20, 1991, the Trade Negotiations Committee distributed a "Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations," which included as Annex III a draft "Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods."¹³⁷ This final draft was intended to supplement, rather than override, the terms of any international IP convention or multilateral agreement that might be reached under the aus-

134. *Swiss Intellectual Property Office Reports on Status of TRIPs Talks*, 5 World Intell. Prop. Rep. (BNA) 185-86 (July 1991).

135. *See GATT Hopeful of Trade Agreement as Year-End Deadline Approaches*, 5 World Intell. Prop. Rep. (BNA) 332 (Dec. 1991).

136. *Id.*

137. *Draft Final Act for Uruguay Round*, GATT Doc. MTN.TNC/W/Fa (Dec. 20, 1991).

pices of the WIPO and provided for a variety of standards with respect to copyright and related rights trademarks, geographical indications, industrial designs, patents, protection of undisclosed information (i.e., trade secrets), and the control of anti-competitive practices in contractual licenses.¹³⁸ In addition, the draft included sections dealing with the enforcement of IP rights, acquisition and maintenance of IP rights, and dispute resolution and settlement.¹³⁹

Some industry representatives have suggested that a better route might be to pursue development of a new IP "code," with limited membership, rather than a GATT article dealing with IP rights.¹⁴⁰ These representatives believe that many newly industrializing countries, such as those in Eastern Europe, would adhere to an IP code in order to insure that incentives exist for innovation and research and development in those countries.¹⁴¹ Such a code might serve as a foundation for further bilateral negotiations¹⁴² and could include provisions on the term of patent protection, limits on compulsory licensing, and patent protection for pharmaceuticals and previously patented products. Such protection would be particularly important for products with an extremely long development time.¹⁴³

Little, if any, progress was made with the TRIPs negotiations during 1992, as the Uruguay Round itself floundered as a result of intense differences regarding agricultural subsidies and growing domestic preoccupation with national politics. The Clinton Administration will need to address the GATT situation as part of its initial assessment of trade policy. However, with "fast-track" authorization scheduled to expire in June 1993, it is unlikely that TRIPs will provide a viable and lasting forum for the multilateral resolution of IP issues.

C. *Bilateral Initiatives by the USTR*

Frustration with the lack of success of the WIPO and GATT multilateral negotiations has led the United States to initiate certain bilateral negotiation efforts relating to IP matters which are included in various domestic trade statutes and regulations.¹⁴⁴ These efforts have been

138. *Id.*

139. *Id.*

140. *See Limited Intellectual Property Code Expected From Talks, PMA's Bale Says*, 4 World Intell. Prop. Rep. (BNA) 218 (Sept. 1990).

141. *Id.*

142. *Id.*

143. *Id.*

144. The first statutory provision was included as an amendment to Section 301 in the reciprocity bill enacted as part of the Trade and Tariff Act of 1984. Trade and Tariff Act of 1984, Pub. L. No. 98-573, 98 Stat. 3002. *See also Portion of U.S. Trade Representative's Fact Sheet on 1988 Trade Act's "Special 301" Provision on Intellectual Property, Released 25 May, 1989*, 3 World Intell. Prop. Rep. (BNA) 162 (July 1989) [hereinafter "*Special 301 Provision*"]. "Super 301" provisions, which deal with unfair foreign trade practices generally, expired in 1990. *Id.* However, a number of bills have been introduced in the U.S. Congress that would reenact, and possibly, strengthen "Super 301." Officials in the Bush Administra-

orchestrated by the USTR's office, which makes a concerted effort to identify countries offering inadequate protection for IP rights.

On May 25, 1989, the USTR, with input from the Interagency Trade Policy Staff Committee, the Patent and Trademark Office, and the Copyright Office, released the results of its initial survey of IP laws and market access issues in various countries.¹⁴⁵ That review¹⁴⁶—as well as subsequent annual surveys and updates¹⁴⁷—focuses on whether countries meet certain minimum standards of adequate IP protection.¹⁴⁸

In 1989, the USTR identified no "Priority Foreign Countries" (PFCs), even though it had concluded that none of the surveyed countries fully satisfied the standards advocated by the United States during the course of multilateral discussions, such as the TRIPs negotiations.¹⁴⁹ Instead, the USTR implemented a new, non-statutory procedure which designated twenty-five countries for special attention based on IP practices or market barriers that concerned the USTR.¹⁵⁰ Of those twenty-five countries, eight were placed on the Priority Watch List (PWL) and the remaining seventeen were placed on the Watch List (WL).¹⁵¹ The USTR developed accelerated action plans for the PWL countries designed to cure deficiencies over the 150 days following the announcement.¹⁵² Watch List countries would simply be the subject of increased efforts to resolve

tion expressed opposition to any extension of these extraordinary measures, citing their discomfort with many of the "artificial" deadlines for negotiations with problem countries. *See Legislative Developments: Reauthorization of Super 301*, 21 INT'L L. NEWS 15, 15 (1992).

145. "Special 301" Provision, *supra* note 144, at 162-63.

146. The review was conducted under the "Special 301" provisions of The Omnibus Trade and Competitiveness Act of 1988 (1988 Trade Act). Trade and Tariff Act of 1984, 19 U.S.C. § 2241(a)(1)(A)(i). A description of the "Special 301" procedures is included in OPERATION OF THE TRADE AGREEMENTS PROGRAM, 41st Rep. 1989, ITC Pub. No. 2317, 61 (Sept. 1990).

147. OFFICE OF THE U.S. TRADE REPRESENTATIVE, NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 1 (1992) [hereinafter 1992 BARRIERS REPORT]. *See also* OFFICE OF THE U.S. TRADE REPRESENTATIVE, NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS 1 (1991) [hereinafter 1991 BARRIERS REPORT].

148. *See* "Special 301" Provision, *supra* note 144, at 162. Section 182 of the Trade Act of 1974, as amended, which was added to the 1974 Trade Act in 1988, requires that the USTR identify those "Priority Foreign Countries" (PFCs) which, *inter alia*, "deny adequate and effective protection" to United States IP or deny "fair and equitable market access" to U.S. citizens who rely on such protection. *IIPA Submission to U.S. Trade Representative on "Priority Foreign Countries,"* 4 World Intell. Prop. Rep. (BNA) 84 (Apr. 1990) [hereinafter *IIPA Submission*].

149. *See* "Special 301" Provision, *supra* note 144, at 162.

150. *Id.*

151. *Id.* Countries originally placed on the WL included Argentina, Canada, Chile, Colombia, Egypt, Greece, Indonesia, Italy, Japan, Malaysia, Pakistan, the Philippines, Portugal, Spain, Turkey, Venezuela, and Yugoslavia. *Id.*

152. The USTR was to review each trading partner on the PWL to determine whether it should identify the trading partner as a PFC. The USTR could have designated a country as a PFC at any time during the period of review. It also could have initiated a "Special 301" action if the country failed to continue negotiations in good faith or ceased to make satisfactory progress on the specified improvements in the IP area. The USTR was to complete this initial review by November 1, 1989. *Id.* at 163.

any problems over the following year.¹⁵³

The original PWL included Brazil, India, South Korea, Mexico, the People's Republic of China (PRC), Saudi Arabia, Taiwan, and Thailand.¹⁵⁴ The USTR expressed several concerns regarding these countries: (1) the need to improve and provide adequate patent protection;¹⁵⁵ (2) the need to provide greater copyright protection, including the need to enhance enforcement efforts against the piracy and counterfeiting of software and sound recordings from the United States;¹⁵⁶ (3) the need to improve protection of foreign trade and service marks;¹⁵⁷ (4) the need to eliminate various market barriers which inhibited the ability of U.S. film manufacturers to penetrate foreign markets;¹⁵⁸ and (5) the need to engage these countries in constructive multilateral IP negotiations, such as the TRIPs discussions.¹⁵⁹

During the year following this initial announcement, Taiwan, Korea, and Saudi Arabia were downgraded to positions on the WL.¹⁶⁰ Mexico was removed from both lists upon its introduction of a government plan to improve existing Mexican patent, trademark, and trade secret laws.¹⁶¹ In April of 1990, when the second survey was issued, the USTR failed once again to designate any country as a PFC.¹⁶² However, the USTR noted that motion pictures were not allowed into various foreign markets, and that copyright protection and enforcement measures against piracy remained inadequate in many parts of the world.¹⁶³ The USTR also voiced concern over insufficient patent protection of pharmaceutical products.¹⁶⁴

153. *Id.*

154. *Id.*

155. Inadequate patent protection was found to be particularly troubling in Brazil, the People's Republic of China (PRC), India, Mexico, and Thailand. *Id.*

156. Brazil, India, Korea, the PRC, Saudi Arabia, Taiwan, and Thailand were all cited for inadequate copyright protection. *Id.* The PRC and Saudi Arabia were asked to enact copyright laws, while Taiwan was cited for its failure to fulfill its obligations under existing bilateral copyright agreements. *Id.*

157. The USTR noted that both India and Thailand failed to protect foreign trade and service marks. *Id.*

158. Brazil and India both maintained such market barriers. *Id.*

159. The USTR particularly sought to involve Brazil, India, Korea, Mexico, and Thailand in the ongoing negotiations. *Id.*

160. *IIPA Submission, supra* note 148, at 84-86. The actions were taken as of November 1, 1989. *Id.* at 84.

161. *United States Trade Representative's Fact Sheet on Offending Countries Under "Special 301" Provision of Trade Act*, 4 World Intell. Prop. Rep. (BNA) 138 (June 1990) [hereinafter *USTR's Fact Sheet*].

162. Report of United States Trade Representative, 55 Fed. Reg. 18,693 (1990). See also *USTR's Fact Sheet, supra* note 161, at 138.

163. *USTR's Fact Sheet, supra* note 161, at 138. A report prepared by the International Federation of the Phonographic Industry (IFPI) claimed that piracy worldwide cost the international recording industry over \$1.1 billion in 1989. *IFPI Issues Report on Worldwide Piracy*, 5 World Intell. Prop. Rep. (BNA) 67 (Mar. 1991).

164. See *USTR, Citing Progress, Declines to Target Offenders Under "Special 301,"* 4 World Intell. Prop. Rep. (BNA) 124 (June 1990).

The USTR's decision not to designate any countries as PFCs in 1990 was based, in part, on the hope that significant progress might be made in the TRIPs discussions during that year.¹⁶⁶ Even at that time, however, some industry representatives suggested that the United States should continue to emphasize bilateral negotiations as the best means to achieve a meaningful multilateral agreement.¹⁶⁶ By early 1991, it had become clear that the multilateral negotiations at both the GATT and the WIPO were hopelessly stalled.¹⁶⁷ As a result, it became almost inevitable that the USTR would take a more activist posture regarding IP-related trade barriers with various trading partners.

The USTR's 1991 report, released on March 29, 1991,¹⁶⁸ described four main categories of restrictive policies and concerns:¹⁶⁹

1. Inadequate protection of pharmaceuticals and chemical products.

Certain countries, notably Argentina,¹⁷⁰ Brazil,¹⁷¹ and India,¹⁷² failed to provide adequate patent protection for pharmaceutical products, chemical compounds, and food stuffs.¹⁷³ Argentine patent law, for example, failed to protect pharmaceutical products, though it did extend protection to manufacturing processes.¹⁷⁴ Brazilian law addressed neither product nor process patent protection.¹⁷⁵ Indian law provided no protection to any substances intended for use as food, medicine, or drugs.¹⁷⁶

2. Compulsory licensing and working requirements. The Philippines,¹⁷⁷ as well as other countries, continued to use compulsory licensing and working requirements as conditions for granting a patent.¹⁷⁸ For example, a patent would lapse under Argentine standards if, within two

165. *See id.*

166. *See, e.g., id.* at 125. In particular, the IIPA expressed disagreement with the USTR position in light of perceived significant piracy problems remaining in Korea, Malaysia, the Philippines, Saudi Arabia, Taiwan, and Thailand. *Id.*

167. *See EC Officials Express Concern Over Unresolved TRIPs Issues*, 5 World Intell. Prop. Rep. (BNA) 15 (Aug. 1991); *see also Swiss Intellectual Property Office Reports on Status of TRIPs Talks*, 5 World Intell. Prop. Rep. (BNA) 185 (July 1991) (citing concerns over the talks' failure to settle controversial issues).

168. 1991 BARRIERS REPORT, *supra* note 147, at 5. *See also USTR Releases Annual Trade Report on Restrictions Around the World*, 5 World Intell. Prop. Rep. (BNA) 121 (May 1991) [hereinafter *USTR Releases Annual Trade Report*].

169. *USTR Releases Annual Trade Report*, *supra* note 168, at 121-24.

170. 1992 BARRIERS REPORT, *supra* note 147, at 7-9 (section on Argentina). *See also* 1991 BARRIERS REPORT, *supra* note 147, at 7-9.

171. 1992 BARRIERS REPORT, *supra* note 147, at 19-24 (section on Brazil). *See also* 1991 BARRIERS REPORT, *supra* note 147, at 19-25.

172. 1992 BARRIERS REPORT, *supra* note 147, at 113-21 (section on India). *See also* 1991 BARRIERS REPORT, *supra* note 147, at 101-08.

173. *USTR Releases Annual Trade Report*, *supra* note 168, at 121-22.

174. *Id.* at 121.

175. *Id.*

176. *Id.* at 122.

177. 1992 BARRIERS REPORT, *supra* note 147, at 208. *See also* 1991 BARRIERS REPORT, *supra* note 147, at 186.

178. *USTR Releases Annual Trade Report*

years of issuance, no local production or processing occurred.¹⁷⁹

3. Limited scope of patent rights. Even among developed countries, the scope of the claims covered by issued patents varied significantly. For example, since Japan narrowly construed patent claims,¹⁸⁰ competitors could legally file an application for protection which required only minimal variation from the original application.¹⁸¹ As a result, the initial applicant was often forced to enter into a cross-license or face the prospect of costly patent infringement litigation.¹⁸²

4. Inadequate copyright law protection and enforcement. Various industry groups, such as the International Intellectual Property Alliance (IIPA),¹⁸³ were greatly concerned about the form and enforcement of copyright laws around the world.¹⁸⁴ In some extreme cases, countries had implemented no national copyright laws.¹⁸⁵ Further, in several countries that had adopted some form of copyright law, the scope of protection was inconsistent with the Berne Convention.¹⁸⁶ Specific problem areas included inadequacies in the protection that countries afforded to computer software,¹⁸⁷ the inability of various countries to prevent unauthorized

179. *Id.* at 121.

180. 1992 BARRIERS REPORT, *supra* note 147, at 145. See also 1991 BARRIERS REPORT, *supra* note 147, at 129.

181. *Id.*

182. 1991 BARRIERS REPORT, *supra* note 147, at 129.

183. The IIPA released a report in April 1989, entitled "Trade Losses Due to Piracy and Other Market Access Barriers Affecting the U.S. Copyright Industries," which attempted to quantify U.S. trade losses in each of the designated countries, to identify statutory and administrative deficiencies in the copyright regimes, and to recommend appropriate remedies for the specified deficiencies. *IIPA Submission, supra* note 148, at 84. The IIPA is an umbrella organization formed in 1984 and consists of eight trade associations. *Id.* Each trade association represents a significant segment of the U.S. copyright industry. *Id.* The IIPA is composed of: the Computer Software and Services Industry Association, the American Film Marketing Association, the Association of American Publishers, the Business Software Alliance, the Computer and Business Equipment Manufacturers Association, the Motion Picture Association of America, the National Music Publishers' Association, and the Recording Industry Association of America. *Id.* By their own estimation, the industries in the IIPA collectively generated over \$270 billion in revenues in 1988. *Id.* This amount approximated 5.7% of the 1988 U.S. GNP. *Id.* The IIPA estimated that the book and journal publishing, film, video, music, record, and computer software industries collected over \$13 billion in surplus to the U.S. trade balance in 1988. *Id.*

184. See *id.* See also *IIPA Targets 22 Countries for "Special 301" Lists*, 5 World Intell. Prop. Rep. (BNA) 63 (Mar. 1991) [hereinafter *IIPA Targets 22 Countries*].

185. See *USTR Names China, India, Thailand as Special 301 Priority Offenders*, Special Report World Intell. Prop. Rep. (BNA) 133, 134 (May 1991) [hereinafter *USTR Names Priority Offenders*].

186. The Berne Convention for the Protection of Literary and Artistic Works of September 9, 1886, was the first multilateral copyright convention in history. 5 ENCYCLOPEDIA BRITANNICA 152 (15th ed. 1975). The Berne Convention requires countries to provide the same protection to foreign works as countries provide to their own works. *Id.*

187. For example, the PRC was then considering new legislation that would provide protection to computer software. However, concerns were raised regarding the adequacy of the protection; *i.e.*, less than 50 years, and available only upon registration. The proposed law, which contained fair use and compulsory licensing provisions, contradicted the terms discussed at the Berne Convention and did not cover pre-existing works. See *IIPA Targets*

public performances of copyrighted works (e.g., motion pictures), and the piracy of records, tapes, motion pictures, videos, books, and computer programs.¹⁸⁸ The unwillingness of many countries to participate in substantive negotiations that might lead to bilateral copyright agreements was identified as a further problem area.¹⁸⁹

On April 26, 1991, the USTR designated India, Thailand, and the PRC as Priority Foreign Countries.¹⁹⁰ Each country had been on the Priority Wait List since 1989, and the USTR noted that the practices of these countries had been egregious, resulting in an adverse impact on U.S. industry.¹⁹¹ The USTR also stressed that no country had made "significant progress," either bilaterally or multilaterally, to address these practices.¹⁹² The USTR criticized all three countries for their unwillingness to provide adequate levels of patent protection—particularly with respect to pharmaceutical and chemical products.¹⁹³ In addition, in December of 1991, the USTR found that Thailand's copyright enforcement procedures were unacceptable.¹⁹⁴ The USTR cited Thailand for its failure to make any progress against piracy in the motion picture, sound recording, and software industries.¹⁹⁵ The USTR also voiced concern about the lack of copyright protection for works of foreign nationals in the PRC.¹⁹⁶

Under the USTR's procedures, the objective of the investigation was to reach a satisfactory bilateral agreement with the designated countries on or before November 26, 1991.¹⁹⁷ The negotiations proceeded slowly,

22 Countries, *supra* note 184, at 63.

188. *Id.* Considerable problems regarding piracy and unauthorized use of copyrighted works existed in many parts of Asia (e.g., Thailand, *IIPA Submission, supra* note 148, at 84; India, *id.* at 85; Taiwan, *id.* at 85; Korea, *id.* at 86; Malaysia, *id.* at 87; Indonesia, *id.* at 87; and the Philippines, *id.* at 87); Latin America (e.g., Brazil, *id.* at 85 and Mexico, *id.* at 86).

189. *USTR Releases Annual Report, supra* note 168, at 122.

190. 56 Fed. Reg. 20,060 (1991). *See also USTR Names Priority Offenders, supra* note 185, at 133. In addition, the USTR included Australia, Brazil, and the European Community (EC) on the Priority Watch List. *Id.* *See also Foreign Trade: China, India, and Thailand Named in First "Priority Foreign Country" List*, 42 Pat. Trademark & Copyright J. 7, 7-8 (1991) (discussing priority watch list and secondary watch list countries). The USTR also placed 23 other countries on a secondary watch list for monitoring including: Argentina, Canada, Chile, Colombia, Cyprus, Germany, Greece, Hungary, Indonesia, Italy, Japan, Korea, the Philippines, Saudi Arabia, Spain, Turkey, and Yugoslavia. *Id.* at 8.

191. 56 Fed. Reg. 20,060 (1991). *See also USTR Names Priority Offenders, supra* note 185, at 133.

192. 56 Fed. Reg. 20,060 (1991). *See also USTR Names Priority Offenders, supra* note 185, at 133.

193. The USTR found patent laws in India deficient due to an inadequate level of patent protection, including overly broad compulsory licensing requirements, too short a term of protection, and specific failures to enforce foreign pharmaceutical patent rights. *USTR Names Priority Offenders, supra* note 185, at 134. The USTR found similar deficiencies with Thai patent laws. *Id.* The PRC also failed to provide product patent protection for pharmaceuticals and other chemicals. *Id.* at 133.

194. 1992 TRADE BARRIERS REPORT, *supra* note 147, at 243.

195. *Id.*

196. For a detailed discussion of IP problems in the PRC, *see* 1992 BARRIERS REPORT, *supra* note 147, at 48-49. *See also* 1991 BARRIERS REPORT, *supra* note 147, at 47-49.

197. Intellectual Property and Market Access Acts, Policies, and Practices of the Gov-

but the USTR was ultimately able to resolve its IP concerns with the PRC through a memorandum of understanding in January of 1992.¹⁹⁸ The discussions with Thailand¹⁹⁹ and India²⁰⁰ continued beyond that date. These two countries, along with Taiwan, were named to the USTR's new list of PFCs announced on May 5, 1992.²⁰¹

In June 1992, the USTR revoked its designation of Taiwan as a PFC.²⁰² The USTR's action came as a result of Taiwan's agreement to establish an export licensing system for compact discs, as well as its commitment to raid MTV studios that broadcast unlicensed videotapes or laser discs.²⁰³ Negotiations with Thailand were delayed due to political unrest in that country.²⁰⁴ Tensions with India remained after the USTR's announcement and local observers predicted that the USTR's actions would have a profound effect upon future Indo-United States political, strategic, and economic relations.²⁰⁵

D. Conclusion

At this point, it appears unlikely that any multilateral agreement will be reached on IP rights within the context of the WIPO or the TRIPs discussions. Accordingly, the United States continues to pursue bilateral discussions with various countries and to address issues that extend beyond IP to include all aspects of the trade relationship between the participants. While this strategy should permit reasonable concessions on both sides, it fails to address many of the legitimate needs of a number of

ernment of India, 56 Fed. Reg. 24,878 (1991) (initiation of section 302 investigation).

198. *China: U.S.-China Intellectual Property Accord Ends Threat of U.S. Retaliatory Duties*, 9 Int'l Trade Rep. (BNA) 139 (Jan. 22, 1992).

199. *Notice of Trading Partners Identified as Priority Foreign Countries*, 57 Fed. Reg. 19,329 (1992) (Thailand named as PFC by the USTR).

200. *Id.* The USTR named India as a PFC in May of 1992. *See also Intellectual Property: USTR Cites India, Taiwan, Thailand as Worst Intellectual Property Offenders*, 9 Int'l Trade Rep. (BNA) 784 (May 6, 1992) [hereinafter *Worst Intellectual Property Offenders*]. The problem with India remains that it does not offer effective patent protection for pharmaceutical products or effective copyright protection. *Id.* At the same time that the USTR named India as a PFC, the White House announced the suspension of duty-free treatment for Indian pharmaceutical products under the Generalized System of Preferences. *Id.*

201. Countries named to the PWL at that time included: Australia, Brazil, Egypt, the European Community, Hungary, the Philippines, Poland, and Turkey. Countries named to the WL included: Argentina, Canada, Chile, Colombia, Cyprus, Ecuador, El Salvador, Germany, Greece, Guatemala, Indonesia, Italy, Japan, New Zealand, Pakistan, Paraguay, Peru, Spain, Saudi Arabia, United Arab Emirates, and Venezuela. *Worst Intellectual Property Offenders*, *supra* note 200, at 784-85.

202. *Termination of Section 302 Investigation of Taiwan*, 57 Fed. Reg. 25,091 (1992) (USTR terminated action against Taiwan).

203. *Taiwan Removed from Priority List Following I.P. Agreement with U.S.*, 6 World Intell. Prop. Rep. (BNA) 188 (July 1992).

204. *USTR Finds Against Thailand, But Delays Taking Actions*, 6 World Intell. Prop. Rep. (BNA) 135 (May 1992).

205. *Indians Angered by 'Special 301' Naming by U.S. Trade Representatives*, 6 World Intell. Prop. Rep. (BNA) 185 (July 1992) [hereinafter *Indians Angered*].

developing countries—countries that do not have markets of sufficient size to justify the time and effort associated with bilateral negotiations.

IV. PATENT PROTECTION AND ECONOMIC DEVELOPMENT: THE DISPARATE VIEWS OF DEVELOPED AND DEVELOPING COUNTRIES

Underlying the debate regarding IP protection is the asserted relationship between the level of protection accorded private rights in technology and knowledge and the corresponding rate of economic development in the country. In this section, we examine many of the arguments raised by economists and policymakers in developed countries of the north and the concerns asserted by their counterparts in developing nations of the south.

A. *Developed Country Arguments for Stronger IP Protection*

Advocates of strong IP protection argue that countries with strong patent systems typically experience more rapid economic growth and development.²⁰⁶ Using multiple regression analysis, one researcher has claimed that the level of economic development is closely correlated with the existing level of IP protection.²⁰⁷ Specifically, this researcher has concluded that many developing countries that failed to implement IP protection systems experienced a correspondingly lower level of economic development, as well as a slower evolution in the size and complexity of their local markets.²⁰⁸ These findings suggest the need for further reforms

206. Rapp & Rozek, *supra* note 1, at 77.

207. *Id.* at 79. The researcher developed an "index" of patent protection based upon conformity of each nation's patent laws to the minimum standards proposed in the *Guidelines for Standards for the Protection and Enforcement of Patents of the U.S. Chamber of Commerce Intellectual Property Task Force*. *Id.* The index ranked the level of patent protection on a scale of zero to five. Zero is assigned to a nation having no patent protection law, and five corresponds to nations whose laws are fully consistent with the minimum standards. For example, Argentina, which does have a patent law, received a score of one on the scale. *Id.* at 79 n.12. Protection under the law extends for 15 years from the date of the grant. *Id.*

Pharmaceutical products, however, are not patentable. A patent must be practiced within two years of registration to remain in force. A century of inflation coupled with a maximum fine fixed in 1864 results in no practical penalty for infringement. Moreover, as the Argentine law makes no provision for preliminary injunctions, enforcement is nearly impossible. By contrast, Singapore, which received a score of four, registers and protects patents under the United Kingdom Patents Act. *Id.* Compulsory licensing may be granted three years after registration for certain classes of invention when the invention is neither being practiced nor imported. Although the government retains the right to supervene pharmaceutical patents for its own purposes, patents are enforceable in all other respects. *Id.* It should be noted that the scores were based solely on the laws as written and did not account for actual enforcement experience.

208. *Id.* at 81. The study determined that Indonesia, New Guinea, Kuwait, Turkey, Bulgaria, Algeria, Iraq, Poland, Yugoslavia, East Germany, Brunei, and most of Central and South America had weaker patent regimes than would be expected, given their stage of economic development. India, Brazil, and Argentina, despite the size and complexity of their economies, were also among the weak protection regimes. *Id.*

to existing law as a precondition to continued growth.

Other studies have focused on a specific subset of developing world countries, such as Argentina, Brazil, Indonesia, South Korea, Mexico, the Philippines, Taiwan, and Turkey.²⁰⁹ These countries, because of the size of their local economies or their scientific and technological capabilities, have either already experienced rapid economic growth or can be expected to enter the front lines of the global economy in the near future.²¹⁰ Researchers claim that IP protection in these countries is "out of phase" with their level of economic development. Moreover, several of these countries have been found to be active participants in the patent systems of developed countries.²¹¹ These findings suggest that their failure to implement a stronger domestic patent system flows, not from a lack of appreciation for the value of such a system, but from a reluctance to incur the associated costs or from the belief that "free-riding" is the preferred strategy.²¹²

A survey of the arguments made supporting enhanced IP protection includes the following:

1. Increased investment in domestic research and development. An innovator's ability to obtain those monopoly rights inherent in a patent grant provides an incentive for higher levels of domestic investment in innovative activities.

2. Increased flow of new products. The availability of patent protection for new products increases the flow of products into the developing country, thereby increasing the welfare of the population. For example, it has been argued that the decision of countries such as India to deny product patent protection for innovation in the food, drug, and chemical industries results in foreign and domestic forfeiture of pharmaceutical research and development benefits, since fewer new products are available on the market.²¹³ If this proposition is true, the effect in the pharmaceutical area is of particular concern, since the overall level of health in the country will ultimately suffer.²¹⁴

3. Increased inbound investment and technology transfer. One of the most logical and practical advantages to developing countries from enhanced IP protection is the anticipated increase in the rate of inbound investment and technology transfer from foreign firms. In the past, foreign firms concerned about the adequacy of the protection that would be afforded to the transferred technology, limited their technology exports to developing countries by allowing only older generation technology or outdated research and development of sensitive product lines to be trans-

209. J. Davidson Frame, *National Commitment to Intellectual Property Protection: An Empirical Investigation*, 2 J.L. & TECH. 209, 212 (1987).

210. *Id.* at 215.

211. *Id.* at 216.

212. Rapp & Rozek, *supra* note 1, at 86.

213. *Id.*

214. *Id.*

ferred.²¹⁵ Once stronger IP protection is enacted, it can be expected that foreign firms will increase the flow of new technologies to developing countries, either in the form of direct investment²¹⁶ or through licensing and technical assistance arrangements.

4. Improvements in local knowledge base. A strong IP regime improves the knowledge base concerning technical development. Such an improvement follows from increased imports, licensing activities, and patent application filings in the local market. Technical information cannot be derived simply from reviewing foreign patent applications or from pirating foreign products. The person-to-person communication that follows from investment activities provides a powerful training and educational tool for the local workforce.²¹⁷ An improved knowledge base is of great use to local firms in negotiating the terms of licenses with foreign firms. In addition, it provides a greater appreciation for the availability of alternatives and the underlying utility of the licensed subject matter.²¹⁸

5. Enhanced value of patent rights. As economic development continues, the value of the patents increases because of enhanced prospects for sales and profits from their use in the marketplace.

6. Reduced enforcement and transaction costs. Welfare gains are realized through a reduction of agency costs attributable to surveillance, verification, compliance, and enforcement. These activities are currently provided on a unilateral basis, but would become the shared responsibility of all parties to a bilateral or multilateral agreement. An additional reduction would occur in the transaction costs attributable to reliance upon pirated foreign technology.²¹⁹

215. Eric Wolfhard, *International Trade in Intellectual Property: The Emerging GATT Regime*, 49 U. TORONTO FAC. L. REV. 106, 118 (1990). See also Carlos Alberto Primo Braga, *The Economics of Intellectual Property Rights and the GATT: A View from the South*, 22 VAND. J. TRANSNAT'L L. 243, 264 (1989) (noting that "technology drives investment" and technology is "reluctant to flow where it is not protected").

216. Multinational trade associations in developing countries such as Brazil argue that due to the increasing cost of research and investment, multinationals will no longer be willing to invest in countries that fail to offer IP protection. *Interview with Brazilian Official on Pharmaceutical Patent Protection*, 5 World Intell. Prop. Rep. (BNA) 128 (Apr. 1991).

217. Cf. Farok J. Contractor, *Technology Importation Policies in Developing Countries: Some Implications of Recent Theoretical and Empirical Evidence*, 17 J. DEVELOPING AREAS 499, 514 (1983) (explaining importance of interpersonal communication and improvement of knowledge base through importation).

218. See Le-Nhung McLeland & J. Herbert O'Toole, *Patent Systems in Less Developed Countries: The Cases of India and the Andean Pact Countries*, 2 J.L. & TECH. 229, 247 (1987).

219. Arguably, these costs include the damage to domestic research and development capacity and the inefficient allocation of resources involving redistribution transactions of illegitimate imitators and pirates (parties who merely redistribute the products of the involuntary suppliers of the IP). Wolfhard, *supra* note 215, at 117.

B. Developing Country IP Protection Concerns

Little doubt exists that developing countries are anxious to reduce what they perceive to be a critical technological gap between developed and developing countries. Even the Committee on Transfer of Technology of the United Nations Committee on Transfer and Development (UNCTAD), which has a decided bias in favor of developing countries, has urged governments "to adopt measures, *including IP rights protection* and technical cooperation, to increase technology flows to developing countries and facilitate access of those countries to technology, in particular those new and advanced technologies of critical importance for their development"220

Developing countries become skeptical when developed countries assert that strong IP protection is the proper means to insure economic development, particularly when firms in the developed countries claim that monopoly rights in new foreign markets, such as in less developed countries (LDCs), are necessary to recover their research and development costs. On the contrary, developing countries fear that patent protection for new products and technologies will merely enable large multinational corporations to secure global monopolies,²²¹ and thereby charge exorbitant prices for their goods.²²²

Lacking the scientific and financial infrastructure necessary to create patent-induced innovations, developing countries are far more interested in technology transfer than in the encouragement of domestic innovation.²²³ However, while these countries seek to maximize technology im-

220. The comments were expressed at the Eighth Session of the Committee on Transfer of Technology (Geneva, April 1991). See Otto A. Stamm, *GATT Negotiations for the Protection of New Technologies*, 73 J. OF THE PATENT AND TRADEMARK OFFICE 680, 690 & n.10 (1991).

221. See Mesevage, *supra* note 9, at 443 (citing Dembo, Dias & Morehouse, *Technology to Aid the Poor: Constraints to Access Resulting from the Privatization—The Case of Biotechnology*, in THE INTERNATIONAL CONTEXT OF RURAL POVERTY IN THE THIRD WORLD 103, 124-25 (1986)). Additionally, Gao Lulin, Director General of the Chinese Patent Office, argued that international consideration should be given to the economic development of less developed countries and stated that developed nations have a greater interest in protecting their own patent rights than in the economic growth of less fortunate countries. *Asia-Pacific Countries Agree to Cooperate on Patent Issues*, 4 World Intell. Prop. Rep. (BNA) 53 (Mar. 1990).

222. Economists from developed countries argue that the fear of high prices arising from patent protection is based on a mistaken view of the competitive marketplace. They assert that while patents allow innovators to capture gains from their innovation, ordinarily the gains take the form of "foothold" access to well-populated, competitive markets which permit sellers to do no more than charge competitive prices and earn competitive returns, including the returns on innovation. There are, to be sure, cases where an innovation represents so drastic a departure from the status quo that an entirely new market is created and prices and profits are high. Rapp & Rozek, *supra* note 1, at 101-02.

223. Robert P. Merges, *Battle of Lateralisms: Intellectual Property and Trade*, 8 B.U. INT'L L.J. 239, 244 n.9 (1990) (citing SCIENCE AND TECHNOLOGY: LESSONS FOR DEVELOPMENT POLICY 353 (R. Evenson & G. Ranis eds., 1990)) (adopting current international intellectual property conventions might be globally optimal for developing countries, but not in the best interests of individual developing countries, since the best regime for them is one that facili-

ports, they must do so with an only meager transfer payment budget. It is not surprising, therefore, that developing countries have little or no interest in creating a system that impedes their own ability to "appropriate" new technologies and products developed by foreign innovators.²²⁴

Some of the concerns of developing countries regarding IP protection can be summarized as follows:

1. Cultural attitudes regarding private property rights. One fundamental problem is that many developing countries do not necessarily share the same cultural attitudes regarding the nature of private rights to own and use various types of tangible and intangible property. For example, in some countries, certain forms of IP are viewed as pure public goods.²²⁵ In fact, some cultures are genuinely hostile to any notion that knowledge is a private capital good, a premise that is fundamental to the IP systems of the industrialized economies.²²⁶

2. Lack of perceived benefits to developing countries. Although certain developing countries have nurtured their own domestic industries, most fail to recognize any potential advantages flowing from granting greater IP protection. Less prosperous countries lack the resources necessary for domestic research and development, and research findings indicate that, historically, the implementation of a new patent regime within a developing country has led to few inventions and fewer relative benefits.²²⁷ Moreover, developing countries may be unable to bear the cost of lost consumer surplus that is the result of higher prices stemming from the "monopolization" associated with the beginning stages of IP development.²²⁸ Finally, these countries may be unable to bear the start-up and maintenance costs associated with developing and enforcing new IP rights, although initially these costs generally accrue to foreign innovators.

3. Underutilization of inventions. A common argument made in favor of granting patent protection is its effect of spurring importation of new products and technologies. Generally, however, the patent holder

tates the transfer of technology).

224. Arguments for the non-implementation of patent systems often refer to the long-standing practice of tariff protection, a practice permitted under the GATT and used to stimulate "infant industries" by protecting them from foreign import competition. See Mesevage, *supra* note 9, at 441-42 & n.95; RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE U.S. § 810 (1987). "Under the General Agreement of Tariffs and Trade, a state party may, notwithstanding other obligations under the Agreement, (a) if it is a developing state, restrict imports and take other measures to promote domestic industry; (b) if it is a developed state, grant specially favorable treatment to developing states." *Id.* Proponents of the non-adoption of patent systems in developing countries claim that such a policy is similar in effect to tariff protections, since local firms may lawfully "copy" new products and technologies to establish domestic industry. Mesevage, *supra* note 9, at 441-42.

225. Wolfhard, *supra* note 215, at 116 & n.32.

226. *Id.* at 116.

227. A. Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831, 844-45. See also Mesevage, *supra* note 9, at 438.

228. Braga, *supra* note 215, at 256. See also Wolfhard, *supra* note 215, at 118.

need not necessarily enter the foreign market in which the patent was granted. Rather, the patent may simply be used as a means of preventing others from making or selling the product in that market. As a result, the patent system, in many cases, actually leads to the underutilization of inventions in the patent-granting country.²²⁹

Developing countries are not without legal remedies in these situations. For example, compulsory licensing and working requirements may be utilized to insure that patented inventions are actually used in the country, either through licensing or direct investment or manufacturing activities. However, these rights are often viewed as ineffectual, as there may be no local firm capable of independently using the technology without additional technical assistance from the patent holder.

4. Availability of essential commodities. Regardless of the local attitude toward private property rights, many countries believe that certain products and technologies must not be included in any IP protection regime. The most common examples are in the areas of pharmaceuticals and chemicals. As the Director of the Philippine Bureau of Patents, Trademarks and Technology Transfer recently stated, “[d]eveloping countries have a need requiring special preferential attention on patent systems—such as on medicine—to make it affordable to the poor people”²³⁰ Similarly, PRC officials believe that pharmaceutical products “are produced for the health of the people.”²³¹ Accordingly, copying should be permitted in order to produce them. In some countries, the markets for these essential commodities may actually be operated by the local government.²³²

5. Autonomy. Developing countries have, in most cases, adopted some form of IP protection regime. However, much resistance exists to the establishment of a uniform global standard simply to conform to the requests of developed countries.²³³ For instance, Indian officials have often expressed a high degree of indignation at the suggestion that they pursue a course undirected by their own program of self-reliance and specific needs. Also, the PRC Government has suggested that “[t]he level of protection for intellectual property should keep pace with the economic development of the country concerned”²³⁴

6. Lack of stimulus for “local-specific” products. Because developed

229. Mesevage, *supra* note 9, at 443. See also Oddi, *supra* note 227, at 852.

230. *Asia-Pacific Countries Agree to Cooperate on Patent Issues*, 4 World Intell. Prop. Rep. (BNA) 53 (Mar. 1990).

231. *China Calls Special 301 Designation Unacceptable, Says Trade Will Suffer*, 5 World Intell. Prop. Rep. (BNA) 146 (June 1991) [hereinafter *China Calls*].

232. For example, Brazil had a public company called CEME which purchased medications on the market for distribution. Firms would submit bids and the winners would then provide the drugs without trademarks or brand identification. However, critics claim that such a system often led to political abuses and to shortages of certain products. *Interview with Brazilian Official on Pharmaceutical Patent Protection*, 5 World Intell. Prop. Rep. (BNA) 129 (Apr. 1991).

233. *China Calls*, *supra* note 231, at 145-46.

234. *Id.*

countries create a majority of the patentable inventions and technology, most of the patents granted in developing countries are issued to foreigners.²³⁵ The largest proportion of inventions covered by patents are thus induced, not by the availability of patent protection in the developing countries, but rather by the domestic patent system of the holder or in conjunction with patent systems in other developed countries.²³⁶ As a result, a developing country cannot expect that implementation of a patent regime will induce foreign innovators to focus their development efforts on new products and technologies that meet the special needs of the developing nations.²³⁷

7. Effect of other factors. Implementation of a patent system does not, in and of itself, guarantee that foreign investment and technology transfer will increase.²³⁸ A variety of political, legal, cultural, social, and economic factors impacts on the perceived risks of undertaking a particular inbound investment transaction and, thus, on the level of foreign investment and technology transfer.²³⁹ For example, a patent is of little value in a country where lack of expendable capital impedes the purchase of patented goods.²⁴⁰ As well, the ability of the patent holder to successfully commercialize any product depends, not only on the competitive environment, but on the ability to effectively market the patented product.²⁴¹

8. Local political environment. Ultimately, the policies of developing countries must be forged in the context of the local political environment. In some cases, the interest in continued blackmarket copying and pirating activities may overwhelm any attempts at reform.²⁴² For example, although the best interests of the country as a whole may demand a stronger IP protection system, certain well-entrenched interest groups, including representatives of the "pirate" industries, possess the necessary political clout to block the proposed changes.²⁴³ These groups often argue that the "costs," expressed in terms of lost revenues, associated with implementing greater protection are too much for the small economy to bear.²⁴⁴

235. See Mesevage, *supra* note 9, at 438 & n.80 (listing developed and developing countries, with percentage figures, giving patents to foreigners).

236. See *id.* at 438-39. The true inducement is the expected economic return from the exercise of a patent monopoly. *Id.* at 439 n.81.

237. *Id.* at 439 (citing Kojo Yelapaala, *Third World Perspectives on Technology Transfers*, in LICENSING AGREEMENTS: PATENTS, KNOW-HOW, TRADE SECRETS AND SOFTWARE 243 (1988)).

238. Mesevage, *supra* note 9, at 439.

239. *Id.* at 439-40.

240. *Id.* at 440.

241. *Id.* at 439 (citing Sanjaya Lall, *The Patent System and the Transfer of Technology to Less-Developed Countries*, 10 J. WORLD TRADE L. 1, 8 (1976) (noting the growing importance of marketing techniques to multinationals in securing market power)).

242. For a discussion of the power that pirate industry special interest groups possess, see Merges, *supra* note 223, at 243-44.

243. *Id.*

244. *Id.* Obviously, the developing countries would argue that any such costs must be

V. INTERNATIONAL PROTECTION OF PHARMACEUTICAL PRODUCTS

One area which vividly illustrates the debate over international IP protection is pharmaceutical products. Every new pharmaceutical product requires years of effort and millions of dollars of research and development funds.²⁴⁵ According to the Pharmaceutical Manufacturer's Association (PMA), these significant levels of investment cannot be sustained unless foreign markets, such as those in developing countries, are available to help U.S. firms recoup their costs.²⁴⁶ As a result, the PMA has adamantly insisted that developing countries immediately implement patent protection for pharmaceuticals.²⁴⁷ The PMA issues the additional reminder to U.S. trade officials that, because of the magnitude of the pharmaceutical industry, any decrease in the international competitiveness of American drug firms will necessarily and significantly increase the U.S. trade deficit.²⁴⁸

Developing countries resist patent protection for pharmaceuticals on a number of grounds. First, these relatively poor countries assert that the principal objective in excluding pharmaceuticals from patent protection is to make all necessary medicines affordable.²⁴⁹ Second, developing countries argue that the WIPO standards permit countries to deny patent protection to products, such as pharmaceuticals, considered vital to a country's national well-being and security.²⁵⁰ Finally, developing countries voice resentment at the pressure applied by developed countries.²⁵¹ In many developing countries, resistance to the implementation of patent protection for pharmaceuticals becomes an issue of national sovereignty.²⁵²

A. *General Considerations*

The research-based pharmaceutical industry has several unique characteristics. First, the costs associated with developing and obtaining mar-

weighed against the anticipated gains from new investment resulting from the stronger IP rights. A recent study confronted this problem by asking how much extra annual growth it would take in various LDC/NIC economies to offset the loss of revenues from industries dependent on weak IP protection. The estimates—stretched over a 25-year time horizon—ranged from .07% for India and Mexico to .2% for Argentina. *Id.* at 243 (citing Michael Gadbow, in *PROTECTING INTELLECTUAL PROPERTY RIGHTS WORLDWIDE* 107 (1988)).

245. Mesevage, *supra* note 9, at 448-49 (citing Gerald J. Mossinghoff, *Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide*, 2 *J.L. & TECH.* 307 (1987)).

246. *Id.* at 449.

247. *Id.* at 448. The Pharmaceutical Manufacturers Association (PMA) filed a formal unfair trade practice complaint against Thailand in early 1991. *Id.* at 448-49 n.128.

248. *Id.* at 449. The aggressive posture of the United States pharmaceutical companies has caused other developing countries, such as the Philippines, to reconsider legislation that would remove patent protection from pharmaceuticals. *Id.* at 449 n.130.

249. McLeland & O'Toole, *supra* note 218, at 245.

250. *Id.*

251. *Id.*

252. *Id.*

ket approval for a new product in the United States, including synthesis, screening, and clinical trials, can be prohibitive. The USITC recently noted that between 1976 and 1990, these costs increased from \$54 million to \$231 million per single drug.²⁵³ Second, significant delays between the time a patent is granted and the time government approval is given for marketing the product often occur. The usual delay in bringing a new pharmaceutical to market in the United States is eight to nine years.²⁵⁴ Third, the high risk of product liability claims requires companies to adhere to strict quality control standards in producing and distributing pharmaceutical products in domestic and foreign markets.²⁵⁵ Finally, the costs of marketing and distributing the products can be quite high.²⁵⁶

Due to the substantial investment required for the exploitation of any new pharmaceutical product, the industry's livelihood depends heavily upon the patent system.²⁵⁷ While most industrialized countries provide some form of patent protection for pharmaceutical products, many countries, particularly in the developing world, do not.²⁵⁸ Developing countries typically exclude the pharmaceutical industry from patent protection.²⁵⁹ Even when some form of protection is available, the duration of the patent and the compulsory licensing provisions limit the period of exclusivity to only a few years.²⁶⁰

Developed countries have long been concerned about the level of copying and piracy of pharmaceutical products that takes place in developing countries.²⁶¹ Interestingly, the LDCs appear to offer the best new market potential for the remainder of this decade.²⁶² The markets in developed countries appear to be near saturation, while sales in LDCs are not commensurate with their population.²⁶³ For example, India has three times

253. *Patent Protection Abroad for U.S. Pharmaceuticals*, 5 World Intell. Prop. Rep. (BNA) 336 (Dec. 1991).

254. McLeland & O'Toole, *supra* note 218, at 245.

255. *Id.*

256. *Id.*

257. *Id.*

258. Nogués, *supra* note 7, at 82. Interestingly, patent protection for pharmaceutical products in some of the developed countries is a relatively new phenomenon. For example, the United Kingdom introduced patent protection for pharmaceutical drugs in 1949. *Id.* Other countries did not introduce patent protection until much later: France, 1960; Germany, 1968; Japan, 1976; Switzerland, 1977; Italy and Sweden, 1978. *Id.*

259. *Id.* at 83. Other products and processes are often excluded from patent protection, including: animal varieties, methods for treatment of human or animal body, plant varieties, biological processes for producing animal or plant varieties, food products, and computer programs. *Id.* at 83 n.1.

260. McLeland & O'Toole, *supra* note 218, at 245. In developed countries, the duration of patent protection traditionally corresponds to the period granted pursuant to a utility patent. The exclusive rights of the patent holder in developed countries, however, are often limited by judicial doctrines of "patent misuse" and antitrust laws which control the content of patent licenses. *Id.*

261. *Id.* at 219.

262. *Id.* at 246 (citing Von Wartensleben, *Major Issues Concerning Pharmaceutical Policies in the Third World*, 11 WORLD DEV. 169, 174 (1983)).

263. *Id.*

the population of the United States, but represents less than two percent of the world market for pharmaceutical products.²⁶⁴ In contrast, the United States represents eighteen percent of the pharmaceutical market.²⁶⁵

Few research-based pharmaceutical companies are located in developing countries.²⁶⁶ Most of the local activity takes the form of "manufacturing" by compounders who purchase the ingredients, the diluents and other drug components from the lowest cost offshore manufacturers.²⁶⁷ The compounders then mix and package the drugs domestically and distribute them under various brand names.²⁶⁸ While owners of the relevant patent comprise a segment of the pharmaceutical drug market in these developing countries, copiers can occupy up to thirty-six percent of the market, as has been estimated in India.²⁶⁹ As well, governments often intervene in the distribution of pharmaceuticals in developing countries to insure that drugs are readily available at low cost to consumers.²⁷⁰

Compulsory licensing requirements have become a second major issue in the debate over protecting pharmaceuticals.²⁷¹ Developed countries argue that compulsory licensing is inconsistent with the GATT framework and criticize the attempts of developing countries to use this requirement to discriminate against foreign products in particular areas, such as chemicals and pharmaceuticals.²⁷² Developed countries would limit the use of compulsory licenses to situations where the supply of the local market is not guaranteed by the patentee.²⁷³ Developed countries seek recognition that these supply requirements can be satisfied by imports, as well as by local manufacturing.²⁷⁴ In addition, developed countries demand exception clauses for firms that do not have the means to produce the products locally, where it is economically unfeasible, or where the exploitation of the patent is impossible due to circumstances beyond the control of the patent holder.²⁷⁵

A third major source of friction in the area of patent protection for pharmaceuticals is the demand by developing countries that concessions

264. *Id.*

265. *Id.* at 246 n.138 (citing White, *Cooperation Among National Drug Manufacturers: Asociacion Latinoamericana de Industrias Farmaceuticas (ALIFAR)*, 11 *WORLD DEV.* 271, 274 (1983)).

266. *Id.* at 245.

267. *Id.*

268. *Id.*

269. Nogués, *supra* note 7, at 86.

270. McLeland & O'Toole, *supra* note 218, at 245.

271. Stamm, *supra* note 220, at 688. Compulsory licensing, or "working" requirements dictate that the patent owner manufacture the patented product locally in order for the patent to be recognized. See McLeland & O'Toole, *supra* note 218, at 245.

272. Stamm, *supra* note 220, at 688.

273. *Id.*

274. *Id.* Additionally, developed countries want licensees to be precluded from producing for export. *Id.*

275. *Id.*

be made to allow them to adapt to a new legal regime.²⁷⁶ Developing countries, concerned about granting potential monopolies to foreign innovators and their effect on local industries, argue for a transition period of up to ten years to allow domestic firms to develop the infrastructure to compete with the multinational drug companies.²⁷⁷ However, developed countries dismiss the need for transition periods, arguing that if the national industries have not already developed, an additional ten years will be of little benefit.²⁷⁸ This is particularly true if foreign investment is delayed until the period has lapsed and protection becomes available.²⁷⁹ Moreover, in view of the long delays between the issuance of the patent and the commencement of marketing, transitional periods of this type would mean that effective protection would be unavailable until the year 2015 or thereafter.

To deal with this situation, the United States and other developed countries have proposed "pipeline protection."²⁸⁰ Under this scheme, the developing country would provide market exclusivity for products which are (1) covered by a valid patent in the country of origin; and (2) not already on the market in the developing country.²⁸¹ The exclusivity would run only until the patent in the country of origin expires.²⁸² This approach would at least protect the investment of the original innovator in the patented process, while preserving to some extent the existing market positions of domestic firms.²⁸³ However, developing countries have expressed little enthusiasm for this solution.²⁸⁴

276. *Id.*

277. *Id.* The transition period actually is a delay in the issuance of product and process patents. Developing countries have insisted on such a provision in the TRIPs negotiations. While the United States attempted to block the provision, little opposition was raised by either the EC or Switzerland. *Mid-April Deadline Set for Talks: TRIPs Document Gets Poor Reviews*, 6 *World Intell. Prop. Rep.* (BNA) 41 (Feb. 1992). Developed countries, including the United States, do recognize that developing countries will need some time to establish the regulatory infrastructure required to enforce the new laws. Stamm, *supra* note 220, at 689.

278. *Interview with Brazilian Official on Pharmaceutical Patent Protection*, 5 *World Intell. Prop. Rep.* (BNA) 130 (May 1991).

279. *Id.* at 127, 130.

280. Stamm, *supra* note 220, at 689.

281. *Id.*

282. *Id.*

283. "In many countries, very similar forms of protection are or were known under names such as patents of importation (*e.g.*, Iran, Iraq, Jamaica, Zaire, formerly Belgium), revalidation patents (*e.g.*, Argentina, Venezuela, Panama, Honduras, Dominican Republic, Paraguay, Uruguay), confirmation patents (*e.g.*, Bolivia, Costa Rica, Belize), patents of introduction (*e.g.*, Venezuela, formerly Spain) and registration patents (*e.g.*, British colonies and ex-colonies—Singapore, Hong Kong, etc.). Recently "pipeline protection" was introduced into the new patent laws of Czechoslovakia and Mexico. *Id.*

284. *Id.*

B. Country Studies

A brief examination of the recent issues that have arisen in various countries serves to highlight the differences that exist between countries regarding protection of pharmaceuticals. In this section, a description of recent developments in Brazil, India, the Andean Pact countries, Argentina, and Thailand is presented. Each of these countries has been the target of USTR investigation.²⁸⁵

1. Brazil

While Brazil remains, in many respects, a developing country, the size of its potential market makes it unique in the international debate regarding IP protection. For example, Brazil has the fourth largest world market in terms of units sold in the pharmaceutical area, with European firms comprising its main investors in recent years.²⁸⁶ The market share of pharmaceutical companies in the United States has dropped from forty percent to twenty-five percent.²⁸⁷ This phenomenon can be attributed, not only to a lack of IP protection for pharmaceutical products and processes, but also to a system of price controls that has kept the price of the average pharmaceutical product in Brazil at about thirty percent of the world market price.²⁸⁸

Brazil was placed on the PWL in 1989 because of serious deficiencies in its patent law regime, including the failure to provide process or product patent protection for chemicals, foodstuffs, and pharmaceuticals.²⁸⁹ In addition, Brazilian piracy in the video and computer software areas resulted in significant business losses to U.S. firms.²⁹⁰ In order to induce changes in the Brazilian IP regime, the USTR imposed \$40 million in economic sanctions.²⁹¹

In June of 1990, as part of a broader effort to reduce tariffs, privatize various industries, and reform foreign investment laws, Brazil announced its intention to enact patent protection legislation.²⁹² A proposed bill provided patent protection for biotechnological products and for both phar-

285. *Brazil Lifts Price Controls on Drugs After Pledging to Change Patent Law*, 4 World Intell. Prop. Rep. (BNA) 203 (Sept. 1990).

286. *Id.*

287. *Id.*

288. *Id.*

289. *Accelerated Action Plans for Countries on Priority Watch List Under Special 301*, 3 World Intell. Prop. Rep. (BNA) 163 (July 1989). Pharmaceutical products have not been patentable in Brazil since 1945 and, under then-existing law, were specifically excluded from patent protection under Article 9 of the Industrial Property Code of January 1, 1972. *Id.*

290. For a discussion of business losses, see *id.*

291. *Id.*

292. *Presidential Committee's Draft Law Would Protect Pharmaceutical Patents*, 5 World Intell. Prop. Rep. (BNA) 111 (May 1991) [hereinafter *Presidential Committee's Draft Law*]. See also *USTR Lifts Sections After Pledge by Brazil to Enact New Patent Law*, 4 World Intell. Prop. Rep. (BNA) 175 (Aug. 1990).

maceutical products and processes.²⁹³ The bill stipulated a twenty-year patent term which could be extended for up to five years for firms engaged in local manufacturing.²⁹⁴ The legislation proposed to delay registration for pharmaceutical processes until 1993; registration for pharmaceutical products would not be allowed until 1994. In addition, the bill provided that if the patent owner did not begin effective development within three years, exclusive rights would be lost and compulsory licenses granted.²⁹⁵

The Brazilian government in August of 1990 followed the proposed patent law changes with a surprising decision to lift price controls on many pharmaceutical products.²⁹⁶ The products affected included all those produced by small and medium-sized pharmaceutical laboratories which, at that time, represented approximately twenty percent of the industry. In addition, the government removed its controls on over-the-counter products of the forty-seven major laboratories in the market. Pursuant to the announcement, a number of restrictions were to be lifted immediately, with the remaining to be phased out over a five-month period.²⁹⁷

The proposed patent law changes invoked swift and direct reaction from local manufacturers. The president of the Brazilian Association of Fine Chemicals (ABIFINA) stated that patent recognition would lead to a "violent increase in the price of medicines."²⁹⁸ He predicted that patent reform would devastate Brazilian pharmaceutical companies—presumably due to foreign competition—and further that foreign firms, rather than investing in local manufacturing, would simply export products into Brazil.²⁹⁹

293. *Presidential Committee's Draft Law*, *supra* note 292, at 111. The bill would provide immediate patent protection with a patent term of 20 years, rather than the initially proposed 15-year term. The bill contains "working" and compulsory license provisions. Under opposing legislation, no patent recognition would occur until after the year 2000. *Industrial Property Bill Suffers Setback in Brazilian Congress*, 5 *World Intell. Prop. Rep. (BNA)* 167 (July 1991) [hereinafter *Industrial Property Bill*].

294. *Presidential Committee's Draft Law*, *supra* note 292, at 111.

295. *Id.* Compulsory licensing provisions are within pre-existing law, but have had little effect in practice. In the 19 years of the provision, only five cases of compulsory licensing were filed. Of those, none had proven to be "truly successful," according to Maria Margarida Mittelbach, Director of Patents at the National Institute of Industrial Property (INPI). *Brazil Lifts Price Controls on Drugs After Pledging to Change Patent Law*, 4 *World Intell. Prop. Rep. (BNA)* 203, 204 (Sept. 1990). Pre-existing law also contains "working" requirements providing that patents "shall be forfeited, *ex-officio*, or by request of any interested third party" when, within four years, "working of the invention has not actually begun in the country," or if working has been discontinued for more than two consecutive years. *Id.* at 204.

296. *Id.* at 203.

297. *Id.*

298. *Presidential Committee's Draft Law*, *supra* note 292, at 111.

299. *Id.* Brazil, similar to other developing countries, continues to review technology transfer arrangements, which presumably would be used by foreign firms seeking to manufacture products in Brazil. Proposed government regulations require the disclosure of a schedule for training and technical assistance. Moreover, "know-how" licenses will not be

The bill was sent to the Brazilian Congress on May 2, 1991.³⁰⁰ Lobbying by local pharmaceutical interests resulted in heated opposition and an eventual delay in the approval of the legislation.³⁰¹ Substantial price increases after controls were lifted for pharmaceutical products not only strengthened opposition arguments, but also prompted the government to consider withdrawing the legislative initiative.³⁰² In addition, the controversial nature of the legislation led to a number of amendments, which finally prompted the issuance of a new version of the bill in June 1992. This version provided for protection of "pipeline" products, while denying patents for drugs on the "essential drugs" list of the World Health Organization.³⁰³ Even though industry representatives expected continued opposition to the bill at the time it was reissued, they remained hopeful that the legislation would be approved by the end of 1992.³⁰⁴ However, the unrest caused by the fall of the Collor Administration has derailed efforts in this area for the time being.

2. India

Like Brazil, India is a developing country with unique characteristics. First, the Indian sub-continent offers a lucrative and untapped market for pharmaceutical products.³⁰⁵ Second, the local industry is relatively sophisticated and diverse. Indian firms are partially vertically integrated—both producing and combining active ingredients.³⁰⁶ Third, a newly implemented drug approval process includes a clinical trial requirement that considers the health profile of local consumers.³⁰⁷ Additionally,

accepted, and all non-patented technology must be directly transferred to the Brazilian firm. Technology transfer agreements must be registered in order for the licensee's use to be recognized and for funds to be remitted abroad. *INPI Issues New Rules on Technology Transfers*, 5 World Intell. Prop. Rep. (BNA) 199 (Aug. 1991).

300. *Industrial Property Bill*, *supra* note 293, at 167.

301. *Id.* at 168.

302. During the final months of 1990, price increases exceeded 800% for some drugs, leading the Brazilian Minister of Health, Alcení Guerra, to accuse 20 pharmaceutical companies of "abusing economic power." *Minister of Health Threatens Delay in Brazilian Pharmaceutical Patents*, 5 World Intell. Prop. Rep. (BNA) 27 (Feb. 1991). On February 8, 1991, the government released that it would resume price controls on pharmaceutical products. *Interview with Brazilian Official on Pharmaceutical Patent Production*, 5 World Intell. Prop. Rep. (BNA) 127 (Apr. 1991).

303. *Debate Continues in Congress Over Patent Reform Legislation*, 6 World Intell. Prop. Rep. (BNA) 208 (Aug. 1992).

304. *Id.*

305. McLeland & O'Toole, *supra* note 218, at 246. The possibility exists for Indian firms to develop lucrative export markets in both developed countries and other lesser developed countries. See Horvath, *Patent Protection as an Efficient Means for Establishing and Developing a National Pharmaceutical Industry*, in *THE IMPORTANCE OF THE PATENT SYSTEM TO DEVELOPING COUNTRIES* 175 (1977). Moreover, Western firms have largely ignored unique health problems indigenous to the Indian sub-continent. McLeland & O'Toole, *supra* note 218, at 246.

306. McLeland & O'Toole, *supra* note 218, at 246. The industry is concentrated primarily in two states, Maharashtra and Gujarat, and a drug approval process is in place.

307. *Id.*

a number of Indian nationals possess sufficient scientific, technical, and managerial skills to establish research-based pharmaceutical companies, in lieu of relying on foreign technologies.³⁰⁸

Given these factors, it would appear that local firms would welcome a strong patent system that would protect the developing industry from more established producers. However, India has not supported a strong patent regime; instead, India views the establishment of a patent system as of questionable utility in encouraging research and development.³⁰⁹ In fact, Indian officials have gone so far as to state that "patent systems can . . . have a *dampening* effect on the promotion of domestic research and development and the building-up of domestic technological capabilities."³¹⁰ India has similarly resisted efforts to harmonize international IP regimes, maintaining that "it is a fundamental principle that . . . [GATT] member states . . . attune their intellectual property systems to their own needs and conditions."³¹¹

India was named to the initial PWL in 1989. The USTR noted the need for (1) improved patent protection; (2) elimination of discrimination against use of foreign trademarks; (3) registration of service marks; (4) protection of well-known marks; (5) improved access and distribution for United States motion pictures; (6) enforcement against piracy; (7) inclusion of an IP annex to the bilateral science and technology agreement; and (8) constructive participation by India in multilateral IP negotiations.³¹²

By 1991, patent protection remained quite weak in India, particularly with respect to pharmaceutical and chemical products. Patent protection was not available to any invention which claimed "substances intended for use or capable of being used as a food, medicine, or drug or related to substances prepared or produced by chemical processes."³¹³ Drugs covered by U.S. patents were being reproduced on a large scale by Indian manufacturers, resulting in substantial amounts of lost revenue to American firms.³¹⁴ Of additional concern was the relatively short term of patent protection for other products and the country's overly broad compulsory licensing provisions.³¹⁵

308. The failure to protect local firms may result in the emigration of Indian nationals trained as scientists and engineers, many of whom received their education in developed countries in Europe, as well as in the United States. *Id.*

309. Wolfhard, *supra* note 215, at 138.

310. *Id.*

311. *Id.* India has argued against combining trade law matters and IP laws, maintaining that, in fact, only the restrictive and anti-competitive practices of the IP owner distort or impede trade. *Id.* at 139-40.

312. "Special 301" Provision, *supra* note 144, at 162.

313. 1991 BARRIERS REPORT, *supra* note 147, at 104.

314. USTR Releases Annual Trade Report, *supra* note 168, at 121-24.

315. USTR Extends Investigation Into India's I.P. Protection, 6 World Intell. Prop. Rep. (BNA) 10 (Jan. 1992) [hereinafter *USTR Extends Investigation*]. During the TRIPS negotiations, India argued for the right "to grant compulsory licenses—at negligible royalty rates—in order to pursue public policy objectives in the pharmaceuticals sector." Also, India would permit compulsory licenses in order to guard against the non-working of patents.

India's continued deficiencies in these patent laws, as well as the inability of Indian officials to prevent piracy of patented products, books, videos, sound recordings, and software,³¹⁶ led to India's designation as a PFC in 1991.³¹⁷ The USTR was originally obligated to complete its investigation of India's deficient IP practices by November 26, 1991. However, discussions with India were extended until February 26, 1992. Thereafter, India was once again designated as a PFC and the United States threatened to impose duties on Indian pharmaceuticals, chemicals, and related products if no progress was made regarding the improvement of India's patent laws in the pharmaceuticals area.³¹⁸

3. Andean Pact Countries

The situation in such Andean Pact countries as Venezuela, is quite different from Brazil and India.³¹⁹ These countries have a number of large local compounders that compete with the subsidiaries of the larger multinational pharmaceutical firms in Ecuador, Peru, and Venezuela. This competition suggests that local firms have established a distribution system.³²⁰ However, none of the Andean Pact economies has become large enough to support a number of research-based pharmaceutical companies; nor do these countries have the skilled researchers, scientists, and engineers necessary to develop new products and processes that might benefit from stronger local patent protection regimes.³²¹ Further, inbound technology transfers are impeded by regulations making it difficult for foreign licensors to control the quality of the products manufactured locally³²²—a problem that is exacerbated by the failure of local governments to develop clinical testing or other quality control procedures.³²³

Wolfhard, *supra* note 215, at 139.

316. *USTR Extends Investigation*, *supra* note 315, at 10.

317. *USTR Releases Annual Trade Report*, *supra* note 168, at 122. For a detailed discussion of IP problems in India, see 1992 BARRIERS REPORT, *supra* note 147, at 113-21; 1991 BARRIERS REPORT, *supra* note 147, at 101-08.

318. *Indians Angered*, *supra* note 205, at 185.

319. The Andean Pact countries—Bolivia, Colombia, Ecuador, Peru, and Venezuela—have common industrial property legislation that is administered by the Commission of the Andean Pact. Decision 313, which was approved by the Commission on February 14, 1992, allows for the patenting of all pharmaceuticals as of that date, unless laws or regulations in the individual countries provide to the contrary.

320. McLeland & O'Toole, *supra* note 218, at 247.

321. *Id.* at 244. For additional barriers to Andean Pact compounders, see *id.* at 247.

322. With regard to new technology transfer regulations adopted in Venezuela in January of 1990, see John R. Pate, *Introductory Note to Decree No. 727 on Foreign Investment, Technology Licensing and Foreign Credit Regulations*, 29 INT'L LEGAL MAT. 273 (1990), reprinted in 29 INT'L LEGAL MAT. 278 (1990). See also *Intellectual Property Law and Licensing Highlights*, 4 World Intell. Prop. Rep. (BNA) 125 (June 1990).

323. See, e.g., McLeland & O'Toole, *supra* note 218, at 247.

4. *Argentina*

Current Argentine patent law provides protection for virtually all products except pharmaceuticals. Each of Argentina's recent governmental regimes has resisted any move toward protection of pharmaceuticals and chemicals.³²⁴ The Argentine government views pharmaceutical patents as impediments to the continued development of local industry, since local manufacturers use foreign companies' patent application information and published test results to replicate the foreign product, obtain required health approvals, and become the first to market the product in Argentina.³²⁵ Thus, the absence of Argentine pharmaceutical patents promotes local manufacture, but forces foreign manufacturers to change the name, dosage, or presentation of their product prior to introduction in Argentina, or risk introducing a product already available.³²⁶

Bilateral negotiation efforts to induce Argentine consideration of pharmaceutical patents have met with strong resistance from the Centro Industrial de Laboratorios Farmaceuticos Argentinos (CILFA), the local coalition of pharmaceutical companies. The CILFA argues that providing patent protection will merely provide the large foreign pharmaceutical companies with an effective monopoly on pharmaceutical manufacturing and sales in Argentina.³²⁷ In this respect, the CILFA predicts that "drug prices will skyrocket" and that "the strains on the healthcare system will be even more acute—similar action in other countries has bankrupted healthcare systems . . . people who need the drugs won't be able to afford them, and [the level of] Argentine unemployment will increase."³²⁸ In mid-1991, several bills were submitted to the Argentine Congress which would provide for the patentability of chemical and pharmaceutical formulas and processes.³²⁹ However, progress of the proposed legislation has been slow, as legislators indicate that Argentina should defer consideration of wholesale changes in its IP laws until the GATT negotiations have been settled, particularly as those discussions relate to such important

324. *Argentina: 1990 Legislative Outlook for Intellectual Property*, 4 *World Intell. Prop. Rep.* (BNA) 3 (Jan. 1990).

325. *Id.*

326. *Id.*

327. *Pharmaceutical Firms, PMA Jab Over Patent Protection in Argentina*, 5 *World Intell. Prop. Rep.* (BNA) 3 (Jan. 1991) [hereinafter *Pharmaceutical Firms*]. The CILFA placed advertisements in the *New York Times* and *Washington Post* attacking efforts of the PMA in "lobbying for swift introduction of restrictive patents." *Id.* The ads prompted PMA President Gerald Mossinghoff to reply and accuse the Argentine drug manufacturers of "attempting to scare the Argentines into believing that patent piracy is an appropriate tactic in international trade." *Id.*

328. *Id.* According to the advertisements, "the suggested retail price of a 'leading brand anti-ulcer drug' is \$55.15 in the United States, but only \$19.63 in Argentina," while a similar comparison of a "popular anti-arthritis drug" showed a \$169.84 U.S. price, contrasted with a price of only \$35.08 in Argentina. *Id.* The price differences were attributed to greater competition without sacrificing quality, since the Argentine drugs were, according to CILFA, "identical to those produced by the multinational companies." *Id.*

329. *Patent Law Would Be Modernized by Draft Bills Now Before Congress*, 6 *World Intell. Prop. Rep.* (BNA) 120 (May 1992).

Argentine products as leather and beef.³³⁰

5. Thailand

Thailand also excludes pharmaceutical products from patent protection,³³¹ a position that contributed to the USTR's decision to designate Thailand as a PFC in 1991.³³² At that time, the USTR, which had already launched a "Section 301" investigation of Thailand's patent law in response to a petition filed by the PMA in January of 1991,³³³ further examined Thailand's patent practices. The USTR noted that the lack of patent protection, as well as the overly broad compulsory licensing provisions in other parts of Thai patent law and an insufficient term of protection, had caused hardship for U.S. companies.³³⁴ However, because the USTR had previously initiated two investigations against Thailand relating to protection of patents and copyrights, it did not initiate a new investigation at the time Thailand was designated as a PFC. As a result, negotiations with Thailand are proceeding on a timeline that differs from those adopted for the PRC and India.³³⁵

The size of the Thai pharmaceutical industry compares favorably with the pharmaceutical industries of other developing countries, although it has yet to achieve the level of maturity exemplified in Brazil

330. *Opposition Keeps Patent Law on Hold Until Conclusion of Uruguay Round*, 6 World Intell. Prop. Rep. (BNA) 207 (Aug. 1992).

331. See Mesevage, *supra* note 9, at 446 & n.114 (citing Thailand's Patent Act).

332. See *USTR Names China, India, Thailand as Special 301 Priority Offenders*, Special Report World Intell. Prop. Rep. (BNA) 133, 134 (May 1991). Thailand was one of the countries on the USTR's original PWL. The action plan for Thailand included, not only improved and adequate patent protection, but also effective copyright protection for U.S. works including software, improved protection of foreign trademarks, and constructive participation in multilateral IP negotiations. "Special 301" Provision, *supra* note 144, at 163. Trade associations expressed grave concerns regarding the worsening level of piracy in Thailand. See *IIPA Submission*, *supra* note 148, at 84. Among the areas mentioned were records, tapes, motion pictures, books, and computer programs. *Id.* at 84-85. Specifically, it was alleged that Thai enforcement agents have failed to prosecute in a number of instances and have imposed burdensome requirements with respect to documentation necessary for piracy prosecution. *Id.* Moreover, fines imposed against retailers selling pirated records and tapes have been too low to be effective, and personal threats reportedly have been made against private sector enforcement agents. *Id.* See Lee D. Green, *Software Protection Problems in South Korea and Thailand: Notes, Trends and Practice Points on "Look and Feel" and Chip Protection in Asia*, in 1990 ANN. FALL MEETING: A.B.A. SEC. INT'L LAW & PRAC. PRESENT INT'L LEGAL ISSUES FOR EMERGING TECH. IN THE 1990'S: THE FUTURE OF CROSS-BORDER TRANSACTIONS, INTELL. PROP. PROTECTION AND TECH. TRANSFER 352-63 (1990). In December of 1990, the USTR initiated a "Special 301" investigation of Thailand's enforcement of its domestic copyright and pharmaceutical practices. See "Special 301" Provision, *supra* note 144, at 163; see also *USTR Initiates Investigation of Thailand*, 5 World Intell. Prop. Rep. (BNA) 107 (Apr. 1991).

333. The PMA petition alleged violations due to patent infringement. See *USTR Names Priority Offenders*, *supra* note 185, at 134.

334. *Id.* at 135. Other concerns included the ineffective enforcement of copyrights which led to significant losses to the United States motion picture, sound recording, and computer software industries. *Id.*

335. See *USTR Extends Investigation*, *supra* note 315, at 10.

and India. As of 1985, more than 190 Thai pharmaceutical factories were in operation, the annual output of which totalled approximately \$255 million—an increase of 300% from 1981.³³⁶ This increasing production is important to a developing country like Thailand. The ready availability of inexpensive drugs in over-the-counter markets is thought to be essential to a country where few doctors practice and a large proportion of people rely on self-medication. Thailand has few laws governing the sale and dispensation of drugs and items that would require a prescription in the United States. In Thailand, such drugs are readily available over the counter.

As in Argentina, U.S. pharmaceutical firms are finding that a number of their largest-selling products are being pirated and marketed under different brand names in Thailand. For example, Smith-Kline Beckman's Tagamet has been copied by Thailand's Biolab Company and marketed in Thailand under the name Cimulcer.³³⁷ In turn, Cimulcer, which costs only \$.61 per daily dose, as opposed to the \$1.68 daily dosage price of Tagamet sold in Bangkok, competes with twenty-five generic versions of the same drug, some of which sell for as little as \$.34 for a daily dose.³³⁸ The share of the Thai pharmaceutical retail market held by foreign manufacturers, which was estimated at around thirty percent in 1983, has been seriously threatened by this type of local production.³³⁹

Thailand has enacted a new Patent Act which became effective in September 1992.³⁴⁰ While the new law provides protection for pharmaceutical products, it fails to cover existing products that have not yet been marketed in Thailand.³⁴¹ As some critics have noted, fairly broad compulsory licensing provisions in the new Act mandate local manufacturing.³⁴² Finally, the legislation provides for a Board of Pharmaceutical Products with the power to control the prices of patented and unpatented pharmaceutical products in the local market.³⁴³ As the USTR commented, the new law is "deficient in several critical respects."³⁴⁴

CONCLUSION

It has become evident that expanded protection of IP rights is not sensible for all countries; neither is it wise to allow the United States and other developed countries to impose their conventions upon the rest of

336. Helen E. White, *Thailand's Drug-Copying Companies Keep Prices Down, Upset Foreign Firms*, WALL ST. J., Dec. 1, 1986, at 25. See also Mesevage, *supra* note 9, at 447 (discussing Thailand).

337. Mesevage, *supra* note 9, at 447-48 (citing Oddi, *supra* note 227, at 845).

338. *Id.* at 448 (citing White, *supra* note 336, at 25).

339. *Id.*

340. *Amendments to Patent Law Will Take Effect in September*, 6 World Intell. Prop. Rep. (BNA) 190 (July 1992).

341. *Id.*

342. *Id.*

343. *Id.*

344. *Id.*

the world.³⁴⁵ The evidence that has emerged linking the level of protection of IP rights to economic development is unconvincing. In fact, the recent rise of Japan and other "technology importers" appears to support the utility of alternative strategies, at least while the country is in a relatively early stage of development.³⁴⁶ Moreover, developing countries are justifiably skeptical of the motives of the United States and other developed countries, especially considering that the focus of most bilateral efforts has been on countries with large domestic markets and industrial capacities capable of competing with U.S. firms.³⁴⁷

Any global agreement or understanding with respect to protection of IP rights must necessarily address the "knowledge gap" between North and South.³⁴⁸ While virtually all developing countries have adopted at least some basic patent law regime, the historical technological disparity between industrialized and developing countries has continued to grow.³⁴⁹ For example, in the late 1970's, ninety percent of all technologists and scientists worked in developed countries, and ninety percent of their activities focused on work for use in the industrialized world.³⁵⁰ As these

345. As one commentator has observed:

Companies in rich countries often imply that all such disputes over intellectual property are a straightforward matter of piracy or theft However, the developing countries are more concerned about patent protection for technologically sophisticated goods such as drugs and chemical fertilizers In many cases, matching rich-country standards of patent protection would make such goods a lot more expensive to third-world buyers [I]n their dealings with the third world, companies regard the conventions agreed at home as self-evidently correct for everywhere else. It is not at all obvious that the developing countries are obliged, either morally or for the sake of sound economics, to meet the rich countries' demands.

Something Old, Something New, THE ECONOMIST, Sept. 22, 1990, at 34-35.

346. Interestingly, it appears that the United States itself obtained the steam engine technology necessary to build its textile industry during the 19th century in apparent violation of British laws intended to prevent the export of engines, parts, and skilled personnel. See *Merges*, *supra* note 223, at 245. While the United States may have ultimately benefitted from recognizing British rights, it is unlikely that America's technological advancement would have occurred as rapidly through lax enforcement of the foreign property rights. *Id.*

347. It has been argued that the lack of progress in expanding patent protection in LDCs has not really caused great concern in the United States because these countries offer little or no market for U.S. goods. *Id.* at 241. As noted above, the USITC and other trade groups have tended to focus on IP inadequacies in countries that pose some sort of threat to American firms. This threat is caused either by the production of infringing goods which are then exported to the United States and other markets or by the fact that infringing goods reduce the market share of American firms in the country where the goods are produced. *Id.*

348. See *UNCTAD Meeting Lacks Consensus on Technology-Transfer Code*, 5 World Intell. Prop. Rep. (BNA) 152 (June 1991) [hereinafter *UNCTAD*] (where a representative of Tunisia was quoted as saying: "In the absence of international action, present trends, including biotechnology, new materials technology, intellectual property and information technologies are simply accentuating the technological gap between developed and developing countries and may lead to technological polarization between them.").

349. Mesevage, *supra* note 9, at 440 (citing Yelapaala, *supra* note 237, at 201).

350. PETER NANYENYA-TAKIRAMBUDE, TECHNOLOGY TRANSFER AND INTERNATIONAL LAW 5 (1980). For further discussion of the concentration of technologists and scientists in the developed countries, see Mesevage, *supra* note 9, at 440.

figures demonstrate, the direction of research and development is largely determined by the ultimate commercial potential of the activities. Newer technologies, such as those in the agricultural area, are threatening to displace Third World products and services, thereby exacerbating the relative poverty in those areas.³⁵¹

All countries—developed and developing—must begin to work together to adapt existing IP systems to address both the disparate positions of the participants and the uncertainties created by new technologies possessing almost limitless potential. Any agenda on these matters should well include the following:

- Developed countries must look for ways to share their knowledge and assist developing countries in building their own technological infrastructure. Until this is done, IP rights will have little or no value to developing countries.
- Developed countries should consider providing funds to developing countries for research activities on products that have commercial potential in the domestic market in which the research is being conducted.³⁵² Developing countries have little stake in a global technological community that fails to address their unique needs.
- Efforts should be made to encourage scientists and technology managers from developing countries to remain in those countries to build the industrial infrastructure necessary for local exploitation of new technologies.
- Developed countries should address some of the concerns of developing countries regarding return on investment for funds expended on new products by reviewing the domestic regulatory hurdles associated with the approval and introduction of new products.³⁵³ Similarly, the type of protection to be afforded to new technologies such as biotechnology must be determined.
- For their part, developing countries must adhere to policies that af-

351. "For example, biotechnology has produced an economical industrial sweetener derived from corn displacing natural sugar in world markets." Mesevage, *supra* note 9, at 441 (citing Dias, Dembo & Morehouse, *Product Displacement: Biotechnology's Impacts on Developing Countries*, in *THE INTERNATIONAL CONTEXT OF RURAL POVERTY IN THE THIRD WORLD* 129, 132 (1988)). Aspartame, an artificial sweetener, is likely to cause further displacement. *Id.* These technological improvements damage the economies of sugar-exporting countries that are unable to control the quantity and price of exports. *Id.* Similarly, as technology improves, researchers gain the ability to greatly improve varieties of the world's major crops, thereby drastically reducing biological diversity. As a result, a number of countries will be unable to compete in these areas, with drastic consequences for their local economies. Acharya, *supra* note 6, at 85.

352. Even in countries such as Romania, where a scientific infrastructure exists, the lack of funds for research and development threatens to cripple future development of a domestic industry. *UNCTAD, supra* note 348, at 152.

353. For example, regulatory hurdles in the United States often delay the introduction of new products for a number of years. The timeline for product introduction, and thus the internal rate of return on investment, can be effected by changes in clinical trials and other testing requirements, provided that material risks are not created for the ultimate consumers of the products. Since substantial differences exist among the developed countries regarding clinical trials requirements, it is clear that some margin for change exists in this area.

ford protection to foreign firms willing to actively participate in local technology transfer programs. In the face of local sentiment against foreign investment, such policies may encounter strong resistance. An effort must be made, however, to demonstrate the long-term utility of obtaining the requisite skills from on-site training.

For such a program to succeed, cooperation is required in a number of areas. First, since investment is necessary to implement technology transfer to developing areas, developing countries may need to concede that IP rights *should* be considered in the larger context of international trade and investment. Developed countries, however, must recognize that new foreign investment, at least in some areas, must seek to accomplish some of the objectives referred to in the above agenda. Second, at least where research and development funding is to be provided, bilateral agreements may be far easier to implement and monitor in the early stages of technology transfer. Finally, the industrial firms in developed countries must be more forthcoming in locating and nurturing new local partners in developing countries.

Resolving the "North-South" debate regarding IP rights will necessarily demand a good deal of political courage from all parties. Little doubt exists that cooperation with foreign concerns, however well meaning, can be extremely dangerous for political leaders in many developing countries. Similarly, a program perceived as drawing funds and jobs outside of developed countries like the United States, especially at this economic juncture, will surely draw criticism from a variety of interests. Nonetheless, such a long-term investment must be made on both sides if the theoretical relationship between economic development and the sanctity of IP rights is finally to be realized.