

Northwestern Journal of International Law & Business

Volume 21
Issue 2 *Winter*

Winter 2001

International Governance through Trade Agreements: Patent Protection for Essential Medicines

Judy Rein

Follow this and additional works at: <http://scholarlycommons.law.northwestern.edu/njilb>



Part of the [International Trade Commons](#)

Recommended Citation

Judy Rein, International Governance through Trade Agreements: Patent Protection for Essential Medicines, 21 Nw. J. Int'l L. & Bus. 379 (2000-2001)

This Article is brought to you for free and open access by Northwestern University School of Law Scholarly Commons. It has been accepted for inclusion in Northwestern Journal of International Law & Business by an authorized administrator of Northwestern University School of Law Scholarly Commons.

ARTICLES

International Governance Through Trade Agreements: Patent Protection for Essential Medicines

Judy Rein^{*}

I. INTRODUCTION

With the internationalization of infectious disease, increased globalization of economic transactions, and technological innovation, we are at a critical juncture in decision-making about pharmaceutical regulation. Advances in medical research have yielded significant improvements in treating diseases that only recently were incurable. This is most stunning in the area of AIDS treatments. Significant public and private investment, particularly in the United States, converted this killer into a manageable chronic disorder for many in the developed world. Simultaneously, an explosion in the infection rate in poor countries has made AIDS a largely developing world disease. As a result, the high-priced life saving drugs are largely unavailable to what amounts to 90% of the infected population.

^{*} Paper written for Fellowship, Center for International Studies, New York University School of Law.

The devastation of the AIDS pandemic and the management of a public health solution present a daunting challenge to global governance on many fronts. A critical source of conflict at the end of the millennium arose from the tension between forces favoring preservation of commercial interest in patent rights and the compelling need for poorer countries to get access to safe medicines at an affordable price. Inaccessibly priced medicines are at the core of a dispute that is not only North-South, but also mobilizes transnational actors, such as AIDS treatment advocates and industry proponents. A combination of the market, state regulation of patent monopolies, and intergovernmental trade regimes manages distributional outcomes. However, this governance structure poorly responds to this particular instance of market failure. As with many problems involving economic governance at the global level, there is a gap between the representative organs that make up the regulatory frameworks (intergovernmental negotiators acting for nationally determined economic interests) and the breadth of interests, constituted both transnationally and domestically, that are stakeholders in policy outcomes.

International Trade

The signing of the North American Free Trade Agreement (“NAFTA”)¹ and the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)² represented a significant departure from traditional multilateral trade diplomacy. From its creation in 1947, the General Agreement on Tariffs and Trade (“GATT”) operated through a process of negotiating tariff reductions on goods. In the 1990s, this gradual reduction of tariff (and some non-tariff) barriers to the free flow of commodities was supplemented with the establishment of enforceable global standards governing intellectual property.

The inclusion of intellectual property rights as a critical aspect of trade negotiations flowed logically from the explosive growth of value generated by intellectual property in industries such as software and biotechnology. Strong intellectual property protections in an otherwise unregulated market are rationalized as necessary interventions to encourage innovation by guaranteeing sufficient return on investment in the development of intellectual property. Rights holders are then able to enjoy monopoly rents on their inventions, a policy which must be balanced with opposing social goals of promoting competition and affordability of consumer goods. By establishing positive protection of “rights” for investors in innovation, the global

¹ North American Free Trade Agreement, Dec. 17, 1992, 32 I.L.M. 612 [hereinafter NAFTA].

² Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter Marrakesh Agreement], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND Vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

trade regime governs the complex balance of interests between intellectual property owners, second-comers in the market, and consumers.

Managing this balance is particularly tricky in the case of pharmaceuticals. Unlike most other consumer goods, access to essential medicines is a basic human need, and an important aspect of many national health policies. According to the World Health Organization ("WHO"), access involves three components: therapeutic access (the discovery and development of appropriate treatments), physical access, and financial access.³ Financial access is greatly affected by the ability of pharmaceutical companies to exercise monopoly control of pricing through exclusive patent rights. At the level of international trade diplomacy, the tradeoff between protection and access takes on a North-South dimension. Where comparative advantage depends on monopoly of intellectual property, developing countries are at a distinct disadvantage. Once intellectual property is part of the international trade regime, the dynamics of access to essential pharmaceuticals can be shaped in this arena.⁴ Through active lobbying, international pharmaceutical companies succeeded in obtaining a high level of pharmaceutical patent protections in the trade agreements.⁵ Increasingly, poor countries affected by the AIDS pandemic and international health organizations actively have sought to preserve state regulatory powers within the confines of the TRIPS agreement.⁶ However, these efforts have been met with considerable resistance, particularly from the United States, which has engaged in aggressive

³ See generally World Health Organization, at <http://www.who.int> (last modified Mar. 6, 2001).

⁴ See Sara Dillon, *Fuji-Kodak, the WTO, and the Death of Domestic Political Constituencies*, 8 MINN. J. GLOBAL TRADE 197, 203 - 203 (1999) (arguing that increased legalism at the international level has eclipsed the ability of domestic constituencies to affect national policies).

⁵ See Robert Weissman, *Long Strange Trips: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PENN. J. INT'L LAW 1069 (1996).

⁶ See *Revised Drug Strategy*, Res. WHA 52.19, Fifty-Second World Health Assembly, May 24, 1999.

Recognizing that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) provides scope for the protection of public health;

Taking note of concerns of many Member States about the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries;

1. URGES Member States: . . .

(3) to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs.

Id.

unilateral action to extend patent protection beyond the international agreements.⁷

This paper examines the current conflicts surrounding the implementation of patent protection for pharmaceuticals. Part II outlines the specifics of trade agreements shaping the global intellectual property regime and the consequences for governments seeking to devise an essential drugs policy. Part III analyzes the process of obtaining consensus and compliance with patent protection rules through the negotiation and implementation of trade agreements, and the utilization of dispute settlement mechanisms. This section also examines the aggressive application of unilateral measures to induce adherence to levels of protection beyond those established at the multilateral and regional level. Part IV considers alternative approaches for international governance of pharmaceuticals that aim to maximize equitable outcomes while preserving incentives for innovation.

II. HARMONIZATION OF PATENT REGIMES

The Interaction of Regional and Multilateral Initiatives

The core GATT principles of national treatment and most favored nation status are incorporated in the two agreements. Both TRIPS and NAFTA provide that each Member (or "Party" in the case of NAFTA) requires that nationals of other participating states may not be treated less favorably in domestic protection and enforcement of intellectual property legislation.⁸ Most-favored-nation treatment (included in Article 4 of the TRIPS) mandates that any advantage conferred to one member country must be extended to all other member countries. However, trade advantages provided within NAFTA most likely are not required to be extended to GATT members. The exception provided within the GATT, permitting customs unions and free trade areas, will probably be applied to World Trade Organization ("WTO") agreements.⁹

Although the increase in regional trade integration initiatives in the 1980s raised concerns about potential weakening of the multilateral frame-

⁷ See Office of the United States Trade Representative, *USTR Announces Results of Special 301 Annual Review* (Apr. 30, 1999), at <http://www.ustr.gov/releases/1999/04/99-41.html> [hereinafter Special 301 Annual Review].

⁸ TRIPS, *supra* note 2, art. 3; NAFTA, *supra* note 1, art. 1703.

⁹ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194, Art. XXIV [hereinafter GATT]. See generally J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE* (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998). But see Frederick M. Abbott, *LAW AND POLICY OF REGIONAL INTEGRATION* 95-96 (1995) (arguing that because the TRIPS agreement itself does not contain an exemption for regional integration areas, higher levels of protection within NAFTA should extend to certain countries).

work, this largely has proven to be of limited significance, especially with the strengthening of the multilateral system through conclusion of the Uruguay Round of the GATT.¹⁰ Rather, at least for the purposes considered here, the shift in U.S. emphasis toward the North American trade arrangement served to bolster its intellectual property agenda at the multilateral level.¹¹ The NAFTA Chapter 17 provisions were negotiated at the same time as TRIPS by mostly the same people, so much of the language in the two agreements is virtually identical or strikingly similar.¹² Intellectual property was included in the GATT Uruguay Round and the NAFTA due to U.S. insistence.¹³ Although they are largely the same, the United States was more successful at securing its agenda in the NAFTA accord than in TRIPS. NAFTA Chapter 17 provisions are often referred to as “TRIPS-plus.”¹⁴

Minimum Standards

The TRIPS and NAFTA intellectual property provisions are exceptional instances of the imposition of minimum standards on domestic legal systems.¹⁵ Other aspects of the trade agreements that address domestic regulatory regimes, such as the Agreements on Technical Barriers to Trade and on the Application of Sanitary and Phytosanitary Measures,¹⁶ mandate limiting constraints on regulations for technical or health purposes. The objective of those provisions is reducing non-tariff barriers to trade, rather than creating internationally enforceable domestic regimes to protect technical and sanitary conditions.¹⁷ The NAFTA Supplemental Agreements on

¹⁰ See Roy Maclaren, *The Geo-Political Changes During the 1980s and Their Influence on the GATT*, in *THE URUGUAY ROUND AND BEYOND* 189 (Jagdish Bhagwati & Mathias Hirsch eds., 1998). See generally *MULTILATERALISM AND REGIONALISM AFTER THE URUGUAY ROUND* (Riccardo Faini & Enzo Grilli eds., 1997).

¹¹ See James A.R. Nafziger, *NAFTA's Regime for Intellectual Property: In the Mainstream of Public International Law*, in *UNAM/ASIL, EL PAPEL DEL DERECHO INTERNACIONAL EN AMERICA: LA SOBERANIA NACIONAL EN LA ERA DE LA INTEGRACION REGIONAL* 377, 384 (1997).

¹² See Joseph Papovich, *NAFTA's Provisions Regarding Intellectual Property: Are They Working as Intended? – A U.S. Perspective*, 23 *CAN.-U.S. L.J.* 253 (1997). Joseph Papovich served as the Deputy Assistant Trade Representative for Intellectual Property in the Office of the U.S. Trade Representative.

¹³ See *id.* at 254.

¹⁴ See Allen Z. Hertz, *Shaping the Trident: Intellectual Property Under NAFTA, Investment and Protection Agreements and the World Trade Organization*, 23 *CAN.-U.S. L.J.* 261, 266 (1997).

¹⁵ The Agreement on Trade-Related Investment Measures (“TRIMS”), part of the Marrakesh Agreement, also establishes positive requirements, but it does not entail the same quantity of elaboration with respect to highly specific harmonizing rules.

¹⁶ These were also included in the Marrakesh Agreement. See NAFTA, *supra* note 1, ch. 9, Standards Related Measures.

¹⁷ See Hertz, *supra* note 14, at 266 (citing Frieder Roessler, former Director of the WTO Secretariat's Legal Affairs Division).

Labor and the Environment¹⁸ do require that parties enforce positive labor and environmental standards, but those agreements only require the enforcement of domestic laws, not the revision of domestic laws to meet an internationally negotiated standard. At most, the Supplemental Agreements contain vague aspirational statements about enacting protective legislation.¹⁹ By contrast, both the TRIPS and Chapter 17 of NAFTA contain fairly detailed requirements for levels of domestic regulation of intellectual property rights. In both cases, parties may provide more extensive coverage to property rights than required by the Agreements.²⁰

Rights of Patent-holders

The substantive provisions most relevant to pharmaceuticals are found in Section 5 of the TRIPS, and in NAFTA Article 1709 covering patents. TRIPS provides that patent holders are to receive the exclusive rights to prevent third parties from making, using, offering for sale, selling, or importing the product or process without the owner's consent.²¹ Rights articulated in NAFTA are similar, but do not include the prevention of third parties from importing patented products, only from importing products derived from patented processes.²² This omission avoids directly addressing the problem of parallel imports, or "gray market" goods. The TRIPS similarly skirts the issue by referring to Article 6, which states that "[f]or purposes of dispute settlement under this Agreement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."²³ Exhaustion of rights doctrine holds that once a rights holder introduces protected goods into the stream of commerce, there is no restriction on how the goods may be further distributed. The practice of parallel imports involves the importation of lawfully made products that were not intended for distribution in the country importing the goods.²⁴

¹⁸ See NAFTA, North American Agreement on Labor Cooperation and North American Agreement on Environmental Cooperation, Sept. 13, 1993.

¹⁹ For example, Article 3 of the North American Agreement on Environmental Cooperation provides as follows:

Recognizing the right of each Party to establish its own levels of domestic environmental development policies and priorities, and to adopt or modify accordingly its environmental laws and regulations, each Party shall ensure that its laws and regulations provide high levels of environmental protection and shall strive to continue to improve those laws and regulations.

Abbott, *supra* note 9, at 109-12.

²⁰ See TRIPS, *supra* note 2, art. 1 (1); NAFTA, *supra* note 1, art. 1702.

²¹ TRIPS, *supra* note 2, art. 28.

²² NAFTA, *supra* note 1, art. 1709(a).

²³ TRIPS, *supra* note 2, art. 28 (1)(a)(n. 6).

²⁴ See Laurinda L. Hicks and James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT'L L. & POLICY 769, 810-11 (1997).

This loophole/ambiguity is especially relevant to the parallel importation of pharmaceuticals, as there are significant price differentials on the same medicines legally produced in, or exported to, different countries.²⁵

By practicing market segmentation, pharmaceutical companies may seek to maximize potential marginal returns in countries with low purchasing power, while preserving high prices in stronger markets. Advocates of restricting parallel importation of medicines claim that such a strategy would encourage companies to sell at below world market prices to poorer countries. However, in practice, poor countries are not necessarily the beneficiaries of market segmentation. The ability to shop the world market offers consumers the advantage of price negotiating leverage with companies.²⁶

Under TRIPS, the term of patent protection is established at a minimum of twenty years from the filing date.²⁷ NAFTA provides for twenty years from filing, or, alternatively, seventeen years from the date of the patent grant, as had been the longstanding U.S. policy.²⁸ In implementing the TRIPS agreement, the United States revised its patent protection period to conform with the single TRIPS standard.²⁹ The only other change to the U.S. patent scheme required by the agreements was nondiscrimination on the basis of place of invention. Drugs developed in other countries must now be afforded national treatment with respect to patent approval.³⁰

The agreements also include extensive norms for the domestic enforcement of property rights. Unlike the substantive provisions, they do not articulate specific rules, but rather general standards to allow for local differences.³¹ The rules cover procedural matters, such as timely, evidence-

²⁵ Price differentials are usually the result of varied approaches to price regulation in different countries. Parallel importing of pharmaceuticals is widely practiced within the European Union. See PATRICIA M. DANZON, *PHARMACEUTICAL PRICE REGULATION* 84-88 (1997) (arguing that savings from parallel importation usually accrue to intermediaries rather than to consumers).

²⁶ See Mohamed Lahouel and Keith Maskus, *Competition Policy and Intellectual Property Rights in Developing Countries: Interests in Unilateral Initiatives and a WTO Agreement*, WORLD BANK GLOBAL CONFERENCE ON DEVELOPING COUNTRIES AND THE MILLENNIUM ROUND (Sep. 20-21, 1999), at <http://redem.buap.mx/rm19.htm>.

²⁷ TRIPS, *supra* note 2, art. 32.

²⁸ NAFTA, *supra* note 1, art. 1709 (12).

²⁹ See Uruguay Round Agreements Act, Pub. L. No. 103-465, §532(a)(1), 108 Stat. 4809, 4984 (1994) (amending 35 U.S.C. § 154 (1988)); see also Weissman, *supra* note 5, at 1074.

³⁰ The European Union has asserted that nonetheless, delays in commercialization of medicinal products developed in Europe are still longer than of U.S.-tested products, in part because of the Food and Drug Administration ("FDA") approval procedures. See EUROPEAN COMMISSION, 1999 REPORT ON UNITED STATES BARRIERS TO TRADE AND INVESTMENT 25 (Aug. 1999), at http://europa.eu.int/comm/external_relations/us/trade_barriers_report_99/usb99.pdf.

³¹ For a discussion of the challenges posed by the difficult fit between domestic rules falling within TRIPS and the dispute settlement mechanisms covering the WTO in general, see

based judicial and administrative enforcement, the availability of judicial review, and the provision of civil and criminal penalties.³²

Regulation of Pharmaceutical Patents

Patentable subject matter is broadly conferred to “any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.”³³ In legal actions involving infringement of a process patent, the agreements shift the burden of proof to the defendant.³⁴ Discrimination as to place of invention, the field of technology, and whether products are imported or locally produced is proscribed.³⁵

These provisions imply a significant retooling of the patent registration and enforcement systems of many countries. Prior to the agreements, some countries only protected pharmaceutical processes, but not products, thus allowing generic drug makers to legally produce substances similar to patented medicines through a distinct process.³⁶ India implemented this method in its Patents Act of 1970 and developed a thriving generic pharmaceutical industry producing cheap medicines.³⁷ Until recently, some countries in the developing world, such as Brazil, did not extend any patent protection to pharmaceuticals.³⁸ Additionally, the equal level of protection mandated for imports and locally manufactured products eliminates a domestic tool for promoting direct investment and technology transfer. With the right to supply imports protected, national governments may not legislate “work-the-patent” rules limiting patents to products manufactured lo-

generally Rochelle Cooper Dreyfuss and Andreas Lowenfeld, *Two Achievements of the Uruguay Round, Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275 (1997).

³² See NAFTA, *supra* note 1, arts. 1714-1717; TRIPS, *supra* note 2, arts. 41-50.

³³ TRIPS, *supra* note 2, art. 27 (1); NAFTA, *supra* note 2, art. 1709 (1).

³⁴ See TRIPS, *supra* note 2, art. 34; NAFTA, *supra* note 1, art. 1709 (10).

³⁵ See TRIPS, *supra* note 2, art. 27 (1); NAFTA, *supra* note 1, art. 1709 (7).

³⁶ According to one study, prior to TRIPS, only 45% of developing countries recognized pharmaceutical product patents. Those that did so had much shorter periods of protection than the twenty-year consensus emerging in the developed countries. See German Velasquez and Pascale Boulet, *Essential Drugs in the New International Economic Environment*, 3 BULLETIN OF THE WORLD HEALTH ORGANIZATION 288, 289 (1999).

³⁷ See Elizabeth Henderson, *TRIPS and the Third World: the Example of Pharmaceutical Patents in India*, 11 EUR. INTEL. PROP. REV. 651, 657-58 (1997). Henderson notes that because of shorter patents for pharmaceuticals than for other technology (five to seven, rather than fourteen years), and the delay in bringing pharmaceuticals to market (up to eight years) there has been no effective patent protection for pharmaceuticals in India.

³⁸ In 1996, Brazil passed legislation that brought pharmaceutical protection in compliance with the TRIPS requirements. See Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L LAW. 835, 860 (1996).

cally, as had been permitted under the Paris Convention.³⁹ Importation of a patented product is thus considered sufficient to meet any requirements that a patent be “worked”.

Both agreements contain special pipeline provisions covering pharmaceutical and agricultural chemical products for countries that had not provided patent protection prior to the agreements coming into force. In the case of NAFTA, parties are required to offer patent protection for the remainder of the patent term granted in another party, as long as the product has not already been marketed in the country newly offering protection.⁴⁰ The TRIPS provision, by contrast, allows countries to ease in patent protection of these areas. It requires that a filing procedure, or “mailbox” system, be established so that the subsequent patent grant will be counted from the filing date.⁴¹ This requirement only covers those patents filed from the date of the enforcement of the agreement.⁴² A product that is the subject of the patent application must be accorded up to five years of exclusive marketing rights until the patent application is granted or rejected.⁴³ Although developing countries are not required to have a fully compliant patent system until 2005,⁴⁴ the pipeline requirement for pharmaceuticals expedites the effective recognition of patents, by preserving the place in line for registration and mandating exclusive marketing in the interim.

Balancing Patent Protection with Social Needs

Despite the unprecedented level of positive rulemaking, the intellectual property provisions of the trade agreements leave substantial room for countries to exercise regulatory control over pharmaceutical pricing. In addition to the omission of any express prohibition on the use of parallel imports, there is nothing in the agreements to bar the use of price controls, a common practice in developed countries, with the exception of the United States.⁴⁵

³⁹ See Reichman, *supra* note 9, at 352 (citing Paris Convention for the Protection of Industrial Property, art. 5A).

⁴⁰ NAFTA, *supra* note 1, art. 1709 (4).

⁴¹ See TRIPS, *supra* note 2, art. 70 (8).

⁴² See *id.*

⁴³ See *id.* art. 70 (9).

⁴⁴ See *id.* art. 65 (4), which provides a 10 year transition period for developing countries which previously did not protect pharmaceuticals to implement a product patent system.

⁴⁵ The wide differentials in pricing between the United States and other countries, and among purchasers within the United States is a growing political problem for international pharmaceutical companies. See, e.g., Jeff Gerth and Sheryl Gay Stolberg, *Drug Makers Reap Profits On Tax-Backed Research*, N.Y. TIMES, Apr. 23, 2000, at A1 (offering the example of a six-week supply of a glaucoma drug that costs a French patient \$18.78, U.S. federal agencies \$25.37, and a U.S. patient purchasing in a drugstore \$49.69.)

Exceptions to the rigorous standards are also specified.⁴⁶ TRIPS explicitly acknowledges the necessity of considering public interest, and specifically health policy, in formulating domestic intellectual property regulations. In its General Provisions and Basic Principles, the agreement allows Members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”⁴⁷ The Agreement further acknowledges the principle that intellectual property rights must be limited so as not to be abused in the restraint of trade or “adversely affect the international transfer of technology.”⁴⁸ With the exception of competition policy, these provisions are not included in the NAFTA agreement.

Members may exclude patents for inventions where the exclusion is needed to protect public order or morality, including to protect human, animal, or plant life or health, or to avoid environmental injury. This statement is predicated, however, on the condition that no commercial use of the invention is permitted in the territory.⁴⁹ This exception lends little support to exempting essential drugs from patent protection requirements under the Agreement. The public order exception essentially authorizes a state to deny patents to harmful substances that are banned for reasons of health, safety, or environmental protection. Robert Weissman suggests that a government pursuing an essential drugs policy can obviate the requirement that no commercial use be allowed in the territory by denying patentability and producing and distributing the target medications through a public or non-profit entity or network. Such a scheme also would require the prohibition of all non-public commercial exploitation of the substance. This seems to be a stretch of the concept underlying “*ordre public*” and probably does not fall within the provision, which states that the exclusion cannot be made “merely because the exploitation is prohibited by . . . law.”⁵⁰

Additionally, diagnostic, therapeutic, and surgical methods for the treatment of humans or animals, and plants, animals other than micro-

⁴⁶ See TRIPS, *supra* note 2, art. 30; NAFTA, *supra* note 1, art. 1709 (5):

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

⁴⁷ TRIPS, *supra* note 2, art. 8 (1).

⁴⁸ *Id.* art.8 (2).

⁴⁹ See *id.* art. 27 (2); NAFTA, *supra* note 1, art. 1709 (2).

⁵⁰ TRIPS, *supra* note 2, art. 27(2). Weissman argues extensively and creatively that a country may be successful at asserting the “necessary” nature of noncommercial exploitation of essential medicines yet this tactic is inconsistent with the plain textual meaning of the provision, which is to preclude patentability of harmful inventions, not inaccessibly priced ones.

organisms, and the biological processes for the production of plants or animals may be excluded.⁵¹ Although this provision also suggests a health exception principle in the Agreement, by its terms, it refers only to patenting "methods" and actual life forms. The United States strongly opposed the exclusion of life forms due to its interest in protecting the growing biotechnology industry. The provision of a five-year review of Article 27 was included in the final draft of the TRIPS agreement.⁵²

Compulsory licensing

Compulsory licensing of patents is one of the most contentious issues in intellectual property regulation. A compulsory or mandatory license waives the patent holder's normally exclusive right to the invention, usually under specified conditions, such as non-utilization, abuses in the restraint of trade, or other circumstances creating a public interest in wider availability.⁵³ Payment of a royalty to the patent-holder is usually required. Compulsory licensing schemes are used to control pharmaceutical prices by allowing generic producers into the market before the patent expiration of brand-name drugs. In the period that Canada instituted compulsory licensing for pharmaceuticals (especially 1969-1987), drug prices dropped significantly.⁵⁴ The United States consistently has opposed any form of compulsory licensing, except perhaps in extreme situations involving national security. The compulsory licensing provisions in the agreements represent a compromise to developing country interests.

Compulsory licensing is permitted under Article 31 of TRIPS and Article 1709 (10) in NAFTA, but is subject to a number of restrictions. Authorization for use of a patent without the consent of the right holder must be considered on its individual merits.⁵⁵ Efforts to obtain a license from the rights holder on reasonable terms for a reasonable period of time must be made before a compulsory license may be granted.⁵⁶ Significantly, prior effort to obtain consent from the right holder may be waived "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use."⁵⁷ However, the patent holder must be paid

⁵¹ See *id.* art. 27 (a) and (b); NAFTA, *supra* note 1, art. 1709 (3).

⁵² See Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPS Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 45 (1998).

⁵³ See F.M. SCHERER, *THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSING* 5 (1977).

⁵⁴ See Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 240-45 (1999). Under challenge from U.S. pharmaceutical companies, Canadian courts upheld the payment of a 4% royalty by generic producers to the brand-name patent-holders.

⁵⁵ See TRIPS, *supra* note 2, art. 31 (a); NAFTA, *supra* note 1, art. 1709 (10) (a).

⁵⁶ See TRIPS, *supra* note 2, art. 31 (b); NAFTA, *supra* note 1, art. 1709 (10) (b).

⁵⁷ *Id.*

adequate remuneration,⁵⁸ and all decisions relating to the compulsory license must be subject to independent review.⁵⁹ Production under the compulsory license must be for domestic consumption, not export.⁶⁰

Development Lag

The TRIPS accord also makes some concessions to the particular needs of developing countries that lack the administrative infrastructure to implement a sophisticated pharmaceutical patent system. Developing country Members of the WTO are granted a ten year transitional period to bring domestic law into compliance with the requirements for product patent protections in TRIPS Article 65 (4). There is no transition period in NAFTA, but Mexico has three years to make enforcement fully operational.⁶¹ Finally, Article 66 of TRIPS calls upon developed country Members to provide incentives to locally-based enterprises for the purpose of encouraging technology transfer to the least developed countries. This particular mandate does not provide any specific requirements or objectives. There is no similar exhortation in NAFTA.

Advocates for implementing a strong intellectual property regime in developing countries often maintain that it is in the best interest of those countries to adopt a high level of protection. This theory holds that patent protection will encourage technologically sophisticated investment in poor countries, leading to a diffusion of technology, if investors can be assured that they can restrict employees from transferring this technology to other employers. There is no reason to believe, however, that offering patent protection will encourage rights holders to "work the patent" in a particular country, if the rights are sufficient to preserve a monopoly on the import market, as is the case with both TRIPS and NAFTA.⁶²

III. CREATING CONDITIONS FOR COMPLIANCE

Although with both agreements, U.S. negotiators encountered resistance to the protection of intellectual property in general, and in particular,

⁵⁸ See TRIPS, *supra* note 2, art. 31 (h); NAFTA, *supra* note 1, art. 1709 (10) (h).

⁵⁹ See TRIPS, *supra* note 2, art. 31 (i)-(j); NAFTA, *supra* note 1, art. 1709 (10) (i) and (j).

⁶⁰ See TRIPS, *supra* note 2, art. 31 (f); NAFTA, *supra* note 1, art. 1709 (f). Incidental export apparently would be tolerated, as the language states specifically that authorization shall extend "predominantly" to the domestic market.

⁶¹ NAFTA, *supra* note 1, Annex 1718.14.

⁶² A. Samuel Oddi, *TRIPS-Natural Rights and a "Polite Form of Economic Imperialism,"* 29 VAND. J. TRANSNAT'L L. 415, 450-52 (1996). Oddi argues persuasively that there is no strong economic policy justification for the particular rules embodied within TRIPS, especially the 20 years of patent protection and the mandatory inclusion of a broad area of subject matter. The only rationale for this type of patent regime stems from an implicit natural rights theory underpinning the position taken by the developed countries, particularly U.S. negotiators.

pharmaceutical patent protection, the NAFTA provisions were easier to obtain both in negotiation and implementation. Undoubtedly, it is easier to obtain at a regional or subregional level what may seem insurmountable at a multilateral level. Chapter 17 provisions were negotiated in one year, whereas TRIPS dragged on for six years, and was only finalized after the NAFTA was already signed. Harmonization of patent rules under NAFTA was essentially accomplished as part of the negotiation and ratification process. The TRIPS implementation process, on the other hand, involving more gradual phase-in of patent protections, has generated more disputes.

A. Negotiation

NAFTA

The bilateral Canada-United States Free Trade Agreement ("FTA"),⁶³ was the precursor to NAFTA. Of special concern to the U.S. FTA negotiators was Canada's 1969 patent law that contained provisions for the liberal use of compulsory licenses for pharmaceuticals at any time during the patent, and only protected processes, not products.⁶⁴ Although a draft of that agreement included specific intellectual property provisions, during the negotiation process, Canada obligingly passed a revised Patent Act that deferred the authority to issue a compulsory license on imported pharmaceuticals for seven to ten years.⁶⁵ The Canadian reform was partially motivated by the concern that lax protection of pharmaceutical intellectual property was discouraging international investment in research and development of new medicines. U.S. pharmaceutical companies offered to increase investment in Canadian medical research in exchange for greater patent protection.⁶⁶ The final version of the FTA only contained a commitment to future efforts at creating an intellectual property agreement.⁶⁷ As a result of the NAFTA negotiations, the Canadian Parliament once again reformed its pharmaceutical patent law, bringing it closer in conformity to the U.S. scheme.⁶⁸

⁶³ Canada-United States Free Trade Agreement, Dec. 22, 1987, 27 I.L.M. 281 (1988).

⁶⁴ For a detailed history of the pre-NAFTA Canadian drug patent regime, see John W. Rogers III, *The Revised Canadian Patent Act, the Free Trade Agreement, and Pharmaceutical Patents: An Overview of Pharmaceutical Compulsory Licensing in Canada*, 10 EUR. INTELL. PROP. REV. 351 (1990).

⁶⁵ See *id.* at 356 (citing Bill C-22, of the 33d parliament, 2d Sess., 35-36 Eliz. II (1986 to 1987)).

⁶⁶ See Carter, *supra* note 54, at 241-42.

⁶⁷ See Rogers, *supra* note 64, at 353, n.31. Article 2004 of the FTA states: "the parties shall cooperate in the Uruguay Round of multilateral trade negotiations and in other international forums to improve the protection of intellectual property." *Id.*

⁶⁸ See Carter, *supra* note 54, at 243, (citing An Act to Amend the Patent Act, S.C., ch. 2, § 3 (1993); Patent Act, R.S.C., ch. P-4, § 39 (1997) ("Bill C-91"). The new law eliminated the compulsory licensing of pharmaceuticals and extended patent protection of pharmaceuticals from 17 to 20 years.

Mexico also passed legislation to bring patent protection in compliance with NAFTA in anticipation of its signing.⁶⁹ Patent protection was extended to both pharmaceutical products (previously unprotected) and processes. Subsequently published regulations clarified the limited use of compulsory licenses for failures to work the patent (whether through local manufacture or importation). A compulsory license can be requested when the patent holder has not executed the exploitation of the patented product⁷⁰ or process after three years from the issue of the patent or four from the application filing date. Additionally, public utility licenses may be granted for emergency causes or national security, as long as the license does not raise prices or hinder production or distribution of basic needs goods.⁷¹ To date, no compulsory license has been granted.

Both Mexico and Canada are now compliant, but U.S. pharmaceutical companies are concerned about the use of price controls (which are legal under both NAFTA and TRIPS), Mexico's failure to expressly prohibit parallel imports (also legal under the agreements), and mandated generic prescribing, which the industry claims infringes trademark protections.⁷²

TRIPS

Intellectual property was first introduced into multilateral trade negotiations by the United States at the opening of the Uruguay Round of the GATT at Punta del Este in 1986. In response to growing insistence by developed countries to include intellectual property within the GATT, a group of developing countries led by Brazil and India offered a draft intellectual property agreement that proposed obligations consistent with the then-current practice in the developing world with respect to patents.⁷³ However, it was the draft put forth by the United States, the European Economic Community, and Switzerland that largely outlined the terms eventually adopted.⁷⁴ After a period of impasse, the developing countries (with the strong exception of India) began to shift toward accepting the northern

⁶⁹ See *Ley de Propiedad Industrial*, D.O., 27 de junio de 1991, amended by D.O., 2 de agosto de 1994.

⁷⁰ See *Reglamento de la ley de Propiedad Industrial*, D.O. art. 50-52 (Nov. 23, 1994), also available at 2G WORLD PATENT LAW AND PRACTICE 165 (2000).

⁷¹ See *id.*

⁷² See PhRMA, *Issues & Policy Watch: Mexico*, at <http://www.phrma.org/issues/nte/mexico.html> (Sept. 26, 1999) (photocopy on file with author); see also PhRMA, *Issues & Policy Watch: Canada*, at <http://www.phrma.org/issues/nte/canada.html> (Sept. 26, 1999) (photocopy on file with author).

⁷³ The prevailing view at the outset of negotiations considered the creation of maximum, rather than minimum, standards to limit the degree that countries could implement protectionist policies. See Reichman, *supra* note 9, at 24.

⁷⁴ See Roy Maclaren, *The Geo-Political Changes During the 1980s and Their Influence on the GATT*, in *THE URUGUAY ROUND AND BEYOND*, *supra* note 10, at 44.

countries' scheme.⁷⁵ The successful adoption of TRIPS resulted from several factors. First, developing countries obtained concessions on textiles, clothing, and some agricultural products in exchange for agreeing to higher levels of intellectual property protection.⁷⁶ Second, changing geopolitical realities, such as the fall of the Berlin Wall, softened resistance to intellectual property protection.⁷⁷

Most importantly, bilateral pressures made acceptance of the developed countries' intellectual property agenda a necessity for some.⁷⁸ For example, the United States threatened unilateral trade sanctions under §301 of the U.S. trade law⁷⁹ in retaliation against Brazil for its failure to protect pharmaceutical products and processes.⁸⁰ A spokesperson for the Pharmaceutical Manufacturers Association ("PMA"), the complainant that brought the charge to the U.S. Trade Representative ("USTR"), stated that Brazil is the "global leader in its opposition to patent protection [for pharmaceuticals.] We hope the imposition of this sanction . . . will impress upon Brazil the seriousness with which the United States views the unauthorized appropriation of its citizens' intellectual property."⁸¹ Despite U.S. resistance, Brazil sought the establishment of a GATT panel to investigate whether the 100% tariff on a basket of Brazilian exports, including paper products and consumer electronics, was legal within the then-established GATT.⁸² Although the Brazilian case was strongly supported within the GATT membership, it was abandoned in the face of the influence of U.S. market strength. The punitive tariffs were terminated after the Brazilian President announced the introduction of legislation to provide patent protection for pharmaceuticals.⁸³

Finally, some compromises to developing country concerns were included in the final draft. These included the exclusion of patents on life

⁷⁵ See *id.*

⁷⁶ See generally MULTILATERALISM AND REGIONALISM AFTER THE URUGUAY ROUND, *supra* note 10.

⁷⁷ See Roy Maclaren, *The Geo-Political Changes During the 1980s and Their Influence on the GATT*, in THE URUGUAY ROUND AND BEYOND, *supra* note 10, at 44.

⁷⁸ See *id.* at 45.

⁷⁹ See Trade Act of 1974 § 301, 19 U.S.C.A. § 2411 (West, Supp. 2000). Section 301 authorizes the U.S. Administration to take action against any foreign country practices it determines to be discriminatory or restrictive of U.S. commerce.

⁸⁰ See Reagan, *Charging Patent Piracy, Imposes Sanctions on \$39 Million of Brazilian Goods*, 5 Int'l Trade Rep. (BNA) 1415 (Oct. 26, 1988).

⁸¹ *Id.*

⁸² GATT art. XXIII. GATT panels were the precursor to the current and more binding WTO dispute settlement body. Because panels could be blocked and consensus was required for the adoption of decisions, countries enjoyed essential veto power over the establishment of panels and adoption of results. See the discussion of dispute settlement, *infra*, for further information.

⁸³ See Determination to Terminate Increased Duties on Certain Articles From Brazil, 55 Fed. Reg. 27,324 (Jul. 2, 1990).

forms, the ten-year transition period for developing countries, and the allowance of compulsory licensing, albeit with stringent restrictions.⁸⁴

B. Dispute Settlement

Although in their substantive provisions, the regional and multilateral trade regimes largely converge, resolution of disputes covered within the agreements differ in several respects. NAFTA Chapter 17 and TRIPS both rely fundamentally on domestic regimes to enforce the substantive and procedural laws each country has established to implement the agreements. However, if a Member (or Party) fails to meet an intellectual property obligation, intergovernmental dispute resolution procedures can be pursued. Chapter 20 of NAFTA and the Dispute Settlement Understanding (“DSU”) of the WTO⁸⁵ both establish permanent administrative bodies to manage disputes⁸⁶ and consultation procedures to promote settlement.⁸⁷ Failing settlement, countries may request the establishment of arbitration panels.⁸⁸

Under the WTO DSU, panels are empowered to render enforceable decisions. Appeals can be made to a standing Appellate Body.⁸⁹ Claims for breach of intellectual property obligations can be remedied by injunctions, monetary damages, or forfeiture of infringing goods or some form of mutually acceptable compensation. Cross-sectoral retaliation in the form of punitive tariffs are available where a country does not comply with panel decisions. Non-violation complaints arising from TRIPS were given a moratorium until January 1, 2000.⁹⁰

Panel decisions under NAFTA Chapter 20 are not binding. Parties are called upon to reach a resolution consistent with the panel report, involving termination of the NAFTA-illegal conduct or appropriate compensation.⁹¹

⁸⁴ See TRIPS, *supra* note 2, arts. 27-3(b), 65-4, and 31.

⁸⁵ See Marrakesh Agreement, *supra* note 2, Annex 2.

⁸⁶ The two bodies are the NAFTA Secretariat and Free Trade Commission and the WTO Dispute Settlement Body (“DSB”).

⁸⁷ Marrakesh Agreement, Annex 2, The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts 404 (1994), 33 I.L.M. 1226, Art. 4 (1994) [hereinafter DSU]; NAFTA, *supra* note 1, art. 2006.

⁸⁸ NAFTA allows for disputes that arise under either the regional or multilateral agreement to be brought in either forum, but where there is disagreement among the Parties, NAFTA will be the preferred forum. See NAFTA, *supra* note 1, art. 2005.

⁸⁹ DSU Article 17-14 states: “An Appellate Body report shall be adopted by the [DSB] and unconditionally accepted by the parties to the dispute unless the DSB decides by consensus not to adopt the Appellate Body report”

⁹⁰ See TRIPS, *supra* note 2, art. 65. Non-violation complaints, or complaints alleging nullification or impairment of benefits, refer to measures that are not facially inconsistent with the TRIPS obligations, but have the effect of undermining them.

⁹¹ See NAFTA, *supra* note 1, art. 2018.

However, suspension of benefits against a nonconforming Party is allowed if an agreement cannot be reached within thirty days of a panel report.⁹²

Investor-Government arbitration

An interesting, if little-noticed, feature of the NAFTA dispute resolution armature is Chapter 11, which provides for the private enforcement of investment rights where a NAFTA Party is in breach of the substantive standards for the treatment of foreign investment. Unlike the government-to-government dispute resolution regime outlined in Chapter 20, this alternative dispute settlement mechanism involves investor-state arbitration. Thus, if an individual investor is unable or unwilling to obtain diplomatic action from his or her government, the investor may opt to initiate arbitration proceedings against the offending government. Additionally, investors may choose Chapter 11 arbitration as an alternative to seeking domestic remedies.

Tribunals are limited to awarding monetary damages; relief in the form of overturning judgments or administrative or legislative actions is not available. An investor seeking relief for a host government action may choose between the World Bank's International Center for the Settlement of Investment Disputes ("ICSID"); ICSID's Additional Facility Rules⁹³; and the rules of the United Nations Commission for the International Trade Law ("UNCITRAL" rules.) There is no judicial review of arbitral tribunals. Proceedings are closed, and there is no publication of decisions or proceedings without consent of both parties. Thus, it is somewhat difficult to obtain information on the nature and outcome of these proceedings. Thus far, there have been only a limited number of arbitrations under Chapter 11.⁹⁴ In one recent case, the threat of bringing an investor action through Chapter 11 was sufficient to persuade the Canadian government to revoke a ban on the importation and trade of a gasoline additive and to settle with the U.S. producer.⁹⁵

⁹² See NAFTA, *supra* note 1, art. 2019.

⁹³ Neither Canada nor Mexico are parties to the ICSID Convention, but have agreed to handle disputes through the additional facility. See generally LEON E. TRAKMAN, DISPUTE SETTLEMENT UNDER NAFTA 44-45 (1997).

⁹⁴ There were only five arbitrations pending in April 2000. See *List of Pending Cases*, (Apr. 2000), available at <http://www.worldbank.org/icsid/cases/pending.htm>.

⁹⁵ See *Canadian Government Withdraws MMT Ban; Ethyl Drops Suit in Exchange For \$13 Million*, 15 Int'l Trade Rep. (BNA) 1280 (Jul. 22, 1998). Ethyl, the sole North American producer of the substance, alleged that political, not environmental, regulatory motivation was behind the ban. The Canadian government also faced suits from several provinces alleging that the ban illegally restricted interprovincial trade.

The definition of an “investment” that falls within Chapter 11 includes intellectual property.⁹⁶ In effect, Chapter 11 provides for compensation of foreign investors in the event of a “regulatory taking” in the host country.⁹⁷ Under the provisions covering expropriation and compensation, a Party that has failed to protect intellectual property rights in accordance with Chapter 17 can be subject to arbitration.⁹⁸ An arbitral judgment of the fair market value of the lost investment and associated costs can be awarded to the aggrieved investor.⁹⁹ There is no analogous facility within the WTO, where all claims are of an intergovernmental nature. However, similar investor protections have been considered within the proposed Multilateral Agreement on Investment (“MAI”).¹⁰⁰

Cases

To date, there have been no actions within the NAFTA dispute framework regarding pharmaceuticals. The WTO, however, has become the locus of pharmaceutical patent protection controversies, several of which are relevant to an emerging WTO case law of interest to developing countries seeking to devise a TRIPS-compliant essential drugs policy. The provision for pipeline protection to pharmaceuticals (and agricultural chemicals) in countries that had not yet instituted a patent system was, understandably, the first issue to generate disputes. The United States brought a complaint against India for failing to provide “mailbox” priority filing for foreign holders of pharmaceutical and agricultural chemical patents as required by TRIPS Art. 70 (8), and for not providing the exclusive marketing rights mandated by Art. 79 (9).¹⁰¹ The Panel found for the United States, and the Appellate Body upheld the decision, ordering India to bring its laws into

⁹⁶ See NAFTA, *supra* note 1, art. 1139(g): “real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes.”

⁹⁷ NAFTA, *supra* note 1, art. 1110-1 provides: “no Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment . . .”

⁹⁸ However, the Agreement explicitly states that “this Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen.” NAFTA, *supra* note 1, art. 1110-7.

⁹⁹ See *id.* art. 1110-2.

¹⁰⁰ See generally PETER S. WATSON ET AL., COMPLETING THE WORLD TRADING SYSTEM: PROPOSALS FOR THE MILLENNIUM ROUND 249-57 (1999). Negotiations within the Organization for Economic Cooperation and Development (“OECD”) came to an end in December 1998 without a draft agreement, but the possibility of resumption was left open.

¹⁰¹ See WTO, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DD50/4 (Nov. 8, 1996).

compliance.¹⁰² India argued that it had complied with the pipeline and exclusive marketing provisions but that it had done so through an administrative act, rather than through legislation. In reviewing the Indian domestic legal system, the Appellate Body concluded that the administrative procedures would not withstand legal challenge, as they were inconsistent with India's Patent Act.¹⁰³

The Indian government had not been able to pass TRIPS-consistent legislation through Parliament and had attempted to substitute an administrative act for the democratic process.¹⁰⁴ Given its well-developed generic medicines industry and the resulting availability of cheap medicines, resistance to introduction of TRIPS-level patent protection within India remains strong. In 1999, India enacted permanent legislation establishing "mailbox" filing procedures in compliance with the Appellate Body mandate.¹⁰⁵ Although refraining from taking further action, the United States expressed disappointment that the exclusive marketing provisions included some exceptions, such as the discretionary use of compulsory licensing.¹⁰⁶

In May 1999, the United States requested formal consultations with Argentina pursuant to WTO rules, alleging that Argentina also had failed to implement the pipeline and exclusive marketing provisions. The United States simultaneously sought consultations about a grandfather provision in Canada's revised patent law. Patent applications filed before Oct. 1, 1989 run 17 years from the date issued, rather than the 20 required under Article 33 of TRIPS.¹⁰⁷

In February of 1999, the Dispute Settlement Body of the WTO established a panel to examine Canada's pharmaceutical patent regime at the request of the European Union.¹⁰⁸ Canada's Bill C-91, passed in conjunction with the NAFTA, allows generic producers of patented pharmaceuticals to carry out experiments required for marketing approval, and for the manufacture and stockpiling of patented products six months before the patent

See WTO, *Report of the Appellate Body*, WT/DS50/AB/R (Dec. 19, 1997), available at http://www.wto.org/english/tratop_e/dispu_e/7428d.doc.

¹⁰³ *See* Watson et al., *supra* note 100, at 34 (noting the legal significance of the Appellate Body's close examination of the domestic legal system to determine compliance).

¹⁰⁴ *See generally* Roy Maclaren, *The Geo-Political Changes During the 1980s and Their Influence on the GATT*, in *THE URUGUAY ROUND AND BEYOND*, *supra* note 10.

¹⁰⁵ *See India Complies With WTO Ruling on TRIPs*, FIN. TIMES, Mar. 11, 1999, available at <http://www.newsbulletin.org/bulletins/getbulletin.CFM?SID=#India> (on file with the Northwestern Journal of International Law & Business).

¹⁰⁶ *See* Special 301 Annual Review, *supra* note 7.

¹⁰⁷ *See U.S. Requests Consultations at WTO on Argentine, Canadian Patent Protection*, 16 Int'l Trade Rep. (BNA) 820 (Dec. 5, 1999).

¹⁰⁸ *See* WTO, *Request for the Establishment of a Panel by the European Communities*, WT/DS114/5 (Nov. 12, 1998) [hereinafter *Request for the Establishment of a Panel*]; *see also* WTO *New Item: 1999 News Item*, at http://www.wto.org/english/news_e/news99_e/114_5.htm (last visited Apr. 2, 2001).

expiration without the approval of the patent holder.¹⁰⁹ By encouraging the market availability of generic products as soon as patents expire, the Canadian policy sought to strike a balance between the requirements of patent protection and the social need of access to pharmaceuticals at an affordable price.¹¹⁰ The European Union alleged that this provision violated the TRIPS requirements prohibiting unauthorized third parties from making or using the protected good within the 20-year patent period.¹¹¹

The WTO panel decision allowed for the Canadian “regulatory review” exception to patent exclusivity as consistent with the established practice of permitting use of patented substances for experimental purposes. However, the panel found that the stockpiling of patented pharmaceuticals prior to patent expiration did not fall within any of the TRIPS Article 30 “limited exceptions.” Even though the Canadian law prohibited introduction into the market until the patent expiration date, manufacture for future commercial sale constituted a competitive commercial activity that substantially curtailed the patent holders’ exclusive rights to make and use, and was therefore in violation of Article 28.1 of TRIPS.¹¹² Although it is a “first world” controversy, the outcome will impact the future policy of developing world countries, such as South Africa, India, Argentina and Brazil, that have a sophisticated pharmaceutical manufacturing capacity.¹¹³

If this last claim had been brought by a U.S.-based international pharmaceutical company, the enterprise itself could take action under NAFTA Chapter 11 investor-state arbitration rules, rather than seek diplomatic representation. Although relief would be limited to monetary damages for the presumed loss related to the “head start” afforded generic producers in the Canadian system, an arbitral award in favor of the pharmaceutical company could have the effect of chilling the application of those provisions.

C. The Limits of Compromise?

Although the United States successfully negotiated strong rights for the multinational pharmaceutical industry within the regional and multilateral trade agreements, it has continued to push the full agenda not achieved at

¹⁰⁹ The United States instituted similar provisions (called “Bolar” exemptions) under the 1984 Waxman-Hatch legislation, which allows generic competitors to manufacture small amounts of a product still under patent for testing purposes. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C.A. § 156 (West 2000).

¹¹⁰ *See* WTO, *Report of the Appellate Body: WTO Dispute Panel Report on Canada, WT/DS114/R* (Mar. 17, 2000), available at http://www.wto.org/English/tratop_e/dispu_e/7428d.doc [hereinafter *WTO Dispute Panel Report*].

¹¹¹ *See* TRIPS, *supra* note 2, arts. 28-1(a) and 33; *see also* *Request for the Establishment of a Panel, supra* note 108.

¹¹² *See* *WTO Dispute Panel Report, supra* note 110.

¹¹³ Although there is no formal precedential effect of WTO decisions, individual case outcomes are widely viewed as having persuasive authority.

those negotiations through bilateral relations.¹¹⁴ 19 U.S.C. § 2411(d)(3)(B) defines as “unreasonable” any “act, policy, or practice . . . which (i) denies fair and equitable (ii) provision of adequate and effective protection of intellectual property rights notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights . . .” The weapon of § 301 sanctions against countries engaged in discriminatory trade practices was augmented by the introduction of “Special 301” in 1988. Under Special 301 provisions, the USTR is required to prepare a list of “priority” foreign countries that are considered the worst offenders of intellectual property rights. The USTR then enters into negotiations with these countries under the threat of sanctions. Less severe offenders are placed on “priority watch” and “watch” lists to notify them that their level of intellectual property protections are not satisfactory to the United States.¹¹⁵

In the wake of U.S. unilateral retaliation against the European Union during the pendency of a WTO dispute panel adjudication,¹¹⁶ the European Union brought a complaint alleging that the unilateral actions established in U.S. trade laws, §§ 301-310, do not comply with the WTO.¹¹⁷ Although the complaint centered on the timing of actions mandated under § 304, the report of the panel applies to actions taken with respect to intellectual property under § 310. Following the Appellate Body’s India patent case ruling that examination of municipal law is an appropriate inquiry, the panel nonetheless came to the opposite outcome in this case. The report notes that the U.S. statute is facially inconsistent with article 23 of the Dispute Settlement Understanding. It then goes on to analyze how this facial inconsistency is cured by representations made to the Dispute Settlement Body by the United States indicating that it has no intention of implementing the broad discretion in the legislation in a WTO-inconsistent manner.¹¹⁸ Thus, a

¹¹⁴ See Special 301 Annual Review, *supra* note 7 (noting that Special 301 was amended with the enactment of the Uruguay Round Agreements “to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement”).

¹¹⁵ See, e.g., *USTR Initiates WTO Consultations on IPR with Argentina, Canada, EU*, 16 Int’l Trade Rep. (BNA) 763 (May 5, 1999).

¹¹⁶ See *European Communities—Regime for the Importation, Sale and Distribution of Bananas—Recourse to Arbitration by the European Communities Under Article 22.6 of the DSU*, WT/DS27/ARB (April 9, 1999), available at http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm.

¹¹⁷ See *WTO Dispute Panel Report on U.S. – Sections 301–310 of the Trade Act of 1974*, WT/DS152/R (December 22, 1999), available at http://docsonline.wto.org/gen_search.asp.

¹¹⁸ See *id.* ¶¶7.117 - 7.131. Paragraph 7.125 states:

We find that these statements by the [United States] express the unambiguous and official position of the [United States] representing, in a manner that can be relied upon by all Members, an undertaking that the discretion of the USTR has been limited so as to prevent a determination of inconsistency before exhaustion of DSU proceedings.

clearly WTO-illegal law may remain on the books as long as it is not enforced. This allowance lets the USTR continue to exercise its mandate under the legislation to conduct investigations and publish “watch lists” of offending countries, as long as it takes no action without first exhausting the WTO dispute settlement process. From the perspective of developing countries that frequently are the targets of pressure exerted “softly” through such threats, this limitation may be very cold comfort. The bilateral exercises in South Africa and Thailand, briefly described below, indicate the scope of the potential chilling effect that such action can have.

South Africa

The human tragedy of the global AIDS epidemic often has been compared to the 14th century plague in Europe. Of the estimated 33.4 million HIV-infected individuals around the world, about two thirds live in sub-Saharan Africa. Currently, between 20% to 26% of the population in some southern African countries is infected.¹¹⁹ One in eight South Africans is HIV positive. Yet, the cost of HIV drugs is prohibitive to most Africans.¹²⁰

In 1997, South Africa enacted legislation designed to give the Minister of Health discretion to ensure the affordable supply of medicine.¹²¹ The law allows the Minister to abrogate patent rights for exclusive marketing of a particular medicine (compulsory licensing).¹²² Additionally, the Minister may license the right to import a substance registered in South Africa so that the drug can be imported from any other country where it is manufactured (parallel importing).¹²³ The Medicines Act also contained a number

Id. at ¶7.125.

¹¹⁹ See David Satcher, *The Global HIV/AIDS Epidemic*, 281 J.A.M.A., No. 16 (Apr. 28, 1999), at <http://jama.ama-assn.org/issues/v281n16/full/jsg91001-1.html>.

¹²⁰ Combination anti-retroviral therapy costs about USD 12,000 in South Africa.

¹²¹ See § 15C of Medicines and Related Substances Control Act of 1965 (as amended 1997), JSRSA 1997 vol. 3 at 1-63 [hereinafter Medicines Act].

¹²² The Medicines Act states:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may . . . determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent.

Id. at 1-64.

¹²³ The Medicines Act, Section 15C (b), allows the Minister to

prescribe the conditions on which any medicine [that] is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but [that] is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and [that] originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.

of other provisions aimed at reducing medicine costs and assuring quality. These provisions prompted a political storm initiated by the multinational research pharmaceutical industry concerned about the global effect that South Africa's actions would have on securing patent rights to pharmaceuticals.¹²⁴

There is little doubt that a country such as South Africa can legally address the AIDS crisis by invoking its TRIPS authority to grant compulsory licenses for the importation or local manufacture of essential drugs.¹²⁵ Indeed, as discussed above, TRIPS does not prohibit the use of parallel imports. Nonetheless, according to the South African Director General of Health, parallel imports were to be strictly controlled: "[I]t has never been the intention of the Department to allow for the unbridled importation of drugs or the flooding of the market with unsafe products."¹²⁶ The broad wording of the statute, however, raises the question of whether the Medicines Act adheres to the highly restrictive TRIPS approach to compulsory licensing. In 1998 and 1999, the USTR placed South Africa on its "Watch List", implicating the Medicines Act's "ill-defined authority to issue compulsory licenses, authorize parallel imports and potentially otherwise abrogate patent rights."¹²⁷ Maintaining that parallel imports are TRIPS-illegal, the United States actively engaged in bilateral negotiations in an effort to achieve the "repeal, termination or withdrawal" of Article 15C of the Medicines Act.¹²⁸ The diplomatic offensive included the suspension of four items from receiving preferential tariff treatment under the Generalized System of Preferences ("GSP").¹²⁹

Id.

¹²⁴ See PhRMA, *Issues & Policy: Priority Foreign Countries, South Africa--Intellectual Property Protection*, at <http://www.phrma.org/issues/nte/safrica.html> (Sept. 26, 1999) (photocopy on file with author). A group of 40 multinational pharmaceutical companies brought suit in South Africa, challenging the constitutionality of the Medicines Act.

¹²⁵ See TRIPS, *supra* note 2, art. 31. See the discussion of compulsory licensing, *supra*.

¹²⁶ Olive Shisana, *New Medicines Bill Will Benefit Consumers*, at <http://www.polity.org.za/govdocs/pr/1997/pr0821a.html> (Aug. 21, 1997). Dr. Shisana served as the Director General of Health for South Africa.

¹²⁷ Special 301 Annual Review, *supra* note 7. Among South Africa's offenses was leadership of "a faction of nations in the WHO . . . calling for a reduction in the level of protection provided for pharmaceuticals in TRIPS." *Id.*

¹²⁸ See U.S. Government Efforts to Negotiate the Repeal, Termination or Withdrawal of Article 15C of the South African Medicines and Related Substances Act of 1965 (Dep't of State Feb. 5, 1999) [hereinafter U.S. Government Efforts], available at <http://www.cptech.org/ip/health/sa/stdept-feb51999.html>. This action was required by the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. No. 105-277).

¹²⁹ See U.S. Government Efforts, *supra* note 128. The GSP is a GATT exception to the most-favored-nation rule that allows developed countries to extend tariff reductions on a bilateral basis to developing countries.

An explosion of publicity generated by AIDS activists in the United States ensued, and the U.S. government backed off its more aggressive stance.¹³⁰ The two countries reached an understanding. The United States recognized South Africa's urgent need for more affordable health care in the context of the AIDS epidemic, and it pledged an end to the issue and restoration of GSP privileges in exchange for assurances that in implementing its health policy, South Africa would comply with TRIPS.¹³¹

Thailand

Thailand also has been hard-hit by AIDS, where only 5% of the estimated one million HIV-infected individuals can afford the two-drug anti-retroviral regime prescribed to them.¹³² The cost of triple therapy is USD 675 a month, whereas the average monthly wage of an office worker is USD120.¹³³ With an active generic industry, and limited protection of exclusive marketing rights, Thailand successfully has reduced the prices of some drugs. When the antifungal fluconazole lost its exclusive marketing rights, competition from three local producers reduced the price by 95%.¹³⁴ Thailand's Government Pharmaceutical Organization ("GPO") has been producing generic AZT for a quarter of the price of the brand name version for several years.¹³⁵ The government has balked, however, at activist pressure to grant a compulsory license for the drug didanosine ("ddi"), owned by Bristol-Myers-Squibb. If the Thai Public Health Minister had authorized the compulsory license, it would have been the first instance of compulsory licensing under Article 31 of TRIPS, but the looming trade pressure was sufficient to forestall the issuing of a compulsory license.¹³⁶ Because one quarter of Thailand's exports are directed to the United States, the threat of trade sanctions has powerful influence.¹³⁷ Not surprisingly, Thailand's

¹³⁰ See, e.g., Charles R. Babcock, *AIDS Activists Dog Gore a 2nd Day*, WASH. POST, June 18, 1999, at A12. Activists targeted campaigning Vice President Gore, who was involved in negotiations through leadership of the U.S.–South Africa Binational Commission.

¹³¹ See Press Release, USTR, *U.S.–South Africa Understanding on Intellectual Property*, (Sept. 19, 1999), available at <http://www.ustr.gov/releases/1999/09/99-76.html>.

¹³² See Sutin Wannabovorn, *Thais Protest U.S. Firm's AIDS Drug Monopoly*, at <http://biz.yahoo.com/rf/991222/bq/html> (Dec. 22, 1999) (photocopy on file with author). Thailand has a population of 61 million.

¹³³ See *Global Trade and Access to Medicines: AIDS Treatments in Thailand*, 354 LANCET 1893, 1894 Nov. 27, 1999 [hereinafter *Global Trade and Access to Medicines*].

¹³⁴ See *id.* Fluconazole treats cryptococcal meningitis, an opportunistic infection that strikes one in five AIDS patients in Thailand.

¹³⁵ See Wannabovorn, *supra* note 132.

¹³⁶ See Aphaluck Bhatisevi, *Korn Refers Drug Call to Council of State – Activists Say Fears of Backlash Unfounded*, BANGKOK POST, December 25, 1999 (photocopy on file with author).

¹³⁷ See *Global Trade and Access to Medicines*, *supra* note 133.

weak enforcement of patents has landed it on the Special 301 Priority and Priority Watch Lists in the past.¹³⁸

Although the Thai government backed away from issuing a compulsory license in the ddi case, mounting pressure, both from within developing countries and from international organizations, such as *Medecins Sans Frontières*, triggered a compromise gesture from the industry. Five multinational pharmaceutical companies (Germany's Boehringer Ingelheim, U.S.-based Bristol-Myers Squibb and Merck, Glaxo Wellcome of the United Kingdom, and Hoffman-La Roche of Switzerland) agreed to provide AIDS treatments at reduced rates to developing countries through the United Nations as part of a broader initiative to improve treatment access.¹³⁹ Treatment advocates are skeptical about this foreign aid approach to solving the affordability crisis. The use of compulsory licenses would allow countries to have more sustainable control over the availability of medicines, rather than relying on patented drugs produced by multinational manufacturers, which will continue to be more expensive.¹⁴⁰

Truce

On December 1, 1999 (World AIDS Day) in the midst of the highly contentious Seattle WTO Ministerial meeting, President Clinton announced that the U.S. trade policy would consider poor countries' need for lifesaving drugs, and would no longer oppose compulsory licensing or parallel importing where there exists a "healthcare emergency, particularly in respect of [sic] HIV-AIDS."¹⁴¹ Countries may review particular medicines on a case-by-case basis, and where there is a determination of emergent need, they may grant a compulsory license after negotiating with the patent-holder. The statement represents a retreat in U.S. policy to TRIPS/NAFTA level protections of intellectual property.¹⁴² However, clear standards are yet to

¹³⁸ See, e.g., *USTR Reviews Whether to Restore Thailand's GSP Benefits Lost in 1989*, 11 Int'l Trade Rep. (BNA) 1176 (1994).

¹³⁹ See *New Public/Private Sector Effort Initiated to Accelerate Access to HIV/AIDS Care and Treatment in Developing Countries* (May 11, 2000) at <http://www.unaids.org/whatsnew/press/eng/pressarc00/geneva110500.html>.

¹⁴⁰ See, e.g., Kelvin Ng, *Rights-Thailand: Struggling to [...] HIV Drugs Cheaper*, Interpress Service (June 26, 2000), at http://www.oneworld.org/ips2/june0013_20_037.html.

¹⁴¹ Frances Williams, *U.S. to Consider Poor Countries' Need for Drugs*, FIN. TIMES (London), Dec. 3, 1999, at 6.

¹⁴² At the request of Health Gap Coalition, a U.S.-based international AIDS activist group, the USTR sent a letter, which was later copied to the Thai government, to the head of a Thai non-governmental organization stating the U.S. commitment that the "application of U.S. trade law related to intellectual property remains sufficiently flexible to respond to public health crises." The letter further stated that "[i]f the Thai government determines that issuing a compulsory license is required to address its health care crisis, the United States will raise no objection, provided the compulsory license is issued in a manner fully consistent with the WTO Agreement on TRIPS. Letter from Joseph S. Papovich, Assistant U.S. Trade Representative for Services, Investment and Intellectual Property, to Mr. Paisan Tan-Ud,

be articulated. In granting compulsory licenses, local officials must be willing to “test” the United States and respond to legal challenges at the domestic and international level, as well as to the threat of unilateral sanctions. Governments are walking a tightrope between pressing health needs, increasing pressures from domestic constituencies and the cost of challenging international pharmaceutical interests. As a political matter, the Clinton announcement in Seattle illustrates the importance of maintaining support from transnational groups that can counter the political pressure exercised by pharmaceutical companies.¹⁴³

Adjudicating compulsory licensing and unilateral responses before the WTO Dispute Settlement Body is problematic. Despite the relative expediency of the process, parties may wait a year or more for a determination. Worse, the adjudication process would place the WTO dispute panel in the politically unsavory position of evaluating whether a true “health emergency” existed, and whether the country in question engaged in sufficient negotiations with the license holder.¹⁴⁴

IV. ALTERNATIVE APPROACHES

As a strategy for promoting investment in the essential drug needs of the developing world, universal intellectual property protection hardly is optimal. Diseases suffered by populations with no purchasing power are not going to be addressed by commercial producers. In fact, treatments for some tropical diseases have begun to disappear from the market due to lack of effective demand, despite significant need.¹⁴⁵ Of the over 1,200 new drugs commercialized between 1975 and 1997, 30% are considered therapeutic innovations, but only 1% are specifically for tropical diseases.¹⁴⁶ Of these, only four may be considered the direct product of research and development activity in the pharmaceutical industry (the rest came out of veterinary research or military research or were updated versions of existing

Chairman of PHA Network of Thailand, (Jan. 27, 2000), available at <http://www.cptech.org/ip/health/c/thailand/ustrletterjan27.html>.

¹⁴³ See Sabin Russell, *World Trade Showdown; Activists, Industry Split Over AIDS Drugs*, S.F. CHRON., Nov. 24, 1999, at A1 (describing the role of James Love, director of the Consumer Project on Technology, and other health and activist organizations in placing the issue before the U.S. public and on the international agenda). In January of 2000, Vice President (and then-Presidential candidate) Albert Gore brought the issue of the international AIDS crisis before the United Nations Security Council in an unprecedented gesture toward raising a health issue to the level of an international security concern.

¹⁴⁴ See generally Dreyfuss and Lowenfeld, *supra* note 31 (describing the difficulties of using the dispute settlement mechanism for inquiring into government decisions “at the borders” of the TRIPS agreement).

¹⁴⁵ See Bernard Pecoul et al., *Access to Essential Drugs in Poor Countries, A Lost Battle?*, 281 J.A.M.A. 361, 364 (1999) (giving examples of medicines for epidemic bacterial meningitis and leishmaniasis).

¹⁴⁶ See *id.*

products.)¹⁴⁷ AIDS is anomalous in that drugs were developed for use in the North, even though the vast majority of sufferers live in developing countries.

From Conflict to Cooperation

Efforts to create viable markets have been undertaken by collaborations among public, nonprofit, and private entities. For example, WHO together with foundations and nonprofit organizations recently announced an effort to raise at least \$500 million to halt the spread of drug-resistant tuberculosis.¹⁴⁸ Buttressing purchasing power, however, only partially will address the issue of inaccessible pricing. Public or nonprofit initiatives also must increase funding flows for research in essential areas,¹⁴⁹ and also can consider opportunities to act within the market as intellectual property rights holders. Rather than conceive of intellectual property as only a zero sum game between assuring return on investment or facilitating widespread access, creative uses of this valuable asset can be deployed.¹⁵⁰

A pioneering example of this approach is the International AIDS Vaccine Initiative ("IAVI"), a nonprofit group that has funded AIDS vaccine development in the academy and the private sector. Funding recipients agree to allow the nonprofit to file patents for discoveries where investigators choose not to do so. Otherwise, IAVI retains flexible rights to the intellectual property. The licensing agreements stipulate, for example, that price must be kept at no more than 10% of production costs.¹⁵¹

Socializing the Risk in Research

¹⁴⁷ See *id.*

¹⁴⁸ See Judith Miller, *In Fight Against Tuberculosis, Experts Look for Private Help*, N.Y. TIMES, Nov. 2, 1999, at A8.

¹⁴⁹ The recently launched "Medicines for Malaria Venture" involves a partnership among international pharmaceutical companies, WHO, the World Bank, government agencies, and the Rockefeller Foundation to engage in drug discovery and development for malaria. See Elizabeth Olson, *Drug Groups and U.N. Offices Join to Develop Malaria Cures*, N.Y. TIMES, Nov. 18, 1999, at A5.

¹⁵⁰ See J.H. Reichman and David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 11 (1998). Reichman and Lange discuss TRIPS as a non-cooperative enterprise. Because developing countries will have difficulty implementing the high standards as a result of the unacceptably high social costs, the authors advocate using the agreement as a set of "default rules" around which governments and private investors can negotiate transactions on a case-by-case basis. Applying this theory in the copyright field, the authors view this kind of private "deal-making" as a way to increase investment in developing countries.

¹⁵¹ IAVI maintains options to make use of the intellectual property rights to produce a vaccine for the developing world under certain circumstances. See Press Release, IAVI, Two Innovative AIDS Vaccine Development Partnerships Launched (Nov. 26, 1998).

Although these nascent strategies are far from commonplace, they point toward a conscious role for government, nonprofits, and philanthropists to rethink policy and strategically view themselves as economic actors in the market to obtain social goals. Progress in this area may evolve more readily from the nonprofit sector than from governments, as it is more flexible, independent, and can act on transnational interests that do not have formal access to national and international public fora. Nonprofits involved in medical research and international health promotion can take a proactive stance within the market and within the policy community based on a strategic assessment of the current status of the pharmaceutical industry and the third sector's (and public sector's) involvement as economic actors. The industry has undergone dramatic change in the last decade. Research and marketing costs are rising at the same time that an explosion of new technology, such as the emergence of biotechnology, and the ability to screen candidate substances at an accelerated rate are fundamentally changing the nature of pharmaceutical research and development. Large pharmaceutical companies increasingly are merging in an effort to save duplication of efforts in research and marketing, but it is in smaller research firms, often spinning off of university laboratories, that the most innovative and cost efficient research is taking place.¹⁵² The latter often are research rich but cash poor, and increasingly are licensing their technology to large pharmaceutical companies for development.

Estimates vary on the actual cost of developing a drug from discovery to market.¹⁵³ Citing a 1997 study in *Pharmacoeconomics*, Pecoul et al. state an average of \$160 million over a period of 8 to 12 years. Industry representatives claim that the amount is closer to \$500 million in a 12 to 15 year period.¹⁵⁴ Industry observers often point out that most large pharmaceutical research companies spend twice as much on marketing than on research.¹⁵⁵ This disparity can be partly attributed to an accounting problem related to research and development. Money invested in research is a "sunk cost." Much like overhead, the value generated from that investment will not be realized for many years, but the expense must be recorded in the year it is made, rather than capitalized over time.¹⁵⁶ At the moment, there is very lit-

¹⁵² See *Addicted to Mergers?*, BUS. WEEK, Dec. 6, 1999, at 8.

¹⁵³ See Danzon, *supra* note 25, at 5. Danzon estimated that average after-tax cost of drug development in the United States in 1993 was \$194 million, based on data from the Office of Technology Assessment ("OTA"). Included in that figure was a 10% annual allowance for forgone capital.

¹⁵⁴ See *PhRMA Policy Papers: Strong Patent Protection is Essential* (Sept. 26, 1999), at <http://www.phrma.org/issues/protect.html> (photocopy on file with author).

¹⁵⁵ See *Addicted to Mergers?*, *supra* note 152, at 88, showing expenditures in research and development as 13% and marketing and sales as 29% of sales revenues.

¹⁵⁶ Thus, given the time value of money, the actual expense/risk to the industry is higher than income statements reflect. See Danzon, *supra* note 25, at 5-8.

tle clarity regarding the actual link between patent protection and innovation in essential medicines.

James Love has pointed out that many of the breakthrough AIDS medications (and other essential drugs) were developed through funding from the U.S. National Institute for Health ("NIH") with public money, and licensed to private industry for manufacturing and marketing.¹⁵⁷ A recent New York Times report details the transformation in the research rewards wrought by a 1980 law intended to spur commercialization of inventions.¹⁵⁸ The law permitted university researchers with public grants to license discoveries to private companies for development. The result has produced a high stakes search for "blockbuster" drugs in university laboratories, the creation of commercial spin-offs from academic research, and a shift away from exclusively basic research to later-stage drug development by academic researchers, leading many pharmaceutical companies to "outsource" discovery and development efforts that previously had been conducted in-house. Provisions in the law that allowed the government to intervene in order to obtain the benefits of tax sponsored research free of royalties have not been utilized; in fact, according to the General Accounting Office, the Health Institutes have not tracked the flow of this investment and the resulting inventions.¹⁵⁹

V. CONCLUSION

Over the long-term, the pharmaceutical industry may be fragmenting into research, development, and manufacturing and marketing functions. This situation may provide significant opportunities for increased publicly responsive control over the fruits of innovation. A general lack of transparent analysis on investment in research, the interaction of public and private resources, and the role of university researchers in disseminating (or retaining and commercializing) knowledge is a major obstacle to public discourse on a truly rational pharmaceuticals policy. On the international plane, trade agreements serve to obfuscate the problem by channeling resolution of conflicts through a regime of elaborately articulated property "rights."

Resolutions to the affordability conundrum are only part of a larger public health challenge to the infectious disease crisis in the developing world, or even the cancer and heart disease complaints of developed world. However, the mechanisms for intellectual property protection established through the trade agreements are ill-suited to overcome this dilemma. Not

¹⁵⁷ For more discussion of this, see documents at <http://www.cptech.org>, especially the letter from Ralph Nader, James Love, and Robert Weissman to Dr. Harold Varmus, Director of NIH, asking for NIH to give the WHO access to U.S. government-funded medical inventions (Sept. 3, 1999).

¹⁵⁸ See Gerth and Stolberg, *supra* note 45 (discussing Public Law 96-517, the Bayh-Dole Act, 35 U.S.C. 200 *et seq.*).

¹⁵⁹ See *id.*

only do they operate in an incongruous context, they also are not reflective of the actual nature of the transnational interests affected by policy outcomes. While the rights of intellectual property holders are enshrined at the international level, the balancing of public health and consumer needs remains a residual category relegated to the domestic sphere.