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TRIPS ARTICLE 27.2: AN ARGUMENT FOR CAUTION

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INTRODUCTION

The subject of the interrelationship of free trade with the environment is well on its way to joining sex, religion, and politics as topics that are barred from polite conversation. The Uruguay Round of the General Agreement on Tariffs and Trade ("GATT") highlighted this controversy.¹ Many detractors argue that the terms of GATT defeat years of domestic and international environmental efforts.² Many supporters believe that GATT is transparent to such efforts and are surprised at the criticism.³ In 1994, the Uruguay Round officially recognized that there is a relationship between free trade and environmental quality, and that the relationship merits discussion.⁴

The context is a general mistrust of environmental efforts as a "pretext for trade protectionism."⁵ The first proposition of modern trade law is that liberal international trade is a social good that is "critical to the enhancement of global welfare."⁶ The second proposition is that a stifling protectionism threatens to rob the world of the economic and environmental

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¹ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I.L.M. 1125 (1994) [hereinafter WTO Agreement]; General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 187 [hereinafter GATT].

² See, e.g., Patti A. Goldman, *Resolving the Trade and Environment Debate: In Search of a Neutral Forum and Neutral Principles*, 49 WASH. & LEE L. REV. 1279 (1992).

³ See, e.g., Thomas J. Schoenbaum, *Free International Trade and Protection of the Environment: Irreconcilable Conflict?*, 86 AM. J. INT'L L. 700 (1992).

⁴ See *After Free Trade Euphoria, Now Comes the Hard Part*, 13 Daily Rep. for Executives (BNA) S-1, S-3 (Jan. 20, 1995). At this meeting, the Uruguay Round formed the World Trade Organization's Committee on Trade and the Environment. See Trade and Environment, Ministerial Decision, Apr. 14, 1994, 33 I.L.M. 1267 (1994).

⁵ *After Free Trade Euphoria, Now Comes the Hard Part*, *supra* note 4, at S-3.

⁶ DAVID VOGEL, *TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY* 134 (1995).

advancements enjoyed since the signing of GATT.⁷ Accordingly, there are several corollaries concerning social and environmental regulation. Environmental protection does not inherently require trade restrictions. In other words, these programs can be crafted in forms that are consistent with free trade principles (trade-neutral) without harming their effectiveness.⁸ In addition, an expansion of the global economy would free up capital to the benefit of trade-neutral social and environmental programs.⁹ If a program is not effective in a trade-neutral environment, then liberal trade could magnify the flaws of that program. That is, it is not a fault of GATT that the effectiveness of a program might depend on a less-than-optimal trade environment.¹⁰ Thus, GATT is transparent to non-protectionist environmental efforts. There is little need for GATT to change in order to accommodate environmental efforts.¹¹ In very general terms, GATT permits environmental controls that do not discriminate between domestic and imported products (the national treatment rule) or imports from different countries (the most favored nation rule).¹²

So when the Uruguay Round addressed the protection of intellectual property, critics justifiably might have expected little consideration of the interrelation between intellectual property and environmental protection. The resulting document, the Agreement on Trade-Related Aspects of Intellectual

⁷ See *id.*

⁸ See *id.* More accurately, the programs can be designed to be consistent with provisions of GATT.

⁹ See *id.*

¹⁰ See Benedict Kingsbury, *Environment and Trade: The GATT/WTO Regime in the International Legal System*, in ENVIRONMENTAL REGULATION AND ECONOMIC GROWTH 189, 193 (A.E. Boyle ed., 1994). Little discussed is the ordering of priorities; for example, why not protect important social programs for a temporary period? Notably absent is any inquiry into the distribution of wealth between nations or between individuals. The preeminence of liberal trade is presumed manifest. This proposition is shown further by the treatment of exceptions to GATT and the perceived need of the Uruguay Round to re-ratify GATT to ensure authority over conflicts with earlier international agreements. See *infra* Part II. Such a perspective might be more convincing if optimal trade were, in fact, more important than the avoidance of potentially irreversible environmental hazards.

¹¹ See GATT, *supra* note 1, art. XX.

¹² See Report by the Chairman of the Group on Environmental Measures and International Trade Presented for the Contracting Parties at Their Forty-ninth Session, GATT B.I.S.D. (40th Supp.) at 79 (1995) (providing a brief, if one-sided, interpretation of GATT's relationship with environmental controls) [hereinafter GEMIT Report].

Property Rights ("TRIPS"),¹³ provided little surprise. Its purpose is the harmonization of international intellectual property rights as a step in the liberalization of trade.¹⁴ To do this, it establishes minimum standards to which member nations must conform their municipal law.¹⁵ TRIPS comprises a total of seventy-three articles, with only two paragraphs of one article touching on environmental issues.¹⁶ Much is unclear. For example, TRIPS authorizes the patenting of plants and animals, but it fails to discuss how nations might prevent the destruction of biodiversity.¹⁷ One provision, Article 27.2, is particularly surprising:

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.¹⁸

The words of this clause are vague and raise many practical questions.¹⁹ To some, this provision is so unclear as to permit protectionist abuse "without a narrowing interpretation or interpretative statement."²⁰ Nevertheless, one point is quite clear: member nations have the authority to refuse to grant

¹³ WTO Agreement, *supra* note 1, Agreement on Trade-Related Aspects of Intellectual Property Rights, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

¹⁴ See TRIPS Agreement, *supra* note 13, pmbl. (explaining the desire "to reduce distortions and impediments to international trade").

¹⁵ See Stephen E. Bondura & Lloyd G. Farr, *Intellectual Property Rights Abroad and at Home After GATT*, S.C. LAW., Sept./Oct. 1995, at 20.

¹⁶ See TRIPS Agreement, *supra* note 13.

¹⁷ See *id.* art. 27.3 ("Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system . . ."); see also Jennifer Schultz, *The GATT/WTO Committee on Trade and the Environment—Toward Environmental Reform*, 89 AM. J. INT'L L. 423, 436-37 (1995).

¹⁸ TRIPS Agreement, *supra* note 13, art. 27.2.

¹⁹ See Michael L. Doane, *TRIPS and International Intellectual Property Protection in an Age of Advancing Technology*, 9 AM. U. J. INT'L L. & POL'Y 465, 478 (1994).

²⁰ *Id.*

patents to environmentally risky inventions.²¹ Unfortunately, the standard for this exception is not clear.

The purpose of this paper is to discuss whether an argument can be made for the precautionary use of Article 27.2 to protect the environment. Because the provision is unclear, its use may be susceptible to challenge by another member state. The validity of a defense depends on a mixture of related elements. First, disputes under TRIPS are bound to the resolution procedures of GATT.²² Disputes under GATT are resolved primarily with reference to "the relevant GATT provisions," and without reference to general international law.²³ In an apparent effort to extricate GATT further from the principles of general international law, the Uruguay Round adopted GATT anew in 1994.²⁴ This measure falls within Articles 31 and 59 of the Vienna Convention on the Law of Treaties, which provide that a more recent treaty takes precedence over a conflicting, older treaty.²⁵ Second, despite the efforts to segregate GATT disputes from general international law, the segregation is incomplete. International law speaks to this issue in several direct and indirect means. Nevertheless, both GATT and international law support the precautionary use of Article 27.2. GATT provides direct support by the invocation of precautionary international standards for private industry. International law plays a lesser role. International law can influence gap-filling decisions in GATT disputes, the conduct of nations prior to GATT disputes, and the formation of international standards.²⁶ The limits

²¹ By definition, the use of Article 27 implies some environmental control over the invention prior to the "making, using, offering for sale, selling, or importing" of the invention. TRIPS Agreement, *supra* note 13, art. 28; *cf.* Schultz, *supra* note 17, at 436-37.

²² See TRIPS Agreement, *supra* note 13, art. 64.

²³ See 1 PIERRE PESCATORE ET AL., HANDBOOK OF WTO/GATT DISPUTE SETTLEMENT pt. 2, 12-13 (1995) (citing the 1989 Understanding on Rules and Procedures Governing the Settlement of Disputes *as modified by* the 1994 Understanding on Rules and Procedures Governing the Settlement of Disputes, Dec. 15, 1993, 33 I.L.M. 112 (1994)).

²⁴ See *id.* pt. 1, at 7.

²⁵ See Vienna Convention on the Law of Treaties, *opened for signature* May 23, 1969, arts. 31 & 59, 1155 U.N.T.S. 331, 8 I.L.M. 679 (1969); see also IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 624-25 (1990).

²⁶ For example, one clear way general international law might be relevant is in the absence of conflict with GATT. This could open a dispute to principles from international conventions, international custom, general principles of law recognized by civilized nations, or even the judicial decisions and teachings of qualified publicists. *Cf.* I.C.J. Stat. art. 38, ¶ 1, *reprinted in* DOCUMENTS OF THE INTERNATIONAL COURT OF JUSTICE 79 (Shabtai Rosenne ed., 1979).

of such a case may lie in the jurisdictional provisions of GATT. More generally, nations and GATT panels may find it in their interests to refrain from challenging well-established international law. Such nuances are illuminated by a review of relevant, if not facially binding, principles of international law and municipal law.

Article 27.2 is a rare and limited meeting of three bodies of international law: patent, trade, and environmental. Unfortunately, the dispersion of legal authority inhibits graceful organization. Part I will discuss the policies involved and a scenario for the precautionary use of Article 27.2. Part II will address the development of international patent law leading to TRIPS. It will be useful to review how international patent law has become intertwined with trade law, the standards for GATT decisionmaking and dispute resolution, and some of the related environmental issues. This section will also interpret Article 27.2 in light of other GATT environmental provisions. Part III presents the ultimate question: what supports the precautionary use of TRIPS? The answer relies primarily on GATT and private international standards. Also relevant are the principles of general international and municipal law, which may aid a GATT dispute settlement panel in filling the interpretive gaps of TRIPS.

I. AN EXAMPLE

A dispute under Article 27.2 might arise from differences in how GATT member states approach environmental risk and patent law. A hypothetical example of a nation's management of the invention and international marketing of new chemicals may illustrate this point. As a gross proposition, environmental law seeks to reduce or control risk through a wide variety of legal mechanisms.²⁷ For example, if a sovereign is uncomfortable with the environmental and health risks of new chemicals, it may require a showing of safety prior to use regardless of the country of origin. If the sovereign bans chemicals found to be dangerous, the process may reduce the risk to society at the cost of the showing of safety. The policy of patent law is likewise cogent: the sovereign who rewards socially useful inventions will benefit society through more inventions.²⁸ Inherent in

²⁷ See ZYGMUNT J.B. PLATER ET AL., *ENVIRONMENTAL LAW AND POLICY: A COURSEBOOK ON NATURE LAW AND SOCIETY* 1-4 (1992).

²⁸ See ROBERT PATRICK MERGES, *PATENT LAW AND POLICY* 2 (1992).

the rewards offered by patent law is a conversion of property rights. The inventor gains a right related to the development of the invention, a right that otherwise would belong to the sovereign or the public.²⁹ Many academics refer to this conversion as the grant of a monopoly, though in U.S. law and in TRIPS, it is actually a right to prevent others from making, using, or selling the invention.³⁰ The result is a market advantage for the life of the patent. These policies come together in the question at hand: what happens if a chemical patentee³¹ from a state that grants patents without regard to the environmental impact seeks a patent from a second state that requires a showing of environmental safety?

Under the language of Article 27.2, the second state appears to have the authority to reject a risky patent on the grounds of a precautionary domestic law.³² The starting point of the analysis is the statutory definition of patentable subject matter. TRIPS offers a liberal definition of patentable subject matter.³³ Then, Article 27.2 excepts subject matter that risks harm to "human, animal or plant life or health" or "serious prejudice to the environment."³⁴ Conceivably, a nation could reject classes of chemicals it believed to pose an unacceptable risk to its citizens. For a more considered approach, a nation might evaluate the safety of individual chemicals. This less severe reaction would require the inventor to satisfy a preliminary showing of safety, giving the nation an opportunity for control prior to the "making, using, offering for sale, selling, or importing" of the invention.³⁵ Thus, a nation could pursue controls ranging from an absolute, per se rejection of classes of chemicals considered to be dangerous, to a case-by-case evaluation of new chemicals, to an unquestioning acceptance of all subject matter. Left unanswered is the question of whether some inventions might pose such a risk.

²⁹ See *id.*

³⁰ See 35 U.S.C. § 271 (1994); TRIPS Agreement, *supra* note 13, art. 28.

³¹ The fictional patentee or inventor in this example includes a corporate employer who usually holds the patent by assignment from the actual inventor under the terms of the employment agreement.

³² See TRIPS Agreement, *supra* note 13, art. 27.

³³ See *id.*; see generally Steve Charnovitz, *The Regulation of Environmental Standards by International Trade Agreements*, 16 Int'l Env't Rep. (BNA) No. 17, at 631 (Aug. 25, 1993).

³⁴ TRIPS Agreement, *supra* note 13, art. 27.2.

³⁵ *Id.* art. 28.

Chemicals pose an uncertain risk to health and the environment; their effects are poorly understood. Indeed, chemicals or mixtures of chemicals compose everything in the environment.³⁶ In total, science recognizes about seven million different chemicals.³⁷ The world economy consumes about eighty thousand of those chemicals, with industry introducing a thousand new chemicals each year.³⁸ This widespread use of chemicals spreads the uncertain risk throughout the world.³⁹ Patent law encourages the development of new chemicals by giving industry a market advantage. Yet the social and economic benefit of these chemicals frequently is much better known than the potential harm. Nations vary in their efforts to predict which of these new chemicals will be dangerous to humans and the environment.⁴⁰ The fear of some, as a recent U.S. General Accounting Office report noted, is that "[f]or many chemicals, there is little knowledge of the ill-effects they might cause to people and the environment exposed to them."⁴¹ In March of 1996, the U.S. National Academy of Sciences held a conference on the subject of "whether common synthetic chemicals, many of them ubiquitous in mundane household and industrial products, reduce the ability of humans to reproduce, fight off disease and develop normal cognition and behavior."⁴² Chief among the issues discussed was the widespread marketing and use of many chemicals for which the effect on humans and the environment is admittedly unknown.⁴³ Most of these chemicals are, or were, protected by patents in one or more nations, giving the inventor an exclusive right to the

³⁶ See Linda L. Black-Covilli, *Basic Environmental Chemistry of Hazardous and Solid Wastes*, in *FUNDAMENTALS OF ENVIRONMENTAL SCIENCE AND TECHNOLOGY* 13-14 (Porter-C. Knowles ed., 1992).

³⁷ See U.S. GEN. ACCOUNTING OFFICE, *TOXIC SUBSTANCES CONTROL ACT—LEGISLATIVE CHANGES COULD MAKE THE ACT MORE EFFECTIVE* 8 (1994) [hereinafter *GAO REPORT*].

³⁸ See *id.*

³⁹ The chemical industry accounted for \$379 billion of world trade in 1994. See *WORLD TRADE ORG., INTERNATIONAL TRADE: 1995 TRENDS AND STATISTICS* 95 (1995).

⁴⁰ See *id.* See *infra* Part III.B.3.b. for a discussion of the variety of national environmental controls used regarding the introduction of new chemicals.

⁴¹ *GAO REPORT*, *supra* note 37, at 8.

⁴² Michael Waldholz, *Scientists Debate the Future Threat of Common Chemicals*, *WALL ST. J.*, Mar. 10, 1996, at A17.

⁴³ See *id.* One EPA researcher noted, "There is a legitimate need to study the impact of these [synthetic] chemicals beyond the usual, more easily detectable impacts . . . although exactly how dangerous and widespread is the danger simply is not known." *Id.*

development of the chemical.⁴⁴

The nature of this risk commends precaution. Uncertainty prevents science from prescribing an optimal balance between safety and economic exploitation. In fact, scientists disagree even as to the minimum necessary toxicological tests.⁴⁵ Nevertheless, the risk has led many nations to adopt some form of pre-manufacture or pre-market control of chemical compounds.⁴⁶ The reasons are quite clear. First, a reactive or tort-type law is unsatisfactory to prevent the harm imposed by an unsafe, but commonly used chemical as in the Bhopal Incident.⁴⁷ For this reason, tort law by itself is an inadequate guard against uncertainty.⁴⁸ Second, pre-market control is the point in the life of the product which enables the greatest risk avoidance for the least cost:

Once the production process is completed, the product created may itself pose a risk to the environment. The product may be dangerous for its intended use, threatening the health or safety of its user or bystanders, or its use may have undesirable side effects upon the environment, as by the emission of chemical substances which disturb some element of the food chain or the atmosphere. Finally, disposal of the product may be difficult or hazardous, giving rise to problems of waste management.⁴⁹

Thus, the nature of the risk endorses some measure of pre-market controls, as recognized by TRIPS Article 27.2.

In practice, nations may find several reasons for coordinating precautionary control with patent law. First, a nation may desire to

⁴⁴ See PATENTS THROUGHOUT THE WORLD J-6 (Alan J. Jacobs ed., 1996).

⁴⁵ See Black-Covilli, *supra* note 36, at 40-41.

⁴⁶ See *infra* Part III.

⁴⁷ See Molly Moore, *Bhopal Gas Leak Victims Caught in Cycle of Despair*, WASH. POST, Sept. 13, 1993, at A1. Following the disaster, India passed a precautionary statute. See PLATER ET AL., *supra* note 27, at 997 n.1.

⁴⁸ See MARTIN A. MATTES, PREMARKET TESTING OF INDUSTRIAL PRODUCTS: A MEANS OF CONTROLLING UNRECOGNIZED ENVIRONMENTAL HAZARDS 58 (1977).

⁴⁹ *Id.* at 12. Note there is a difference between pre-manufacture and pre-market controls. The choice of control is not a matter of concern here, so the term "pre-market control" refers to both methods.

discourage the use of risky, but innovative products within its territory. Indeed, the positive effects of an invention are inseparable from its negative effects. For example, it is easy to conceive of an invention that offers a great social benefit aside from its intense hazard. Yet if the product presents a risk to society, then that risk bears a social cost. For that invention, there is a less compelling argument for the sovereign to encourage economic exploitation. Congruently, there is a lesser interest in rewarding the inventor. Second, a nation simply may wish to use the grant of a market advantage offered by a patent to encourage a greater level of pre-market testing and disclosure by industry. Third, it makes sense for a sovereign to coordinate its grants and its regulations. To isolate the decision to control from the decision to reward invites competition between the two policies and weakens both. Otherwise, a nation might find itself in the ambivalent position of rewarding an inventor for a highly dangerous invention, which may require intense and expensive safety measures even if the invention offers only marginal utility. In order for those safety measures to be effective, they would need to correct not only the market failure or economic externalities that encourages polluting, but also the market advantage the state provided in the form of a patent.⁵⁰

II. THE DEVELOPMENT OF LAW LEADING TO THE TRIPS AGREEMENT

A. *Before TRIPS*

Before TRIPS, the preeminent authority pertaining to international patent law was the Paris Convention for the Protection of Industrial Property.⁵¹ A brief history of this document will provide background for a discussion of TRIPS. The Paris Convention arose from the Congress of Vienna for Patent Reform in 1873.⁵² This Congress addressed inconsistencies in national patent laws and the need for international reform.⁵³ Such a need had not been articulated until the 1873 International Exposition

⁵⁰ See generally Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & ECON. 1 (1960). In other words, the patent, which was erroneously granted based on an assumption of positive social utility, would pose an additional externality for the environmental regulation to correct or overcome.

⁵¹ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (last revision, July 14, 1967) [hereinafter Paris Convention].

⁵² See 1 STEPHEN P. LADAS, *PATENTS, TRADEMARKS, AND RELATED RIGHTS* § 45 (1975).

⁵³ See *id.*

at Vienna. Austria-Hungary intended the exposition to provide a forum for the exhibition of recent inventions in a variety of technologies. Yet many foreign inventors feared that the restrictive Austrian patent laws would provide little protection for them. Austria was forced to respond by passing a temporary law protecting the exhibiting inventors and removing discriminatory procedural requirements.⁵⁴ Thus, the exhibition was a timely setting for patent specialists to form a congress to discuss patent reform.⁵⁵ The next international exposition in 1878 similarly hosted the second meeting: the International Congress on Industrial Property at Paris.⁵⁶ The product of this congress was the Paris Convention for the Protection of Industrial Property of March 20, 1883.⁵⁷ This document was the parent of the modern Paris Convention, which is recognized by TRIPS.⁵⁸

Two substantive themes of the Paris Convention were national treatment and harmonization.⁵⁹ The principle of national treatment requires each member to grant the same protection to member applicants that it provides to its own national applicants. The Paris Convention advanced national treatment by the recognition of a common filing date, which could protect an inventor's priority of invention in foreign member nations.⁶⁰ Harmonization is the establishment of a common set of legal principles with which the member states must comply. The Paris Convention cautiously began the trend of harmonization by setting some modest rules for the protection of patents and industrial designs and common procedures for the recognition of international filing priority.⁶¹ Some critics faulted the Paris Convention for providing too little substantive protection for inventors.⁶² However, it did mark the birth of concepts for intellectual property protection that survive in both GATT and TRIPS.

The TRIPS Agreement arose largely due to the increasing importance of intellectual property rights to U.S. trade. Over the last twenty-five years, innovative technology, creative works, and famous consumer names have

⁵⁴ See *id.* § 44 & n.1.

⁵⁵ See *id.* § 45.

⁵⁶ See *id.* § 46.

⁵⁷ See *id.* § 48.

⁵⁸ See TRIPS Agreement, *supra* note 13, art. 2.

⁵⁹ See 1 LADAS, *supra* note 52, § 174.

⁶⁰ See Paris Convention, *supra* note 51, art. 4.

⁶¹ See *id.* arts. 4-5.

⁶² See 1 LADAS, *supra* note 52.

become more important to the U.S. export economy; intellectual property law seeks, among other things, to protect these creative products.⁶³ The United States became concerned that the weak intellectual property rights under the Paris Convention could allow piracy and infringement to erode its trade advantage.⁶⁴ In response, the United States insisted that the issue of intellectual property rights be placed on the 1986 agenda for the Uruguay Round of GATT Negotiations.⁶⁵

This proposal pulled the subject of intellectual property out of its historically isolated realm in international law and placed it within the realm of international trade law. For the United States, GATT was the appropriate forum because its primary function is the liberalization of international trade.⁶⁶ The United States estimated that it suffered an annual trade loss of \$60 billion because of the weakness of international intellectual property protection.⁶⁷ This posed a significant distortion in the natural balance of trade. At the time, however, some nations disagreed that the Uruguay Round should be extended to include intellectual property issues.⁶⁸ Nevertheless, the parties to the Uruguay Round acceded to the U.S. request.⁶⁹ TRIPS is the first multinational agreement to address in depth issues such as the scope of international intellectual property rights, the means to enforce those rights, dispute resolution, the applicability of earlier international agreements, and transitional arrangements.⁷⁰ As of December 1995, twenty-six of the 107 countries in GATT accepted the Uruguay Round.⁷¹

B. GATT

GATT is made up of a General Agreement and various side

⁶³ See Doane, *supra* note 19, at 465.

⁶⁴ See *id.* at 466-67.

⁶⁵ See *id.*

⁶⁶ See 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 8 ("The General Agreement was intended to implement and protect the results of tariff reductions that had been agreed upon during the I[n]ternational T[rade] O[rgan]ization negotiations.").

⁶⁷ See Doane, *supra* note 19, at 466 (citing U.S.I.T.C., PUB. NO. 2065, REP. TO THE U.S. TRADE REPRESENTATIVE, FOREIGN PROTECTION OF INTELLECTUAL PROPERTY RIGHTS AND THE EFFECT ON U.S. INDUSTRY AND TRADE (1988)).

⁶⁸ See *id.* at 466-67.

⁶⁹ See *id.*

⁷⁰ See TRIPS Agreement, *supra* note 13, pmbl.

⁷¹ See Bondura & Farr, *supra* note 15, at 20.

agreements, with the General Agreement covering most aspects of restrictions on the trade of goods and ancillary issues.⁷² Some of the many side agreements include the Dispute Settlement Understanding ("DSU"),⁷³ the General Agreement on Trade in Services ("GATS"),⁷⁴ TRIPS, and the Agreement Establishing the World Trade Organization ("WTO").⁷⁵ The WTO oversees international economic relations in the execution of GATT.⁷⁶ It operates by consensus, although the following issues require a super-majority vote: the adoption of interpretations of the agreements,⁷⁷ the waiver of obligations in "exceptional circumstances,"⁷⁸ and a limited amendment function.⁷⁹ The foundation of GATT policy lies in the most favored nation rule⁸⁰ and the national treatment rule.⁸¹ These rules require member nations to forbear from conduct that discriminates between domestic and imported products (the national treatment rule) or between imports from different countries (the most favored nation rule). The Uruguay Round added several of the side agreements, such as the DSU and TRIPS Agreement, and refined the national treatment and most favored nation rules.

At the Uruguay Round, the forces supporting free trade tended to

⁷² GATT, *supra* note 1; *see* 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 7. GATT often is used to refer to both the total system of agreements and the General Agreement alone.

⁷³ Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, 33 I.L.M. 1226 (1994) [hereinafter DSU] (describing the procedure for dispute resolution).

⁷⁴ General Agreement on Trade in Services, Apr. 15, 1994, 33 I.L.M. 1168 (1994).

⁷⁵ WTO Agreement, *supra* note 1.

⁷⁶ *See* 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 7-8, 12-13.

⁷⁷ This is presumably a post hoc, but limited, interpretation of intent. *See id.* at 13.

⁷⁸ *See id.*

⁷⁹ *See id.* at 13-14; *see also* Kingsbury, *supra* note 10, at 207.

⁸⁰ GATT, *supra* note 1, art. I.

With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports . . . any advantage, favor, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties.

Id.

⁸¹ GATT, *supra* note 1, art. III ("The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws . . .").

expand the reach of GATT. In support of harmonization, the members put into effect the complicated agreements on the Technical Barriers to Trade ("TBT") and Sanitary and Phytosanitary Standards.⁸² The TBT is of primary concern here. It comes into effect when a state seeks to apply a domestic standard, environmental or otherwise, to an imported product.⁸³ For imports, the TBT requires either the use of "relevant international standards"⁸⁴ or a domestic standard that passes the "least restrictive" test, defined as "not . . . more trade-restrictive than necessary to fulfill a legitimate objective."⁸⁵ Legitimate objectives include the "protection of human, animal, or plant life or health, and protection of the environment."⁸⁶ When a nation uses an international standard, it gains a rebuttable presumption of consistency with the TBT.⁸⁷ Generally, a nation should be able to show a scientific basis for using a domestic standard different from an international standard.⁸⁸ Without valid justification, a nation may use a non-TBT domestic standard if it is willing to risk a ruling by the WTO that the standard is illegal and to subject itself to tariffs.⁸⁹

The Uruguay Round also changed the terms of dispute resolution under GATT. A typical GATT dispute might allege trade discrimination in violation of the national treatment rule. Early procedures offered a preliminary phase in which the parties could request a consultation in order to resolve the dispute informally.⁹⁰ If this failed, the complaining party could resort to the body of GATT members.⁹¹ The membership was then required to investigate the complaint and arrive at a resolution by consensus. If no members objected (vetoed), then the punishment could include a loss of

⁸² Agreement on Technical Barriers to Trade, GATT B.I.S.D. (26th Supp.) at 8 (1979) [hereinafter TBT Agreement]; see Steve Charnovitz, *The World Trade Organization and Environmental Supervision*, 17 Int'l Env't Rep. (BNA) No. 2, at 89 (Jan. 26, 1994). The Agreement on Sanitary and Phytosanitary Measures addresses food safety and disease prevention. See *id.*

⁸³ See Charnovitz, *supra* note 82.

⁸⁴ TBT Agreement, *supra* note 82, art. 2.4.

⁸⁵ *Id.* art. 2.2.

⁸⁶ Kingsbury, *supra* note 10, at 213.

⁸⁷ See *id.*; Charnovitz, *supra* note 82.

⁸⁸ See Kingsbury, *supra* note 10, at 213; Charnovitz, *supra* note 82.

⁸⁹ See Charnovitz, *supra* note 82.

⁹⁰ See GATT, *supra* note 1, art. XXII.

⁹¹ See *id.* art. XXIII.

GATT concessions.⁹² This awkward procedure proved frustrating.⁹³ The Tokyo Round in 1979 started a reformation of the dispute process, but retained much of the awkwardness, including the requirement of a consensus.⁹⁴ The Uruguay Round brought drastic change to GATT dispute resolution.⁹⁵ Formal disputes are now resolved by dispute settlement panels, access to which is guaranteed; the panel reports become final unless there is a consensus to reject.⁹⁶ The DSU streamlines punishment as well.⁹⁷

In a dispute, the one source of binding legal authority is GATT.⁹⁸ As stated in the DSU, a dispute settlement panel "cannot add to or diminish the rights and obligations provided in the covered agreements."⁹⁹ The GATT provisions include the General Agreement and the side agreements, such as TRIPS.¹⁰⁰ The complaining member identifies the initial, relevant terms of reference, although a dispute settlement panel may refer to any GATT provision.¹⁰¹ If there is a conflict between a general and a side agreement, the side agreement takes precedence.¹⁰² WTO interpretations and the decisions of the members provide a source of persuasive but non-binding GATT law.¹⁰³ The decisions of the members may include earlier dispute settlement panel reports.¹⁰⁴

Can a dispute settlement panel, which apparently is limited to the provisions of GATT, ever consider other public international law? Putting aside the case where there is a direct conflict between other international law

⁹² See *id.*

⁹³ See Myles Getlan, Comment, *TRIPS and the Future of Section 301: A Comparative Study in Trade Dispute Resolution*, 34 COLUM. J. TRANSNAT'L L. 173, 202-04 (1995).

⁹⁴ See *id.*

⁹⁵ See DSU, *supra* note 73.

⁹⁶ See *id.* arts. 6.1, 16.4.

⁹⁷ See *id.* art. 22.6.

⁹⁸ See 1 PESCATORE ET AL., *supra* note 23.

⁹⁹ DSU, *supra* note 73, art. 3.2.

¹⁰⁰ See GATT, *supra* note 1, art. XXXIV; 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 18-21.

¹⁰¹ See 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 12-13.

¹⁰² See *id.* pt. 1, at 18 (citing WTO Agreement, *supra* note 1, Annex 1A, general interpretive note, 33 I.L.M. 1154 (1994)).

¹⁰³ See GATT, *supra* note 1, art. XXXIV; 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 18-21. Dispute settlement panel reports are not binding law for cases not involving the same parties. See *id.* at 20.

¹⁰⁴ See 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 19-20.

and GATT,¹⁰⁵ the first hurdle is jurisdictional. That is, the preliminary question is whether the dispute could be resolved solely on the basis of trade issues.¹⁰⁶ If not, such a dispute might present a conflict arising from the vagueness of the relevant GATT provisions. Is there any mechanism for a dispute settlement panel to choose an interpretation that accords with public international law? Perhaps in this narrow case. Such gap-filling falls short of a change in rights and obligations while advancing predictability and security.¹⁰⁷ Further, dispute settlement panels have the ability to consult with a variety of non-GATT experts.¹⁰⁸ Yet to date, no dispute settlement panel has referred to the rules of general international law.¹⁰⁹ On the other hand, Article 31 of the Vienna Convention does appear to have guided the decisions of some dispute settlement panels.¹¹⁰ Article 31 could allow contextual consideration of subsequent agreement, subsequent practice, and "any relevant rules of international law applicable to the relations between the parties."¹¹¹ This could provide a direct role for general international law in a GATT dispute; undoubtedly, such a proposition could be challenged.¹¹² Nevertheless, it would be consistent with GATT.

C. TRIPS

The TRIPS Agreement addresses many of the inadequacies of earlier international patent law. With this remedial intent, the United States advanced the proposal for TRIPS in 1987 and carried it through to the Uruguay Round in 1989.¹¹³ Perhaps the primary achievement of TRIPS is its relationship with GATT, which enabled the application of the national treatment and most favored nation rules to the trade aspects of intellectual

¹⁰⁵ The subject of conflict between GATT and public international law is addressed *infra* Part III.B.

¹⁰⁶ See 1 PESCATORE ET AL., *supra* note 23, pt. 2, at 26 & n.47.

¹⁰⁷ See DSU, *supra* note 73, art. 3.2.

¹⁰⁸ See Kingsbury, *supra* note 10, at 225.

¹⁰⁹ See 1 PESCATORE ET AL., *supra* note 23, pt. 2, at 26.

¹¹⁰ See *id.* Article 31 is the General Rule of Interpretation for treaties.

¹¹¹ Vienna Convention on the Law of Treaties, *supra* note 25, art. 31.3; see Kingsbury, *supra* note 10, at 217-27.

¹¹² See Kingsbury, *supra* note 10, at 226-27 n.97 (citing the Tuna-Dolphin Case (Mex. v. U.S.), Dispute Settlement Panel Report on United States Restrictions on Imports of Tuna, Aug. 16, 1991, GATT B.I.S.D. (39th Supp.) at 155 (1991) [hereinafter Tuna-Dolphin Case]).

¹¹³ See Getlan, *supra* note 93, at 173.

property.¹¹⁴ Substantively, TRIPS provided a minimum set of standards to which member nations must conform their intellectual property law.¹¹⁵ Many of these standards were the product of a coordinated effort to fill the gaps in international patent law left by the Paris Convention.¹¹⁶ Some of the major changes include a broad definition of patentable subject matter,¹¹⁷ a prohibition of discrimination by the place of origin,¹¹⁸ a uniform patent term of twenty years from filing,¹¹⁹ and sanctioned importing.¹²⁰ An additional concern of the United States was dispute resolution. Accordingly, TRIPS accepts the dispute resolution mechanisms of GATT.¹²¹

D. *GATT and Environmental Issues*

Some of the recent environmental issues associated with GATT include the potential disruption of multilateral environmental agreements,¹²² whether U.S. laws protecting extra-territorial dolphins were consistent with GATT (Tuna-Dolphin Case),¹²³ the validity of U.S. gas guzzler taxes and corporate average fuel economy requirements,¹²⁴ and whether unilateral environmental measures affecting trade in general will survive GATT.¹²⁵ The most far-reaching of concerns is the first, whether the trade-oriented provisions of GATT will eviscerate the already weak enforcement mechanisms of public environmental law.¹²⁶ The issue that is of greatest consequence to environmentalists is how GATT affects environmental

¹¹⁴ See TRIPS Agreement, *supra* note 13, arts. 3-4.

¹¹⁵ See *id.* art. 1.

¹¹⁶ See J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, 29 INT'L LAW. 345, 351-52 (1995).

¹¹⁷ See TRIPS Agreement, *supra* note 13, art. 27.1.

¹¹⁸ See *id.*

¹¹⁹ See *id.* arts. 27, 28, 33.

¹²⁰ See *id.* art. 28.1. In some nations, importing was considered a form of patent abuse by failure to work the patent in the importing nation.

¹²¹ See *id.* art. 64.

¹²² See Steve Charnovitz, *Green Roots, Bad Pruning: GATT Rules and Their Application to Environmental Trade Measures*, 7 TUL. ENVTL. L.J. 299 (1994).

¹²³ See Tuna-Dolphin Case, *supra* note 112.

¹²⁴ See Dispute Settlement Panel Report on the United States Taxes on Automobiles, Oct. 11, 1994, 33 I.L.M. 1397 (1994); Steve Charnovitz, *The GATT Panel Decision on Automobile Taxes*, 17 Int'l Env't Rep. (BNA) No. 22, at 921 (Nov. 2, 1994).

¹²⁵ See Charnovitz, *supra* note 82.

¹²⁶ See Schultz, *supra* note 17, at 433-34.

agreements that use trade measures.

Some critics question GATT's hostility to international environmental law. GATT supporters posit that the "gains from trade are real and are distributed among all the participants," including environmental efforts.¹²⁷ Yet many of the major impediments to trade remain unchallenged,¹²⁸ in contrast to the minor impediments posed by environmental laws.¹²⁹ Indeed, even the GATT Group on Environmental Measures and International Trade reported that, "few of the more than 150 M[ultilateral] E[nvironmental] A[greement]s negotiated to date contain any trade provisions."¹³⁰ Nevertheless, the treaty date of GATT was reset from 1947 to 1994, enabling it to "leapfrog" in priority over all environmental treaties, which under international law's "more recent treaty" rule would have trumped GATT on environmental issues.¹³¹

GATT defenders have responded that "the considerable extent to which the GATT rules already accommodate trade measures used in conjunction with environmental policies to protect national environmental resources" obviates the need for refinement.¹³² As noted above, environmental efforts that observe the national treatment and most favored nation rules are quite likely to survive scrutiny under GATT. In addition, the General Agreement provides an exception from these rules in Article XX for measures "necessary to protect human, animal or plant life or health," or "relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."¹³³ As a recent report by the GATT Group of Environmental Measures and International Trade¹³⁴ argued:

There is wide agreement in the Group that GATT does not prevent any contracting party from adopting appropriate domestic environmental policies by providing countries with

¹²⁷ 1 PESCATORE ET AL, *supra* note 23, at vii.

¹²⁸ See 1 *id.*

¹²⁹ See Charnovitz, *supra* note 122, at 350-52.

¹³⁰ GEMIT Report, *supra* note 12, at 78.

¹³¹ See Charnovitz, *supra* note 82, at 91.

¹³² GEMIT Report, *supra* note 12, at 77-78.

¹³³ GATT, *supra* note 1, art. XX (b), (g).

¹³⁴ This group is a non-negotiating contracting party group that is subordinate to the Committee.

very considerable scope to use trade-related policies to protect national environmental resources without calling into question their GATT obligations In addition, recourse can be taken to the provisions of Article XX of the GATT in exceptional circumstances. These provisions permit a contracting party to apply trade measures which could otherwise be considered inconsistent with its GATT obligations but which are felt to be necessary to protect human, animal or plant life or health or which relate to the conservation of exhaustible natural resources. However, such measures must not constitute a means of arbitrary or unjustifiable discrimination between countries Checks and balances . . . are needed as essential safeguards against protectionist abuse, which would be as detrimental to the environmental agenda as to trade, and to avoid unduly disturbing the balance of rights and obligations accruing to contracting parties from the GATT system.¹³⁵

If it is accepted that environmental programs can and should be crafted in a trade neutral fashion, the problem posed is minor.

Even if GATT suffers the existence of environmental efforts, it may promote a downward harmonization in environmental law to the most lax, generally accepted standard.¹³⁶ There is simply no source of authority within GATT for weighing environmental issues with trade issues. GATT contains "only a politically limited and arduous process for making new rules, and a system of dispute settlement and supervision that has not hitherto been environment-oriented or as open as environmentalists wish."¹³⁷ Nevertheless, there exists an extensive body of substantive, international environmental law in apparent conflict with GATT, which augurs a greater problem. Consider how the United States might fare under GATT if in response to harmful transboundary pollution from the Trail Smelter, it banned the importation of the metals produced there.¹³⁸ The ultimate relationship between trade and

¹³⁵ GEMIT Report, *supra* note 12, at 79.

¹³⁶ See generally VOGEL, *supra* note 6, at 141-49 (describing the "Delaware effect").

¹³⁷ Kingsbury, *supra* note 10, at 191.

¹³⁸ See *id.* at 216-17 (citing the Trail Smelter Arbitration (U.S. v. Can.) 3 R.I.A.A. 1911 (1941)).

environmental law remains both unsettled and unsettling.¹³⁹

The TRIPS Agreement also has spawned controversy over environmental issues. Article 27 raises a number of environmental questions in addition to those raised by paragraph 2. The concern over paragraph 3 centers on issues of morality, conservation, and the preservation of biodiversity. This provision permits member nations to exclude "diagnostic, therapeutic, and surgical methods"¹⁴⁰ and seems to leave unresolved the question of patenting genetic material, defined as "plants and animals other than microorganisms, and essentially biological processes."¹⁴¹ Related topics include the morality of patenting pharmaceuticals,¹⁴² medical methods, and genetic material.¹⁴³ One environmental concern is that TRIPS might encourage a rush to exploit, and likely destroy, biodiversity in developing nations that formerly did not allow the patenting of genetic material.¹⁴⁴ South American nations may find themselves to be the host, by virtue of TRIPS, of a genetic marketplace; the profits for transnational pharmaceutical companies could be enormous and arguably, unhealthful.¹⁴⁵ The loss of genetic biodiversity may depend more on how well drug companies share their profits with the host nation than on scientific principles of preservation.¹⁴⁶ In this respect, the vague language of TRIPS offers little help; one suggested remedy is to revise Article 27.3 in order to reward sound environmental management and preservation in addition to exploitation.¹⁴⁷

¹³⁹ See Goldman, *supra* note 2.

¹⁴⁰ TRIPS Agreement, *supra* note 13, art. 27.3(a).

¹⁴¹ *Id.* art. 27.3(b). See generally Charnovitz, *supra* note 82, at 92 (stating that "[a]nimals may be excluded from the WTO patent requirements, but plant varieties must be legally secured either through patents or an alternative system").

¹⁴² See Rana Gosain & Henry K. Sherrill, *Despite TRIPS, the PTO Is Not Granting Drug or Food Patents—So Why File?*, LATIN AM. L. & BUS. REP., Oct. 31, 1995, available in 1995 WL 10426914.

¹⁴³ See generally Schultz, *supra* note 17.

¹⁴⁴ See *id.* at 436.

¹⁴⁵ See *id.*

¹⁴⁶ See Julia Preston, *A Biodiversity Pact with a Premium*, WASH. POST, June 9, 1992, at A16.

¹⁴⁷ See Schultz, *supra* note 17, at 436-37 (arguing that these issues should be included in the future GATT/WTO work program on the environment).

E. *GATT Article XX as an Analogy for Interpreting TRIPS Article 27.2*

An examination of the use of GATT Article XX may illuminate the discussion of TRIPS Article 27.2. As mentioned above, Article XX exempts from compliance with the principles of GATT, those measures that are:

- (a) necessary to protect public morals;
- (b) necessary to protect human, animal or plant life or health;
-
- (f) imposed for the protection of national treasures of artistic, historic or archeological value;
- (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption¹⁴⁸

There are many difficulties in drawing this analogy, but there are also some arguments in its favor. The simple terms of GATT force a first order, or preliminary analysis of whether national conduct is facially GATT compliant, regardless of other issues. Indeed, this is a jurisdictional question.¹⁴⁹ Thus, GATT divides conduct into three categories: GATT compliant, GATT deviant, and GATT Article XX excepted. In this respect, the analogy may hold. Article 27 of TRIPS can be seen as dividing a nation's treatment of patentable subject matter into three categories: compliant with the broad grant of TRIPS, TRIPS deviant, or TRIPS Article 27 excepted. In some parts, the language is similar.¹⁵⁰ Further, GATT would treat both deviant categories as impermissibly protectionist.

However, difficulties abound. Fundamentally, the two articles relate to their respective documents differently. Article XX removes the obligation for general compliance with the fundamental policies of GATT when a state seeks affirmative conduct matching the exceptions. Article 27.2 removes the obligation of a sovereign to respond to a request for an affirmative grant. A dispute under Article 27.2 is more likely to constitute gap-filling than

¹⁴⁸ GATT, *supra* note 1, art. XX.

¹⁴⁹ See 1 PESCATORE ET AL., *supra* note 23.

¹⁵⁰ For example, both exceptions must be "necessary." See GATT, *supra* note 1, art. XX; TRIPS Agreement, *supra* note 13, art. 27.2.

interpretation, as have many of the Article XX cases.¹⁵¹ Prior to any grant of patentable subject matter in TRIPS is the cautionary phrase “[s]ubject to the provisions of paragraphs 2 and 3.”¹⁵² The exception is limited to the term “patentable subject matter,” which is a statutory tool for defining the types of inventions that can be patented.¹⁵³ For TRIPS, this is the primary inquiry into whether an invention merits national treatment. Therefore the first step is the satisfaction of the provisions of paragraphs 2 and 3. The second step is a presumption of patentability that merits national treatment. The grant that follows is affirmative: “patents shall be available for 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.”¹⁵⁴ It is the exception, which frames the grant of patentable subject matter, that allows member nations to exclude from national treatment certain categories of inventions. In contrast, Article XX is a separate article that presents a general exception to all the obligations of the General Agreement. Further, it is conceivable that TRIPS Article 27.2 could be read to conflict with GATT Article XX in both terms of obligation and wording. In that case, Article 27.2 would govern.¹⁵⁵

Assuming the analogy, this interpretation would produce a narrow but viable exception to patentable subject matter. In general, a party claiming an exception under Article XX must show necessity for the conduct.¹⁵⁶ This entails a showing that the affirmative conduct is no more restrictive than GATT consistent alternatives—that is, the alternative that is the least inconsistent with GATT.¹⁵⁷ In such a case, a dispute settlement panel is to construe Article XX narrowly.¹⁵⁸ On the other hand, a uniformly applied

¹⁵¹ For a discussion of the application of GATT to environmental measures, see Charnovitz, *supra* note 122.

¹⁵² TRIPS Agreement, *supra* note 13, art. 27.1.

¹⁵³ *Cf.* MERGES, *supra* note 28, at 42-45.

¹⁵⁴ TRIPS Agreement, *supra* note 13, art. 27.1.

¹⁵⁵ See 1 PESCATORE ET AL., *supra* note 23, pt. 1, at 18 (citing WTO Agreement, *supra* note 1, Annex 1A, general interpretive note). Conflict in wording might arise over any difference in wording, such as “serious prejudice to the environment.”

¹⁵⁶ See WORLD TRADE ORG., GATT, ANALYTICAL INDEX: GUIDE TO GATT LAW AND PRACTICE 563 (6th ed. 1995).

¹⁵⁷ See *id.* at 566-67, 575.

¹⁵⁸ See *id.* at 563.

standard that satisfies generally accepted scientific principles may survive.¹⁵⁹ In such a case, a GATT panel may look to expert information provided by non-GATT organizations.¹⁶⁰ Consider the hypothetical from above involving the import of a new chemical. Assume that the receiving nation provided a valid, scientific justification for setting a standard of unacceptable risk, moderate regulations, and a universal, good faith applicability that is otherwise GATT compliant. In such a case, the precautionary use of TRIPS Article 27.2 might survive a test of narrow interpretation similar to that accorded to GATT Article XX.

At this point, the procedural aspects are worth noting. GATT Article XX is primarily a defensive measure raised in disputes.¹⁶¹ In contrast, the exercise of Article 27.2 could implicate other parts of TRIPS prior to a dispute. Article 29 requires inventors to disclose information about an invention "in a manner sufficiently clear and complete" for enablement, or simple exercise of the invention.¹⁶² A nation also may impose "reasonable procedures and formalities" as long as they are consistent with TRIPS.¹⁶³ Opponents may raise the argument that because a disclosure of environmental impact is not explicit in Article 29, it is inconsistent. However, because Article 27.2 is discretionary, the disclosure requirement should not be included in a generally applicable requirement for patentability. Instead, it is better accommodated as a conditional "reasonable procedure." Moreover, that objection itself would be inconsistent with the plain language of Article 29.2. As will be seen below, such an objection may also prove difficult in view of the TBT and international law. In short, TRIPS envisions Article 27.2 as an intermediate tool of environmental control. Thus, a requirement of a pre-market showing of safety could satisfy GATT if it observes the TBT, national treatment rule, and most favored nation rule.

III. WHAT SUPPORTS A PRECAUTIONARY USE OF ARTICLE 27.2?

In the context of international trade and environmental law, it is

¹⁵⁹ See *id.* at 566-68 (citing 1990 Panel Report on Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes, Nov. 7, 1990, GATT B.I.S.D. (37th Supp.) at 200 (1991)).

¹⁶⁰ See *id.*

¹⁶¹ See, e.g., Charnovitz, *supra* note 122, at 323.

¹⁶² TRIPS Agreement, *supra* note 13, art. 29.1.

¹⁶³ *Id.* art. 62.1.

useful to identify two loose categories: public and private.¹⁶⁴ Typical public international law comprises binding legal agreements or treaties between states, such as GATT or the Convention on Early Notification of a Nuclear Accident.¹⁶⁵ Industry developed standards, such as those produced by the International Organization for Standardization ("ISO"), fall into the category of private law.¹⁶⁶ Because GATT, through the TBT, has adopted aspects of private law as municipal law, the two categories may overlap. This phenomenon has arisen with the European Community's official recognition of international standards.¹⁶⁷ In the case at hand, both public and private international law support the precautionary use of Article 27. GATT incorporates private industrial standards that support information access and responsible life cycle management. This is a direct support. International and municipal law play a more modest role. In disputes, non-GATT law may be relevant to show subsequent dealings between the parties, customs, or generally accepted principles of conduct.¹⁶⁸ In addition, it may shape the scope of the dispute indirectly. These indirect effects may range from guiding the requirements of ISO standards to a dispute settlement panel's consideration of comparative municipal solutions.¹⁶⁹

A. *The Technical Barriers to Trade and Article 27.2*

GATT requires this interpretation of TRIPS Article 27.2 through a two-step argument. First, as discussed above, the TBT creates a rebuttable presumption supporting the use of international industrial standards. Second,

¹⁶⁴ See generally Naomi Roht-Arriaza, *Shifting the Point of Regulation: The International Organization for Standardization and Global Lawmaking on Trade and the Environment*, 22 *ECOLOGY L.Q.* 479 (1995).

¹⁶⁵ Convention on Early Notification of a Nuclear Accident, *opened for signature* Sept. 26, 1986, 25 *I.L.M.* 1370 (1986); see Roht-Arriaza, *supra* note 164, at 480-85; see generally HARALD HOHMANN, *PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW* 34-35 (1994).

¹⁶⁶ See Roht-Arriaza, *supra* note 164, at 486-88; see generally Kerry E. Rodgers, *The ISO Environmental Standards Initiative*, 5 *N.Y.U. ENVTL. L.J.* 181 (1996) (discussing ISO 14000).

¹⁶⁷ See, e.g., Council Regulation 1836/93, art. 1, 1993 *O.J. (L 168)* 1 (regulating the European Union Environmental Management and Audit System).

¹⁶⁸ See Vienna Convention on the Law of Treaties, *supra* note 25, art. 31.3; Kingsbury, *supra* note 10, at 217-27.

¹⁶⁹ See 1 PESCATORE ET AL., *supra* note 23, pt. 2, at 26 & n.46.

the international standards of widest applicability endorse product life cycle management, pollution prevention, and product impact disclosure. This two-step argument clearly supports a nation that requires a showing of safety prior to manufacture. The national patent proponent who objects faces the burden of rebutting a presumption of compliance with the TBT in the dispute settlement proceedings.

The primary source of international standards is the ISO. The ISO includes over one hundred nations, which are represented by their most representative industrial-standard-setting organizations.¹⁷⁰ The ISO objective is to advance international trade through standardization.¹⁷¹ Accordingly, the ISO has issued thousands of standards for industrial fields ranging from mechanical engineering to information technology.¹⁷² These standards are, by themselves, voluntary. Yet when a GATT member uses an international standard, it raises a presumption of compliance with the TBT.¹⁷³ A major attraction these standards hold for GATT is that they provide a ready, industry-accepted, form of harmonization.¹⁷⁴

The first ISO series to approach the issue of environmental protection was ISO 9000.¹⁷⁵ This standard introduced the concept of managing a product's life cycle, from the recognition of a market need to the ultimate disposal at the end of use.¹⁷⁶ When developing a product, the ISO 9000 manufacturer should consider the ultimate disposal to be an important aspect of the product's quality. Effective quality control includes identifying the disposal requirements (scientific and legal), ensuring that disposal capacity is available, and communicating this to the consumer.¹⁷⁷ The consumer expects safe usage and disposal, and the manufacturer should be confident that "output actually meets customer expectations."¹⁷⁸ Yet the total environmental message is somewhat general and oblique. A clearer message

¹⁷⁰ See Roht-Arriaza, *supra* note 164, at 489.

¹⁷¹ See PERRY L. JOHNSON, ISO 9000: MEETING THE NEW INTERNATIONAL STANDARDS 6 (1993).

¹⁷² See Roht-Arriaza, *supra* note 164, at 490.

¹⁷³ See *id.* at 518-20.

¹⁷⁴ See *id.* at 488.

¹⁷⁵ See FRANK VOEHL ET AL., ISO 9000: AN IMPLEMENTATION GUIDE FOR SMALL TO MID-SIZED BUSINESSES 156-59 (1994).

¹⁷⁶ See *id.*

¹⁷⁷ See JOHNSON, *supra* note 171, at 49-53.

¹⁷⁸ *Id.* at 51.

of caution in ISO 9000 is the requirement for product safety. ISO 9000 requires facilities to “identify all safety aspects of the quality of output,” “test output for effectiveness of safety measures,” and “institute output traceability to ensure effective recall.”¹⁷⁹ The objective is to treat safety and product liability as a “special category of critical quality characteristics.”¹⁸⁰ A fair reading of these requirements certainly would include environmental responsibility for a pre-market showing of safety.

ISO 14000, some parts of which were due in 1996, promises an even broader, holistic approach to environmental protection.¹⁸¹ In general, these standards address environmental management systems, labeling, auditing, life cycle assessment, performance evaluation, and product standards.¹⁸² In ISO 14000, there is a very definite trend towards risk avoidance, pollution prevention, responsible management, and information availability.¹⁸³ In particular, ISO 14041 through 14044 advance the message that a corporation should exercise environmental control of a product’s life.¹⁸⁴ This “life cycle analysis” includes a study of the environmental impacts at every step, an assessment of the associated risks, and an effort to minimize those risks.¹⁸⁵ This module of the standard is due to be complete between 1997 and 1998. Nevertheless, one principle is consistent. The identification and communication of environmental and health risks at all stages of a product’s life is critical.¹⁸⁶

A tangential, but misleading controversy has arisen over performance evaluations. Some of the early proposals required extensive publication of the environmental impacts of industrial operations.¹⁸⁷ In the United States, the fear arose that an informed public might not tolerate a polluting industry that was otherwise desirable; in particular, industry concern focused on the

¹⁷⁹ *Id.* at 91.

¹⁸⁰ *Id.* at 92.

¹⁸¹ See *ISO Standards Would Encourage Compliance with Environmental Standards*, *Official Says*, 25 *Env’t Rep. (BNA)* 283 (June 10, 1994).

¹⁸² See generally W. LEE KUHRE, *ISO 14001 CERTIFICATION: ENVIRONMENTAL MANAGEMENT SYSTEMS* (1995). Information about ISO 14000 also may be found at the Internet web site <<http://es.inel.gov/partners/iso/iso.html>>.

¹⁸³ See Roht-Arriaza, *supra* note 164, at 516-17.

¹⁸⁴ See KUHRE, *supra* note 182, at 31-32.

¹⁸⁵ See *id.*

¹⁸⁶ See *id.* at 171-73.

¹⁸⁷ See *id.* at 67.

publication of toxic releases from operations.¹⁸⁸ On that subject, U.S. industry has pushed through a measure in ISO 14000 for the confidentiality of this information.¹⁸⁹ This confidentiality requirement has little bearing on the subject of life cycle analysis.

B. *Principles of Non-GATT Law: General International Law*

1. *Introduction*

Public international law supports this application of Article 27.2. As mentioned above, because GATT is more recent than multilateral environmental treaties, many consider that it preempts general international law.¹⁹⁰ Even if it does, this does not mean that the environmental treaties have no role. The international principle of precaution and the need for coordination of development with environmental control can influence GATT decisionmaking directly and indirectly.¹⁹¹ The general municipal acceptance of pre-market disclosures and patentable subject matter limitations also can influence a GATT dispute settlement panel.¹⁹² First, when there is no clear contradiction between the environmental law and GATT, then environmental law should be direct and relevant evidence of the practice of the parties.¹⁹³ As discussed above, this may be a limited, but gap-filling role in the context of facial compliance with GATT. Presumably, this direct role could include a range of authority including subsequent agreement, custom, and general principles of law. Second, public law can influence private law in a number

¹⁸⁸ See *ISO Standards Would Encourage Compliance with Environmental Standards*, *Official Says*, *supra* note 181, at 283. The ISO 14000 standards form two categories, "one for evaluating an organization and another for assessing its products." *Id.*

¹⁸⁹ See Allison Lucas & Michael Roberts, *Environmental Management Standard Set for 1995 Debut; Manufacturers Seek to Merge Auditing Schemes*, *CHEMICAL WK.*, Nov. 9, 1994, at 33.

¹⁹⁰ Cf. Charnovitz, *supra* note 82, at 91.

¹⁹¹ A clear example of this was seen when French President François Mitterand invoked Article 128 of the Treaty of Maastricht in defending statutes designed to protect French culture from a challenge under GATT. See Kirsten L. Kessler, *Protecting Free Trade in Audiovisual Entertainment: A Proposal for Counteracting the European Union's Trade Barriers to the U.S. Entertainment Industry's Exports*, 26 *L. & POL'Y INT'L BUS.* 563, 577 (1995), available in LEXIS, WORLD Library, ALLNWS File.

¹⁹² See 1 *PESCATORE ET AL.*, *supra* note 23, pt. 1, at 20 & n.46.

¹⁹³ See Kingsbury, *supra* note 10, at 218.

of indirect ways. For example, the 1992 United Nations Conference on Environment and Development sparked the creation of ISO 14000 as a new environmental standard to work towards sustainable industrial development.¹⁹⁴ Similarly, municipal environmental law can influence international industrial standards; ISO 14000 has embraced the theme of the U.S. Pollution Prevention Act.¹⁹⁵ In this fashion, environmental notions may enter GATT through the back door of harmonization. In addition, the interests that drove the creation of environmental law are no less compelling after the Uruguay Round. These concerns can govern the conduct of GATT member states in their dealings outside of a dispute. For example, it is unlikely that a nation would be willing to pit GATT against a popular environmental treaty, such as the Montreal Protocol on Substances that Deplete the Ozone Layer.¹⁹⁶ The political costs would be too high. As a final note, because the role of non-GATT law is limited in GATT disputes, it is referred to as mere interpretive principles; perhaps one day an audacious defendant will confront this parochial aspect of GATT with an argument based on international custom.¹⁹⁷

2. *International Environmental Law*

The policies of international environmental protection are diverse; the principles may be articulable, but their application is complex.¹⁹⁸ At a minimum, a state materially harmed by activities clearly traceable to another state may be able to recover.¹⁹⁹ In the realm of international agreements, notions of ecological responsibility have intruded on the anthropocentric concept of maximum use.²⁰⁰ Some of these environmental notions grow from

¹⁹⁴ See Roht-Arriaza, *supra* note 164, at 501.

¹⁹⁵ The Pollution Prevention Act of 1990, 42 U.S.C. §§ 13,101-13,109 (1994). "The Congress hereby declares it to be the national policy of the United States that pollution should be prevented or reduced at the source whenever feasible . . ." *Id.* § 13,101(b); see Roht-Arriaza, *supra* note 164, at 505.

¹⁹⁶ Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, 26 I.L.M. 1541 (1987); see Kingsbury, *supra* note 10, at 218-19.

¹⁹⁷ Cf. I.C.J. Stat. art. 38, ¶ 1(b), (c), *supra* note 26.

¹⁹⁸ See PLATER ET AL., *supra* note 27, at 1009-12.

¹⁹⁹ See Trail Smelter Arbitration (U.S. v. Can.), 3 R.I.A.A. 1911 (1941).

²⁰⁰ See HOHMANN, *supra* note 165, at 340-41.

the maxim *sic utere tuo ut alienum non laedas*.²⁰¹ These include a duty to prevent a known harm or risk (a duty that has evolved to include potential harms or risks),²⁰² a duty to prevent crises,²⁰³ and a duty to notify other nations of environmental risks.²⁰⁴ At the same time, there is an increasing trend towards a holistic environmental management in which nations and industry cooperate to avoid risks,²⁰⁵ making "environmental protection . . . an integral part of the development process."²⁰⁶ In short, international law provides several principles relevant to Article 27.2: a closer coordination of development with environmental protection and a precautionary principle that seeks to identify and account for imperfect knowledge. These principles support the coordination of environmental considerations with the decision to grant a patent by requiring the applicant to make a pre-market showing of safety.

a . *The Coordination of Development and Protection of the Environment*

It is a historic principle of international law to coordinate development with environmental protection. Any effort to segregate the two issues misunderstands their relationship. The very failure to consider the environmental effects of development led to the early cases of international environmental law. In the *Lac Lanoux Arbitration*, the dispute arose over the potential of adverse environmental effects caused by France's development of its water interests in the Carol River.²⁰⁷ The *Trail Smelter Case* concerned transboundary pollution from a Canadian lead smelting operation that injured the U.S. environment.²⁰⁸ By the very nature of the dispute, international law

²⁰¹ Cf. *Corfu Channel (U.K. v. Alb.)*, 1949 I.C.J. 4 (Apr. 9, 1949) (finding that one should use one's property in such a manner as not to injure that of another). See RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 601 (1987) for a concise explanation of these duties.

²⁰² See HOHMANN, *supra* note 165, at 341; see, e.g., *The Rio Declaration on Environment and Development*, June 13, 1992, princ. 15, U.N. Doc. A/Conf.151/5/Rev. 1, 31 I.L.M. 874 (1992) [hereinafter *Rio Declaration*].

²⁰³ See HOHMANN, *supra* note 165, at 342; see, e.g., *Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency*, Sept. 26, 1986, 25 I.L.M. 1377 (1986).

²⁰⁴ See HOHMANN, *supra* note 165, at 341-43.

²⁰⁵ See *id.* at 342-45; PLATER ET AL., *supra* note 27, at 1034-37.

²⁰⁶ *Rio Declaration*, *supra* note 202, princ. 4.

²⁰⁷ *Affaire du Lac Lanoux (Fr. v. Spain)*, 12 R.I.A.A. 281 (1957).

²⁰⁸ *Trail Smelter Arbitration*, 3 R.I.A.A. 1911 (1941).

regularly has commingled the interests of development and the need for environmental protection.

This principle permeates the growth of public environmental law, starting with the Stockholm Conference on the Human Environment.²⁰⁹ Prior agreements had dealt primarily with the allocation of resources.²¹⁰ Yet the Stockholm conference recognized a need for principles governing more than this, principles that would enable states to cooperate in both development and the preservation of natural resources.²¹¹ The principle reappears in subsequent international statements such as the World Charter for Nature,²¹² the Rio Declaration on the Environment and Development,²¹³ and Agenda 21.²¹⁴ Interestingly, public environmental law contemplates the issue of international trade and seeks to clear the field of protectionist municipal law:

Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on international consensus.²¹⁵

Yet at the same time, the Rio Declaration cautions that any development policy that does not include sound environmental policy is itself unsound.²¹⁶

As shown above, environmental concerns symmetrically have entered

²⁰⁹ See HOHMANN, *supra* note 165, at 34-35; cf. PLATER ET AL., *supra* note 27, at 1001-02.

²¹⁰ See, e.g., Agreement with Mexico, Nov. 14, 1944, U.S.-Mex., 59 Stat. 1219.

²¹¹ See *id.*; see, e.g., *Stockholm Declaration of the United Nations Conference on the Human Environment*, Report of the U.N. Conf. on the Human Environment, July 5-16, 1972, princ. 18, U.N. Doc. A/Conf.48/14 (1972), 11 I.L.M. 1416 (1972) [hereinafter Stockholm Declaration].

²¹² *World Charter for Nature*, U.N. GAOR, 37th Sess., Supp. No. 51, at 21, addendum 1, U.N. Doc. A/37/L.4 (1982), 21 I.L.M. 455 (1983).

²¹³ *Rio Declaration*, *supra* note 202.

²¹⁴ *United Nations Conference on Environment and Development*, U.N. GAOR, 46th Sess., Agenda Item 21, U.N. Doc. A/Conf.151/4 (1992) [hereinafter Agenda 21].

²¹⁵ *Rio Declaration*, *supra* note 202, princ. 12.

²¹⁶ See *id.* princ. 4.

international law concerning development. The Uruguay Round negotiations established a Committee on Trade and the Environment "to identify the relationship between trade measures and environmental measures, in order to promote sustainable development."²¹⁷ The statement further noted that there need not be "any policy contradiction between upholding and safeguarding an open, non-discriminatory and equitable multilateral trading system on the one hand, and acting for the protection of the environment, . . . on the other."²¹⁸ Moreover, the general exceptions of GATT voice this symmetry by express accommodation of those trade restrictions that are "necessary to protect human, animal or plant life or health."²¹⁹

The plain language of TRIPS is consistent with the coordination of development and environmental protection. TRIPS purports to set minimum standards in the definition of intellectual property rights.²²⁰ If the environmental exception is read out of the document, the foundation of the plain language is rendered meaningless—the Article would no longer be a working procedure, but a hortatory afterthought. This is necessarily so because the broad grant of Article 27.1 is made subject to paragraph 2. The exceptions must be taken with the broad definition or the liberal grant also becomes hortatory. The plain language and the structure of the Article clearly overcome any argument that patent law should remain free of environmental concerns.

b. *The Precautionary Principle*

Current public environmental law supports scientific risk avoidance in the interest of environmental protection, but early on, uncertainty was not recognized as a major aspect of environmental science. In 1972, the Stockholm Declaration provided that "[s]cience and technology . . . must be applied to the identification, avoidance and control of environmental risks . . . for the common good of mankind."²²¹ Yet to effect this goal, the Stockholm Convention required only a "free flow of up-to-date scientific

²¹⁷ Committee on Trade and the Environment, Ministerial Decision of Apr. 14, 1994, 33 I.L.M. 1267 (1994).

²¹⁸ *Id.*

²¹⁹ GATT, *supra* note 1, art. XX(b).

²²⁰ See TRIPS Agreement, *supra* note 13, pmbl.

²²¹ Stockholm Declaration, *supra* note 211, princ. 18.

information and transfer of experience.”²²² The cautionary approach evolved in later multilateral environmental agreements. The World Charter for Nature provides that: “Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed.”²²³ Particularly relevant are the provisions relating to chemical wastes: “Discharge of pollutants into natural systems shall be avoided and . . . [s]pecial precautions shall be taken to prevent discharge of radioactive or toxic wastes.”²²⁴ Logically, this means that special precautions should apply to potentially toxic materials, including if needed, a ban on production or importation. Importantly, the burden is on the proponent to show that prior to production, the adverse effects are “fully understood” and that the benefits “outweigh potential damage to nature.”²²⁵ Inherent in these special precautions is the prerequisite that citizens be given “appropriate access” to information concerning the environment.²²⁶ This compelling principle is reflected in the international standards discussed above.

In 1992, the Rio Declaration gave the precautionary principle an even clearer voice. Principle 15 provides that: “In order to protect the environment, the precautionary approach shall be widely applied by States Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.”²²⁷ Accordingly, this principle informs many aspects of modern environmental law.²²⁸ In 1993, the Convention for the Protection of the Marine Environment of the North-East Atlantic embraced the precautionary principle as requiring “preventive measures . . . when there are reasonable grounds for concern” of pollution that “directly or indirectly . . . may bring about hazards to human

²²² *Id.* princ. 20.

²²³ *World Charter for Nature*, *supra* note 212, princ. 11(b).

²²⁴ *Id.* princ. 12.

²²⁵ *Id.* princ. 11.

²²⁶ See *Rio Declaration*, *supra* note 202, princ. 10; HOHMANN, *supra* note 165, at 320.

²²⁷ *Rio Declaration*, *supra* note 202, princ. 15.

²²⁸ See Agenda 21, *supra* note 214, arts. 2.10, 2.22, 4.19, 4.22, 4.26, 5.16, 8.1, 19.1, 20.1, 21.1, 22.1, 30.1, 31.1, 35.1, 36.8, 40.1.

health [or] harm living resources.”²²⁹ This statement requires action even with imperfect knowledge. Typically, obligations under the precautionary principle are “unconditional [and] triggered by mere *prima facie* cases of risks and, thus, independent[] of costs/economic criteria and of proofs of thresholds, causality and full scientific certainty.”²³⁰ It is worth note that the legal status of these multilateral environmental agreements varies widely. For example, the World Charter for Nature is considered to be “politically binding” overall with legally binding aspects which have been incorporated into subsequent U.N. documents.²³¹ However, in terms of an accepted interpretive principle, the message is clear.

Also worth note is that international environmental law requires exporting nations to disclose information about known, dangerous chemicals to importing nations.²³² In 1987, the United Nations Environmental Program convened a group of experts to produce guidelines to improve the exchange of information available for chemicals in international trade.²³³ The product was the London Guidelines for the Exchange of Information on Chemicals in International Trade, as amended in 1989.²³⁴ The United Nations further supports the domestic restriction and ban of chemicals by publishing an annual report of affected chemicals and the acting governments.²³⁵ The London Guidelines require the national exporter of a chemical to disclose information on the chemical being imported, the reasons for the restrictions or ban, and any alternatives to the chemical.²³⁶ It is indeed true that “[e]fforts to control uncertain hazards almost always involve an increase in government restriction of private conduct. Some degree of freedom, usually of an economic nature, must be sacrificed for the sake of protecting the community

²²⁹ Convention for the Protection of the Marine Environment of the North-East Atlantic, done at Paris Sept. 22, 1992, 32 I.L.M. 1069, 1076 (1993).

²³⁰ HOHMANN, *supra* note 165, at 341.

²³¹ *See id.* at 180.

²³² *See* MICHAEL S. BARAM & DANIEL G. PARTAN, CORPORATE DISCLOSURE OF ENVIRONMENTAL RISKS 191-92 (1990) (citing *London Guidelines for the Exchange of Information on Chemicals in International Trade*, U.N. Env'tl. Program, U.N. Doc. UNEP/GC. 14/17 (1987)).

²³³ *See id.*

²³⁴ *London Guidelines for the Exchange of Information on Chemicals in International Trade*, U.N. Env'tl. Program, UN Doc. UNEP/GC. 14/17 (1987) as amended, adopted by UNEP Governing Council Decision 15/30 (May 25, 1989) [hereinafter *London Guidelines*].

²³⁵ *See* BARAM & PARTAN, *supra* note 232, at 192.

²³⁶ *See London Guidelines*, *supra* note 234.

at large.”²³⁷

In these examples, the international community is shown as accepting the precautionary principle. Such broad acceptance would compel a gap-filling interpretation of TRIPS Article 27.2 that permits a nation to require a showing of safety prior to national treatment.

3. *Municipal Law*

a. *Patent Law*

The history and the variety of municipal systems provide some support for the proposition that a dangerous invention is not useful to society and, therefore, is not appropriate subject matter for a patent.²³⁸ For example, early U.S. cases held that a finding of social harm, which was defined as being “injurious to the morals, the health and the good order of society,” rendered an invention unpatentable.²³⁹ The principle derives from an early British patent statute, which excluded otherwise patentable inventions that were “contrary to the law, . . . mischievous to the State, by raising prices of commodities at home, . . . or generally inconvenient.”²⁴⁰ The modern concept sees the legal requirement of utility²⁴¹ to be composed of both a positive and negative utility.²⁴² For an invention to be patentable, its positive utility must outweigh its negative utility.²⁴³ In practice in most countries, the consideration of negative utility is manifested as an exception to patentable subject matter.²⁴⁴ Many nations retain this ability to exclude patents that are

²³⁷ MATTES, *supra* note 48, at 14.

²³⁸ See 1 ERNEST BAINBRIDGE LIPSCOMB III, WALKER ON PATENTS § 5:12 (1984) (citing *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568)).

²³⁹ *Id.*

²⁴⁰ 1 LADAS, *supra* note 52, § 4 (quoting the Statute of Monopolies, 21 Jam. I, ch. III (1623)).

²⁴¹ See 35 U.S.C. § 101 (1994) (defining utility as “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”).

²⁴² See 1 LIPSCOMB, *supra* note 238, § 5:12.

²⁴³ See *id.*

²⁴⁴ See, e.g., PATENTS THROUGHOUT THE WORLD S-32.2 (Alan J. Jacobs ed., 4th ed. 1996) (explaining that the Slovak Republic excludes from patentable subject matter “inventions that are contrary to principle of humanity and public morality”).

contrary to morality or social benefit;²⁴⁵ indeed, Article 27 of TRIPS accommodates this consideration of negative utility.²⁴⁶ Nevertheless, some nations, including the United States, have discarded this notion.

Although early U.S. patent law embraced the concept of negative utility, modern cases have rejected it. In its place, the courts seem to support a concept of beneficial or nominal utility; that is, a nominal showing of beneficial use is enough for patentability in the United States, regardless of the negative effects. The transformation in the U.S. concept of utility is striking. One early Supreme Court case held that where the inventor finds it necessary to reach his objective through risky (imminently dangerous) means, then the patenting of that invention exceeds the intent of Congress.²⁴⁷ In the twentieth century, the test for utility evolved into whether the invention is "used or is designed and adapted to be used to accomplish a good result."²⁴⁸ Notably, the U.S. patent statute does not speak to the issue, requiring only that an invention be "useful."²⁴⁹ More recently, courts have rejected the past practice of denying patentability on the grounds of morality, as with gambling devices, or because the invention might injure the health, as with drug safety.²⁵⁰ Thus, in nations like the United States, any positive social benefit (for example, industrial) merits reward regardless of the potential social injury. In contrast to a balancing of positive and negative utility, this form of utility test might be described as a nominal utility.

However, the U.S. standard is by no means common. Many nations limit the subject matter of patents because of negative utility; the practice is widespread and encompasses both developed and developing nations. For example, in Japan "[i]nventions contrary to public order or morals, or injurious to health are not patentable."²⁵¹ Belgium rejects inventions with a subject matter "the exploitation of which would be contrary to public order or morals."²⁵² Likewise, Argentina retains the authority to refuse "inventions

²⁴⁵ See, e.g., *id.*

²⁴⁶ See TRIPS Agreement, *supra* note 13, art. 27.

²⁴⁷ See 1 LIPSCOMB, *supra* note 238, § 5:13 (citing *Mitchell v. Tilghman*, 86 U.S. 287 (1874)).

²⁴⁸ 1 *Id.* § 5:12 (citing *Mills v. Industry Novelty Co.*, 230 F. 463 (N.D. Ill. 1963)).

²⁴⁹ See 35 U.S.C. § 101 (1994).

²⁵⁰ See 1 LIPSCOMB, *supra* note 238, § 5:13 (citing *Ex Parte Murphy*, 200 U.S.P.Q. 801 (Bd. App. 1977); *Application of Anthony*, 414 F.2d 1383 (C.C.P.A. 1969)).

²⁵¹ PATENTS THROUGHOUT THE WORLD, *supra* note 244, at J-6.

²⁵² *Id.* at B-22.1 to -23.

contrary to morals.”²⁵³ The grounds of rejection seem to range from hygiene and beneficial custom to public interest.²⁵⁴ The European Patent Convention also excepts inventions that threaten morality or *ordre public*.²⁵⁵

Accordingly, TRIPS accommodates negative utility through restrictions on patentable subject matter. The terms of the exception are broad: “to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.”²⁵⁶ It is telling that there was sufficient support among the GATT member nations to include this provision when it is clearly contrary to the municipal law of the United States. TRIPS limits the exception by forbidding exclusion “merely because the exploitation is prohibited by domestic law.”²⁵⁷ In other words, a state should be able to supply a non-protectionist justification for the exclusion. Thus, with the notable exception of U.S. patent law, a comparison of municipal patent law supports the precautionary use of Article 27.2.

b. *Environmental Law*

It is quite common for nations to require, under environmental law, a showing by industry that its activity will not harm health or the environment. Indeed, nations customarily place a high burden on the chemical industry. The burden takes two general forms: industry must either prove that a new chemical is safe or make some lesser showing. Germany and Sweden are typical, in that they require the producer to provide sufficient information for the classification of the new chemical into levels or categories of toxicity for appropriate regulation.²⁵⁸ Other states burden industry to a lesser degree. The burden can fall on industry, government, or someplace in between.

One nation in which more of the burden seems to fall on industry is France. France regulates the chemical industry by a system of pre-market

²⁵³ *Id.* at A-33.

²⁵⁴ *See id.* at T-2, U-6 (Taiwan and Ukraine, respectively).

²⁵⁵ European Patent Convention, Oct. 5, 1973, art. 53, *reprinted in* PATENTS THROUGHOUT THE WORLD, *supra* note 244, at App. B-169, -187.

²⁵⁶ TRIPS Agreement, *supra* note 13, art. 27.2. Apparently an *Ex Parte Murphy* test of utility would comply with TRIPS.

²⁵⁷ *Id.*

²⁵⁸ *See* GAO REPORT, *supra* note 37, at 26.

controls; chemical manufacturers bear the burden of disclosing to the Ministry of the Environment the chemical composition, health and environmental effects during use, and the procedures for safe use.²⁵⁹ There are grades of toxicity, which drive the extent of disclosure and the regulatory controls. The most toxic chemicals are subject to a complete prohibition.²⁶⁰ The European Community has affirmed or motivated much of this regulation of the chemical industry; for example, EC directives prohibit the marketing of certain chemical compositions, impose safety measures, and require regulatory schemes.²⁶¹

In Japan, government and industry seem to share the burden. Industry is required to report the identity of a chemical to the Ministry of Health and Welfare prior to manufacture.²⁶² The government then bears the burden to test the material for risk to health or the environment.²⁶³ The method of control is by permit, and production is forbidden until testing is completed.²⁶⁴ However, lodging the burden of testing with the government has created problems. Since the enactment of the law in 1973, industry has reported 6000 new chemicals, of which only 270 have been tested.²⁶⁵ Interestingly, industry bears a precautionary presumption of risk, which means that there is no production until government completes the testing.²⁶⁶

In the United States, political and economic concerns weakened pre-market controls of chemical manufacturing, resulting in a burdened government. Prior to any legislation addressing the production of toxic substances, the U.S. National Academy of Sciences warned that "society suffers large and unnecessary expense because of inadequate investment in

²⁵⁹ See J. ANDREW SCHLICKMAN ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND REGULATION § 2.9, Fr-24 (1995). Note that some French law is derived from European Community regulations: Law No. 77-771 of July 12, 1977, *as modified by* Law No. 82-905 of Oct. 21, 1982 and its Decree No. 85-217 of Feb. 13, 1985. See *id.*

²⁶⁰ See *id.*

²⁶¹ See, e.g., Council Directive 79/117, 1979 O.J. (L 033) 36 (prohibition on the placing on the market and use of plant protection products containing certain active substances); Council Directive 82/501, 1982 O.J. (L 230) 1 (the "Seveso Directive").

²⁶² See SCHLICKMAN ET AL., *supra* note 259, § 2.5, Jpn-20-22 (discussing the Law Concerning Examination of Chemical Substance and Regulation of its Manufacture).

²⁶³ See *id.*

²⁶⁴ See *id.*

²⁶⁵ See *id.*

²⁶⁶ See *id.*

determining the hazards of chemicals.”²⁶⁷ Nevertheless, the chemical industry objected that there would be “serious and unnecessary economic penalties on the public”²⁶⁸ Because of industry protestation and political might, the legislation produced was weak, complicated, and unworkable. Industry is merely required to notify government prior to manufacture of a new chemical.²⁶⁹ The government is required to review the chemical and if necessary, object by the burdensome process of issuing a regulation.²⁷⁰

In 1994, the U.S. Environmental Protection Agency (“EPA”) identified over 16,000 existing chemicals that were “of some concern because of their production volume and chemical structure.”²⁷¹ With tens of thousands of chemicals waiting review, EPA has issued regulations to control only four new and five existing chemicals.²⁷² The only U.S. law suitable for the pre-market control of new industrial use chemicals is the Toxic Substance Control Act.²⁷³ But that legislation burdens the EPA with the requirement of showing, within ninety days of notification by industry, substantial evidence that the new chemical poses an “unreasonable risk.”²⁷⁴ The U.S. General Accounting Office recommended shifting the burden to the chemical industry to show that their products could be consumed safely; this burden should be a “cost of doing business.”²⁷⁵ The bottom line is that “TSCA does not require industry to test new chemicals for their toxicity, and industry generally does not voluntarily perform this testing.”²⁷⁶

IV. CONCLUSION

It is appropriate under Article 27.2, for a nation to presume that certain inventions pose an environmental risk. To protect against this risk,

²⁶⁷ COMMITTEE ON PRINCIPLES OF DECISION MAKING FOR REGULATING CHEMS. IN THE ENV'T, NATIONAL ACADEMY OF SCIENCES, DECISION MAKING FOR REGULATING CHEMICALS IN THE ENVIRONMENT 52-53 (1975), in MATTES, *supra* note 48, at 60.

²⁶⁸ Remarks of W. Driver, President, Manufacturing Chemists Ass'n, *quoted in* 4 PESTICIDE CHEM. NEWS 13 (1976), in MATTES, *supra* note 48, at 60.

²⁶⁹ See PLATER ET AL., *supra* note 27, at 749-50.

²⁷⁰ See *id.*

²⁷¹ GAO REPORT, *supra* note 37, at 4.

²⁷² See *id.*

²⁷³ See *id.* at 18.

²⁷⁴ 15 U.S.C. § 2603 (1994); see GAO REPORT, *supra* note 37, at 9.

²⁷⁵ GAO REPORT, *supra* note 37, at 40-41.

²⁷⁶ *Id.* at 32.

a nation might require a pre-market showing from both domestic and foreign producers that an invention is safe. If the burden is not carried at all, then that nation could then ban the invention as unsafe. If an invention fails to meet a lesser standard of safety, then the nation could discourage its development by refusing to patent it. If the nation complies with fundamental GATT policies of the national treatment and most favored nation rules, then "[t]here is wide agreement in the Group that GATT does not prevent any contracting party from adopting appropriate domestic environmental policies by providing countries with very considerable scope to use trade-related policies to protect national environmental resources without calling into question their GATT obligations"²⁷⁷

The example at hand envisions two responses by the applicant.²⁷⁸ Depending on the subject matter of the invention, a patent applicant could rebut the presumption of risk by a showing that the use of the invention, including its ultimate disposal, would not threaten "human, animal or plant life or health," nor pose a "serious prejudice to the environment."²⁷⁹ In the alternative, the exporting nation of the applicant might challenge this use of Article 27 as inconsistent with GATT and TRIPS. Such a challenge would present a question of gap-filling interpretation. The complaining nation would identify the relevant terms of reference from GATT and TRIPS, though the ultimate decision could incorporate other provisions.²⁸⁰

The defending nation could resort to two general arguments in the alternative.²⁸¹ Fundamental policy conflicts are not implicated by this example so the defense is guided by facial compliance with GATT and TRIPS.

1. *The GATT system supports the precautionary use of TRIPS Article 27.2.*

If the safety standards are scientifically valid, and the trade mechanism is in accord with basic GATT policy, then the problem becomes more refined. The TBT Agreements invoke international standards as

²⁷⁷ GEMIT Report, *supra* note 12, at 79.

²⁷⁸ Inaction or alternative dispute resolution are certainly available alternatives. However, they intersect with the topic of this paper only inasmuch as the principles of law might guide their conduct.

²⁷⁹ TRIPS Agreement, *supra* note 13, art. 27.2.

²⁸⁰ See 1 PESCATORE ET AL., *supra* note 23, pt. 2, at 12-13.

²⁸¹ This example neglects a possible GATT article XX argument.

presumptively compliant with GATT. Both ISO 9000 and ISO 14000 support precaution and life cycle analysis.²⁸² The challenging state must then overcome a presumption of compliance.

2. *General international law accepts precaution and coordination of environmental protection and development.*

The first step in this argument is finding that GATT does not speak to this issue. The conflict is bound up in GATT and non-GATT law. This hurdle is jurisdictional.²⁸³ If the dispute settlement panel refers to non-GATT sources, then it could rely on the contextual consideration of subsequent agreements, subsequent practice, and to "any relevant rules of international law applicable to the relations between the parties," including comparative municipal law.²⁸⁴ The second step is to argue the highest level of interpretive authority. These sources could support arguments both as interpretive custom or "principles of law recognized by civilized nations."²⁸⁵ Here, it is clear that international environmental law would support this use of the precautionary principle and the coordination of environmental and developmental concerns. Municipal patent law commonly recognizes limitations on patentable subject matter to serve the public interest. Further, it is the practice of states to require in municipal law some pre-market control of inventions, and this use accords with the more successful of those practices.

V. A FINAL NOTE

It is appropriate to step back and to consider that this recommendation envisions Article 27.2 as a tool for encouraging responsible industry behavior at whatever standard a nation should choose. The issues here are very similar to those that arose in the decision of the United States to embark on pre-market control of new chemicals:

²⁸² See *supra* Part III.A.

²⁸³ See *supra* Part II.

²⁸⁴ Vienna Convention on the Law of Treaties, *supra* note 25, art. 31.3; see Kingsbury, *supra* note 10, at 217-27.

²⁸⁵ Cf. I.C.J. Stat. art. 38, ¶ 1(b)-(c), *supra* note 26.

The law's traditional orientation has been one of hindsight, looking to past conduct and legal relationships to determine the proper allocation of benefits and responsibilities in a matter The law has hesitated to look forward, to settle conflicts before they arise. Rather, judges and legislators have tended to assume, in accordance with the principle of judicial and legislative restraint, that it is best, or at least more politic, for the law to deal with problems and injuries only once they have become manifest.²⁸⁶

Not mentioned in the conclusion above is the role of general international law in shaping the scope of the dispute. The great weight of non-GATT law commends precaution in dealing with risk. It is likely that this force will solidify in both private international standards and public international law. It is hoped that precaution also will govern state conduct in exploiting the resources that make not only trade, but life, possible.

²⁸⁶ MATTES, *supra* note 48, at 12.