TRIPS Article 27.2: An Argument for Caution

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

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advancements enjoyed since the signing of GATT. 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. In addition, an expansion of the global economy would free up capital to the benefit of trade-neutral social and environmental programs. 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. Thus, GATT is transparent to non-protectionist environmental efforts. There is little need for GATT to change in order to accommodate environmental efforts. 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).

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

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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.
Property Rights ("TRIPS"), provided little surprise. Its purpose is the harmonization of international intellectual property rights as a step in the liberalization of trade. To do this, it establishes minimum standards to which member nations must conform their municipal law. TRIPS comprises a total of seventy-three articles, with only two paragraphs of one article touching on environmental issues. 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. 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.

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

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14 See TRIPS Agreement, supra note 13, pmbl. (explaining the desire "to reduce distortions and impediments to international trade").
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.
20 Id.
patents to environmentally risky inventions.\textsuperscript{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.\textsuperscript{22} Disputes under GATT are resolved primarily with reference to "the relevant GATT provisions," and without reference to general international law.\textsuperscript{23} In an apparent effort to extricate GATT further from the principles of general international law, the Uruguay Round adopted GATT anew in 1994.\textsuperscript{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.\textsuperscript{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.\textsuperscript{26}

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.\textsuperscript{22} See TRIPS Agreement, supra note 13, art. 64.\textsuperscript{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)).\textsuperscript{24} See id. pt. 1, at 7.\textsuperscript{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 BROWNIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 624-25 (1990).\textsuperscript{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
interwined 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

\(^{28}\) 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.
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.
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. In total, science recognizes about seven million different chemicals. The world economy consumes about eighty thousand of those chemicals, with industry introducing a thousand new chemicals each year. This widespread use of chemicals spreads the uncertain risk throughout the world. 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. 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.” 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.” 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. Most of these chemicals are, or were, protected by patents in one or more nations, giving the inventor an exclusive right to the

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.
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.
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


45 See Black-Covilli, supra note 36, at 40-41.
46 See infra Part III.
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.


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. Thus, the exhibition was a timely setting for patent specialists to form a congress to discuss patent reform.

The next international exposition in 1878 similarly hosted the second meeting: the International Congress on Industrial Property at Paris. The product of this congress was the Paris Convention for the Protection of Industrial Property of March 20, 1883. This document was the parent of the modern Paris Convention, which is recognized by TRIPS.

Two substantive themes of the Paris Convention were national treatment and harmonization. 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. 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. Some critics faulted the Paris Convention for providing too little substantive protection for inventors. 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

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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. 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. 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.

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. The United States estimated that it suffered an annual trade loss of $60 billion because of the weakness of international intellectual property protection. 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. Nevertheless, the parties to the Uruguay Round acceded to the U.S. request. 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. As of December 1995, twenty-six of the 107 countries in GATT accepted the Uruguay Round.

B. GATT

GATT is made up of a General Agreement and various side

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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 [International] T[rade] O[rganization] 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. Some of the many side agreements include the Dispute Settlement Understanding ("DSU"), the General Agreement on Trade in Services ("GATS"), TRIPS, and the Agreement Establishing the World Trade Organization ("WTO"). The WTO oversees international economic relations in the execution of GATT. It operates by consensus, although the following issues require a super-majority vote: the adoption of interpretations of the agreements, the waiver of obligations in "exceptional circumstances," and a limited amendment function. The foundation of GATT policy lies in the most favored nation rule and the national treatment rule. 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

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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.


75 WTO Agreement, supra note 1.


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. 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. For imports, the TBT requires either the use of "relevant international standards" or a domestic standard that passes the "least restrictive" test, defined as "not . . . more trade-restrictive than necessary to fulfill a legitimate objective." Legitimate objectives include the "protection of human, animal, or plant life or health, and protection of the environment." When a nation uses an international standard, it gains a rebuttable presumption of consistency with the TBT. Generally, a nation should be able to show a scientific basis for using a domestic standard different from an international standard. 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.

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. If this failed, the complaining party could resort to the body of GATT members. 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

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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. The Tokyo Round in 1979 started a reformation of the dispute process, but retained much of the awkwardness, including the requirement of a consensus. The Uruguay Round brought drastic change to GATT dispute resolution. 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. The DSU streamlines punishment as well.

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

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

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92 See id.  
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.  
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.  
and GATT, the first hurdle is jurisdictional. That is, the preliminary question is whether the dispute could be resolved solely on the basis of trade issues. 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. Further, dispute settlement panels have the ability to consult with a variety of non-GATT experts. Yet to date, no dispute settlement panel has referred to the rules of general international law. On the other hand, Article 31 of the Vienna Convention does appear to have guided the decisions of some dispute settlement panels. 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." This could provide a direct role for general international law in a GATT dispute; undoubtedly, such a proposition could be challenged. 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. 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

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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.
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.
113 See Getlan, supra note 93, at 173.
property. Substantively, TRIPS provided a minimum set of standards to which member nations must conform their intellectual property law. Many of these standards were the product of a coordinated effort to fill the gaps in international patent law left by the Paris Convention. Some of the major changes include a broad definition of patentable subject matter, a prohibition of discrimination by the place of origin, a uniform patent term of twenty years from filing, and sanctioned importing. An additional concern of the United States was dispute resolution. Accordingly, TRIPS accepts the dispute resolution mechanisms of GATT.

D. GATT and Environmental Issues

Some of the recent environmental issues associated with GATT include the potential disruption of multilateral environmental agreements, whether U.S. laws protecting extra-territorial dolphins were consistent with GATT (Tuna-Dolphin Case), the validity of U.S. gas guzzler taxes and corporate average fuel economy requirements, and whether unilateral environmental measures affecting trade in general will survive GATT. 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. The issue that is of greatest consequence to environmentalists is how GATT affects environmental

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114 See TRIPS Agreement, supra note 13, arts. 3-4.
115 See id. art. 1.
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.
123 See Tuna-Dolphin Case, supra note 112.
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. Yet many of the major impediments to trade remain unchallenged, in contrast to the minor impediments posed by environmental laws. 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.” 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.

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. 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.” As a recent report by the GATT Group of Environmental Measures and International Trade 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

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127 Pescatore et al., supra note 23, at vii.
128 See 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").


\(^{143}\) 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 consumption . . . .148

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. Prior to any grant of patentable subject matter in TRIPS is the cautionary phrase “[s]ubject to the provisions of paragraphs 2 and 3.” 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. 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.” 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.

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. 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. In such a case, a dispute settlement panel is to construe Article XX narrowly. On the other hand, a uniformly applied

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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.
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.”
157 See id. at 566-67, 575.
158 See id. at 563.
standard that satisfies generally accepted scientific principles may survive.\textsuperscript{159} In such a case, a GATT panel may look to expert information provided by non-GATT organizations.\textsuperscript{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.\textsuperscript{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.\textsuperscript{162} A nation also may impose “reasonable procedures and formalities” as long as they are consistent with TRIPS.\textsuperscript{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


\textsuperscript{160} See id.

\textsuperscript{161} See, e.g., Charnovitz, supra note 122, at 323.

\textsuperscript{162} TRIPS Agreement, supra note 13, art. 29.1.

\textsuperscript{163} Id. art. 62.1.
useful to identify two loose categories: public and private. 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. Industry developed standards, such as those produced by the International Organization for Standardization ("ISO"), fall into the category of private law. 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. 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. 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.

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,

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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. The ISO objective is to advance international trade through standardization. Accordingly, the ISO has issued thousands of standards for industrial fields ranging from mechanical engineering to information technology. These standards are, by themselves, voluntary. Yet when a GATT member uses an international standard, it raises a presumption of compliance with the TBT. A major attraction these standards hold for GATT is that they provide a ready, industry-accepted, form of harmonization.

The first ISO series to approach the issue of environmental protection was ISO 9000. 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. 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. The consumer expects safe usage and disposal, and the manufacturer should be confident that “output actually meets customer expectations.” Yet the total environmental message is somewhat general and oblique. A clearer message

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170 See Roht-Arriaza, supra note 164, at 489.
172 See Roht-Arriaza, supra note 164, at 490.
173 See id. at 518-20.
174 See id. at 488.
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." The objective is to treat safety and product liability as a "special category of critical quality characteristics." 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. In general, these standards address environmental management systems, labeling, auditing, life cycle assessment, performance evaluation, and product standards. In ISO 14000, there is a very definite trend towards risk avoidance, pollution prevention, responsible management, and information availability. In particular, ISO 14041 through 14044 advance the message that a corporation should exercise environmental control of a product's life. 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. 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.

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. 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

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179 Id. at 91.
180 Id. at 92.
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. On that subject, U.S. industry has pushed through a measure in ISO 14000 for the confidentiality of this information. 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. 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. The general municipal acceptance of pre-market disclosures and patentable subject matter limitations also can influence a GATT dispute settlement panel. 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. 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

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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. Similarly, municipal environmental law can influence international industrial standards; ISO 14000 has embraced the theme of the U.S. Pollution Prevention Act. 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. 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.

2. International Environmental Law

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

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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.
198 See PLATER ET AL., supra note 27, at 1009-12.
200 See HÖHMANN, supra note 165, at 340-41.
the maxim *sic utere tuo ut alienum non laedas*. These include a duty to prevent a known harm or risk (a duty that has evolved to include potential harms or risks), a duty to prevent crises, and a duty to notify other nations of environmental risks. At the same time, there is an increasing trend towards a holistic environmental management in which nations and industry cooperate to avoid risks, making "environmental protection ... an integral part of the development process." 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. The *Trail Smelter Case* concerned transboundary pollution from a Canadian lead smelting operation that injured the U.S. environment. By the very nature of the dispute, international law

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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.


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.
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." 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." 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."

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. 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." Yet to effect this goal, the Stockholm Convention required only a "free flow of up-to-date scientific

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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."\textsuperscript{229} This statement requires action even with imperfect knowledge. Typically, obligations under the precautionary principle are "unconditional [and] triggered by mere \textit{prima facie} cases of risks and, thus, independent[] of costs/economic criteria and of proofs of thresholds, causality and full scientific certainty."\textsuperscript{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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{233} The product was the London Guidelines for the Exchange of Information on Chemicals in International Trade, as amended in 1989.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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


\textsuperscript{230} HOHMANN, \textit{supra} note 165, at 341.

\textsuperscript{231} See \textit{id.} at 180.


\textsuperscript{233} See \textit{id.}


\textsuperscript{235} See BARAM \& PARTAN, \textit{supra} note 232, at 192.

\textsuperscript{236} See \textit{London Guidelines}, \textit{supra} note 234.
at large.″

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. 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. 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.” The modern concept sees the legal requirement of utility to be composed of both a positive and negative utility. For an invention to be patentable, its positive utility must outweigh its negative utility. In practice in most countries, the consideration of negative utility is manifested as an exception to patentable subject matter. Many nations retain this ability to exclude patents that are

237 MATTES, supra note 48, at 14.
239 Id.
240 1 LADAS, supra note 52, § 4 (quoting the Statute of Monopolies, 21 Jam. I, ch. III (1623)).
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; indeed, Article 27 of TRIPS accommodates this consideration of negative utility. Nonetheless, 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. 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." Notably, the U.S. patent statute does not speak to the issue, requiring only that an invention be "useful." 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. 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." Belgium rejects inventions with a subject matter "the exploitation of which would be contrary to public order or morals." 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)).
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." The grounds of rejection seem to range from hygiene and beneficial custom to public interest. The European Patent Convention also excepts inventions that threaten morality or ordre public.

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." 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." 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. 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

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253 Id. at A-33.
254 See id. at T-2, U-6 (Taiwan and Ukraine, respectively).
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. 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. 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.

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. The government then bears the burden to test the material for risk to health or the environment. The method of control is by permit, and production is forbidden until testing is completed. 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. Interestingly, industry bears a precautionary presumption of risk, which means that there is no production until government completes the testing.

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


260 See id.


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.


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 . . . .”

The example at hand envisions two responses by the applicant. 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.” 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.

The defending nation could resort to two general arguments in the alternative. 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

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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.
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. 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. 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. 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.” 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:

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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.

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.  

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.

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286 Matte, supra note 48, at 12.