SWINE FLU, BIRD FLU, SARS, OH MY! APPLYING THE PRECAUTIONARY PRINCIPLE TO COMPULSORY LICENSING OF PHARMACEUTICALS UNDER ARTICLE 31 OF TRIPS

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INTRODUCTION

The year is 2015. The avian flu, SARS, and H1N1 virus scares seem like distant memories,[1] but what is lurking around the corner could be far worse—a superbug, the likes of which have never before been seen.[2] The outbreak begins slow and steady but quickly gains momentum causing widespread panic throughout the world. This novel pathogen brings with it a great deal of uncertainty regarding its potency and pathogenicity, resulting in differing opinions within the scientific community and misinformation being spread by the media.

A Swiss pharmaceutical company holds the patent to the only drug proven effective in treating this disease and in slowing its spread, but the company is commanding an extremely high price for its product, making it cost-prohibitive for most countries to access the vital drug in the amounts needed. With the clock ticking, the U.S. Congress takes a proactive approach. Rather than wasting precious time trying to negotiate a cost-effective license to use the Swiss company's patent, Congress authorizes a compulsory license for the patent so that the United States can begin to manufacture or import a generic version of the drug as quickly as possible.[3] Congress hopes to stockpile enough of the drug so that it can react swiftly

1. For more information on the avian flu, SARS, and the H1N1 virus, see World Health Org., *Global Alert and Response (GAR)*, DISEASES COVERED BY GAR, http://www.who.int/csr/disease/en (last visited Jan. 14, 2011).

2. *See* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 323 (2005) ("New public health challenges requiring low-cost access to newer medicines are almost certain to arise. The SARS outbreak gave notice that the TRIPS Agreement should provide the flexibility for responding to such challenges without the need for multiyear negotiations at the WTO.").

3. For a discussion on possible importation options of the United States when issuing a compulsory license, see *infra* notes 81-84 and accompanying text.

and comprehensively if needed to prevent the spread of the potentially deadly disease and to minimize its potential death toll. The Swiss government files a complaint with the World Trade Organization (WTO) claiming the United States is infringing its national's patent under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement) because this precautionary use does not fall within the acceptable reasons for issuing a compulsory license without prior negotiation under Article 31(b) of the TRIPS Agreement.[4] Would the Swiss government prevail?[5]

With the ever-present threat of a new superbug pandemic, the accessibility of pharmaceuticals—and not just in developing countries—is a growing concern.[6] Article 31 of the TRIPS Agreement allows countries to legally circumvent the patents of nationals from other treaty-members' countries via a compulsory license, provided certain procedural requirements are met, such as prior good faith negotiation and adequate remuneration.[7] In cases of a national emergency or other circumstance of extreme urgency, or in cases of public non-commercial use, the prior negotiation provision is waived, but the requirement for adequate remuneration remains.[8] Although each member has a right to determine the grounds on which to grant a compulsory license and to determine which health risks constitute "a national emergency or other circumstances of extreme urgency,"[9] the TRIPS Agreement gives very little guidance for nations wishing to enact TRIPS-consistent legislation, stating only that "authorization . . . shall be considered on its individual merits."[10] This ambiguity leaves countries vulnera-

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4. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 333 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

5. This hypothetical was almost a reality when the U.S. Congress threatened Roche Pharmaceuticals with a compulsory license during the avian flu scare in 2003 to ensure that adequate stockpiles of the drug Tamiflu were available if needed. *See* James Packard Love, *Recent Examples of the Use of Compulsory Licenses on Patents*, KNOWLEDGE ECOLOGY INT'L (Mar. 31, 2007), *available at* http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf. A settlement was eventually agreed upon without the need for a compulsory license. *Id.* In November 2005, Taiwan became the first country to issue a compulsory license for Tamiflu. *See* Int'l Cent. for Trade and Sustainable Dev., *Taiwan Issues Compulsory License for Tamiflu*, BRIDGES WKLY. TRADE NEWS DIG., Nov. 30, 2005, at 11, *available at* http://ictsd.net/downloads/bridgesweekly/bridgesweekly9-41.pdf.

6. *See* Marília Bernardes Marques, *Pandemic Diseases: Pharmaceutical Drugs and Vaccines Accessibility in Brazil*, 6 J. INT'L BIOTECHNOLOGY L. 210, 210 (2009) (examining the challenges developing countries face in accessing life-saving pharmaceuticals).

7. TRIPS Agreement art. 31.

8. TRIPS Agreement art. 31(b), (h).

9. *See* World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov. 14, 2001) [hereinafter Doha Declaration].

10. TRIPS Agreement art. 31(a).

ble to the constant threat of trade sanctions if the compulsory license is found to be unjustified.[11] In an age of pandemics, superbugs, and bioterrorism, it is more important than ever for nations to be sufficiently prepared with the best pharmaceutical defenses possible, as well as to have adequate guidance with which to make these crucial policy decisions.[12] Accordingly, the "better-safe-than-sorry" precautionary principle is available and is supported by Article 31 of the TRIPS Agreement as adequate justification for issuing compulsory pharmaceutical licenses without prior negotiation during the threat of a pandemic or similar urgent potentially life-threatening health crisis.[13]

Part I of this Note gives a general background of patent protection and compulsory licensing, both in the United States and internationally under the TRIPS Agreement. Part II examines the evolution of the precautionary principle in detail, while also exploring various definitions of the principle as well as demonstrating its increasing pervasiveness at the WTO. Part III analyzes whether there is room for the precautionary principle in TRIPS Article 3l by first inquiring as to whether the principle is binding on WTO members when the WTO's Dispute Settlement Body (DSB) interprets the TRIPS Agreement during a dispute, and next by determining whether TRIPS can be interpreted to support the use of precaution even without the precautionary principle as a binding principle. Part IV proposes a four-

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11. *See* TRIPS Agreement art. 64.1 (mandating that the binding dispute resolution mechanism "of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein"). In 1997, as a response to the growing HIV/AIDS epidemic, South Africa passed the Medicines and Related Substances Control Act Amendment permitting broad use of compulsory licensing. *See* Anthony P. Valach, Jr., Comment, *TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries*, 4 CHI.-KENT J. INTELL. PROP. 156, 173-74 (2005). Forty pharmaceutical companies and the South African Pharmaceutical Manufacturers Association sued the South African government alleging that the amendment violated TRIPS. *Id.* at 174. The United States also threatened to impose trade sanctions against South Africa if the amendment was implemented. *Id.*

12. For example, in October 2009, the president of Ecuador issued a decree allowing its Ministry of Public Health to issue compulsory licenses based on public interests such as access and costs. *See* Rafael Correa Delgado, Decreto Ejecutivo No. 118 del 23 de octubre de 2009 (Ecuador), *available at* http://www.eluniverso.com/data/recusos/documentos/PDFDECRETOMEDICAMENTOS.pdf.

13. E. Richard Gold & Danial K. Lam, *Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing*, 6 J. WORLD INTELL. PROP. 5, 12 (2006) (illustrating the ongoing debate regarding the meaning of "public non-commercial use"). This Note focuses on the language of TRIPS Article 31(b) authorizing a waiver for prior negotiation of a compulsory license in the event of a "national emergency or other circumstances of extreme urgency." *Id.* at 13. The "public non-commercial use" waiver, as it relates to public health crises, is the subject of much debate and is outside the scope of this Note. *Id.*

factor test to use as guidance when issuing precautionary pharmaceutical compulsory licenses under TRIPS Article 31.

I. PROMOTING SCIENCE AND THE USEFUL ARTS

Modern U.S. patent law, now codified in Title 35 of the United States Code, predates the Constitution and originated as an exception to the English Statute of Monopolies of 1624.[14] Empowered by the Constitution "[t]o promote the Progress of Science and useful Arts,"[15] the first Congress adopted the Patent Act of 1790, granting an applicant the "sole and exclusive right and liberty of making, constructing, using and vending to others to be used" for a term of fourteen years.[16] Patent protection gained momentum during the Industrial Revolution, where courts began to recognize the granting of patent rights as a quid pro quo tradeoff between the inventor and the public.[17] This bargain gives the inventor exclusive rights to the invention for a fixed period of time, and the public gains the benefit of the new art as well as the technological know-how to make and use the invention upon expiration of the patent term.[18] In the 1920s and 1930s, antitrust law began to focus on the exclusionary power of patents and the anticompetitive dangers associated with this market power.[19] As a result, an anti-patent movement arose unsuccessfully calling for compulsory licensing of patents for anyone who wanted to use them.[20] The rationale for compulsory licensing, just as it is today, centered on the growth of big businesses at the expense of the public interest.[21] Conversely, compulsory licensing runs the risk of disincentivising pharmaceutical companies from investing the enormous capital required to bring a new drug to market.[22]

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14. ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 7 (4th ed. 2007).

15. U.S. CONST. art. I, § 8.

16. Patent Act of 1790, ch. 7, 1 Stat. 109-112 (1790). The patent term was subsequently amended in 1995 to a term twenty years from the date of filing, in part, to comply with the United States' obligations under the TRIPS Agreement. *See* 35 U.S.C. § 154(c)(1) (2010) ("The term of a patent that is in force on or that results from an application filed before the date that is 6 months after the date of the enactment of the Uruguay Round Agreements Act shall be the greater of the 20-year term as provided in subsection (a) . . . ."); *see* Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q. J. 369, 372 (1994) (tracing the evolution of the American patent term).

17. MERGES & DUFFY, *supra* note 14, at 6.

18. *Id.*

19. *Id.* at 10.

20. *Id.*

21. *Id.*

22. *See* Joseph A. Yosick, *Compulsory Patent Licensing for Efficient Use of Inventions*, 2001 U. ILL. L. REV. 1275 (illustrating the competing interests of patent protection).

A. Compulsory Licensing

Compulsory licenses are administrative contracts granted by governments, whereby consent to use the patent is granted by the government rather than by the patent owner herself.[23] These rights can be granted to governments or to third-party government contractors.[24] The United States has addressed compulsory licensing though a variety of common law[25] and statutory[26] mechanisms. One of the most notable decisions dealing with compulsory licensing in the United States is *eBay Inc. v. MercExchange, L.L.C.*, where the Supreme Court held that the traditional remedy of injunctive relief is not the automatic remedy for patent infringement claims.[27] Instead, courts must apply an equitable four-factor test to determine if injunctive relief is appropriate.[28] When the public interest overrides the rights of patent-holders as determined by application of the four-factor test, the appropriate remedy is damages rather than an injunction, thus creating a form of de facto common law compulsory licensing.[29]

Statutorily, Section 1498(a) of the United States Code permits a patentee to recover "reasonable and entire compensation" for the unauthorized use of a patent or manufacture of a patented product where such use or manufacture is by the United States government or its third party contractor.[30] Interestingly, the government does not have to negotiate a license for

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23. NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 315 (2d ed. 2005).

24. Compulsory licenses are called *ex officio* when initiated by the government. *See id.* at 323.

25. *See* Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d 941, 944-45 (9th Cir. 1945) (finding that public interest warranted refusal of injunction on irradiation of oleomargarine); *see also* Love, *supra* note 5, at 3-5 (illustrating that compulsory licenses are also addressed through merger reviews and non-merger remedies for anticompetitive practices).

26. *See* 28 U.S.C. § 1498 (2010); Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015, 3019-27 (1980) (codified at 35 U.S.C. §§ 200-211 (2010)); Clean Air Act, 42 U.S.C. § 7608 (2010). Compulsory licensing is also addressed in bilateral agreements such as North American Free Trade Agreement, where the relevant provision closely tracks the language of TRIPS Article 31. *Compare* North American Free Trade Agreement, art. 1709(10), U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 605 (1993) [hereinafter NAFTA], *with* TRIPS Agreement art. 31 (illustrating the similar language used in both agreements).

27. 547 U.S. 388 (2006).

28. *Id.* at 391. The four factors that

> [a] plaintiff must demonstrate are: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id.

29. *See generally id.*

30. 28 U.S.C. § 1498(a) (2010).

use of the patent and the patentee has no right to an injunction of such use.[31] The patent owner's sole remedy for the unauthorized use is reasonable compensation.[32] This statute was invoked in 2001, when Human Health and Services Secretary Tommy Thompson threatened to authorize the production and stockpiling of ciprofloxacin, the generic form of Cipro™ owned by German company Bayer AG, during the perceived threat of an anthrax attack following the terrorist attacks on September 11, 2001.[33] An agreement was eventually reached with Bayer AG, precluding the invocation of a compulsory license in this instance.[34]

B. International Patent Protection

Internationally, patent protection originated with the Paris Convention for the Protection of Industrial Property (Paris Convention), enacted in 1883 and administered by the World Intellectual Property Organization (WIPO).[35] The Paris Convention was the first international intellectual property treaty and provides protection for "industrial property"[36] through national treatment, priority rights, and common rules.[37] Compulsory licensing is addressed in Article 5(A)(2), which allows countries "to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[38] Although the Paris Convention's compulsory licensing provision is still operative today, there is extensive overlap with the more recent TRIPS Agreement.[39] Given that most of the 173 contracting parties to the Paris Convention are also parties to TRIPS,[40] it is more desirable to bring patent disputes before the WTO's

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31. *Id.*

32. *Id.* An important limitation on this provision is § 1498(c) which precludes recovery for claims arising in a foreign country.

33. Gold & Lam, *supra* note 13, at 6-7.

34. *Id.* at 7.

35. *See* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

36. *See id.* art. 1. The term "industrial property" is interpreted broadly to include patents, marks, industrial designs, utility models, trade names, and geographical indications, and unfair competition. *Id.*

37. *See Summary of the Paris Convention for the Protection of Industrial Property of 1883*, WORLD INTELL. PROP. ORG., http://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Jan. 14, 2011).

38. Paris Convention, *supra* note 35, at art. 5(A)(2).

39. *See* TRIPS Agreement arts. 1-3 (incorporating by reference specific provisions of the Paris Convention and requiring national treatment for parties of the Paris Convention).

40. *Compare* World Intellectual Prop. Org., *Paris Convention Contracting Parties*, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Jan. 14, 2011), *with* World Trade Org., *Members and Observers*, http://www.wto.org

binding dispute settlement mechanism[41] rather than through WIPO, which has no comparable mechanism.[42]

1. *The TRIPS Agreement*

The TRIPS Agreement claims to be "the most comprehensive multilateral agreement on intellectual property,"[43] and was negotiated in 1994 at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT)[44] as Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization.[45] Through the TRIPS Agreement, the WTO seeks to harmonize international intellectual property rights through the use of trade mechanisms.[46] Developed countries such as the United States, Japan, and members of the European Union lobbied for the implementation of TRIPS to prevent the exploitation of their intellectual property rights in developing countries by linking strict protection of intellectual property rights to market access through the WTO.[47] As part of the WTO's "single-undertaking," membership in the WTO is contingent upon ratification of all multilateral agreements administered by the WTO, including the TRIPS

/english/theWTO_e/whatis_e/tif_e/org6_e.htm (last visited Jan. 14, 2011) (illustrating the extent of parallel membership).

41. *See infra* text accompanying notes 60-64 (outlining the WTO's dispute settlement mechanism).

42. *Compare* Paris Convention, supra note 35, art. 28, *with* TRIPS Agreement art. 64 (illustrating the differences between the respective treaties' dispute settlement provisions).

43. World Trade Org., *Overview: The TRIPS Agreement*, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Jan. 14, 2011). The scope of the agreement includes

> copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); trademarks including service marks; geographical indications including appellations of origin; industrial designs; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data.

Id.

44. General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT].

45. *See* Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

46. *See* TRIPS Agreement pmbl.

47. *See* 4 THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1994), 1478-79 (Terence P. Stewart ed., 1999).

Agreement.[48] As such, the WTO requires all members to provide minimum standards of protection for intellectual property rights in order to receive trade-related benefits under multilateral agreements such as GATT.[49]

a. The Structure of the TRIPS Agreement

The TRIPS Agreement is comprised of seven main parts, which include general provisions, standards, enforcement, *inter partes* procedures, dispute settlement, transnational arrangements, and institutional arrangements.[50] Part I of the Agreement outlines the scope, objectives, and principles of the agreement and incorporates by reference the substantive obligations of intellectual property agreements that preceded TRIPS.[51] Part I also requires that minimum standards of protection are provided by its members,[52] while Part III requires that members have a minimum level of national enforcement legislation in place to adequately protect the intellectual property rights of all members and to deter infringement in such a manner as to avoid creating barriers to trade.[53] The substantive provisions relating to intellectual property subject matter are found in Part II and mandate protection for a broad array of intellectual property rights including copyrights, trademarks, geographical indications, industrial designs, patents, integrated circuits, and trade secrets.[54]

Patent protection is addressed specifically in Articles 27-34.[55] Patentable subject matter is defined as "products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application," which is analogous to the novelty, nonobviousness, and usefulness requirements in American patent law.[56] With respect to patent protection, the TRIPS Agreement requires that members prevent unauthorized parties from making, using, offering for sale, selling,

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48. WTO Agreement art. II(2) ("The agreements and associated legal instruments included in Annexes 1, 2 and 3 (hereinafter referred to as 'Multilateral Trade Agreements') are integral parts of this Agreement, binding on all Members.").

49. *See id.* art II. Trade-related benefits include National Treatment as well as Most Favored Nation treatment. *Id.*

50. *See generally* TRIPS Agreement.

51. TRIPS Agreement arts. 1-8.

52. *See* TRIPS Agreement art. 1. TRIPS requires only a *minimum* level of protection, allowing Members the freedom to choose higher levels of protection, provided the measures do not constitute unreasonable barriers to trade. *Id.*

53. *Id.* at art. 41.

54. *Id.* at arts. 9-40.

55. *Id.* at arts. 27-34.

56. *Compare* TRIPS Agreement art. 27 *with* 35 U.S.C. § 103 (2010) (illustrating the similarities between the provisions).

or importing an invention without consent from the rights holder[57] for a period of twenty years,[58] although members are free to exclude from patentability certain inventions that are necessary to protect public order or morality, or those that are necessary to protect human, animal or plant life or health.[59]

Perhaps the most powerful aspect of TRIPS is Part V, which requires disputes over the Agreement's obligations to be subject to the WTO's binding dispute settlement procedures.[60] The multilateral agreements administered by the WTO, including the TRIPS Agreement, are interpreted by the WTO's Dispute Settlement Body (DSB) using the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU) in accordance with customary rules of interpretation of public international law.[61] This procedure involves the submission of complaints by the disputing parties to a panel of three experts chosen by the DSB (the Panel), and any appeals are handled by the Appellate Body.[62] The DSB reports containing the Panel and Appellate Body decisions are binding on the parties to the dispute, and although they are not binding precedent on subsequent dispute settlements, they are nevertheless persuasive in future cases.[63] The DSU provision of the TRIPS Agreement is significant because it gives the agreement the required teeth to enforce its provisions, which the multilateral intellectual property agreements administered by WIPO lack.[64]

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57. TRIPS Agreement art. 28. This is analogous to U.S. patent law. *See* 35 U.S.C. § 103 (2010).

58. TRIPS Agreement art. 33. This is analogous to U.S. patent law. *See supra* note 16.

59. TRIPS Agreement art. 27. Some have argued that the precautionary principle should be used to prevent the patentability of certain potentially harmful inventions. *See* Shawn Kolitch, Comment, *The Environmental and Public Health Impacts of US Patent Law: Making the Case for Incorporating a Precautionary Principle*, 36 ENVTL. L. 221. (2006).

60. TRIPS Agreement arts. 41-61.

61. Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 354 (1999), 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994) [hereinafter DSU].

62. *Id.*

63. *See* Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, ¶ 9, WT/DS8/AB/R (Oct. 4, 1996) (holding that reports "are not binding, except with respect to resolving the particular dispute between the parties to that dispute."); *see also* Appellate Body Report, *United States—Tax Treatment For Foreign Sales Corporations*, ¶ 115, WT/DS108/AB/RW (Feb. 24, 2000) [hereinafter *US-Carbon Steel*] (recognizing that prior panel reports could provide guidance to the WTO during dispute settlement).

64. *See supra* note 42 and accompanying text.

b. Exceptions to Patent Protection Under the TRIPS Agreement

Despite the strict minimum level of protection and strong enforcement mechanism afforded by the TRIPS Agreement, the agreement does allow, in certain instances, for unauthorized parties to make use of a patent without the consent of the rights-holder.[65] Article 30, also known as the "limited exception" provision, allows "[m]embers [to] provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[66] Negotiations relating to third-party compulsory licensing for exportation to countries with inadequate manufacturing capabilities have shown that unauthorized use of a patent to address an epidemic would be unlikely to fall under the limited exception provision of Article 30 because such use would be too broad to be considered "limited."[67]

In contrast to Article 30, which provides for substantive limited exceptions to authorized use, Article 31 deals procedurally with non-authorized uses that do not fall within the limited exceptions outlined in Article 30.[68] Article 31, also known as the "compulsory licensing" provision, permits the use of a patent by unauthorized parties, provided certain procedural stipulations are met.[69] Such use is only permitted if the user has unsuccessfully attempted to negotiate a voluntary license on reasonable commercial terms and conditions prior to the use within a reasonable timeframe.[70] In the event of "a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use," the negotiation requirement is waived, although the user must still notify the patent-holder of the unauthorized use.[71] Regardless of whether prior negotiation is waived under Article 31(b), unauthorized use of a patent must also comply with the remainder of Article 31, requiring that the patent-holder be paid adequate remuneration;

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65. *See* TRIPS Agreement arts. 30-31.

66. *Id.* at 30.

67. DE CARVALHO, *supra* note 23, at 313-14; *see also* Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada-Pharmaceuticals*].

68. *Compare* TRIPS Agreement art. 30 *with* TRIPS Agreement art. 31 (illustrating the substantive vs. procedural nature of the provisions).

69. While the term "compulsory licensing" is not expressly used in the patent provisions of the TRIPS Agreement, the term is used in the trademark provision. *See* TRIPS Agreement art. 21. Compulsory licensing is also addressed under Article 44.2, which allows for the sole remedy of infringement to be adequate remuneration, akin to 28 U.S.C. §1498(a). TRIPS Agreement art. 44.2. For a discussion on the reasons for omitting the term "compulsory license" from TRIPS Article 31, see DE CARVALHO, *supra* note 23, at 315 n.837.

70. TRIPS Agreement art. 31(b).

71. *Id.*

that such use be non-exclusive, non-assignable, and limited to domestic use;[72] that the patent is used only for the purpose for which it was authorized; and that the use is extinguishable when circumstances necessitating the use have been extinguished.[73]

2. *The Declaration on the TRIPS Agreement and Public Health*

Article 31 of the TRIPS Agreement is a powerful but vague tool lacking substantive guidance. Article 31(b) requires members to engage in good faith negotiation to obtain a voluntary license except in cases of "a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,"[74] but the provision gives no further guidance as to which specific circumstances give rise to these exceptions. The Declaration on the TRIPS Agreement and Public Health (Doha Declaration), issued in 2001 as a mandate of the WTO's Fourth Ministerial Conference, clarifies this ambiguity by defining the relationship between intellectual property rights and public health.[75] The Doha Declaration made clear the pro-health interpretation of TRIPS by stating that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and that TRIPS "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[76] With respect to Article 31, the Doha Declaration clarified that nations have the freedom to determine appropriate grounds for granting compulsory licenses, as well as the right to determine what constitutes a national emergency or other circumstances of extreme urgency, which can include public health crises such as HIV/AIDS, tuberculosis, malaria, and other epidemics.[77]

Further evidence of this pro-health objective is Paragraph 6, which takes into consideration the problem faced by many developing countries that lack the infrastructure to manufacture generic pharmaceuticals under a compulsory license as permitted by TRIPS Article 31(f).[78] Prior to the is-

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72. *See infra* notes 76-81 and accompanying text (discussing the recent developments that have waived the domestic use requirement in certain circumstances).

73. TRIPS Agreement art. 31.

74. TRIPS Agreement art. 31(b).

75. *See* Doha Declaration.

76. *Id.* ¶ 4.

77. *Id.* ¶ 5.

78. *Id.* ¶ 6.

> We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

Id.

suance of the Doha Declaration, TRIPS Article 31(f) authorized compulsory licensing only for domestic use.[79] Paragraph 6 broadens access to vital pharmaceuticals by allowing third-party countries to produce and supply drugs to developing countries that are unable to produce their own domestic supply.[80] The WTO Council officially adopted and implemented this waiver provision in August 2003,[81] and an amendment to the TRIPS Agreement making permanent the Paragraph 6 waiver was subsequently negotiated in 2005 and is currently awaiting ratification.[82] In addition to broadening access to vital pharmaceuticals, the implementation of the Paragraph 6 waiver also recognizes the need for rapid response when dealing with public health emergencies.[83] Although all nations are permitted to invoke the Paragraph 6 waiver, twenty-three developed nations have declared they will not do so, while eleven nations have declared only to use the waiver to import drugs in the event of a national emergency.[84]

Despite the admirable intentions inherent in the Doha Declaration, the procedures required to invoke the Paragraph 6 waiver are said to be in-

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79. TRIPS Agreement art. 31(f).

80. Doha Declaration ¶ 6.

81. *See* World Trade Org. General Council Decision, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003).

82. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Proposal for a Decision on an Amendment to the TRIPS Agreement*, IP/C/41 (Dec. 6, 2005) [hereinafter *Implementation of Paragraph 11*]. Currently, twenty-seven Members, plus the EC, have ratified the amendment (Article 31*bis*). World Trade Org., *Members Accepting Amendment of the TRIPS Agreement* (last updated Dec. 8, 2010), http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm. The deadline for ratification of the amendment by two-thirds of the Members was December 31, 2007, which was extended to December 31, 2009. *See* World Trade Org. General Council Decision, *Amendment of the TRIPS Agreement – Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/711 (Dec. 21, 2007). At the conclusion of the Doha Round negotiations in October 2009, another extension was granted until December 31, 2011. *See* World Trade Org, General Council Decision, http://www.eluniverso.com /data/recursos/documentos/pdfdecretomedicamentos.pdf, WT/L/785 (Dec. 18, 2009).

83. *See Implementation of Paragraph 11*, *supra* note 82, at ¶ 4 ("*Recognizing*, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement.").

84. *See Implementation of Paragraph 11*, *supra* note 82. Although the United States is one of the twenty-three countries that have pledged not to take advantage of the Paragraph 6 waiver allowing the importation of drugs for which it issues a compulsory license, this restriction does not apply to the importation of drugs from countries that do not provide patent protection for the drug at issue. Therefore, the United States could still conceivably import drugs for which it issues a compulsory license, if needed.

volved and onerous, resulting in only a single use of the provision to date.[85] This procedural barrier could prove problematic during a pandemic, where time is of the essence. However, it has been suggested that a country who issues a compulsory license for domestic use under Article 31(f) may export a portion of its manufactured output as long as the license is *predominantly* for the supply of the domestic market.[86] This possibility leaves the door open for countries with large manufacturing capacities such as China and India to become temporary exporters of generic drugs to countries who issue a compulsory license in extremely urgent situations, especially where the initial ramp-up time for domestic manufacturing and the notification requirements of Paragraph 6 would take some time.[87]

By reaffirming the right of WTO members to use the flexibilities within the TRIPS Agreement to their fullest extent, the Doha Declaration makes it apparent that members have the freedom to take steps necessary to combat urgent health crises and that the Agreement should be interpreted in light of public health concerns. Nevertheless, the question still exists as to whether TRIPS can support the use of precaution when interpreting what constitutes "a national emergency or other circumstances of extreme urgency" under Article 31(b).

II. THE PRECAUTIONARY PRINCIPLE

The precautionary principle is an ancient[88] "better-safe-than-sorry" approach to risk management that advocates taking immediate measures to avoid imminent harm; a principle that lends itself well to an urgent pandemic scenario.[89] Although the principle was first articulated during the days of Aristotle, its modern articulation is rooted in environmental law and has

85. *See* Christina Cotter, Note, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT'L L. REV. 177 (2008) (explaining the the use of the Paragraph 6 waiver is prohibitively difficult and complex as evidenced by the experience of Rwanda's use of the Paragraph 6 waiver to import drugs from Canada); *see also* Markus Nolff, *Paragraph 6 of the* Declaration on the TRIPS Agreement and Public Health *and the Decision of the WTO Regarding Its Implementation: An "Expeditious Solution"?*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 291 (2004).

86. *See* Abbott, *supra* note 2, at 319.

87. *See id.*

88. Roberto Andorno, *The Precautionary Principle: A New Legal Standard for a Technological Age*, 1 J. INT'L BIOTECHNOLOGY LAW 11, 11-12 (2004) (tracing the origin of the principle to Aristotle).

89. Matthew Daly, *Medical Necessity as a Defense for Crimes Against Humanity: An Examination of the Molokai Transfers*, 24 ARIZ. J. INT'L & COMP. L. 645, 687 (2007) ("While the Precautionary Principle has been applied mainly to environmental and trade cases that lack the urgency of the lethal pandemic scenario, its focus on the 'seriousness and irreversible damage' makes it an appropriate standard for considering the level of response to a lethal pandemic.").

since penetrated the laws of Europe and abroad, not just with respect to environmental issues, but increasingly as applied to public health.[90] The precautionary principle has been incorporated in more than fifty international treaties,[91] and although there is no single agreed upon definition, most encompass the same idea—that scientific uncertainty should not prevent precautionary measures from being taken to prevent harm to the environment and public health.[92]

A. The Evolution of the Modern Precautionary Principle

The modern incarnation of the precautionary principle originated in Germany in 1971 as a duty of care incorporated into environmental protection laws enacted at that time.[93] The principle was nurtured in its infancy in Europe where it is considered a pillar of European Union law and is often noted as a "European export."[94] The principle was officially recognized in 1992 in the Treaty on European Union[95] and again in 2000 when the European Communities published its *Communication of the Precautionary Principle*.[96] The first international treaty to explicitly incorporate the precautionary principle was the Ministerial Declaration of the Second International Conference on the Protection of the North Sea in November 1987.[97] Nu-

90. Andorno, *supra* note 88, at 11 (discussing the relationship between Aristotle's concept of prudence as it relates to the modern Precautionary Principle).

91. JACQUELINE PEEL, THE PRECAUTIONARY PRINCIPLE IN PRACTICE: ENVIRONMENTAL DECISION-MAKING AND SCIENTIFIC UNCERTAINTY, app. B, at 1-24 (2005) (illustrating the numerous treaties incorporating the Precautionary Principle).

92. *See infra* Section II.B.

93. Lawrence A. Kogan, *The Precautionary Principle and WTO Law: Divergent Views Toward the Role of Science in Assessing and Managing Risk*, 1 SETON HALL J. DIPL & INT'L REL. 77, 91 (2004). The principle was known as "vorsorgeprinzip," meaning "forecaring principle" or "care." *Id.*

94. *See* Lawrence A. Kogan, *The Extra-WTO Precautionary Principle*: *One European "Fashion" Export the United States Can Do Without*, 17 TEMP. POL. & CIV. RTS. L. REV. 491 (2007) (arguing that the EU has become the global regulator).

95. Treaty on European Union art. 130r2, Feb. 7, 1992, 1992 O.J. (C 191), 31 I.L.M. 253.

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies.

Id.

96. Communication from the Commission on the Precautionary Principle, Commission of the European Communities, art. 1, Feb. 2, 2000, COM (2000).

97. Ministerial Declaration of the Second International Conference on the Protection of the North Sea, London, ¶ 7, Nov. 25, 1987 ("[I]n order to protect the North Sea from

merous subsequent international treaties have reaffirmed the use of the precautionary principle for environmental protection.[98]

The principle perhaps gained the most notoriety from its incorporation into the Rio Declaration at the 1992 United Nations Conference on Environment and Development (Rio Declaration).[99] Paragraph 15 of the Rio Declaration states, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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."[100] The principle gained further momentum, and yet another definition, in January 1998 when the Wingspread Conference on the Precautionary Principle was convened by the Science and Environmental Health Network "to define and discuss implementing the precautionary principle, which has been used as the basis for a growing number of international agreements."[101] The conference, attended by treaty negotiators, activists, scholars and scientists from the United States, Canada, and Europe,[102] concluded that "[w]hen an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[103]

The definition set forth in the Rio Declaration is one of the most widely relied upon definitions, and was subsequently incorporated into the Cartagena Protocol on Biosafety, signed in January 2000 as a supplementary agreement to the Convention on Biological Diversity.[104] The Cartagena Protocol specifically addresses the issue of genetically modified organisms stating that

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possibly damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence.").

98. *See* PEEL, *supra* note 91.

99. United Nations Conference on Environment and Development: Rio Declaration on Environment and Development, Principle 15, June 14, 1992, U.N. Doc. A/CONF.151/5/Rev.1, 31 I.L.M. 874.

100. *Id.*

101. *Wingspread Conference on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK, http://www.sehn.org/wing.html (last visited Jan. 14, 2011).

102. *Id.*

103. *The Wingspread Consensus Statement on the Precautionary Principle*, SCI. & ENVTL. HEALTH NETWORK, http://www.sehn.org/wing.html (last visited Jan. 14, 2011).

104. *See* Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pmbl., Jan. 29, 2000, 39 I.L.M. 1027. The Rio Declaration is also recognized in Article 1 of the Cartagena Protocol on Biosafety, which outlines that the objective of the Protocol is "[i]n accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development." *Id.* at art. 1.

> [l]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism . . . on biological diversity . . . taking into account risks to human health, shall not prevent [a] Party [of import] from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . , in order to avoid or minimize such potential adverse effects.[105]

B. A Rose by Any Other Name

As illustrated above, the myriad applications and interpretations of the precautionary principle in international law, treaties, and judicial decisions have expectedly given rise to an abundance of varying definitions of the principle. When discussing workable definitions of the precautionary principle, "[i]t is important to note . . . that different formulations of the precautionary principle exhibit different degrees of conservatism."[106] Much debate centers on the notions of a "weak" version that *permits* action to be taken to mitigate harm in the absence of scientific certainty, versus a "strong" approach that *requires* such action be taken.[107] This uncertainty has led commentators to attempt to find commonality among the various permutations of the principle.[108] In fact, some have argued that even confining the notion of precaution strictly to the term "precautionary principle" unduly narrows its scope, excluding equivalents or near-equivalents with equal relevance and importance but with differing labels.[109] Regardless of the ongoing debates and uncertainly, one can glean that most definitions share the same central idea that "scientific uncertainty should not be used to postpone measures to prevent, mitigate, or reduce the adverse environmental impacts of the activity."[110]

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105. *See id.* at art. 10.6. Notably, the United States is not a signatory to this Protocol.

106. Jonathan Hughes, *How Not to Criticize the Precautionary Principle*, 31 J. MED. & PHIL. 447, 449 (2006).

107. *Id.* at 451; *see also* BIODIVERSITY & THE PRECAUTIONARY PRINCIPLE: RISK AND UNCERTAINTY IN CONSERVATION AND SUSTAINABLE USE 6-8 (Rosie Cooney & Barney Dickson eds., 2005).

108. Hughes, *supra* note 106, at 45; *see also* J. Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323 (2002) (outlining a new approach to harmonize the precautionary principle with the SPS Agreement).

109. *See* Stephen G. Wood et al., *Whither the Precautionary Principle? An American Assessment from an Administrative Law Perspective*, 54 AM. J. COMP. L. 581, 581 (Supp. 2006) (arguing through a comparative law lens that the precautionary principle has informed numerous laws and policy decisions, not necessarily in name, but in principle).

110. Kolitch, *supra* note 59, at 227.

III. IS THERE ROOM FOR PRECAUTION IN A "NATIONAL EMERGENCY OR OTHER CIRCUMSTANCES OF EXTREME URGENCY"?

In a public health context, the precautionary principle requires that "where scientific proof of a practice's adverse health and environmental impact is uncertain, policymakers should err on the safe side by curtailing the practice sufficiently to ensure that its health and environmental risks do not exceed accepted levels."[111] The determination as to whether there is room for the precautionary principle in a "national emergency or other circumstances of extreme urgency" under TRIPS Article 31(b) requires two separate inquiries: first, whether the precautionary principle constitutes customary international law that is therefore binding on the DSB when interpreting the TRIPS Agreement during a dispute, and second, whether TRIPS can be interpreted to support the use of precaution even without the precautionary principle as a binding rule of customary international law.

A. Can the Precautionary Principle Be Applied to TRIPS Article 31(b)?

To determine if the precautionary principle can be applied to the TRIPS Agreement, one must first investigate the status of the principle as a rule of customary international law. This point of contention is critical because the WTO dispute settlement system interprets its agreements "in accordance with customary rules of interpretation of public international law."[112] If the precautionary principle is considered customary international law, it effectively binds the principle to the WTO and to the DSB's interpretation of the TRIPS Agreement, thus precluding members from arguing that the principle does not apply.[113] If the precautionary principle is found to be merely a principle of international law, and therefore not binding, the party asserting its use has the heavy burden of persuading the DSB that the principle is nonetheless implied in the Agreement.[114]

1. *Defining Customary International Law*

The status of the precautionary principle as a rule of customary international law has been a contentious topic of debate for decades and contin-

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111. M. Gregg Bloche, *WTO deference to National Health Policy: Toward and Interpretive Principle*, 5 J. INT'L ECON. L. 825, 833 n.41 (2002).

112. DSU art. 3.2.

113. Andrew D. Mitchell, *The Legal Basis for Using Principles in WTO Disputes*, 10 J. INT'L ECON. L. 795, 800 (2007) ("Notwithstanding academic critiques of the definition of customary international law, it is generally acknowledged as a binding source of law."); *see also* HANS KELSEN, CUSTOMARY INTERNATIONAL LAW 314 (2003).

114. *See infra* Subsection II.A.4 (illustrating various WTO disputes where one of the parties asserted the precautionary principle as a defense to trade-restrictive measure).

ues to be a controversial issue.[115] Customary international law is derived from international custom, taking into account general principles of law, treaties, and customs that are considered by the International Court of Justice, jurists, the United Nations, and the United Nations' member countries.[116] To determine if a rule or practice is customary international law, the proponent must demonstrate: (i) a stable and uniform international practice as reflected by legislation and judicial decisions (state practice); and (ii) that the practice is observed as legally binding (*opinio juris*).[117] While it has been argued that the precautionary principle has undoubtedly "obtained in communitarian law the status of a legal principle of direct application,"[118] there are some who maintain that the principle is merely a discretionary approach.[119]

2. *Not Just a European Principle*

The precautionary principle is now one of the foundations of European law and is steadily gaining popularity throughout the rest of world as a risk

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115. *See* Per Sandin et al., *Five Charges Against the Precautionary Principle*, 5 J. RISK RES. 287 (2002); *see generally* Mitchell, *supra* note 113.

116. Sources of international law are contained in Article 38(1) of the Statute of the International Court of Justice. *See* Statute of the International Court of Justice, 3 Bevans 1179; 59 Stat. 1055, 1060; T.S. 993; 39 AJIL Supp. 215 (1945)

> The court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states; (b) international custom, as evidence of a general practice accepted as law; (c) the general principles of law recognized by civilized nations; (d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

Id.

117. RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 102(2) (1987) ("Customary international law results from a general and consistent practice of states followed by them from a sense of legal obligation.").

118. Andorno, *supra* note 88, at 13 (quoting Philippe Kourilsky & Geneviève Viney, Le Principe de Précaution, Rapport au Premier Ministre, La Documentation Française 132 (2000).

119. *See* Appellate Body Report, *European Communities – EC Measures Concerning Meat and Meat Products (Hormones)*, ¶¶ 43, 60, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC-Hormones*] (illustrating Canada's and the United States' position that the precautionary principle is an approach, rather than customary international law); *see also* Kogan, *supra* note 93, at 104.

> [T]he United States acknowledges that the WTO has narrowly ruled that governments may lawfully employ precautionary measures under certain limited provisional conditions, as set forth within the SPS Agreement. It does not, however, recognize the existence of a formal precautionary principle either as a substantive WTO treaty norm or a customary international legal norm.

Id.

management tool in environmental law and, increasingly, in public health.[120] The principle has even made its way to North America, where numerous examples of the reliance on the precautionary principle can be observed despite both Canada's and the United States' persistent challenges to the European Union's use of the principle at the WTO.[121] Notably, precaution has been incorporated into state and federal legislation in the United States[122] as well as in Canadian legal instruments[123] and jurisprudence,[124] and even in the North American Free Trade Agreement.[125] One can contend that the precautionary principle has also been integrated into GATT and the WTO, where precautionary language can arguably been seen in the preamble to the WTO Agreement and in Article XX of GATT, as well as in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS

120. PEEL, *supra* note 91, at app. B (illustrating the numerous treaties incorporating the Precautionary Principle).

121. *See EC-Hormones*, supra note 119; *see also* Appellate Body Report, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, WT/DS135/AB/R (Mar. 12, 2001) [hereinafter *EC-Asbestos*].

122. *See* Lawrence A. Kogan, *Exporting Precaution: How Europe's Risk-Free Regulatory Agenda Threatens American Free Enterprise*, WASH. LEGAL FOUND. MONOGRAPH, 43-65, http://www.wlf.org/upload/110405MONOKogan.pdf (2005) (listing and explaining the numerous examples of precaution in American legislation); *see also* Nicholas A. Ashford, *The Legacy of the Precautionary Principle in US Law*, *in* IMPLEMENTING THE PRECAUTIONARY PRINCIPLE: APPROACHES FROM THE NORDIC COUNTRIES, EU, AND USA (de Sadeleer ed. 2006) ("In the US, a precautionary approach has been applied in various ways in decisions about health, safety and the environment for about 30 years, much longer than recent commentaries would have us believe, and earlier than the appearance of the precautionary principle in European law."); *see also* Wood, *supra* note 109 (arguing through a comparative law lens that the precautionary principle has informed numerous laws and policy decisions, not necessarily in name, but in principle).

123. *See* Canadian Environmental Protection Act, 1999 § 76.1. For Canada's official stance on the Precautionary Principle, see Government of Canada, A Canadian Perspective on the Precautionary Approach/Principle, Discussion Document (Sept. 2001), *available at* http://www.ec.gc.ca/econom/discussion_e.htm.

124. *See* 114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town), [2001] 2 S.C.R. 241, 267; 2001 SCC 40.

> [S]cholars have documented the precautionary principle's inclusion "in virtually every recently adopted treaty and policy document related to the protection and preservation of the environment.' . . . As a result, there may be 'currently sufficient state practice to allow a good argument that the precautionary principle is a principle of customary international law."

Id.

125. NAFTA, *supra* note 26, art. 715(4).

> [W]here a Party conducting a risk assessment determines that available relevant scientific evidence or other information is insufficient to complete the assessment, it may adopt a provisional sanitary or phytosanitary measure on the basis of available relevant information, including from international or North American standardizing organizations and from sanitary or phytosanitary measures of other Parties.

Id.

Agreement)[126] and in the Agreement on Technical Barriers to Trade (TBT Agreement).[127]

3. *WTO Agreements Incorporating the Precautionary Principle*

The preamble of the WTO Agreement "highlights the ever closer links between international trade and environmental protection" by recognizing the need for members to balance trade with "the objective of sustainable development, seeking both to protect and preserve the environment."[128] The general exceptions under Article XX of GATT further illustrate this recognition of the balance between trade and the public interest. Under Article XX(b), a measure that is "necessary to protect human, animal or plant life or health" that would otherwise be prohibited is allowable as long as the measure is not a disguised restriction on trade or a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail.[129] This commitment to public health and sustainable development was reiterated by the Doha Declaration.[130]

The SPS Agreement expands on Article XX's notion of precaution as it relates to public health and welfare.[131] The preamble of the SPS Agreement allows members to adopt and enforce measures "necessary to protect human, animal or plant life or health" and underscores the Agreement's goal "to improve the human health, animal health and phytosanitary situation in all [m]embers" provided the measure is based in international standards.[132] Article 3.3 allows for a level of protection higher than that prescribed by international standards provided there is scientific justification

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126. Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND 59-72 (1999) [hereinafter SPS Agreement].

127. Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1995 U.NT.S. 120, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND (1999) [hereinafter TBT Agreement].

128. WTO Agreement pmbl.

129. GATT art. XX(I)(b).

130. *See* Doha Declaration ¶ 6.

> We strongly reaffirm our commitment to the objective of sustainable development, as stated in the Preamble to the Marrakesh Agreement . . . . We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate . . . .

Id.

131. *See EC-Hormones*, *supra* note 119, at ¶¶ 124-25 (holding that precaution was incorporated in paragraph 6 of the preamble, Article 3.3, and Article 5.7 of the SPS Agreement but that it did not override the specific requirement of adequate risk assessment based on international standards).

132. SPS Agreement pmbl.

supporting the heightened protection.[133] Article 5.7 contains the most powerful precautionary language allowing provisional measures to be adopted in cases where relevant scientific evidence is insufficient, provided members "seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."[134]

The preamble of the TBT Agreement is similar to that of the SPS Agreement in that it "[r]ecogniz[es] that no country should be prevented from taking measures necessary . . . for the protection of human, animal or plant life or health, of the environment . . . at the levels it considers appropriate."[135] The main precaution-related provision of the TBT is Article 2.2, which allows members to consider legitimate objectives such as "protection of human health or safety, animal or plant life or health, or the environment" when enacting technical regulations that are potentially trade restrictive, provided any available scientific and technical information is considered when assessing such risks.[136]

4. *The Views of International Courts*

International courts have also weighed in on the status of the precautionary principle, though as of yet, none have ruled on the validity of the principle as customary international law. In the *Nuclear Tests* dispute between New Zealand and France over nuclear testing in the South Pacific, although the International Court of Justice dismissed New Zealand's claim without ruling on the substantive issues of the case, the dissent stated that New Zealand, in relying on the precautionary principle, had made a prima facie case.[137] Even more importantly, the dissent announced that the precautionary principle may now be a principle of customary international law.[138]

Perhaps the most famous case dealing with the precautionary principle is the *EC-Hormones* dispute brought before the WTO by the United States and Canada objecting to the European Communities' import ban of meat and meat products from animals treated with specific growth hormones.[139] The European Communities used the precautionary principle as a defense to its import ban, arguing that the principle had become "a general customary

133. *Id.* at art. 3.3.
134. *Id.* at art. 5.7.
135. TBT Agreement pmbl.
136. *Id.* at art. 2.2.
137. Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 Dec. 1974 in the Nuclear Tests (New Zealand v. France) Case, 1995 I.C.J. 288.
138. *Id.*
139. *See EC-Hormones*, *supra* note 119.

rule of international law or at least a general principle of law."[140] The United States, however, maintained the opposite, insisting that the precautionary principle does not represent customary international law, but rather, represents an "approach," the content of which may vary from context to context.[141] Canada took the middle ground arguing that the precautionary approach was an emerging principle of international law that may one day crystallize into a general principle of law under Article 38(1)(c) of the Statute of the International Court of Justice.[142] The WTO Appellate Body held that the precautionary principle had indeed been incorporated into Article 5.7 of the SPS Agreement.[143] However, it refused to rule on the issue of whether the precautionary principle was customary international law, stating that while some view the principle as having crystallized into customary international environmental law, its status and acceptance as a general or customary international law remains unclear.[144]

In a subsequent WTO dispute between the United States and the European Communities over the European Communities' import ban on genetically modified food, the DSB had another opportunity to rule on the precautionary principle, but the Panel found it prudent not to do so.[145] In *EC-Biotech*, after finding that the principle's legal status was outside the boundaries of international trade law, the Panel passed on offering its own opinion on the matter, instead stating that "there has, to date, been no authoritative decision by an international court or tribunal which recognizes the precautionary principle as a principle of general or customary international law."[146]

Although the DSB has refused to rule specifically on whether the precautionary principle is customary international law, in the *EC-Asbestos* dispute, the Appellate Body did illustrate that precaution is alive and well at

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140. *Id.* at ¶ 16.

141. *Id.* at ¶ 43. While there is an ongoing debate as to whether there is a difference between the precautionary principle and the precautionary approach, many commentators find the distinction simply one of semantics. *See* Ashford, *supra* note 122; *see also* COONEY, *supra* note 107, at 5.

142. *EC-Hormones*, *supra* note 119, at ¶ 43.

143. *Id.* at ¶ 124 (holding that "the precautionary principle indeed finds reflection in Article 5.7 of the *SPS Agreement*"). Although the Appellate Body held the precautionary principle to be incorporated into Article 5.7 of the SPS Agreement, it found the principle to be inapplicable to the case because it still could not override Articles 5.1 and 5.2 of the SPS Agreement requiring SPS measures to be based on risk assessment and scientific evidence, which the Appellate Body concluded the EC did not comply with. *Id.* at ¶ 124-25.

144. *Id.*

145. Panel Report, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291/R, WT/DS292/R, & WT/DS293/R (Sept. 29, 2006).

146. *Id.* at ¶ 7.88.

the WTO.[147] While interpreting Article XX in conjunction with the SPS Agreement, the Appellate Body arguably read precaution into the provisions by stating that "'responsible and representative governments may act in good faith on the basis of what, at a given time, may be a *divergent* opinion coming from qualified and respected sources'" and that "a [m]ember may also rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion."[148]

This precaution-friendly reading of the SPS Agreement and GATT Article XX may imply a movement, albeit slow, towards permitting members to use precautionary measures more liberally while not abrogating their WTO obligations.[149] Nevertheless, without a ruling on point by an international court on this issue, the vigorous debate will no doubt continue. Perhaps one commentator put it best by saying:

> [I]f we leave aside the highly academic discussion whether it is a principle of customary international law or not, the fact is that the use by national and international courts, by international organizations, and in treaties, shows that the precautionary principle does have a legal important core on which there is international consensus. In this sense we can affirm that it is "a principle of international law on which decision makers and courts may rely in the same way that they may be influenced by the principle of sustainable development."[150]

B. Can Precaution Be Read Into TRIPS Article 31(b)?

Although it is still unclear whether the precautionary principle is customary international law, and therefore binding in WTO disputes, what is clear is that the notion of precaution has nevertheless become inextricably linked to risk management when it comes to the protection of the environment and public health. Armed with persuasive evidence of the WTO's slow but steady movement towards a more precaution-friendly interpretation of its agreements, the next inquiry seeks to determine whether TRIPS Article 31(b) can support the use of precautionary measures during the threat of a pandemic through the interpretation of TRIPS Article 31 itself.[151] As noted by the DSB, the absence of text explicitly authorizing the use of

147. *EC-Asbestos*, *supra* note 121.

148. *Id.* at ¶ 178.

149. Sabrina Shaw & Risa Schwartz, *Trading Precaution: The Precautionary Principle and The WTO*, UNU-IAS REPORT 8 (2005).

150. Adorno, *supra* note 88, at 16 (citations omitted).

151. *EC-Hormones*, *supra* note 119, at ¶ 124 ("[T]he precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the *SPS Agreement*.").

precaution does not necessarily exclude the possibility of the use of precaution being implied in a provision.[152]

1. *Interpreting TRIPS Article 31(b)*

The rules of treaty interpretation are codified in Articles 31 and 32 of the 1969 Vienna Convention on the Law of Treaties (Vienna Convention),[153] and have been recognized by the DSB to be customary international law that WTO dispute settlement panels and the Appellate Body must apply when interpreting WTO agreements during a dispute.[154] Article 31(1) of the Vienna Convention requires that "[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[155] The Appellate Body's approach to interpreting WTO agreements places particular emphasis on the ordinary text of a provision in its given context, looking to the object and purpose of the provision to resolve any ambiguity.[156]

a. Ordinary Meaning of the Text

Article 31(1) of the Vienna Convention requires that words be given their ordinary meaning.[157] Because the TRIPS Agreement does not define "national emergency or other circumstances of extreme urgency," the words

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152. *See* Appellate Body Report, *United States—Countervailing Duties on Certain Corrosion-Resistant Carbon Steel Flat Products from Germany*, ¶ 65, WT/DS213/AB/R (Nov. 28, 2002) ("Such silence does not exclude the possibility that the requirement was intended to be included by implication.").

153. Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331, 8 I.L.M. 679 (May 23, 1969), *available at* http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf [hereinafter Vienna Convention].

154. Appellate Body Report, *United States—Standards for Reformulated and Conventional Gasoline*, ¶ 17, WT/DS2/9 (May 20, 1996) (holding that Articles 31 & 32 of the Vienna Convention have "attained the status of a rule of customary or general international law").

155. Vienna Convention, *supra* note 153, at art. 31(1).

156. *See* Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, 11, WT/DS10/AB/R (Oct. 4, 1996) ("[A]rticle 31 of the *Vienna Convention* provides that the words of the treaty form the foundation for the interpretative process: 'interpretation must be based above all on the text of the treaty.'"); *see also* Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 114, WT/DS58/AB/R (Oct. 12, 1998) [hereinafter *US-Shrimp*]

> It is in the words constituting that provision, read in their context, that the object and purpose of the states parties to the treaty must first be sought. Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usefully be sought.

Id.

157. Vienna Convention, *supra* note 153, art. 31(1).

must be given their ordinary meaning, "focus[ing] upon [] the text of the particular provision to be interpreted."[158] Dictionary definitions can be useful to ascertain ordinary meaning, provided the definition is appropriate within the context of the agreement.[159] The *Oxford English Dictionary* defines an "emergency" as a "serious . . . situation requiring immediate action."[160] When the modifier "national," defined as "common to a whole nation,"[161] is taken into account, the meaning becomes "a serious situation common to a whole nation requiring immediate action." The phrase "national emergency," however, is also a term of art denoting an official state of emergency or crisis giving a head of state broader executive powers to address a crisis, such as the power to seize property, organize and control the means of production, seize commodities, and regulate the operation of private enterprise.[162]

So must a country officially declare a "national emergency" to take advantage of the waiver provisions in Article 31(b) of the TRIPS Agreement? Not necessarily. The inclusive language of Article 31(b) permits a waiver for a "national emergency *or other* circumstances of extreme urgency."[163] Therefore, even if a public health crisis is not officially recognized as a national emergency, the use of Article 31(b) can still be justified if the public health crisis constitutes a circumstance of extreme urgency. The *Oxford English Dictionary* defines "urgency" as "requiring swift action," and "extreme" as "very great."[164] Based on these definitions, one can conclude "circumstances of extreme urgency" means "a very great situation

158. *US-Shrimp*, *supra* note 156, at ¶ 114.

159. Appellate Body Report, *European Communities—Customs Classification of Frozen Boneless Chicken Cuts*, ¶ 7.105, WT/DS269/R (Sept. 30, 2005) ("While dictionaries are the primary source for determination of the ordinary meaning of treaty terms," it is "necessary in this case to test the appropriateness of those dictionary definitions against the factual context in which the concession in question exists and is being applied."); *see also* Appellate Body Report, *United States—Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶ 164, WT/DS285/AB/R (Apr. 7, 2005) [hereinafter *US-Gambling*] ("In order to identify the ordinary meaning, a Panel may start with the dictionary definitions of the terms to be interpreted.").

160. OXFORD ENGLISH DICTIONARY (2d ed. 2005).

161. *Id.*

162. *See* Harold C. Relyea, *National Emergency Powers*, CRS Report for Congress, Order Code 98-505 GOV, *available at* http://fpc.state.gov/documents/organization/6216.pdf (last updated Sept. 18, 2001). For instance, on October 24, 2009, President Barack Obama declared a national emergency in the United States to address the H1N1 outbreak, giving the President the power to temporarily loosen federal restrictions relating to health care, and allowing health care providers increased flexibility to respond to the outbreak. *See* Flu.gov, *October 14, 2009—President Obama Signs Emergency Declaration for H1N1 Flu*, http://www.flu.gov/professional/federal/h1n1emergency10242009.html (last visited Jan. 14, 2011).

163. TRIPS Agreement art. 31(b) (emphasis added).

164. OXFORD ENGLISH DICTIONARY, *supra* note 160.

requiring swift action."[165] These dictionary definitions, although informative, are still rather ambiguous and fail to resolve the critical issue of whether the waiver provision Article 31(b) can be invoked as a precautionary or preventative measure in cases of stockpiling drugs during the threat of a potentially life-threatening outbreak, or merely in response to such an outbreak. Accordingly, further inquiry is required to determine which of the meanings to attribute to the measure at issue.[166]

b. In Light of the Object and Purpose of the TRIPS Agreement

When the meaning imparted by the text itself remains ambiguous, Article 31(1) of the Vienna Convention prescribes that the terms in Article 31(b) be interpreted in light of the object and purpose of the TRIPS Agreement.[167] The objectives and basic principles of TRIPS are laid out in both Articles 7 and 8, respectively, and illustrate the competing interests inherent in the Agreement. Article 7 mandates the weighing of the protection of intellectual property rights with social and economic welfare,[168] while Article 8 permits members to adopt measures that are necessary to protect public health and social welfare.[169] It is noteworthy that Article 8.1 allows measures to *protect* public health, which would seem to encompass not only responsive measures, but could also include preventative measures.[170] This precautionary interpretation is confirmed by the Appellate Body's reading

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165. *Id.*

166. *See US-Gambling*, *supra* note 159, at ¶ 167.

> Overall, the Panel's finding concerning the word 'sporting' was premature. In our view, the Panel should have taken note that, in the abstract, the range of possible meanings of the word 'sporting' includes *both* the meaning claimed by Antigua and the meaning claimed by the United States, and then continued its inquiry into *which* of those meanings was to be attributed to the word as used in the United States' GATS Schedule.

Id.

167. *See US-Shrimp*, *supra* note 156, at ¶ 114 ("Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usefully be sought."); *see also Canada-Pharmaceuticals*, *supra* note 67, at ¶ 7.26 ("Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."). This provision of the Vienna Convention was subsequently incorporated into the Doha Declaration. *See* Doha Declaration ¶ 5(a) ("In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."); *see also* INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR? 146-48 (Justin Malbon & Charles Lawson eds., 2008) (illustrating negotiating positions that resulted in a interpretation of Articles 7 and 8 of TRIPS).

168. TRIPS Agreement art. 7.

169. TRIPS Agreement art. 8.

170. *See id.* at art. 8.1.

of similar language in the SPS Agreement allowing for trade-restrictive measures necessary to protect public health.[171]

c. Within Context of Other WTO Provisions

Although the TRIPS Agreement is considered *lex specialis* when dealing with patent issues in WTO disputes, examining how the DSB has interpreted language from other WTO Agreements such as GATT and the SPS Agreement and comparing those interpretations to analogous language in TRIPS is not only extremely useful in ascertaining the object and purpose of TRIPS, but is also required.[172] Article 31(2) of the Vienna Convention, which outlines additional context with which to define the terms of the treaty, permits the use of an agreement's preamble and annexes as well as "any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty" when interpreting an ambiguous treaty provision.[173] The TRIPS Agreement is part of the WTO's "single-undertaking" approach, requiring members to ratify all WTO agreements as a condition of membership to the WTO.[174] As such, although

171. *See supra* Subsection III.A.3.

172. The principle of *lex specialis derogat legi generali* holds that "in the event of conflict, the more special norm prevails over the more general norm." JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW 385 (2003). Although TRIPS is more specialized and narrower than GATT, and thus takes priority, WTO jurisprudence nevertheless requires the use of other WTO Agreements when interpreting TRIPS. *See* Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 7.19, WT/DS50/R (Sept. 5, 1997) [hereinafter *India—Patent Protection*] (holding that "[s]ince the TRIPS Agreement is one of the Multilateral Trade Agreements, we must be guided by the jurisprudence established under GATT 1947 in interpreting the provisions of the TRIPS Agreement unless there is a contrary provision"); *see also US-Gambling*, *supra* note 159, at ¶ 291 ("[W]e find previous decisions under Article XX of the GATT 1994 relevant for our analysis under Article XIV of the GATS."). In *US—Gambling*, the Appellate Body used its interpretation of "necessary" in previous disputes as it applied to Article XX of GATT, which is a Multilateral Agreement on Trade in Goods located in Annex 1A of the WTO Agreement, to inform its decision relating to necessity as it applies to the General Agreement on Trade in Services, located in Annex 1B of the WTO Agreement. *US—Gambling*, *supra* note 159, at ¶ 291. This is analogous to using the same Appellate Body's interpretation of "necessary" to inform the interpretation of similar language in TRIPS located in Annex C of the WTO Agreement; *see also* Susy Frankel, *WTO Application of "The Customary Rules of Interpretation of Public International Law" to Intellectual Property*, 46 VA. J. INT'L L. 365, 419-28 (2005) (illustrating the open-textured nature of both GATT and TRIPS and arguing that GATT interpretation methods should be applied to TRIPS).

173. Vienna Convention, *supra* note 153, art. 31(2)(a); *see US—Gambling*, *supra* note 159, at ¶ 178 (stating that the substantive provisions of GATS constitute context under Vienna Convention 31(2)).

174. WTO Agreement art. II(2) ("The agreements and associated legal instruments included in Annexes 1, 2 and 3 (hereinafter referred to as 'Multilateral Trade Agreements') are integral parts of this Agreement, binding on all Members.").

not all current WTO members negotiated the terms of the WTO Agreement as it currently stands, as part of the WTO's package deal, nations that agree to the TRIPS Agreement also simultaneously agree to be bound by the entire WTO Agreement inclusive of its Annexes.[175] Therefore, in accordance with Article 31(2) of the Vienna Convention, agreements such as GATT and the SPS Agreement, which are ratified in connection with the conclusion of the TRIPS Agreement, are subject to use when interpreting Article 31 of TRIPS.[176]

The preamble of the SPS agreement allows members to adopt and enforce measures "necessary to protect human, animal or plant life or health."[177] This language is almost identical to TRIPS article 8.1, which allows measures "necessary to protect public health."[178] In *EC-Hormones*, the Appellate Body found that precaution was incorporated into the SPS Agreement but that it did not override the specific requirement of adequate risk assessment based on international standards.[179] Since the TRIPS Agreement requires no such adherence to international standards, it seems likely that the Appellate Body would similarly find precaution incorporated into TRIPS, without being burdened by the requirement of a risk assessment based on international standards.

d. The Declaration on the TRIPS Agreement and Public Health as a "Subsequent Agreement"

The object and purpose of the TRIPS Agreement can also be ascertained from the Doha Declaration, which clarifies the Agreement within the context of public health.[180] Some have suggested that the Doha Declaration constitutes a "subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" under Article 31(3)(a) of the Vienna Convention and, therefore, should be taken into account as persuasive authority when interpreting the TRIPS Agreement or the application of its provisions.[181] Some have even argued that actions

175. *Id.* at art. II.

176. *See India—Patent Protection*, *supra* note 172, at ¶ 5.19.

> Indeed, in light of the fact that the TRIPS Agreement was negotiated as a part of the overall balance of concessions in the Uruguay Round, it would be inappropriate not to apply the same principles in interpreting the TRIPS Agreement as those applicable to the interpretation of other parts of the WTO Agreement.

Id.

177. SPS Agreement pmbl.

178. TRIPS Agreement art. 8(1).

179. *EC—Hormones*, *supra* note 119, at ¶¶ 124-25.

180. *See supra* Subsection I.A.2 (illustrating the pro-health language of the Doha Declaration).

181. James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. & TECH.

taken by the TRIPS Council to implement specific provisions of the Declaration could also constitute "subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation" under Article 31(3)(b) of the Vienna Convention.[182]

The pro-public health language of the Doha Declaration, "affirm[ing] that the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all," should be used as an interpretive gloss on Article 31(b) of the TRIPS Agreement.[183] The Doha Declaration recognizes the flexibility that is required to address critical public health concerns by broadening members' access to vital drugs through more permissive use of compulsory licensing. Nations are afforded the discretion to determine what constitutes a "national emergency or other circumstances of extreme urgency" and are provided with a waiver of the burdensome domestic use requirement that precluded developing countries from taking advantage of TRIPS Article 31.[184]

With respect to the interpretation of "national emergency or other circumstances of extreme urgency," Paragraph 5(c) of the Doha Declaration explicitly states that a public health crisis can constitute a national emergency or circumstance of extreme urgency and gives specific examples of "HIV/AIDS, tuberculosis, malaria and other epidemics."[185] The language of

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291, 299-301 (2002) (illustrating how "the Declaration was the result of the lawful process of negotiation and agreement that characterizes the GATT/WTO," that "[u]nder recent WTO Appellate Body jurisprudence, there is precedent for giving a subsequent agreement between parties to a WTO treaty the same legal status as the WTO treaty," and that as '"an agreement as to the interpretation of a provision reached after the conclusion of the treaty [the Declaration] represents an authentic interpretation by the parties which must be read into the treaty for purposes of its interpretation'" according to the ICJ). *See* Sandra Bartelt, *Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INTELL. PROP. 283, 302 (2003) (arguing that the Doha Declaration should be considered "subsequent practice in the application of the treaty" under Article 31(3) of the Vienna Convention); *see also* Frankel, *supra*, note 172, at 400; *see also* MARCO SLOTBOOM, A COMPARISON OF WTO AND EC LAW: DO DIFFERENT OBJECTS AND PURPOSES MATTER FOR TREATY INTERPRETATION? 194-96 (2006).

182. The implementation of the Paragraph 6 waiver of the Doha Declaration seems to satisfy the test set out in *US—Gambling*, *supra* note 159, at ¶ 192 ("[I]n order for 'practice' within the meaning of Article 31(3)(b) to be established: (i) there must be a common, consistent, discernible pattern of acts or pronouncements; *and* (ii) those acts or pronouncements must imply *agreement* on the interpretation of the relevant provision."); *see also* Bloche, *supra* note 111, at 842 ("[T]he Doha Declaration has interpretive weight under the Vienna Convention on the Law of Treaties, as either a 'subsequent agreement between the parties regarding the interpretation' of TRIPS or 'subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation.'"); Gathii, *supra*, note 181; Frankel, *supra* note 172.

183. Doha Declaration ¶ 4.

184. *Id.* at ¶¶ 5-6.

185. *Id.* at ¶ 5(c).

this provision implies that an epidemic is inclusive of, but not limited to, HIV/AIDS, tuberculosis, and malaria. Since the *Oxford English Dictionary* defines "epidemic" as "a widespread occurrence of an infectious disease in a community,"[186] the scope of this provision would also logically include the recent outbreaks of SARS, avian flu, and H1N1, all of which have been included in the World Health Organization's (WHO) "Global Alert and Response" program for managing epidemics and other public health emergencies.[187]

Reading TRIPS Article 31(b) in light of the pro-health flexibilities recognized by and affirmed in the Doha Declaration indicates that the waiver provision is intended to be broadly interpreted and that epidemics, as well as similar life-threatening public health crises, undeniably fall within its scope. Moreover, one can argue that these broad pro-health flexibilities may also permit the use of compulsory licensing as a precautionary measure during such a threat. While there is no doubt that the TRIPS Agreement acknowledges the importance of protecting public health, the inquiry does not end there. The TRIPS Agreement is first and foremost a trade agreement, and therefore any measure that restricts trade or infringes on intellectual property rights in the name of public health must be balanced against the potentially adverse trade effects of that public health measure, regardless of how noble the cause or how serious the threat.[188]

2. *"Necessary" to Protect Public Health*

When TRIPS Article 31(b) is read in light of the precautionary language of Article 8.1 and is informed by the flexibilities outlined in the Doha Declaration, it can be concluded that members have the right to implement measures that are necessary to prevent an urgent public health crisis, including life-threatening outbreaks of disease. Although this language is quite permissive, it does not give nations free reign to impose compulsory licenses whenever they see fit. Articles 7 and 8 of the TRIPS Agreement also call for the balancing of public health with the protection of intellectual property rights.[189] Perhaps the strongest indicator of this balancing requirement is the Article 8 mandate that a measure enacted to protect public health must be *necessary*.[190] It is interesting to note that in clarifying the

186. OXFORD ENGLISH DICTIONARY, *supra* note 160.

187. World Health Org., *Global Alert and Response (GAR)*, DISEASES COVERED BY GAR, http://www.who.int/csr/disease/en (last visited Jan. 14, 2011).

188. *See* TRIPS Agreement pmbl. ("*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.").

189. TRIPS Agreement art. 7-8.

190. TRIPS Agreement art. 8.1.

TRIPS Agreement, the Doha Declaration does not require the measure to be *necessary* to protect public health, but rather "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."[191] Regardless, the Doha Declaration is an interpretive tool for the TRIPS Agreement and is not considered a replacement agreement that would trump existing TRIPS language. Thus, the necessity inquiry of TRIPS Article 8.1 is unaffected by the Doha Declaration and therefore remains essential.

a. Weighing and Balancing What is "Necessary"

A composite definition of "necessary" can be found in WTO jurisprudence interpreting the general exceptions provision in GATT outlined in Article XX.[192] Article XX of GATT allows members to derogate from GATT obligations in narrow instances and contains precautionary language that is strikingly similar to the language of TRIPS Article 8.1. While TRIPS Article 8.1 permits members to "adopt measures necessary to protect public health," GATT Article XX(b) allows WTO-inconsistent measures to be taken when "necessary to protect human, animal or plant life or health."[193] Appellate Body jurisprudence relating to the GATT Article XX general exceptions has clarified the meaning of necessity and has created a "weighing and balancing" approach to be used when determining if a measure is necessary.

In *Korea-Various Measures on Beef*, the Appellate Body found that the term "necessary" refers to a continuum of necessity, placing "indispensable" at one end and "making a contribution to" at the other end, and that a "necessary" measure was "located significantly closer to the pole of 'indis-

191. Doha Declaration ¶ 4.

192. The provisions setting out necessity tests are found in paragraphs (a), (b), and (d) of Article XX. The relevant parts of the provision state:

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
> (a) necessary to protect public morals;
> (b) necessary to protect human, animal or plant life or health;
> . . .
> (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices; . . .

GATT art. XX.

193. *Compare* GATT art. XX(b) ("necessary to protect human, animal or plant life or health"), *with* TRIPS Agreement art. 8.1 ("necessary to protect public health and nutrition").

pensable' than to the opposite pole of simply 'making a contribution to.'"[194] The Appellate Body also set forth the "weighing and balancing" approach, which considers the following factors: (i) the importance of the value or interest pursued by the laws with which the challenged measure sought to secure compliance; (ii) whether the objective pursued by the challenged measure contributed to the end that was sought to be realized; and (iii) whether a reasonably available alternative measure existed.[195] In *EC-Asbestos*, the Appellate Body affirmed the use of the "weighing and balancing" approach outlined in *Korea-Various Measures on Beef* and clarified that WTO members have the right to determine the level of health protection that they consider appropriate in a given situation, and that specific factors must be considered when determining whether a suggested alternative measure is reasonably available.[196] The "weighing and balancing" approach was also affirmed by the Appellate Body's decision in *US-Gambling*, which addressed necessity in the context of Article XIV of the GATS.[197]

i. *Importance of Objective*

When looking at the importance of the value or interest pursued by the laws with which the challenged measure sought to secure compliance, the Appellate Body in *EC-Asbestos* noted that "the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks . . . is both vital and important in the highest degree."[198] The objective of preserving human life and health is contained in Article 8.1 of the TRIPS Agreement and is at the very core of the Doha Declaration.[199] In a WTO dispute involving a compulsory license invoked to prevent an outbreak or pandemic, it seems likely that the vital policy objective of protecting human health through the prevention of an epidemic would pass muster.

ii. *Means to an End*

When determining whether the objective pursued by the challenged measure contributed to the end that was sought to be realized, the Appellate Body in *EC-Asbestos* noted that it is undeniable that WTO members have

194. Appellate Body Report, *Korea —Measures Affecting Imports of Fresh, Chilled and Frozen Beef*, ¶ 161, WT/DS161/AB/R, WT/DS169/AB/R (Dec. 11, 2000) [hereinafter *Korea—Various Measures on Beef*].

195. *Id.* at ¶ 164.

196. *EC—Asbestos*, *supra* note 121, at ¶¶ 171-75.

197. *US—Gambling*, *supra* note 159, at ¶¶ 305-08.

198. *EC—Asbestos*, *supra* note 121, at ¶ 172.

199. *See supra* Subsection III.B.1.d.

the right to determine the level of protection of health that they consider appropriate in a given situation.[200] In *EC-Asbestos*, France instituted an import ban on asbestos in an effort to "halt" the spread of asbestos-related health risks, and the Appellate Body found that the ban was "designed and apt to achieve France's chosen level of health protection."[201] In *Brazil-Tyres*, the Appellate Body further clarified that a challenged measure must not be merely related to the achievement of an objective sought but that it must "bring[] about a material contribution to the achievement of its objective."[202] In a dispute involving compulsory licensing, the policy objective would similarly be a "halt" to the spread of epidemic-related health risks. And just as in *EC-Asbestos*, a measure enacted to issue a compulsory license as quickly as possible to prevent the spread of a potentially deadly pathogen is not only materially related to the objective sought, but designed and apt to achieve such a level of health protection.

iii. *Reasonably Available Alternative*

When determining if a reasonably available alternative is plausible, the issue is whether there exists an alternative measure that would achieve the same policy objective and that is less trade restrictive than the measure at issue.[203] The burden is on the party challenging the restrictive measure to prove the existence of any reasonably available alternatives.[204] In its inquiry in *EC-Asbestos*, the Appellate Body considered: (i) the extent to which the alternative measure contributes to the realization of the end pursued; (ii) the difficulty of implementation; and (iii) the trade impact of the alternative measure compared to the measure at issue.[205] Simply put, while "[a] measure with a relatively slight impact upon imported products might more easily be considered as 'necessary' than a measure with intense or broader restrictive effects,"[206] '"[t]he more vital or important [the] common interests or values' pursued, the easier it would be to accept as 'necessary' measures designed to achieve those ends."[207]

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200. *EC—Asbestos*, *supra* note 121, at ¶ 173.

201. *Id.*

202. Appellate Body Report, *Brazil—Measures Affecting Imports of Retreaded Tyres*, ¶ 151, WT/DS332/AB/R (Dec. 3, 2007) [hereinafter *Brazil—Tyres*].

203. *EC—Asbestos*, *supra* note 121, at ¶ 172.

204. *See US—Gambling*, *supra* note 159, at ¶¶ 309-11 (explaining that although "necessity" is an affirmative defense, the burden is on the complaining party to show a reasonably available alternatives to the challenged measure).

205. *EC—Asbestos*, *supra* note 121, at ¶ 172.

206. *Korea—Various Measures on Beef*, *supra* note 194, at ¶ 163.

207. *EC—Asbestos*, *supra* note 121, at ¶ 172 (quoting *Korea—Various Measures on Beef*, *supra* note 194, at ¶ 163).

The Appellate Body illustrated this point in *EC-Asbestos* by holding that any measure short of an import ban on asbestos, even one that is less trade restrictive such as controlled use, would involve a continuation of the very risk that France intended to "halt," thus preventing France from achieving its chosen level of protection.[208] Similarly, in a hypothetical situation involving the threat of a potentially deadly pandemic, anything less than a measure quickly compelling the licensing of needed pharmaceuticals to reduce loss of life by ensuring adequate national supplies would seem to involve the continuation of the very health risk intended to be prevented.

b. Necessity Defined for TRIPS Article 8.1

By interpreting and synthesizing WTO jurisprudence, it becomes evident that a measure is considered "necessary" under Article XX only if there is no alternative measure consistent with, or less WTO-inconsistent, which a member could reasonably be expected to employ to achieve its health policy objectives.[209] Due to the similarities in language and objectives between GATT Article XX and TRIPS Article 8.1, if a precautionary compulsory license was issued under Article 31(b) to prevent a public health crisis such as an outbreak or pandemic, the measure would likely be subjected to similar scrutiny and the necessity inquiry would likely be the same.

3. *Summation*

The waiver provision of TRIPS Article 31(b) allows members to issue compulsory licenses without prior negotiation in a national emergency or other circumstance of extreme urgency, but gives no further guidance as to when such circumstances exist. Although nations have a right to choose when to issue compulsory licenses, in gray areas such as this, the threat of a WTO complaint always looms. Deciphering from the language of the TRIPS Agreement when it is acceptable to issue a compulsory license as a precautionary measure is of utmost importance in allowing countries to make informed good faith policy decisions. Interpreting TRIPS Article 31(b) in light of the object and purpose of the TRIPS Agreement, and in the context of the Doha Declaration and analogous language in GATT and the SPS Agreement, greatly clarifies this uncertainty. This interpretation suggests that members have the right to implement precautionary measures to prevent an urgent, life-threatening public health crisis, such as a potentially deadly outbreak of disease, provided there are no alternative measures available that interfere less with the patent-holders' rights and could be rea-

208. *Id.*
209. *See supra* Subsection III.B.2.a.

sonably expected to be employed to achieve the member's desired health policy objectives.

IV. EFFECTIVE USE OF THE PRECAUTIONARY PRINCIPLE WHEN INVOKING ARTICLE 31 OF THE TRIPS AGREEMENT

It is evident that TRIPS Article 31 supports the use of precautionary measures, but members may still be vulnerable to the threat of a WTO complaint when invoking the provision as a precaution if proper procedural steps are not taken.[210] As the use and acceptance of precaution in policy-making increases in prevalence and continues to shift from environmental health towards public health,[211] it becomes increasingly important to have defined factors on which to rely when considering trade-restrictive policies. Four important factors can be deduced and should be considered when invoking a precautionary compulsory license: (i) there must be a threat of grave or irreversible damage to public health if action is not taken; (ii) there must be an uncertainty of risk associated with that threat; (iii) a good faith assessment of that risk must be performed; and (iv) the measure must be necessary to achieve the desired health objective.

A. Threat of Serious or Irreversible Damage to Public Health

The preservation of human life and health through the elimination or reduction of well-known and life-threatening health risks is both vital and important in the highest degree.[212] Nevertheless, not all public health issues can or should prompt the issuance of compulsory licenses to address them, at the risk of trampling the rights of patent-holders and disincentivising further pharmaceutical innovation.[213] The threshold requirement of a threat of grave or irreversible damage to public health is reflected by the pressing language of Article 31(b), requiring a national emergency or other circumstance of extreme urgency.[214] This threshold requirement is also reflected in the narrowing language of Article 8.1, requiring that the measure be *necessary* to protect public health, rather than merely having a tangential effect.[215] Logically, if a public health threat did not rise to such an extreme level of urgency, for example, the common cold or seasonal flu, immediate pre-

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210. *See* Valach, Jr., *supra* note 11 (illustrating the dispute between the United States and South Africa over South Africa's amendment permitting broad use of compulsory licensing).

211. *See supra* Part II.

212. *EC—Asbestos*, *supra* note 121, at ¶ 172.

213. *See* Yosick, *supra* note 22 (illustrating the competing interests of patent protection).

214. TRIPS Agreement art. 31(b).

215. TRIPS Agreement art. 8.1.

emptive action through the use of a precautionary compulsory license would not be *necessary* as it would be during an outbreak of the Ebola virus or anthrax. Instead, the proper course of action would be to engage in good-faith negotiations to obtain authorization from the patent-holder on reasonable commercial terms and conditions, as required by Article 31(b).[216]

B. Uncertainty of Risk

The invocation of precautionary measures also requires an uncertainty of risk associated with the threat of harm. If the risk of harm was known, a measure addressing the threat would be responsive and clearly discernable as justifiable and proportional, rather than precautionary in nature and requiring deference.[217] During the early stages of an outbreak, it is possible that scientists may not always agree on the severity of the threat, or may not even have enough information to make that determination.[218] In such cases of uncertainty, the precautionary principle allows for a margin of error with respect to protective action before there is complete scientific proof of a risk and, indeed, the WTO Appellate Body has recognized as much.[219]

C. Good Faith Risk Assessment

The SPS Agreement requires a risk assessment based on scientific evidence and international standards to determine if a trade-restrictive measure is justified, while the TRIPS Agreement has no such risk-

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216. TRIPS Agreement art. 31(b) ("[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.").

217. *EC—Hormones*, *supra* note 119, at ¶ 124 (commenting that Panels should give some deference to "responsible, representative governments [who] commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned").

218. *See* World Health Org., *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza*, WHO/CDS/EPR/GIP/2007.2, 1, *available at* http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf [hereinafter *Ethical Considerations*] ("Morbidity and mortality have varied across pandemics, making accurate predictions of the impact of the next pandemic impossible.").

219. *See EC—Asbestos*, *supra* note 121, at ¶ 178 ("A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion."); *see also EC—Hormones*, *supra* note 119, at ¶ 194 (noting that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources"); *see also Brazil—Tyres*, *supra* note 202, at ¶¶ 150-51 (noting the inherent uncertainties associated with "preventive actions to reduce the incidence of diseases that may manifest themselves only after a certain period of time").

assessment requirement.[220] Nevertheless, based on WTO jurisprudence, it seems the Appellate Body would be more likely to accept the use of an infringing precautionary measure invoked to protect public health when some form of good faith risk assessment is performed.[221] It also seems that such a risk assessment does not necessarily have to be quantitative.[222] In the case of a potentially deadly outbreak, the risk to be assessed is that of the pathogen and the likely consequences that may result if no action is taken. If there is inadequate time to negotiate a license for a preventative drug such as a vaccine, there is unlikely to be adequate time to perform an in-depth scientific risk assessment. As such, a member seeking to invoke Article 31(b) as quickly as possible might wish to rely on other sources to aid in its risk assessment and risk management, such as reports and recommendations published by the WHO, which is seen as the standard setting body for international health.[223]

While quantifiable data such as mortality rates or other indicia of pathogenicity can be useful in setting a threshold for invoking a precautionary measure, due to the diversity and unpredictability of pathogens,[224] relying on WHO publications and recommendations to aid in epidemic preparedness and response would not only be more efficient than an independent national assessment, but would also be more transparent.[225] For example, a nation may choose to condition the use of a compulsory license upon the WHO's classification of an outbreak as a pandemic, or perhaps on a specific epidemiological phase of an outbreak based on the WHO's 6-phase classification system.[226] Although the TRIPS Agreement makes it clear that members have a right to decide what constitutes a public health emergency,

220. *See EC—Hormones*, *supra* note 119, at ¶ 43.

221. *Id.* Some consider the Appellate Body's recognition of the precautionary principle in the SPS Agreement as guidance for applying elements of precaution in risk regulation. Shaw & Schwartz, *supra* note 149, at 8.

222. *EC—Asbestos*, *supra* note 121, at ¶ 167 (noting that when invoking a measure necessary to protect human health, "risk may be evaluated either in quantitative or qualitative terms").

223. The World Health Organization "is the directing and coordinating authority for health within the United Nations system" and "is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends." *About WHO*, WORLD HEALTH ORG., http://www.who.int/about/en/ (last visited Jan. 14, 2011).

224. *See Ethical Considerations*, *supra* note 218, at 1.

225. *See, e.g.*, World Health Org., *Pandemic Influenza Preparedness and Response*, *available at* http://www.who.int/csr/disease/influenza/PIPGuidance09.pdf (last visited Jan. 14, 2011). In 2009, during the height of the H1N1 scare, the Global Health Programme of the WHO published a paper aimed at national health authorities outlining a series of response recommendations for an influenza pandemic such as H1N1, based on specific epidemiological phases of the disease. *Id.*

226. *Id.*

members relying on publications and recommendations put forth by an international health body to justify a compulsory license in a situation where risks of irreversible damage to human health are concerned would likely be seen as having made a good faith effort at risk assessment, given the time constraint, and one which would likely pass muster if challenged.[227]

D. Necessity

Once a risk assessment is performed and it has been concluded that immediate pre-emptive action is required, the measure must be scrutinized to ensure that it is proportional to the threat. The notion that a measure cannot be more trade restrictive than necessary is one of the hallmarks of the WTO,[228] and is reflected in Article 8.1 requiring that the measure be *necessary* to protect public health.[229] Proportionality is also addressed in Article 31(c) which limits use of the license to the purpose for which it was authorized and Article 31(g) which requires the use to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.[230] The WHO similarly advises that necessity should be a crucial consideration for nations invoking compulsory health measures.[231] When applied to the TRIPS Agreement, the focus is on balancing public health with intellectual property rights. Therefore, under TRIPS, a precautionary measure addressing a potentially life-threatening outbreak must be materially related to and designed to achieve the public health objective sought, and there must be no reasonable alternatives available that are less likely to interfere with the rights of patent-holder, while still achieving this public health objective.

CONCLUSION

Scholars have been debating the merits and proper application of the precautionary principle for centuries.[232] This "better-safe-than-sorry" ap-

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227. *See supra* note 217.

228. *See* WTO Agreement ("*Being desirous* of contributing to these objectives by entering into reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs and other barriers to trade and to the elimination of discriminatory treatment in international trade relations . . . .").

229. TRIPS Agreement art. 8.1.

230. TRIPS Agreement art. 31.

231. *See Ethical Considerations*, *supra* note 218, at 1.

> Public health powers are exercised under the theory that they are necessary to prevent an avoidable harm. Government, in order to justify the use of compulsion, must therefore act only in the face of a demonstrable health threat. The public health officials must be able to prove that they had "a good faith belief, for which they can give supportable reasons, that a coercive approach is necessary."

Id.

232. *See supra* Part II.

proach is extremely useful for protecting public health and safety, and, as such, its value should be explored beyond the boundaries of environmental protection. Just as the precautionary principle has found its way into GATT, the SPS Agreement, and the TBT Agreement, it can similarly be supported by the language of Article 31(b) of the TRIPS Agreement. When invoking Article 31(b) as a precautionary measure, four factors should be considered: whether there is a threat of grave or irreversible damage to public health, the uncertainty of the risk, a good faith risk assessment should be performed, and the necessity of a compulsory license to alleviate the risk to public health. There is always the threat of a complaint to the WTO when invoking measures that are trade restrictive or that interfere with a member's rights, especially when the measure is precautionary in nature. However, if appropriate procedures are followed and the proper considerations are met in good faith, the likelihood that the measure will be seen as a disguised restriction on trade or interference with intellectual property rights can be greatly reduced.