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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, but what is lurking around the corner could be far worse—a superbug, the likes of which have never before been seen. 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**.

Congress hopes to stockpile enough of the drug so that it can react swiftly 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. Would the Swiss government prevail? [fn5]…**

…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.

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…With the ever-present threat of a new superbug pandemic, the accessibility of pharmaceuticals—and not just in developing countries—is a growing concern. 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. **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**. [fn8]

… 8. TRIPS Agreement art. 31(b), (h)

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…**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. 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**.

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…

…II. THE PRECAUTIONARY PRINCIPLE

…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…

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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).

(p. 419)

…**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**…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…

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…**1. Defining Customary International Law**

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

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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). [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).]

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*.**

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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 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 States122** as well as in Canadian legal instruments123 and jurisprudence,124 and even in the North American Free Trade Agreement.125

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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).

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