HEALTH, TECHNOLOGY & INTERNATIONAL LAW—HEALTH TECHNOLOGIES AND INTERNATIONAL INTELLECTUAL PROPERTY: A PRECAUTIONARY APPROACH

Reviewed by:
Priscila Santos*

"[The] main premise [of the Precautionary Approach] is that where the threat of particular harm is serious and the damage is irreversible, the notion of precaution should take priority over scientific justification."

Phoebe Li†

I. INTRODUCTION

The free movement of people as a result of globalization facilitates the transmission of infectious disease. The fluid movement of people and commerce raises various questions about regulating technology, world trade, and intellectual property that interface to preserve human health. Global institutions attempted to address how to contain a public health emergency without disrupting trade and preserving intellectual property rights, such as patent ownership. The Precautionary Approach (“PA”) emerged

* Priscila Santos is a candidate for J.D., Class of 2018, Suffolk University Law School, Boston, Massachusetts. Ms. Santos may be reached at psantos@suffolk.edu.
† PHOEBE LI, HEALTH TECHNOLOGIES AND INTERNATIONAL INTELLECTUAL PROPERTY: A PRECAUTIONARY APPROACH (Routledge 2014). The quote explains the purpose of the precautionary approach in the case of scientific uncertainty. Id. at 47.
‡ See Infectious Disease, MERRIAM-WEBSTER (2017), https://www.merriam-webster.com/medical/infectious%20disease (defining infectious disease to mean a disease caused by an organism that grows and multiplies); DAVID A. RELMAN ET AL., INFECTIOUS DISEASE MOVEMENT IN A BORDERLESS WORLD: WORKSHOP SUMMARY (National Academies Press 2010).
§ See Li, supra note 1, at 9 (describing the international origins of WHO and WTO).
¶ See id. at 32, 88 (explaining how international organizations look to preserve health without disrupting trading). World Health Organization is the leading international institution that promotes “global health concerns”. Id. “The goal of the WHO is to ensure the right of
at the United Nations ("U.N.") Conference on Environment and Development known as either “Rio Declaration on Environment and Development” or “Rio Earth Summit” in 1992.5 The underlying principle of the PA is the notion that when threat of a particular harm is serious with irreversible damage, precaution should take priority over scientific justification with the purpose of protecting environment and human health.6 Prior to 1992, the PA was met with major criticism as people struggled with the question of “how [to] solve a problem that is uncertain or without scientific justification[.]”7 This criticism has significantly delayed the popularity of the PA among political agendas, until Rio Earth Summit in 1992 recognized the PA as a tool that could help preserve the environment and human health.8

II. BACKGROUND

This book grew out of the author’s personal experience which inspired her to explore the intersection of health technologies, intellectual property, and international law.9 Phoebe Li’s PhD thesis at Edinburgh University was on intellectual property and

everyone to the enjoyment of the highest attainable standard of physical and mental health (the right to health).” Id. “The protection and promotion of human health and safety is regarded as the first priority in the WHO regime, thus the concept of precaution has been widely promoted in the WHO system.” Id.

5 See id. at 48 (defining the precautionary approach through various international organizations). “There is no current consensus on using the term ‘precautionary approach’ (PA) or ‘precautionary principle’ (PP) in international law.” See Li, supra note 1, at 50. See also U.N. Conference on Environment and Development, Rio Declaration on Environment and Development, U.N. Doc. A/CONF.151/26/Rev.1 (Vol. I, Annex 1 1992). Principle 15 of the “Earth Summit” in Rio includes the precautionary approach as a means to protect the environment even without scientific proof. Id.

6 See Li, supra note 1, at 49-50 (defining the origin, purpose, and application of the PA). The purpose of the PA in part was to address the global concern of how to preserve the environment and human health in case of a global emergency. Id.

7 See EUROPEAN ENV’T AGENCY, LATE LESSONS FROM EARLY WARNINGS THE PRECAUTIONARY PRINCIPLE 1896-2000; infra note 29, at preface (noting that “certainty” played a key role to delay the preventative actions).

8 Id.

9 Dr. Phoebe Li, Biography, UNIVERSITY OF SUSSEX, http://www.sussex.ac.uk/profiles/305243 (last visited Apr. 17, 2018).
technology law with a focus “on the adoption of risk analysis into compulsory licensing of pharmaceutical patents”\(^\text{10}\). In 2004, Dr. Li lost her daughter to severe acute respiratory syndrome (“SARS”).\(^\text{11}\) This tragic event drove Dr. Li to move abroad to pursue a PhD on the “ethical debates over pharmaceutical patents [in case of] a public health emergency”.\(^\text{12}\) Currently, Dr. Li is a Senior Lecturer at Sussex University in the United Kingdom where she continues to research the interface of intellectual property, the regulation of technology, and international trade and development.\(^\text{13}\)

\textit{A Precautionary Approach}, by Phoebe Li, proposes that individual sovereign states apply the principle of the PA to public health to address infectious disease outbreaks.\(^\text{14}\) Dr. Li proposed solution is the “granting of compulsory licensing [that] can offer a margin of safety to promote public health protection by means of provisional limitation to IP”.\(^\text{15}\)

\(\text{See Biography, supra note 9 (explaining what prompted Dr. Li to write about precautionary approach dealing with compulsory licenses). “She received her PhD from Edinburgh University working on the adoption of risk analysis into compulsory licensing of pharmaceutical patents, from which she published a monograph ‘Health technologies and international intellectual property law: A precautionary approach.’” Id.}

\(\text{See Severe Acute Respiratory Syndrome (SARS), CENTER FOR DISEASE CONTROL AND PREVENTION (last updated Dec. 6, 2017), https://www.cdc.gov/sars/about/fs-sars.html (defining SARS and educating people on how the disease is transmitted). “Severe acute respiratory syndrome (SARS) is a viral respiratory illness caused by a coronavirus, called SARS-associated coronavirus (SARS-CoV). SARS was first reported in Asia in February 2003.” Id. “The main way that SARS seems to spread is by close person-to-person contact.” Id. “The virus that causes SARS is thought to be transmitted most readily by respiratory droplets (droplet spread) produced when an infected person coughs or sneezes.” Id. “Droplet spread can happen when droplets from the cough or sneeze of an infected person are propelled a short distance (generally up to 3 feet) through the air and deposited on the mucous membranes of the mouth, nose, or eyes of persons who are nearby.” Id. “The virus also can spread when a person touches a surface or object contaminated with infectious droplets and then touches his or her mouth, nose, or eye(s).” Id. “In addition, it is possible that the SARS virus might spread more broadly through the air (airborne spread) or by other ways that are not now known.” See Severe Acute Respiratory Syndrome (SARS), supra.}

\(\text{See Li, supra note 1, at Acknowledgment (explaining what led Dr. Li to write about this subject).}

\(\text{See Biography, supra note 9 (developing the biography of Dr. Li).}

\(\text{See Li, supra note 1, at 32. See also States, MERRIAM-WEBSTER (2017), https://www.merriam-webster.com/dictionary/states (defining states as “body of people occupying a definite territory, especially one that is sovereign”).}

\(\text{Li, supra note 1, at 185-86 (finding solution for infectious outbreak control by using compulsory licensing). See ERIC BONG & KAMAL SAGGI, VANDERBILT U., COMPULSORY}

\(\text{2018 JOURNAL OF HEALTH & BIOMEDICAL LAW 409}
She further suggests that “based upon the rationale of risk management and the PA health technologies associated with significant risk to human life or health may receive differential treatment in the IP regime.” The different treatment would not be constituted discrimination by the World Trade Organization (“WTO”) as it can be justified by “harmonization of risk management in WTO law”. Dr. Li summarizes the elements of the PA in compulsory license as the following: (1) trigger threshold, (2) the granting of the compulsory license as a precautionary conditional right, (3) duty to review, and (4) other non-scientific factors.

Licensing, Price Controls, and Access to Patented Foreign Products 2 (2012) (explaining patent compulsory licensing). “When faced with no or limited access to a patented foreign product, a country may choose to engage in compulsory licensing, i.e., an authorization granted by a government to someone other than the patent-holder to produce the product without the patent-holder’s consent.” Id. “Along with the freedom to allow parallel imports, the option to use compulsory licensing constitutes one of the major flexibilities available under TRIPS to member countries of the WTO.” Id.

16 Li, supra note 1, at 33, 186 (justifying differential treatment in instances that the PA applies). “The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less than that accorded to like products of national origin in respect of laws, regulation and requirements affecting their internal sale, offering sale, purchase, transportation, distribution or use.” Id. at 33. See Curtis Reitz, Enforcement of the General Agreement on Tariffs and Trade, 17 U. PA. J. INT’L ECON. L. 555, 573 (1996) (explaining principle of national treatment found on Article III: 4 GATT 1947).

17 See Li, supra note 1, at 186 (concluding precautionary granting of compulsory license solves problem of containing outbreak with minimal trade restrictions); What is the World Trade Organization, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact1_e.htm (last visited Apr. 17, 2018) (explaining WTO’s purpose is to promote trade liberalization). Notably the WTO was established after the Rio Summit that introduced the PA. What is the World Trade Organization, supra. However, the WTO considered the PA when it came into being given that it was predecessor of the GATT, which under Article XX consisted of language that related to the PA. Id. The WTO is an international organization that promotes free trade and helps to remove trade barriers that impede free trade. Id. The WTO is famous for settling disputes among member States in case a conflict arises. Id.; see WORLD TRADE ORG., TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 5-6 (2008), available at https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/88_bgd_trips_89_e.pdf (protecting intellectual property rights internationally is the sole purpose of “TRIPS”). TRIPS is a multilateral treaty that came into force on January 1, 1995 to protect intellectual property rights on an international scale. WORLD TRADE ORG., supra.

18 See Li, supra note 1, at 186 (explaining elements of PA compulsory licensing). See also, infra pp. 19-22 (analyzing in detail Dr. Li’s proposed solution).
The purpose of this principle is to balance the equities between preserving human health and protecting intellectual property rights. States view the PA differently depending on their economic status, because in essence health technologies are often created in developed states rather than undeveloped states. For example, developed states such as the United States, Germany, Switzerland have pharmaceutical companies within their territories. In this instance, developed states are mainly concerned with protecting intellectual property rights to promote innovation in their own territories. Developed states are concerned with public health, however, they possess the financial resources and biotechnology to contain the spread of an infectious disease immediately after the outbreak. Furthermore, in the event of a public health emergency, developed states have tremendous bargaining power to persuade foreign pharmaceutical companies to provide a drug at a more favorable price. As a result, the primary focus for developed

19. See Li, supra note 1, at 32 (balancing rights between IP and health through compulsory licensing).

20. See Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905) (requiring adults to undergo vaccination is within scope of state’s police power). According to Jacobson, developed states such as the United States require their citizens to undergo vaccination that is substantially related to the protection of public health and safety. See id.; WENDY E. PARMET, POPULATIONS, PUBLIC HEALTH, AND THE LAW 42 (2009) (analyzing public health through a population-based legal analysis). See also PHILLIP STEVENS, INT’L POLICY NETWORK, DISEASES OF POVERTY AND THE 10/90 GAP (Nov. 2004), available at http://www.who.int/intellectualproperty/submissions/InternationalPolicyNetwork.pdf (comparing mortality rate of preventable infectious diseases in low-income versus high-income states). Citizens in third world states might not have access to vaccines or programs in place that require them to get vaccinated, which as result it increases the amount of deaths due to infectious diseases due to the lack of infrastructure to contain the outbreak. STEVENS, supra.


22. See STEVENS, supra note 20, at 8 (finding that the necessary intellectual property rights are owned by companies within high-income states).

23. See Li, supra note 1, at 160 (demonstrating influence Canada and United States exercised to acquire the drug in a favorable price). Vanessa Bradford Kerry & Kelley Lee, infra note 106, at 9 (forcing Bayer to negotiate with Canada for a reasonable price to stockpile Cipro).

24. See Li, supra note 1, at 160.
states is to protect intellectual property rights to prevent misuse of compulsory licenses, instead of the financial barriers to obtaining a patented drug. On the other hand, undeveloped states are primarily concerned with protecting the health of their citizens in case of a public health emergency. Undeveloped states do not possess the bargaining power to influence foreign pharmaceutical companies to provide an affordable price in case of an emergency. Therefore, undeveloped states are often left with compulsory licensing as its strongest bargaining power and solution to a public health emergency.

III. THE EVOLUTION OF THE PRECAUTIONARY APPROACH

The PA received its roots from international environmental protection policy created to address significant and particular harms that are scientifically unjustifiable. Precautionary thinking arguably originated as early as 1875 by Albert Schweitzer. Schweitzer’s early philosophy of the PA was that if a, “[m]an has lost the capacity to foresee and forestall . . . he will end up destroying the earth”. The PA began to gain

---

26 See Cherian, infra note 107, at 43, 49 (comparing Taiwan’s Tamiflu to Canada’s need to stockpile Cipro).
27 Id.
28 See Taiwan to Bypass Roche, Make Tamiflu, infra note 106 (threatening to use compulsory license if negotiation falls through).
29 See Li, supra note 1, at 47 (finding the roots of the PA in environmental protection policies);
EUROPEAN ENV’T AGENCY, LATE LESSONS FROM EARLY WARNINGS THE PRECAUTIONARY PRINCIPLE 1896-2000 (2001), available at http://www.iss.it/binary/saan/cont/Issue_Report_No_22.1127378189.pdf (explaining the evolution of the precautionary principle). “However, the precautionary principle and its application to environmental hazards and their uncertainties only began to emerge as an explicit and coherent concept within environmental science in the 1970s, when German scientists and policy-makers were trying to deal with ‘forest death’ (Waldsterben) and its possible causes, including air pollution.” Id at 13.
31 See EUROPEAN ENV’T AGENCY, supra note 29, at 13 (finding failure to act or foresee future calamities to be destructive).
momentum and popularity in the political agenda only in the 1970’s. In 1992, the PA was given a definition in the U.N. Rio Declaration on Environmental Development that focused on the protection of the environment.

A. Rio Earth Summit

Prior to the Summit, the PA was only incorporated into bilateral international agreements. The use of the PA in international agreements led the United Nations to incorporate this principle into a multilateral treaty that protects the entire environment. Global recognition of the PA occurred at the 1992 Rio Summit. The purpose of Principle 15 was to reverse the notion that states require scientific certainty to use cost-effective measures in addressing certain harms. The purpose of Principle 15 was to

---

32 See id. at 13 (marking 1970 as the year that the PA started to become popular within the political agenda).

33 See LI, supra note 1, at 48 (defining PA in the Rio Summit). “In order to protect the environment, the precautionary approach shall widely be applied by States according to their capacities.” Id. “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 preserve environmental degradation.” Id.

34 See EUROPEAN ENV’T AGENCY, supra note 29, at 13 (understanding correlation between the data collected and impact it causes the environment).

Since the 1970s, the precautionary principle has risen rapidly up the political agenda, and has been incorporated into many international agreements, particularly in the marine environment, where an abundance of ecological data on pollution yielded little understanding but much concern: ‘huge amounts of data are available, but despite these data...we have reached a sort of plateau in our understanding of what that information is for...”

Id. “This is what led to the precautionary principle’ (Marine Pollution Bulletin, 1997).” Id. “More generally, Principle 15 of the UN Rio Declaration on Environment and Development 1992 extended the idea to the whole environment.” Id.

35 See id. The incorporation of the PA into a UN Treaty allowed many countries to be signatories to the agreement versus previous agreements that included mainly countries or institutions that were interested in marine biology. EUROPEAN ENV’T AGENCY, supra note 29, at 13.


37 Jose Maria Ochave, The Precautionary Principle and Modern Biotechnology, NAT’L ACAD. SCIENCE & TECH. 1, 5 (Sept. 8, 2016). See G.A. Res. 151/26, supra note 5, at ¶ 15 (developing the precautionary approach under Principle 15); MEYER, supra note 36, at § 2.2.1 (understanding Rio
reverse the notion that before states use cost effective measures to address certain harms, scientific certainty was necessary.\(^\text{38}\)

**B. International Organizations**

As a matter of public policy, many international organizations started to implement precautionary activities into their legal instruments to “meet the demands of various risks under scientific uncertainty.”\(^\text{39}\) The PA has become a relevant part of public international law because states use the PA as a vehicle to prevent further harm to the environment and human health from activities with scientifically uncertain risks.\(^\text{40}\) Dr. Li demonstrates how organizations like the World Trade Organization can issue sanctions on states that take advantage of precautionary activities for their own benefit and not Declaration and how Cartagena Protocol further develops the precautionary approach). Principle 15 states that “[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities.” G.A. Res. 151/26, supra, at ¶ 15. “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.” Id. \(^\text{38}\) See MEYER, supra note 36, at § 2.2.1 (showing that under the precautionary approach, states can act without scientific certainty).

\(^\text{39}\) See LI, supra note 1, at 51 (demonstrating the PA is solution to significant risk of harm without scientific certainty). Precautionary activities are precautionary measures taken by a state in order to prevent irreparable harm even if harm is not scientifically certain. Id. An example of precautionary activities is invoking a compulsory license, when a state is in the verge of an outbreak. Id. at 160-64 (demonstrating examples of the PA in compulsory license).

\(^\text{40}\) See id. at 51 (describing how the PA started with air pollution registration in Germany); ARIE TROUWBOST, PRECAUTIONARY RIGHTS AND DUTIES OF STATES 7 (Martinus Nijhoff 2006) (explaining prevalence of PA in international law and how it acquired customary international law status). Trouwborst states in her book that:

[T]he precautionary principle is an important general principle of international environmental law. The origins, evolution and statutes of the principle in public international law have been researched at length. States have expressly endorsed the precautionary principle in (or under) at least 58 legally binding agreements and in many dozens of declarations, resolutions, and action programs with a bearing on the environment. In line with developments at the international level, increasing numbers of states are implementing the principle within their domestic jurisdictions. There is, moreover, copious evidence that the precautionary principle, at some point in the past two decades, has attained the status of customary international law.

*Id.* at 6-7.
because of significant threat of harm. The following subsections will describe the international organizations that Dr. Li referred to in her book as being important to the development of the PA.

1. United Nations

The U.N. is responsible for the proliferation of the PA in areas of environment degradation through the use of resolutions that are influential in international law. On a question of human health, Article 25 of the Universal Declaration of Human Rights states, “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care...” This provision established a bases for extending the scope of the PA to expand to human health and food safety. The International Covenant on Economic, Social and Cultural Rights under Article 15.1(c), recognizes a parallel consideration that states can protect intellectual property rights within their borders. The U.N. has proposed that the

---

41 See Li, supra note 1, at 56, 104 (demonstrating that WTO can resolve disputes through dispute settlement system); Introduction to the WTO Dispute Settlement System, infra note 62 (explaining the dispute and settlement system of the WTO).
42 See Li, supra note 1, at 3 (explaining that international organizations can use the PA to further their goals).
43 See id. at 53 (describing best available technologies should be used to minimize significant risks to nature).
44 See G.A. Res. 217 (III) A, Universal Declaration of Human Rights (Dec. 10, 1948) (declaring that every human has the right to health and food). The full language of Article 25 states that:

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.
(2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

Id. at Article 25.
45 See Li, supra note 1, at 6-7 (discussing expansion of PA into new realms).
International Court of Justice ("ICJ") resolve the disputes given the various rights and duties these treaties established.47

2. World Health Organization

The World Health Organization ("WHO") is the main international body that deals with global health concerns.48 The United Nations established the WHO, in 1948, to “ensure the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (the right to health).”49 As the main advocate for the PA, the WHO has embraced a moderate version of precaution by taking into consideration the impact that the PA might have in free trade.50 As a result, WHO created the International Health Regulations ("IHRs") to “regulate the activities of State Parties as they relate to infectious diseases.”51 The WHO established IHRs to prevent the spread of infectious disease by imposing obligations on state signatories to WHO, while minimizing the interference with world trade.52 “The purpose of IHRs is to prevent, protect against,
control and provide a public health response to the international spread of disease... and avoid unnecessary interfaces with international traffic and trade."\(^{53}\)

3. **European Union**

The European Union uses the word “principle” vs. “approach” asserting that the word “principle” encompasses a stronger meaning in the European territory.\(^{54}\) The European Union is the main supporter of the PA and it has implemented this concept in various forms.\(^{55}\) Through Treaties, Directives and Regulations, the European Union expanded the precautionary principle to safeguard human health, environment and food.\(^{56}\)

The Court of First Instance referred to the PA enshrined in Article 130r(2) of the Treaty, \(^{53}\) See id. at 93. “The IHRs vest in State Parties the ‘right to quarantine’, which allows them to take some action to restrict and protect their populations as they see fit, and the WHO is not in a position to uniformly constrain quarantine policy.” Id. “The 2003 SARS outbreak in Singapore provides an example of State Parties’ right to quarantine.” See Li, supra note 1, at 93 (internal citations omitted). “Possible patients were required to report to treatment centres, remain in quarantine with electronic tagging, and destroy all contaminated property.” Id. “All of these above-mentioned measures are adaptive to circumstances in individual states and are deemed acceptable under the IHRs.” Id. “However, every procedure to enforce quarantine inevitably results in compromise of civilians’ human rights to a certain extent. It is therefore required that the health measures need to be ‘not more intrusive to the persons than reasonably available alternatives that would achieve the appropriate level of health protection.’” Id. See also id. at 96 (providing the elements of the PA in the IHRs).

\(^{54}\) See Li, supra note 1, at 56 (finding that the European Union prefers the term principle instead of approach). “The word ‘principle’; instead of ‘approach’ is preferred in order to suggest that the employment of the ‘precaution’ enjoys a stronger assertion in the EU domain than in other areas.” Id.

\(^{55}\) See id. at 56 (adopting PA from the perspective of consumer health in the regulation of food and safety).

\(^{56}\) See id. at 57 (examining the current practice of the precautionary principle in the EU and relevant cases). See also Treaty, BLACK’S LAW DICTIONARY (6th ed. 1991) (defining treaty as an “agreement, league, or contract between two or more nations or sovereigns”). Sources and Scope of European Union Law, EUROPEAN PARLIAMENT (Oct. 1, 2015), http://www.europarl.europa.eu/ftu/pdf/en/FTU_1.2.1.pdf (describing that a regulation automatically applies to every member state). Regulations are of general application meaning that applies to every citizen, member state, and institution of the European Union with the common goal of unifying EU Law into one body. Id. In areas where national law substantially differs from EU law, EU regulations “supersede national incompatible with their substantive provisions.” Id. In contrast to regulations, directives are binding among EU member states, however in order for them to take effect on a national level, “National legislators must adopt a transposing act or ‘national implementing measure’ to transpose directives and bring national law into line with their objectives.” Id. at 3. Under this type of secondary legislative measure, the member state has the power to choose whether they want to be bound by the directive. Id.
Pfizer Animal Health v. Council of the EU and Alpharma Inc. v. Council of the EU, to support its refusal to import animals that had antibiotics in their feed. The Court applied the PA in both cases stating that scientific certainty is not necessary when state action is necessary to protect the health of its citizens. Nevertheless, precautionary measures must be non-discriminatory to international trade and least restrictive measure to trade. In both cases, the European Union only discriminated against animals fed antibiotics, because it could

---

57 See Li, supra note 1, at 59-60 (using case studies to explain how the precautionary approach correctly works). The practice of adding antibiotics to an animals feed to promote growth and eliminate diseases has been prevalent for many years around the world. Id. This practice has been controversial among scientists as some claim that this practice may result in humans becoming resistance to antibiotic through eating the meat, however “no scientific proof of the link between antibiotics concerned and resistance.” Id. “The WHO recommended the immediate or gradual discontinuance of the practice.” Id. (emphasis in original). The producers for these antibiotics brought “actions for annulment of the regulation before the Court of First Instance.” Id. The producers argument was based on the fact that no scientific proof existed to link the antibiotics to resistance. Id. In the contrary, the Court responded by stating that “in cases relating to food safety . . . based on the precautionary principle, Community institutions may take protective measures without having to wait until the reality and seriousness of the risks perceived become fully apparent . . .” Li, supra note 1, at 59-60. Like in Pfizer, the Court in, Alpharma Inc. v. Council of the E.U., Case T-70/99, [2002] E.C.R. II-3499, a case also dealing with antibiotics within an animal feed, found that “while the causal relationship of adding antibiotics to animal feed and the risks of resistance of human antibiotics is not yet established, the PA is employed to legitimize the ban on using several antibiotics as additives in animal feed.” Id. at 61. See also Case T-13/99, Pfizer Animal Health v. Council of the EU, 2002 E.C.R. II-3305 (finding within the Community policy to protect human health and environment according to the PA). “In accordance with Article 130r(2) of the Treaty (now, after amendment, Article 174(2) EC), the precautionary principle is one of the principles on which Community policy on the environment is based.” Id. “The principle also applies where the Community institutions take, in the framework of the common agricultural policy, measures to protect human health.” Id.

It is apparent from Article 130r(1) and (2) of the Treaty that Community policy on the environment is to pursue the objective inter alia of protecting human health, that the policy, which aims at a high level of protection, is based in particular on the precautionary principle and that the requirements of the policy must be integrated into the definition and implementation of other Community policies.

58 See Pfizer, [2002] E.C.R. II-3316 ¶ 15 (stating that it is necessary to take preventive measures in spite of existing scientific uncertainty); Alpharma Inc. v. Council of the E.U., Case T-70/99, [2002] E.C.R. II-3499 ¶ 6 (stating that it is necessary to take preventive measures in spite of existing scientific evidence).

59 See Pfizer, [2002] E.C.R. II-3316 ¶ 15 (stating a difference in treatment between groups must be objectively justified). “[T]here is no equality in illegality, since the principle of non-discrimination does not find an entitlement to the non-discriminatory application of unlawful treatment.” Id.
pose a risk to human health.\textsuperscript{60} Therefore, the European Union properly used precautionary measures to prevent a public health emergency.\textsuperscript{61}

4. World Trade Organization

The WTO is one of the world’s most important international organizations; its successful Dispute Settlement System (“DSS”) allows for winning parties to assert trade sanctions against the losing party.\textsuperscript{62} The WTO is the successor to General Agreement on Tariffs and Trade (“GATT”) and is the principal advocate for the maximization of free-trade given its regulatory dispute resolution rule.\textsuperscript{63} The PA is ambiguously defined in the

\textsuperscript{60} See id. (stating that the human safety interest is great enough to warrant disparate treatment of animals); \textit{Alpharma}, [2002] E.C.R. II-3499 ¶ 6 (stating the policy to protect human health aims at a high level of protection).


\textsuperscript{62} See \textit{Li}, supra note 1, at 104 (stating WTO created rules exempting members from compliance when it comes to protecting human health). See also \textit{Introduction to the WTO Dispute Settling System}, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/dispu_settlement_ebtr_e/c181p1_e.htm (last visited Apr. 17, 2018) (settling dispute systems ensure member states comply with their obligations under the WTO agreement).

Settling disputes in a timely and structured manner is important. It helps to prevent the detrimental effects of unresolved international trade conflicts and to mitigate the imbalances between stronger and weaker players by having their disputes settled on the basis of rules rather than having power determine the outcome. Most people consider the WTO dispute settlement system to be one of the major results of the Uruguay Round. After the entry into force of the WTO Agreement in 1995, the dispute settlement system soon gained practical importance as Members frequently resorted to using this system.

\textit{Id.}

\textsuperscript{63} See \textit{Li}, supra note 1, at 103 (discussing the primary goals of the WTO: promotion of global markets and removing trade restrictions). See also \textit{General Agreement on Tariffs and Trade}, ENCYCLOPEDIA BRITANNICA, https://www.britannica.com/topic/General-Agreement-on-Tariffs-and-Trade (last visited Apr. 17, 2018) (discussing the history of the GATT and how it turned into the WTO). GATT was a multilateral treaty signed by twenty-three countries in 1947 with the goal of reducing or eliminating trade barriers by cutting tariffs to increase global trading. \textit{Id.} GATT’s main contribution to the successful establishment of a free market was the principle of trade without discrimination. \textit{Id.} “Once a country and its largest trading partners had agreed to reduce a tariff, that tariff cut was automatically extended to every other GATT member.” \textit{Id.} This is called the Most Favored Nation clause, and it greatly contributed to non-discriminatory
WTO’s legal instruments. References to protection of human health is found in Article XX of the GATT, the Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS”) Agreement, and the Agreement on Technical Barriers to Trade (“TBT”). The WTO is concerned with human health but are constrained by their main purpose which is to maximize economic growth by eliminating tariffs and trade barriers. By 1993, the GATT had around 125 contracting states that in 1994 succeeded into WTO. See LI, supra note 1, at 103 (noting AP is often only noted as an exception to members’ obligations to the WTO). See also WTO Rules and Environmental Policies: GATT Exceptions, WORLD TRADE ORG., https://www.wto.org/english/tratop-e/envir-e/envir_rules_exceptions_e.htm (last visited Apr. 17, 2018) (stating members can adopt policies inconsistent with GATT if necessary to protect human life).

The Agreement on the Application of Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health standards. It allows countries to set their own standards. But it also says regulations must be based on science. They should be applied only to the extent necessary to protect human, animal or plant life or health. And they should not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.

Id. See also Agreement on Technical Barriers to Trade, WORLD TRADE ORG., https://www.wto.org/english/docs-e/legal_e/17-tbt_e.htm (last visited Apr. 17, 2018) (recognizing countries have the right to establish appropriate protections for human life and health); Technical Trade Barriers to Trade, WORLD TRADE ORG., https://www.wto.org/english/tratop-e/tbt_e/tbt_e.htm (last visited Apr. 17, 2018) (explaining barriers to trade can be created so as to promote trade, and not discriminate).

The Technical Barriers to Trade (“TBT”) Agreement aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognizes WTO members’ right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment.

Id.

See LI, supra note 1, at 104 (describing the WTO’s primary focus which is to promote global free trade). WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat, WTO & WHO at 13 (2002) (describing the WTO’s primary focus of promoting global free trade).
Therefore, regarding non-economic values that affect global trade, such as preserving the environment and human health, the WTO created two types of exemptions from the typical WTO obligations.  

The first exemption involves, “provisions that establish an exception to a rule, which can be referred to as ‘exemption provision.’” This provision is seen as an affirmative defense that has the weakest status in the legal hierarchy of exemptions. The second exemption is known as, “provisions that exclude the application of other provisions, which can be regarded [the] ‘excluding provision,’ is also understood as [recognizing] ‘conditional rights’ that are only valid under certain circumstances.” The conditional rights provision enjoys higher legal status since it is considered as a right instead of a defense. The GATT introduced the PA in legal agreements as a ‘health exception’ provision in the weakest category of exceptions in the legal hierarchy. The SPS Agreement adopted a slightly more favorable view of the PA in their legal agreements by viewing the PA as a ‘conditional right.’ Like the SPS Agreement, the TBT Agreement was created to minimize trade restrictions while recognizing that states have the right to take necessary measures to ensure the protection of health and environment. The TBT

---

67 See Li, supra note 1, at 104-105 (describing the two types of exemptions from WTO obligations).
68 Id. (distinguishing the differences between exception provisions and excluding provisions).
69 Id. at 105 (explaining the legal hierarchy of exemptions from WTO obligations).
70 Id. (elaborating the conditional rights that enjoy a higher legal status than exception provisions).
71 Id. (finding the burden of proof is reversed in an excluding provision).
72 See Li, supra note 1, at 108 (describing the health and security exceptions adopted in order to protect human health). See also WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat, supra note 66, at 30-31 (explaining Article XX of the GATT that deals with the health exception). “Since the inception of GATT . . . Article XX of GATT guarantees the Members’ right to take measures to restrict imports and exports of products when those measures are necessary to protect the health of humans, animals and plants . . .” Id. at 30.
73 See Li, supra note 1, at 118-120 (adopting a SPS view in the asbestos case).
74 See Technical Trade Barriers to Trade, supra note 65, at 1 (comparing the purpose SPS and TBT agreement).
Agreement acts as a regulatory document that assures WTO members are properly using the PA to achieve their objective without disrupting trade.\textsuperscript{75}

\section*{C. Trade-Related Aspects of Intellectual Property Rights \& Doha Declaration}

Trade-Related Aspects of Intellectual Property Rights ("TRIPS") agreement recognized the PA in Article 8 of the treaty.\textsuperscript{76} It was not until the Doha Declaration in 2001 that the TRIPS Agreement provided guidelines for the public health sector.\textsuperscript{77} This convention established guidelines to protect intellectual property rights, while providing members of the WTO with the ability to obtain any medicine necessary to protect human health by invoking the PA.\textsuperscript{78}

The Doha Declaration provides two categories of exceptions to patent rights: "[1.] limited exceptions . . . [and] [2.] other uses without the authorization of the right

\textsuperscript{75} See Agreement on Technical Trade Barriers to Trade, supra note 65, at Article 2 (using precautionary methods that is non-discriminatory to other member states and undisruptive to trade).


\textsuperscript{77} The Doha Declaration Explained, WTO, https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm#trips (last visited Apr. 17, 2018) ("In the declaration, ministers stress that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines."). "They refer to their separate declaration on this subject." \textit{Id.} "This separate declaration on TRIPS and public health is designed to respond to concerns about the possible implications of the TRIPS Agreement for access to medicines." \textit{Id.} "It emphasizes that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health." \textit{Id.} "It affirms governments’ right to use the agreement’s flexibilities in order to avoid any reticence the governments may feel." \textit{Id.} "The separate declaration clarifies some of the forms of flexibility available, in particular compulsory licensing and parallel importing." \textit{Id.} See Chapter 24 Trade-Related Aspects of Intellectual Property Rights, supra note 76, at 24.14 – 24.15 (applying the precautionary approach to patented medicine).

\textsuperscript{78} WTO, supra note 77 (summarizes the DOHA and highlights the impact on intellectual property rights).
holder which cover compulsory licenses and government use.” Furthermore, the Agreement provides that its Members may use their discretionary judgment to invoke a compulsory license as such use can be challenged by the intellectual rights holder. As a result, if the WTO’s Dispute Settlement System rules that the Member State’s use of the compulsory license was inappropriate the consequence would be trade retaliation.

79. See Chapter 24 Trade-Related Aspects of Intellectual Property Rights, supra note 76, at 24.1 (detailing the two exceptions to patent rights). Limited exception is one of the permissible exceptions which states that:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30). The exception is thus subject to a variation of the “three-step test” referred to in the copyright section above.

Id. at 24.13. The other exception provided entails:

Compulsory licensing, including government use without the authorization of the right holder, are allowed without limitation as to grounds but subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licences [sic] only if an unsuccessful attempt has been made to acquire a voluntary licence [sic] on reasonable terms and conditions within a reasonable period of time; to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence [sic]; and that decisions be subject to judicial or other independent review by a distinct higher authority. Members may relax certain of these conditions in cases of emergency and public non-commercial use and where compulsory licences [sic] are employed to remedy practices that have been established as anticompetitive by a legal process. See also the section on TRIPS and Public Health below.

Id. at 24.13.

80. See id. at 24.15 (highlighting that the TRIPS Agreement increased the discretionary powers of the members).

81. See Id., supra note 1, at 41 (explaining how developing countries hesitate to use compulsory licensing for fear of retaliation).
D. Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety ("CPB") was the first international legal instrument to apply the PA by linking free trade with environmental protection. CPB is a response to uncertainty genetic modified organisms ("GMO") brought to trade channels as conflicts emerged with respect to labeling and regulating GMO products, since GMOs may pose harm to human health. As a result, the CPB was designed to regulate modern biotechnology products due to the possible effects of such products on human health and the environment. CPB used the PA along with international law to create an effective framework that takes into consideration precautionary activities with cost-benefit considerations. For example, the health risks modern biotechnology poses are scientifically uncertain, therefore states have the right to use a certain level of precaution to educate consumers regarding the content of the products they consume. At the same

82 See id. at 100 (explaining CPB provides regulatory framework for free trade and environmental protection); MEYER, supra note 36 (exploring the contributions that the Cartagena Protocol has made to the precautionary approach); Cartagena Protocol on Biosafety to the Convention on Biological Diversity, SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY (2000), https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.

83 See LI, supra note 1, at 100; GMO Facts, NON-GMO PROJECT, https://www.nongmoproject.org/gmo-facts/ (last visited Apr. 17, 2018) (defining genetically modified organisms as living organisms that have been modified in a lab).

84 See LI, supra note 1, at 100 (exemplifying CPB purpose in protecting biological diversity from potential risks of living modified organisms). See also Kevin Keener et al., Biotechnology and its Applications, N. C. COOPERATIVE EXTENSION SERV.—N. C. ST. U. 3,4, https://fams.ncsu.edu//extension_program/documents/biotech_applications.pdf (last visited Apr. 17, 2018) (explaining the differences between biotechnology and modern biotechnology). Modern Biotechnology emerged after the discovery of DNA. Id. Scientists learned that "[g]enetic engineering is the technique of removing, modifying, or adding genes to a DNA molecule in order to change the information it contains." Id. Through the modifications and splicing of genetic materials farmers are able to purchase genetic modified seeds that give them a better yield in a particular crop. Id. Furthermore, genetic engineering can change the DNA composition of a living organism to achieve specific goals for that organism particular use, for example producing a crop that diverts common pests or like the Burbank potato producing a potato that will be easier to fry. Id.

85 See LI, supra note 1, at 100 ("Cartagena Protocol arises to provide a regulatory framework for the international trading of biotechnology products.").

86 See id. (explaining scientific uncertainty to GMOs but precaution should be taking to label products).
time, states should be mindful of benefits that modern biotechnology introduced to society, especially the expansion of farmers’ production capabilities.\(^7\) Thus under the CPB, precautionary activities used should not interfere with the development and trade of modern biotechnology products, but such activities may regulate to inform consumers that a product contains GMOs.\(^8\)

**IV. THE INTERSECTION OF WORLD TRADE, INTELLECTUAL PROPERTY, AND HEALTH**

Dr. Li uses many case studies to demonstrate various uses of the PA related to the intersection of health, trade and intellectual property.\(^9\) The right to health and the right to intellectual property create entitlements that many international organizations have attempted to address these conflicts through multilateral treaties.\(^9\) The opposing priorities for either protection of trade or health have increased with evolved technology and the exponential expansion of free trade.\(^9\) Dr. Li explains that the PA developed

---

\(^7\) See Keener, *supra* note 84, at 3 (promoting modern biotechnology by explaining how genetic engineering occurs and its benefits). “Modern biotechnology has offered opportunities to produce more nutritious and better tasting foods, higher crop yields and plants that are naturally protected from disease and insects.” *Id.*

\(^8\) See Li, *supra* note 1, at 108 (explaining WTO members left with sufficient space to employ precautionary measures through health and security exceptions).

\(^9\) See *id.* at 9 (demonstrating the trade, health, and technology intersect when dealing with compulsory licensing). *See also Contra WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat, supra* note 66, at 13 (arguing that trade restrictions used for infectious disease do not conflict with WTO rules).

\(^9\) See Li, *supra* note 1, at 9 (discussing the goals and principles of the WHO and the WTO). The goal of the WHO is to “ensure the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,” whereas the WTO’s principles stress the movement of good and IP protections. *Id.*

\(^9\) See *id.* at 9 (discussing the clash between the two organizations). There are situations where the organizations can be on the same side, such as the seizure of generic medicines causing unnecessary barriers to free trade. *Id.* It is more common for the organizations to oppose each other, for example when the WHO opposed the WTO in response to the H1N1 outbreak in 2009. *Id.*
through the clash of these two rights, where disputes and settlements have molded the scope and limit of the PA.92

A. Proper Use of the Precautionary Approach

1. Brazil – HIV

The public health system in Brazil was not only overwhelmed by the vast outbreak of HIV/AIDS in the mid-1990’s, but most importantly, it lacked the necessary funds to provide every contaminated citizen with a free drug to fight HIV.93 Through precautionary activities, the Brazilian authorities reversed engineered the HIV/AIDS drug to manufacture a generic version that was accessible to everyone in Brazil affected by the disease.94 The Brazilian government was very successful with its AIDS program; however,

92 See id. at 6-9 (discussing domestic constitutional rights to both health and IP and the rights individually).

HIV stands for human immunodeficiency virus. It is the virus that can lead to acquired immunodeficiency syndrome or AIDS if not treated. Unlike some other viruses, the human body can’t get rid of HIV completely, even with treatment. So once you get HIV, you have it for life. HIV attacks the body’s immune system, specifically the CD4 cells (T cells), which help the immune system fight off infections. Untreated, HIV reduces the number of CD4 cells (T cells) in the body, making the person more likely to get other infections or infection-related cancers. Over time, HIV can destroy so many of these cells that the body can’t fight off infections and disease. These opportunistic infections or cancers take advantage of a very weak immune system and signal that the person has AIDS, the last stage of HIV infection.

Id.

Brazil’s actions violated its’ obligations under the WTO and TRIPS agreement, “because it discriminated against locally made and imported products.”95 In 2001, the United States filed a complaint with the WTO Dispute and Settlement Body to reprimand Brazil’s infringement of Article 68.96 The United States was forced to withdraw the case six months due to vast international criticism.97

2. European Community - Asbestos

France was concerned with unknown effects that the exposure to asbestos in construction products posed to the public health.98 In 1996, France invoked GATT

95 See Li, supra note 1, at 16 (discussing manufacturing of generic drugs and how that violated the TRIPS agreement). “US officially filed a complaint to the WTO Dispute Settlement Body against Brazil’s Intellectual Property Law (IPL) Article 68, which allows compulsory licenses to be issued in situations where the patent holder does not locally manufacture the patent product (known as a ‘local working’ provision).” Id. “The US argued that this provision was a breach of Articles 27 and 28 of TRIPS because it discriminated against locally made and imported products.” Id.

96 See Li, supra note 1, at 16 (“[A]llow[ing] compulsory licenses to be issued in situations where the patent holder does not manufacture the patented product . . .”). The provision in Article 68 is known as the “local working” provision. Id. Discussing Article 68’s breach of TRIPS because of the discrimination of “locally made and imported products”. Id.


98 See Li, supra note 1, at 110 (stating that France’s leaders enacted laws to prevent importation of such products). See also European Communities-Asbestos, WORLD TRADE ORG., https://www.wto.org/english/tratop_e/dispu_e/cases_e/1pagesum_e/ds135sum_e.pdf (last visited Apr. 17, 2018) (outlining the dispute regarding asbestos products imported into the European Union). See also Learn About Asbestos, EPA, https://www.epa.gov/asbestos/learn-about-asbestos (last updated Nov 6, 2017) (educating people as to what is asbestos and the harms it can cause humans).

Asbestos fibers may be released into the air by the disturbance of asbestos-containing material during product use, demolition work, building or home maintenance, repair, and remodeling. In general, exposure may occur only when the asbestos-containing material is disturbed or damaged in some way to release particles and fibers into the air.

Id. “Three of the major health effects associated with asbestos exposure are: lung cancer [3] mesothelioma, a rare form of cancer that is found in the thin lining of the lung, chest and the
Article XX (b) to ban the importation and sale of products containing asbestos from Canada. In 1998, Canada filed a complaint arguing that its asbestos containing products were similar to France’s substitute products and that domestic products should not receive favored treatment. The Appellate Body found that France’s ban on asbestos products was proper under Article XX (b) GATT, and that decision serves as an example of how the PA can be sustained by WTO law. France took action when science was still uncertain and the Panel stated that France’s ban was legitimate as science subsequently proved the horrible harms of asbestos exposure.

3. **Taiwan**

In 2005, the WHO warned the world that an outbreak of H5N1, commonly known as bird flu, might occur in the Spring of that year. The WHO recommended abdomen and heart; and asbestosis, a serious progressive, long-term, non-cancer disease of the lungs.

---

99 Id., supra note 1, at 110.
100 See id. (elaborating on Canada’s rationalization for justifying domestic products not receiving favorable treatment).
101 See id. at 110 (developing the asbestos case in France in accordance with the Precautionary Approach). “The Appellate Body also referred to various factors in the weighting and balancing process: ‘contribution of the measure to the realization of the value pursued’ and ‘importance of the value pursued.’” Id. See also Appellate Body, WORLD TRADE ORG., https://www.wto.org/english/tratop-e/dispu-e/appellate-body-e.htm (last visited Apr. 29, 2018) (defining the purpose of the Appellate Body within the WTO). The Appellate Body was established in 1995 under Article 17 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU). It is a standing body of seven persons that hears appeals from reports issued by panels in disputes brought by WTO Members. The Appellate Body can uphold, modify or reverse the legal findings and conclusions of a panel, and Appellate Body Reports, once adopted by the Dispute Settlement Body (DSB), must be accepted by the parties to the dispute.

102 Id., supra note 1, at 110.
103 Id. at 160. See Influenza, WORLD HEALTH ORG., http://www.who.int/influenza/human_animal_interface/avian_influenza/h5n1_research/faqs/en/ (last visited Apr. 17, 2018) (describing H5N1 to be a type of influenza that emerged out of birds). “H5N1 is a type of influenza virus that causes a highly infectious, severe respiratory disease in birds called avian influenza (or ‘bird flu.’)” Id. See also Influenza (Avian and other zoonotic),
that states stockpile on an antiviral drug, Tamiflu – Oseltamivir – that is manufactured and patented by Roche. Roche is a small single manufacturer that was not able to produce the amount needed by the global market. Taiwan’s Department of Health attempted to negotiate with Roche to ensure that its citizens would have access to this vital drug. After negotiations with Roche failed, Taiwan filed a compulsory licensing application with the Taiwan Intellectual Property Office. Eventually, Taiwan did not suffer from a bird flu outbreak like its neighbors and its use of the compulsory license was highly criticized as not being legitimate. Taiwan government officials firmly believed that bird flu outbreak constituted a national emergency. The absence of a disease outbreak, however, is not sufficient grounds to call into question the legitimacy of Taiwan’s actions in obtaining a compulsory license.


LI, supra note 1, at 161.

See LI, supra note 1, at 161 (discussing Taiwan’s unsuccessful negotiations with Roche). See also Jessie Ho, Taiwan to bypass Roche, make Tamiflu, TAIPEI TIMES (Nov. 26, 2005), http://www.taipeitimes.com/News/front/archives/2005/11/26/2003281793 (attempting to stockpile Tamiflu amid the anticipation of an avian flu outbreak); Vanessa Bradford Kerry & Kelley Lee, TRIPS, the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines?, 3:3 GLOBALIZATION & HEALTH 4 (2007) (finding ways to ensure that Taiwan would have sufficient Tamiflu for the outbreak).

See LI, supra note 1, at 161 (explaining Taiwan’s actions in declaring a national health threat to trigger a compulsory license). See also Neil George Cherian, Using Compulsory License to Access Pharmaceuticals: A Cross Case Analysis on Outcome, DEPT OF HEALTH MANAGEMENT & HEALTH ECON. 42 (2016) (explaining the Taiwan conundrum and how they used compulsory license to stockpile Tamiflu).

See LI, supra note 1, at 161 (discussing the scrutiny required for compulsory licenses in terms of actual threats).

See Cherian, supra note 107, at 42-44 (legitimizing compulsory license to stockpile sufficient drugs in the verge of an avian flu outbreak).

See LI, supra note 1, at 161 (discussing the Department of Health’s warning and insistence that the compulsory license was legitimate).
B. Misuse of the Precautionary Approach

1. Brazil – Retreaded Tyres Ban

Brazil banned imports of retreaded tires from the European Union claiming that it was justified by GATT Article XX (b). Brazil argued the ban was necessary to reduce public health risks as tires waste fuels mosquito-borne diseases such as dengue and releases poisonous chemicals into the environment. The European Union challenged Brazil’s ban claiming that it was discriminatory without “well-known and life-threatening health risks,” linked to retreaded tires. Furthermore, the European Union argued that Brazil’s main motive for the ban was to protect its domestic industry as Brazil still

112 See Li, supra note 1, at 111 (claiming it was for the purpose of reducing public health risks); Brazil-Retreaded Tyres, WTO DISPUTE AND SETTLEMENT, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds332sum_e.pdf (last visited Apr. 17, 2018) (outlining the dispute regarding retreated tyres that was imported into Brazil from the European Union).
113 See Li, supra note 1, at 111. See also Dengue and Severe Dengue, WORLD HEALTH ORG., http://www.who.int/mediacentre/factsheets/fs117/en/ (last updated Apr. 2017) (educating individuals about dengue and its severe effects).

Dengue is a mosquito-borne viral disease that has rapidly spread in all regions of WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species Aedes aegypti and, to a lesser extent, Ae. albopictus. This mosquito also transmits chikungunya, yellow fever and Zika infection. Dengue is widespread throughout the tropics, with local variations in risk influenced by rainfall, temperature and unplanned rapid urbanization. Severe dengue (also known as Dengue Haemorrhagic Fever) was first recognized in the 1950s during dengue epidemics in the Philippines and Thailand. Today, severe dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions.

Id. Dengue has become a huge concern to the WHO due to the severe effects that the virus has had on the population of people in tropical countries and the fact that there is no specific treatment for the dengue fever. Id.
114 See Li, supra note 1, at 111 (challenging the validity of Brazil’s ban). See also Brazil-Retreaded Tyres, supra note 112, at 137 (summarizing the dispute between the EU and Brazil).
imported used tires for local retreading industries. The Appellate Body and Panel determined that while the ban was necessary to protect human health and the environment, the ban contradicted Brazil’s import of used tires for the local tires retreading industries. As a result, the Appellate Body and Panel concluded that “the ban [failed] to meet the requirements of the Chapeau in the GATT XX (b) and constituted arbitrary or unjustifiable discrimination,” because Brazil trading with discrimination.

2. Thailand

Thailand is the first country that has tested the scope of compulsory licensing of medications that deal with chronic disease. In 2007, Thailand permitted the manufacturing of a patented drug for heart disease, Plavix – clopidogrel bisulphate – through compulsory licensing. A compulsory license is properly invoked either by a public non-commercial use or national emergency. After negotiations with pharmaceuticals firms fell through, Thailand granted a compulsory license to manufacture generic drugs claiming non-commercial use. Thailand stated that its grant of a compulsory license was legitimate as the drug was for public non-commercial use.

115 See Li, supra note 1, at 111 (arguing that the ban was needed to protect Brazilians from dengue). See also Brazil-Retreated Tyres, supra note 112, at 137 (arguing the Brazil is inconsistent with its protective measures).
116 See Brazil-Retreated Tyres, supra note 112, at 137 (outlining the findings of the Appellate Body and Panel on Brazil’s retreaded tyre ban and why it is unjustified).
117 Li, supra note 1, at 111, 112 (findings on validity of Brazil’s ban). See also Brazil-Retreated Tyres, supra note 112, at 137 (complying with findings by Panel). See supra text accompanying notes 16-17.
118 See Li, supra note 1, at 162 (describing Thailand’s imposed regulations). See also Cherian, supra note 107, at 19 (claiming that Thailand’s use of compulsory license did not constitute a health emergency).
119 See Li, supra note 1, at 162 (aiding in the development of quick and life-saving patent products). See Vanessa Bradford Kerry & Kelley Lcc, supra note 106, at 4 (questioning the legitimacy of the Thailand’s compulsory license of the Plavix drug).
120 See Li, supra note 1, at 162.
121 See Cherian, supra note 107, at 18-19 (negotiating discount prices for patented drugs).
122 See Li, supra note 1, at 162 (receiving some support towards compulsory licensing for chronic diseases). See also Cherian, supra note 107, at 18, 19 (arguing legitimate use of compulsory license).
Furthermore, TRIPS 31(b) provides that a state invoking non-commercial use of the compulsory license is not required to negotiate prior the grant of a compulsory license and “this provision only obliged the government to inform[] the patentee promptly.” Li explains that Thailand was met with major criticism for the compulsory license for Plavix as it was “overstepping the appropriate application of compulsory licensing.” As a consequence of Thailand’s misuse of the compulsory licensing, Abbott Laboratories, the patent owner, refused to market any other drug in Thailand and withdrew seven new pharmaceutical products. Furthermore, Thailand suffered trade sanctions and retaliation for misusing compulsory licensing.

C. Proposed Solution by Li

The solution that the author, Phoebe Li, proposes is:

[T]o redefine compulsory licensing through the lens of precaution and also to create the legal status of the PA in compulsory licensing . . . It is argued in this book that the PA can serve as a tool for reconciling the discrepancies between the WHO and the WTO agendas, and for harmonizing the domestic policy-making of legal preparedness in a public health emergency.

Using precautionary activities to redefine compulsory licensing in the TRIPS agreement will encourage states to appropriately use compulsory licenses without fear of trade retaliation as this approach balances the agendas of the WTO and WHO.


124 See Li, supra note 1, at 162.

125 See id. (explaining consequences of using compulsory license for instances that are not considered an immediate emergency); Cherian, supra note 107, at 22 (withdrawing new products in response to Thailand’s misuse of compulsory licensing).

126 See Li, supra note 1, at 162 (finding trade retaliation can be effective when compulsory license is misused); Cherian, supra note 107, at 22 (showing Thailand received retaliation for its improper use of compulsory license).

127 See Li, supra note 1, at 42 (proposing an effective solution that balances the clashing interests of the WTO and WHO).

128 See id. at 185 (removing fear from countries that legitimately need to use compulsory license).
Compulsory licensing is the vehicle that harmonizes the interests of promoting public health by allowing “provisional limitation[s] to IP,” while advancing trade. Policy-makers can tailor the agreements to protect patents in which infringement is the last resort and only used by states in the event of an immediate emergency. Li also covers the issue of differential treatment under WTO regime in the context of compulsory licensing of pharmaceutical patents. Li proposes that if the differential treatment is deemed to be legitimate “based upon the rationale of risk management and the PA, health technologies associated with significant risk to human life or health may receive differential treatment in the IP regime.” Li divides the elements of the PA in compulsory licensing into four categories: (1) the trigger threshold, (2) the action, (3) duty to review, and (4) other non-scientific facts.

1. The Trigger Threshold

Li uses the pandemic virus to illustrate the operation of the proposal. Li divides the trigger threshold of the precaution in six phases of pandemic alert: (1) Uncertain: no animal influenza virus reported to cause human infection, (2) Uncertain: an animal influenza virus known to have caused human infection, (3) Uncertain: an animal or human/animal influenza virus has caused sporadic cases or small clusters of diseases in

---

129 See id. at 186 (protecting trade and health as compulsory licenses can only be used as a last resort); Vanessa Bradford Kerry & Kelley Lee, supra note 106, at 2, 3 (limiting IP rights for a period of time allows poor countries to have access to generic drugs).
130 See Li, supra note 1, at 186 (finding policy-makers can tailor agreements encouraging compulsory licenses only to be used for legitimate reasons); WTO Agreements & Public Health: A Joint Study by the WHO and the WTO Secretariat, supra note 66, at 57 (stating that governments have the power to address issues of access and price of drugs).
131 See Li, supra note 1, at 173 (explaining differential treatment in the context of compulsory licensing of pharmaceutical patents); supra notes 16-17 and accompanying text.
132 See Li, supra note 1, at 186 (finding differential treatment should be excused in the context of compulsory licensing).
133 See id. (dividing elements of the PA in the realm of compulsory licensing into four categories).
134 See id. at 174 (explaining how to apply PA to public health through pandemic virus).
people, but no human-to-human transmission, (4) Medium to high: human-to-human transmission of an influenza virus able to sustain community-level outbreak, (5) High to certain: the same virus as caused sustained community-level outbreaks in countries in at least one WHO region, and (6) Pandemic in progress: in addition to the criteria defined in Phase 5, the same virus has caused sustained community-level outbreaks in at least one other country in another WHO region. Under precautionary thinking the PA may be invoked “when the threat of harm passes the ‘significant threshold.’”

In consideration of the adverse economic effects to the patent holder when a compulsory license is invoked as a precaution, Li suggests that the invocation of a compulsory license should be between phases 4 and 5. Li states that “Phases 4 and 5 of the WHO’s pandemic phases [is] when the risk [passes] the ‘significant threshold’, and should be based on risk assessment or available, pertinent information.”

2. The Granting of a Compulsory License as a Precautionary Action

The PA under WTO law in the grant of a compulsory license is viewed as a conditional right endowed to signatory states that can be invoked if they are faced with a public health emergency. A compulsory license cannot have the effect of restricting

---

135 See id. at 174, 175 (describing the six phases of pandemic alert for the influenza). “The PA is suggested to be invoked when the threat of harm passes a ‘significant’ threshold.” Id. The trigger threshold is simply the phase of the pandemic alert in which the harm has reached a significant threshold in which the PA should be invoked. Id. at 175.

136 See Li, supra note 1, at 174 (discussing the trigger threshold for a pandemic alert). “[T]he application of the PA should be based on uncertain risks which are real and tangible rather than hypothetical, minor, or trivial.” Id.

137 See id. at 186 (asserting the PA should be significant for a compulsory license to be invoked). “[T]he precautionary granting of a compulsory license is a state’s conditional right in WTO, but it still has to be least restrictive to international trade.” Id. “In other words, it should be used as a last resort; there should be no other available alternatives to relieve a state’s burden of disease.” Id.

138 See id. (shifting burden of proof to complaining party to prove emergency does not exist). “The precautionary grant of the compulsory license should be presumed legitimate unless the complaining party proves otherwise.” Id.
international trade; as a result, a Member State of the WTO should only invoke a compulsory license as the last resort to “relieve [the] state’s burden of disease.”

3. Duty to Review

The State that obtains a legitimate compulsory license has the duty continually to review the risk that the emergency poses on the health of its citizens. In addition, the State must abolish the grant when the emergency is no longer identified as a significant threat to human health.

4. Other Non-scientific Factors

When granting a compulsory license the PA should be conscious of public engagement in a public health emergency. Specifically, the general public should be informed of the "scope of pharmaceutical patent" before an outbreak because the public are the ultimate drug consumers. Patent owners enjoy a monopoly over the patented drug for twenty years. The author argues that the non-competitive use of the patented drugs creates a difference between pharmaceutical patents versus other patents and as a result it should be treated different. As a result of having “a precautionary track for compulsory licensing of pharmaceutical patents” must be treated differently in the international trade market by having an exception for the laws of discrimination in the

---

139 See Li, supra note 1, at 186. The precautionary granting of a compulsory license is a state’s conditional right in the WTO. Id.
140 See id. (abolishing the grant after the risk has been identified as non-significant).
141 See id. (suggesting state’s duty to review suggests abolishment when risk is decided to be non-apparent).
142 See id. at 181, 186 (promoting importance of policy-making in democratic society).
143 See id. at 181-82 (suggesting that given limited time constraints communication to public must be preemptive).
144 See 35 U.S.C. § 154(a)(2). The statute provides that utility patents have a term of 20 years. Id.
145 See Li, supra note 1, at 182 (explaining that patients have a necessary prerequisite for purchasing products which differentiates them from others).
WTO. The public can participate in case a dispute arises over the grant of a compulsory license in a public health emergency. WTO Members can participate as parties or third parties by submitting amicus briefs to the WTO Dispute Settlement System. Li proposes “the precautionary grant of a compulsory license should be presumed legitimate unless the complaining party proves otherwise.”

V. ANALYSIS: THE INEFFECTIVENESS OF THE PRECAUTIONARY APPROACH IN LESS DEVELOPED STATES

Modern health technologies have enhanced the quality of human health through the development of pharmaceutical drugs that can combat a deadly outbreak. Yet, the cost of patented drugs can be expensive as the patent owner has a monopoly over the drug for twenty years. Alternatively, the company might not be large enough to supply a world on the verge of an epidemic, as was the case with Roche in Taiwan. Viewed through the lens of trade law, compulsory license that grants access to a patented drug, should be used as a last resort and must be the least restrictive measure. Li’s proposed

---

146 See id. (detailing how separating medical patents from other patents resulted in different international trade regulations).
147 See id. at 184 (discussing legal rights of WTO Members to participate through submission of amicus briefs).
148 See id. An amicus brief can be a document or simply a letter to the DSB. Id. Both WTO Members and non-Members could submit amicus curiae briefs to the DSB. Id.
149 See id. at 186. The granting of a compulsory license is a state’s conditional right, but it still must be the least restrictive to international trade. See Li, supra note 1, at 186.
150 See Alyson Krueger, 6 Ways Technology is Improving Healthcare, BUS. INSIDER (Dec. 20, 2010), http://www.businessinsider.com/6-ways-technology-is-improving-healthcare-2010-12?op=1/#the-internet-has-become-a-main-source-of-medical-information-1 (concluding that modern technology will improve the healthcare system and quality of life).
152 See Li, supra note 1, at 161 (describing WHO’s recommendation to stockpile antiviral in response to avian flu pandemic alert); Cherian, supra note 107, at 42 (explaining that Roche was unable to stockpile Taiwan with Tamiflu).
153 See Li, supra note 1, at 173 (achieving “appropriate level of public health protection while avoiding unnecessary interference to the international trade”).
solution is effective as it applies the PA to compulsory license to harmonize interests of the WTO and WHO.\(^{154}\)

The PA is a balancing test that weighs health rights against economic rights.\(^{155}\) The issue with Li’s proposed solution is that the invocation of precaution at Phases 4 to 5 might not be effective in less developed states.\(^{156}\) The author proposes late invocation of the PA in compulsory licensing is due to the uncertainty that the pandemic outbreak will occur in Phases 1 through 3.\(^{157}\) Because lack of adequate health care professionals and health care delivery systems, it might be too late to invoke a compulsory licenses in Phase 4 to 5 in undeveloped states.\(^{158}\) Controlling a viral outbreak is much easier before it becomes an epidemic and doing so prevents the outbreak from reaching a global scale.\(^{159}\) In addition to controlling the outbreak in an earlier phase, granting the PA earlier would also slow down the spread of the virus globally. Thus, considering the shortage of resources in undeveloped states invoking the PA at Phase 3 would save lives in both developing and more developed states lives.\(^{160}\)

\(^{154}\) See id. at 42 (“[R]edefin[ing] compulsory licensing through the lens of precaution.”). “I propose to redefine compulsory licensing through the lens of precaution and also to create the legal status of the PA in compulsory licensing . . . .” Id. “It is argued in this book that the PA can serve as a tool for reconciling the discrepancies between the WHO and the WTO agendas, and for harmonizing the domestic policy-making of legal preparedness in a public health emergency.” Id.

\(^{155}\) See id. at 196 (describing purpose of PA approach).

\(^{156}\) See id. at 174-75 (highlighting Dr. Li’s proposed variation to PA test).

\(^{157}\) See Li, supra note 1, at 175 (preparing at Phase 3 might be crucial in developing countries). “Specifically, from Phase 3 of a pandemic alert period onwards, the major objective regarding antiviral drugs is to coordinate positioning of a possible global stockpile . . . .” Id.

\(^{158}\) See id. at 175 (explaining the medium to high risk to certain phases for the probability of pandemic).

\(^{159}\) See id. (explaining human to human interaction and community level outbreaks in phase 3 and 4).

\(^{160}\) See id. Directing resources to undeveloped states will save lives because the outbreak has not reached human to human transmission of an influenza virus. Id.
A. The Invocation of the Precautionary Approach at Phases 4 to 5 Might be Too Late for Less Developed States

Li’s solution needs to take into account the economic differences between developed and less developed states. Less developed states should invoke precautionary measures at Phase 3 where, “an animal or human/animal influenza virus has caused sporadic case or small cluster of disease in people, but no human-to-human transmission.” Many undeveloped states have serious problems with a lack of sanitation and clean water which increases the transmission of diseases and possibility of an outbreak.

For example, in 2010, during the cholera outbreak in Haiti, if a generic drug and treatment had been provided at Phase 3, which is the onset of the outbreak, many deaths could have been prevented. Therefore, the amount of death caused by the pandemic in less developed states could be diminished if precautionary measures take place at an earlier Phase, especially since diseases tend to spread faster in places with poor sanitation and unfiltered water. Likewise, the Ebola outbreak of 2014 in West Africa is another example of why the precautionary measures should be invoked at Phase 3 in undeveloped states. Ebola is an infectious disease easily spread to others through contact with bodily

161 See Li, supra note 1, at 42 (explaining the author’s solution). “I propose to redefine compulsory licensing through the lens of precaution and also to create the legal status of the PA in compulsory licensing in Chapter 6.” Id.
162 See id. at 175 (explaining the trigger threshold of the PA in phase of pandemic alert).
165 Ebola Virus Infection, WEBMD, https://www.webmd.com/a-to-z-guides/ebola-fever-virus-infection (last visited Apr. 17, 2018) (explaining that Ebola is a deadly virus that causes internal bleeding). “Ebola is a rare but deadly virus that causes fever, body aches, and diarrhea, and sometimes bleeding inside and outside the body.” Id. “As the virus spreads through the body, it damages the immune system and organs . . . [causing] levels of blood-clotting cells to drop . . . [which leads] to severe, uncontrollable bleeding.” Id. See Anna Roca et al., Ebola: A Holistic Approach is Required to Achieve Effective Management and Control, 135(4) J. OF ALLERGY AND
fluids.\textsuperscript{165} As a result, prompt diagnosis of infected individuals is critical to contain the disease effectively and even prevent death.\textsuperscript{166} Ebola outbreaks are typically more prominent in African countries considered to be less developed.\textsuperscript{167} Given the high mortality rate for this particular disease, containing the outbreak at Phase 3 would be more efficient than waiting for Phase 4 in which the virus is able to sustain a community-level outbreak.\textsuperscript{168}

Therefore, the PA in less developed states should be invoked at Phase 3 to ensure that necessary measures of precaution are efficiently taken to preserve human health. The use of a compulsory license at Phase 3 should be carefully monitored to balance containing an outbreak with measures that are least disruptive to trade. Governments that invoke precautionary measures at an earlier stage should be diligent and should constantly revise the legitimacy of the license to immediately revoke it after the public health emergency has ended.\textsuperscript{169} Moreover, countries that misuse the granting of a compulsory license in Phase 3 should be subject to trade retaliation and sanctions, like Thailand when they used compulsory license for chronic diseases that was not an irreversible threat of harm.


\textsuperscript{166} See \textit{Roca}, supra note 165, at 860 (describing efforts to shorten the time for diagnoses in order to treat patients quickly).

\textsuperscript{167} See \textit{Roca}, supra note 165 (allowing virus to spread too far is harder to control due to the mortality rate).

\textsuperscript{168} See \textit{Li}, supra note 1, at 175 (expanding need for precaution in a public health emergency even without scientific reason).
B. The Precautionary Approach at Phases 4 to 5 in Developed States is Reasonable Considering Infrastructure and Wealth

Li’s proposed solution is adequate for developed states as they have the health care delivery infrastructure to manage an outbreak and the economic means to negotiate with the patent owner.\textsuperscript{171} For example, in the early 2000s, the United States and Canada were “threatened with a terrorist attack of a particular strain of anthrax” that was resistant to common antibiotics.\textsuperscript{172} This particular strain of anthrax was believed to be treated with Cipro – ciprofloxacin – a patented drug made by Bayer Inc., a German company.\textsuperscript{173} Bayer did not have the necessary amount of Cipro stockpiled to meet the demand for two years.\textsuperscript{174} Canada was on the verge of granting a compulsory license to create a generic version of the drug, but conflict ended with a mutual agreement between the parties, with Bayer promising a price reduction of the drug.\textsuperscript{175} The price reduction allowed Canada to afford stockpiling Cipro and permitted Bayer to ensure that production would meet the demand.\textsuperscript{176} This resolution demonstrates that developed states not only have the health care delivery infrastructure, but they possess bargaining power to persuade a company to

\begin{flushright}
\textsuperscript{171} See \textit{id.} at 160 (using compulsory licensing for manufacture of generic drugs to cope with potential outbreaks); see also Indur M. Goklany, \textit{Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment} 24 (2001) (making the correlation between wealth and new technological developments).

\textsuperscript{172} See Li, \textit{supra} note 1, at 160 (negotiating allowed U.S. and Canada to prepare for a believed public health emergency).

\textsuperscript{173} See \textit{id.} (using example of disease threats requiring needing medicines held as patented drugs).

\textsuperscript{174} See \textit{id.} (discussing both the US and Canada’s consideration of issuing a compulsory license to the due to the treat of anthrax). \textit{See also} Vanessa Bradford Kerry & Kelcey Lee, \textit{supra} note 106, at 9 (forcing Bayer to negotiate with Canada for a reasonable price to stockpile Cipro).

\textsuperscript{175} See Li, \textit{supra} note 1, at 160 (discussing the non-issuance of a compulsory license when Bayer reduced their prices) \textit{See also} Cherian, \textit{supra} note 107, at 43, 49 (comparing Taiwan’s Tamiflu to Canada’s need to stockpile Cipro).

\textsuperscript{176} See generally Li, \textit{supra} note 1, at 160 (finding reduction in price prevented Canada to use compulsory license).
\end{flushright}
enter into a favorable agreement, because of their political power and influence in the world.\footnote{177}{See Li, supra note 1, at 160 (discussing how both countries worked together to influence Bayer into lowering their prices).}

C. The Proposed Solution Does Not Discuss the Precautionary Approach in Noninfectious or Rare Diseases

Li focuses on contagious diseases and does not provide a solution for noninfectious or rare diseases.\footnote{178}{See id. at 174 (focusing on infectious diseases that are transmitted by contact).} Contrary to infectious diseases that may quickly spread globally, noninfectious diseases cannot be transmitted by human contact.\footnote{179}{Noninfectious, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/noninfectious (last visited Apr. 17, 2018) (defining noninfectious disease as “not infectious or caused by infection”).} The lack of animal-to-human or human-to-human transmission eliminates the urgent need in containing the outbreak.\footnote{180}{See Li, supra note 1, at 176 (finding risk analysis to be lower when disease is not transmitted by contact).} Therefore, Li’s proposed solution for the trigger threshold would not be applicable, because noninfectious disease is not transmitted by contact.\footnote{181}{See id. at 174.}

Li references Thailand’s attempt to use compulsory license for noninfectious diseases, but its use was met with criticism and trade retaliation.\footnote{182}{See id. at 162 (finding Thailand’s use to be improper and unnecessary).} Thailand granted a compulsory license for non-commercial use after failed negotiations with the pharmaceutical firms.\footnote{183}{See Cherian, supra note 107, at 22 (finding use to improper because of lack of emergency).} Trade retaliations in this case was a little harsh, because Thailand attempted to negotiate a favorable price, but it lacked political influence to obtain a desired discounted price.\footnote{184}{See id. (failing to negotiate for a favorable price result in compulsory license).} India in following the footsteps of Thailand invoked a compulsory license for a kidney cancer drug, where the compulsory license was upheld by India’s Supreme Court as reasonable.\footnote{185}{See Li, supra note 1, at 162-63 (explaining differences between India and Thailand’s grant of compulsory license.)} The Court held that:
[T]he number of patients required treatment by this drug is higher than the patentee expected and that patentee’s conduct of not making the drug available to the public for four years since the grant of the patent is not justifiable. The Court questioned why the patentee did not provide differential pricing for different classes of the public.  

The main difference between Thailand and India arguably is that Thailand could acquire the drug at a reasonable price and the drug was available to the public, whereas in India the drug was not publicly available at a reasonable price.  

On the other hand, rare diseases are not common and finding an effective treatment may take years. Cure for a rare disease is slow to be found, especially since it occurs to a small percentage of the world’s population. Therefore, not only would Li’s solution not apply to rare diseases for lack of transmission by contact, the fact that a fraction of the world’s population possesses or may develop such disease would not justify granting a compulsory license.

VI. CONCLUSION

The book comprehensively provides the reader with a detailed evolution of the PA and how it expanded into the realm of public health. The author effectively argues that further development of the PA in public health will empower states to take precautionary measures in the case of an emergency without the fear of trade retaliation. In effort to balance conflicting rights, the solution that Li provides is an efficient harmonization of the interests of the WTO and WHO through the use of compulsory licensing as permitted by TRIPS. By viewing compulsory licensing as a vehicle through

186 See id. at 163 (holding India’s grant of compulsory license for cancer drug to be proper).
187 See id. at 163.
188 Greg Breining, Rare Diseases Difficult to Diagnose, Cures Hard to Come By, ASSOCIATION OF AMERICAN MEDICAL COLLEGES (Apr. 11, 2017) (explaining that diagnoses and treatment for a rare disease may take years).
189 See id.
190 See Li, supra note 1, at 174 (proposing a solution for infectious disease outbreak).
the lens of precaution, this book proposes a detailed solution defining the PA in the interface of international trade, intellectual property, and health in the event of a public health emergency.