

Fordham International Law Journal

Volume 35, Issue 1

2016

Article 7

Global Access to Medicine: The Influence of Competing Patent Perspectives

Cynthia M. Ho*

*Loyola University Chicago School of Law

Copyright ©2016 by the authors. *Fordham International Law Journal* is produced by The Berkeley Electronic Press (bepress). <http://ir.lawnet.fordham.edu/ilj>

ARTICLES

GLOBAL ACCESS TO MEDICINE: THE INFLUENCE OF COMPETING PATENT PERSPECTIVES

*Cynthia M. Ho**

INTRODUCTION.....	3
I. BACKGROUND.....	8
A. Intellectual Property Rights.....	8
1. Patents.....	9
2. Trademarks.....	11
B. Drugs in the Marketplace.....	13
1. Drug Safety.....	13
2. Terminology.....	15
a. What is a Generic Drug?.....	15
b. Generic vs. Counterfeit Drugs.....	16
II. A NEW FRAMEWORK.....	18
A. Social Science Foundation.....	19
1. Schemas.....	19
2. Confirmation Bias.....	22
3. Naïve Realism.....	27
B. The Two Patent Policy Schemas.....	29
1. The Privilege Perspective.....	30

* Clifford E. Vickrey Research Professor of Law, Loyola University Chicago School of Law, J.D., Duke University School of Law; B.A., Boston University. The author thanks Sean Flynn, Leah Chan Grinvald, Nancy Kim, Peter Lee, Chunlin Leonard, Jacqueline Lipton, Henning Grosse Ruse-Khan, and Song Richardson for comments on earlier drafts. This Article also benefitted from faculty workshops and conference symposia at American University, Benjamin Cardozo School of Law, University of Arizona Rogers College of Law, University of South Carolina School of Law, Villanova Law School, and the University of Hyderabad (India). The author thanks Melissa Miltonberger, Patricia Scott, Keri Schaubert, Brad Snyder, and Alan Velasco for their research assistance. This Article is based in part on *Suspensions of In-Transit “Generic Drugs:” A Case Study of Competing Perspectives*, in CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS (2011).

2. The Uber-Right Perspective	34
III. EXPOSING THE IMPACT OF PERSPECTIVES ON	
FACTS.....	39
A. Background	39
1. EU Regulation.....	39
2. EU Seizures	42
3. The ACTA and Beyond	47
B. A Case Study of Patent Perspectives	47
1. The Privilege View	48
2. The Uber-Right View	56
3. Reflections on the Perspectives.....	61
IV. THE LEGAL FRAMEWORK.....	64
A. TRIPS	65
1. TRIPS Border Measures—Articles 51 and 52.....	65
2. TRIPS Ceiling?—Article 1	70
B. The ACTA	72
1. Scope of Intellectual Property Rights Covered	72
2. In-Transit Policing	75
3. Impact on Global Trade in Generic Drugs	76
V. EXPOSING THE IMPACT OF PERSPECTIVES ON THE	
LAW	78
A. Privilege View.....	78
1. TRIPS.....	79
a. TRIPS Article 51	79
b. TRIPS Article 51 Footnote	79
c. TRIPS Article 52	81
d. TRIPS Articles 1 & 41	83
e. TRIPS Context—Doha (Over-Reliance).....	84
f. TRIPS Context—Articles 7 and 8	86
g. TRIPS “Context”—Territoriality.....	87
2. The ACTA—Privilege View	89
B. Uber-Right View	91
1. TRIPS Border Measures	91
2. The ACTA and Beyond	95
CONCLUSION	96

INTRODUCTION

Promoting access to affordable medicine for poor countries is considered an important goal to a wide range of actors including not only poor countries, but also rich countries, patent owners, and scholars.¹ However, promoting such access has thus far been a challenge. In fact, over the last decade, changes in international laws that require most countries of the world to patent drugs have arguably impeded access to low-cost generic drugs.²

This Article posits that a major hurdle to actually addressing access issues is that there are fundamentally different views of patent policy (“patent perspectives”) that have a significant impact on how facts, laws, and proposed solutions are viewed. Unless and until there is a better understanding of the existence of these different views, viable solutions are likely to remain elusive.

It is well documented in the field of social science that all individuals perceive new information based on pre-existing “schemas.”³ This Article suggests that different views of patent policy similarly function as schemas. Although there are many

1. *See, e.g.*, European Parliament Resolution of 12 July 2007 on the TRIPS Agreement and Access to Medicines, 2008 O.J. C 175 E/59; INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 1–32 (Thomas Pogge et al. eds., 2010); GLAXOSMITHKLINE, 2010 CORPORATE RESPONSIBILITY REPORT 2 (2010), *available at* <http://www.gsk.com/responsibility/downloads/GSK-CR-2010-CR-at-GSK.pdf>; *see also* World Trade Organization, Ministerial Declaration of 20 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 544 (2002) [hereinafter Doha Public Health Declaration], *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (stating that the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”) “can and should be interpreted and implemented” in a manner consistent with public health, including access to medicine).

2. The most important change to international law is the Agreement on Trade Related Aspects of Intellectual Property, which requires all members of the World Trade Organization—including countries at all levels of development—to provide patents on drugs. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS], *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf.

3. *E.g.*, SUSAN T. FISKE & SHELLEY E. TAYLOR, SOCIAL COGNITION 97–99 (2d ed. 1991); ZIVA KUNDA, SOCIAL COGNITION: MAKING SENSE OF PEOPLE 17–19 (1999). A schema has been defined as a “mental structure which contains general expectations and knowledge of the world.” MARTHA AUGOSTINOS & IAIN WALKER, SOCIAL COGNITION: AN INTEGRATED INTRODUCTION 32 (1995); *see infra* note 54 (describing use of the term schema in this Article).

views of patent policy that exist along a continuum, the two most divergent views are the ones that dominate discussion and thus play a key role in how laws are developed and interpreted. On one end of the spectrum, there is a view of patents as a privilege granted by the state and inherently subject to limitations—especially if necessary to promote other social policies, such as access to medicine—this is referred to as the “privilege view.” On the other end of the spectrum, patents are considered essential to promoting innovation, with more protection considered to be necessarily beneficial to promoting more innovation; this view is referred to as the “uber-right” view because it suggests a very strong right. The existence and impact of these competing perspectives are well illustrated with respect to recent seizures of in-transit generic drugs that allegedly infringed local patent rights. Consider the following situation:

An Indian company makes a generic HIV medication and ships it to Nigeria through the Netherlands, a traditionally popular destination for global transport of goods. The drug is unpatented in both India and Nigeria, such that it can be made as a low-cost, generic version of the patented drug sold as Ziagen. However, the drugs are seized at the Amsterdam airport by Dutch customs authorities pursuant to [a European Union (“EU”)] regulation that has been interpreted to consider in-transit goods to infringe local patent rights.⁴

4. Technically, Dutch patent law would not consider in-transit goods to infringe patents. See 1 PATENTS THROUGHOUT THE WORLD § 121:27, § 121:5 (Henry D. Teegarden ed., 4th ed. 2011), available at Westlaw PATWORLD (discussing importation as a patent right but not specifically including in-transit imports). However, the European Union (“EU”) regulation has been interpreted by a Dutch court to permit suspension of in-transit goods on grounds of patent infringement based on the legal fiction that the good was manufactured in the country where suspensions occur. See *Rechtbank’s-Gravenhage* 18 juli 2008, 311378/KG ZA 2008, 08-617 m.nt. (Sosecal/Sisvel) (Neth.). An unofficial English translation of the *Sisvel v. Sosecal* decision is available at http://www.eplawpatentblog.com/PDF_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf. See also Council Regulation No. 1383/2003 Concerning Customs Action against Goods Suspected of Infringing Certain Intellectual Property Rights and the Measures to Be Taken against Goods Found to Have Infringed Such Rights, 2003 O.J. L 196/7 [hereinafter *Customs Action Regulation*].

Suspensions of drugs, like the one above, have prompted very different reactions. Brazil and India have decried the suspensions as “baseless” and clearly in violation of international law under the Agreement on Trade-Related Aspects of Intellectual Property (“TRIPS”).⁵ The EU, on the other hand, suggests that a few instances have been overblown and asserts that its laws are clearly consistent with TRIPS, although generally with no explanation.⁶ In addition, patent owners refer to suspended generic drugs as “counterfeit,”⁷ and also suggest that generics are not “safe or effective” simply because they were not made by the patent owner.⁸

Whether nations can consider in-transit goods to infringe patent rights and thus be subject to suspension by customs

5. See, e.g., *Intervention by India—TRIPS Council June 2009*, INTELLECTUAL PROPERTY WATCH, <http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/intervention-by-india-seizure-of-generic-drug-consignments-at-ec-ports.pdf> (last visited Sept. 23, 2011) [hereinafter *Intervention by India, June 2009*] (stating that “[t]he fact that the drugs were subsequently released are [sic] a proof that the allegations were baseless”); *Intervention by Brazil, TRIPS Council*, INTELLECTUAL PROPERTY WATCH, <http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/brazil-statement-trips-june-09.pdf> (last visited Sept. 23, 2011) [hereinafter *Intervention by Brazil, June 2009*], (stating that TRIPS does not allow suspension of goods in transit). Health Advocates have also echoed the sentiments of India and Brazil. See, e.g., Letter from Christian Wagner-Ahlfs, BUKO Pharma-Kampagne et al., to Margaret Chan, Dir. Gen., World Health Org. 3 (Feb. 18, 2009), available at <http://www.haiweb.org/07032009/18%20Feb%202009%20Open%20Letter%20to%20WHO%20on%20Dutch%20seizure%20of%20generics.pdf> (last visited Sept. 23, 2011) [hereinafter NGO Letter to Chan, Feb. 2009] (stating that the EU seizures are “clearly inconsistent” with the Doha Declaration and TRIPS).

6. See *infra* notes 211-21 and accompanying text (suggesting that suspended drugs were minimal and misconstrued); see also *infra* note 240 and accompanying text (suggesting that suspensions are in full compliance with TRIPS, but without any detailed analysis).

7. In the first reported suspension of in-transit drugs, patent owner Sanofi Aventis initially asserted that the drugs were suspended as “counterfeit,” but subsequently stated that the drugs violated patent and related protection for clopidogrel. Letter from Patent Dept. Sanofi Aventis to Betalactamicos S.A. (Oct. 29, 2008), available at <http://online.wsj.com/public/resources/documents/eudrugs2009letter2.pdf> [hereinafter Sanofi Letter 1]; Letter from Annemarie Kwaspén, Sanofi Aventis Legal Counsel, to C.A. Franco, Sales Manager, Betalactaminos S.A. (Nov. 24, 2008), available at <http://online.wsj.com/public/resources/documents/eudrugs2009letter2.pdf> [hereinafter Sanofi Letter 2].

8. Letter from B.E.M. van Kessel, Attorney for Eli Lilly, to the Board of Directors, Cipla Ltd. (Dec. 9, 2008), available at <http://online.wsj.com/public/resources/documents/eudrugs2009letter3.pdf> [hereinafter Eli Lilly Letter] (stating that Cipla’s product “may not be safe or effective” because it is not made by the patent owner Eli Lilly or any of its global licensees).

officials provides a new opportunity to consider not only a proper interpretation of TRIPS but also the importance and impact of competing patent perspectives. As this Article demonstrates, no one is immune from perspectives; even scholars may be influenced by perspective.⁹ Moreover, perspectives may play a central role in the development of new laws. For example, simultaneously with the suspensions of drugs in the EU, the EU and other countries negotiated a new international agreement called the Anti-Counterfeiting Trade Agreement (“ACTA”).¹⁰ As will be explained, this new agreement reflects more of an uber-right view that stronger patent rights are socially beneficial.

This Article provides an interpretation of the relevant provisions of TRIPS and the ACTA concerning suspensions of in-transit goods as a backdrop to understanding the significance of the patent perspective schemas discussed above. In particular, this Article suggests—consistent with social science on schemas in general—that countries, companies, and scholars may all have patent perspective schemas that influence their view of facts and interpretation of laws. The schemas may help explain differing interpretations of whether EU suspensions of drugs are consistent with TRIPS. Brazil and India’s views that the EU’s actions were inconsistent led to official requests for consultations,¹¹ which is the first step to a formal legal dispute before a World Trade Organization (“WTO”) panel.¹² Although

9. See *infra* notes 290–97 and accompanying text (discussing interpretations by Daya Shanker and Frederick Abbott).

10. Anti-Counterfeiting Trade Agreement (Apr. 15, 2011) [hereinafter ACTA], available at http://trade.ec.europa.eu/doclib/docs/2011/may/tradoc_147937.pdf. The Agreement has not yet been formally signed and will enter into force when six instruments of ratification, acceptance, or approval have been deposited. *Id.* art. 40.

11. Request for Consultations by Brazil, *European Union and a Member State—Seizure of Generic Drugs in Transit*, WT/DS409/1 (May 19, 2010) [hereinafter Brazil Consultation Request], available at http://trade.ec.europa.eu/doclib/docs/2011/february/tradoc_147567.pdf; Request for Consultations by India, *European Union and a Member State—Seizure of Generic Drugs in Transit*, WT/DS408/1 (May 19, 2010) [hereinafter India Consultation Request], available at <http://www.worldtradelaw.net/cr/ds408-1%28cr%29.pdf>.

12. See Understanding on Rules and Procedures Governing the Settlement of Disputes arts. 4(5), 4(7), 6, Apr. 15, 1994, Marrakesh Agreement Establishing the

the countries seem to have reached an understanding that obviates the need for a formal panel at this time, an interpretation of TRIPS, together with the impact of the different patent perspectives on interpretations is nonetheless important.¹³ Not only may the current understanding collapse but there is also a related issue concerning what the ACTA permits or requires for in-transit suspensions of drugs.¹⁴ Accordingly, this Article addresses appropriate interpretations of TRIPS and the ACTA concerning suspensions of in-transit drugs, together with the impact of patent perspectives on these interpretations. In addition to these legal interpretations, the analysis of patent perspectives should promote a better understanding of why questions concerning the proper balance between patent rights and access to medicine are so contentious as a first step to resolving them.

This Article proceeds in four Parts. Part I provides fundamental information about intellectual property rights and how drugs enter the global marketplace. Part II introduces the two patent perspectives, including how the existence of these perspectives is supported by social science. Parts III and IV then demonstrate the impact of perspectives on how facts and laws are perceived. This Article concludes with considerations of the importance of the patent perspectives for understanding and anticipating broader global conflicts concerning the intersection of patents and access to medicine.

World Trade Organization, Annex 2, 1869 U.N.T.S. 401, 33 I.L.M. 1226 (1994); *see also* Sue Ann Mota, *TRIPS: Ten Years of Disputes at the WTO*, 9 *COMPUTER L. REV. & TECH. J.* 455, 462 (2005) (providing explanation of the dispute settlement process and noting that consultations are a necessary step before a formal WTO panel is requested).

13. *See, e.g.*, Press Release, India Ministry of Commerce and Indus., India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit (July 28, 2011), available at <http://pib.nic.in/newsite/erelease.aspx?relid=73554>; William New, *EU-India Agreement in WTO Dispute Raises Bar for EU Drug Seizures*, IP-WATCH (July 30, 2011), <http://www.ip-watch.org/weblog/2011/07/30/eu-india-agreement-in-wto-dispute-raises-bar-for-eu-drug-seizures/>.

14. In addition, even if the WTO eventually rules on this issue, that may not resolve the issue definitively for those with a schema that is inconsistent with the WTO interpretation.

I. *BACKGROUND*

This Part explains intellectual property rights related to drugs, as well as regulations that promote drug safety, to lay a foundation for understanding why certain claims concerning suspensions of in-transit drugs are improper. First, this Part will clarify and distinguish the intellectual property rights that have been implicated for in-transit drugs—patents and trademarks. Second, this Part will address how other issues involving drugs in the marketplace can influence global access to medicine and define key terms relevant to global trade in drugs.

A. *Intellectual Property Rights*

There is one commonality to all types of intellectual property rights. Namely, that they are limited by national boundaries. There is currently no such thing as a global patent or trademark.¹⁵ Rather, a company that wants global protection must seek and obtain protection in each country where rights are desired.¹⁶ For example, a US patent gives its owner rights against others in the United States, but not Canada; to obtain rights against others in Canada, a Canadian patent is necessary.¹⁷ In addition, although an inventor may seek and obtain a patent

15. Some have suggested, however, that there should be limited versions of global patents or trademarks. *E.g.*, Edward Lee, *The Global Trade Mark 1* (Apr. 4, 2011) (unpublished manuscript), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1804985 (advocating global trademarks with respect to the limited category of “well known marks”); Commission Communication to Member States on Europe 2020: A Strategy for Smart, Sustainable and Inclusive Growth 12 (2010), *available at* <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF> (proposing an EU-wide patent).

16. *E.g.*, Paris Convention for the Protection of Industrial Property, art. 4 bis (1), Mar. 20, 1883, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 (noting that “patents applied for in the various countries . . . shall be independent of patents obtained for the same invention in other countries . . .”); *see also* WORLD INTELLECTUAL PROP. ORG., PATENTSCOPE: WIPO GUIDE TO USING PATENT INFORMATION 4 (2010), http://www.wipo.int/freepublications/en/patents/434/wipo_pub_1434_03.pdf (explaining that patents are applied for and enforced in different countries)

17. *See supra* note 16 and accompanying text.

in these countries, the scope of the patent rights may differ since each country decides on the scope of its own protection.¹⁸

While all intellectual property rights share the principle of territoriality, there are important distinctions between the different rights. Identifying what rights are at issue is important since there are different scopes of protection related to different rights, as discussed in this section. Accordingly, this section discusses the intellectual property rights most pertinent to selling drugs—patents and trademarks.

1. Patents

A patent is an official document granted by a nation that entitles its owner to certain rights.¹⁹ The patent owner typically can exclude others from the patented invention for a limited time that is usually less than twenty years.²⁰ In particular, the patent owner has the right to exclude others from making, using, selling, or importing the patented invention within the nation that granted the patents.²¹ This right to exclude provides a powerful commercial benefit, such that the owner of a patented drug can generally charge a premium price for the patented drug since no one else can make the identical drug.²²

18. *E.g.*, JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE 8 (2010) (stating that patents are territorial and national in nature); *see also supra* note 16 and accompanying text (explaining territorial limits of patents).

19. *See* BLACK'S LAW DICTIONARY 970 (9th ed. 2009) (defining a patent as "the governmental grant of a right, privilege, or authority").

20. *See e.g.*, 35 U.S.C. § 154(a)(2) (2006) (stating that the US patent term begins on the date that patent issues and ends twenty years from the application date); TRIPS, *supra* note 2, art. 33 (stating that patent term must end no later than twenty years from the date of filing). Notably, although the patent term ends twenty years from the application date, there are no patent rights while the patent application is pending, such that the actual term is twenty years, less the time spent examining the patent. For example, the average amount of time to evaluate a US patent application is currently 34.6 months; therefore, the average patent term is slightly less than seventeen years. U.S. Patents and Trademark Office, Patent Pendency Statistics–FY09, <http://www.uspto.gov/patents/stats/patentpendency.jsp> (last visited Sept. 3, 2010).

21. *E.g.*, 35 U.S.C. § 271(a) (2006) (providing patent infringement where one "makes, uses, offers to sell, or sells the patented invention, *within* the United States") (emphasis added); TRIPS, *supra* note 2, art. 27.

22. Although there may be competitive drugs within the same class (such as acid reflux or depression), patented drugs within a class do not usually compete based on price unlike generic drugs, such that each patented drug within a class usually still commands a substantial premium in price. *See Z. John Lu & William S. Comanor,*

Today, most countries are members of the WTO, and as such, must provide patent rights for all “inventions.”²³ In particular, countries can not categorically exclude all drugs from patentability²⁴—a major change in the laws of some countries that previously did not permit patents on drugs.²⁵ However, because patent obligations under TRIPS only apply prospectively to new inventions, some member states in full compliance with TRIPS may nonetheless continue to make drugs that were unpatented and unpatentable before TRIPS. For example, India can continue to make certain HIV drugs as generics since they were unpatentable before 2005, when India was required to grant patents on new drugs.²⁶ Even though these drugs may be patented in other countries (such as the United States), because patents are territorially limited, the same drug could be legally

Strategic Pricing of New Pharmaceuticals, 80 *REV. ECON. & STAT.* 108, 115–17 (1998); CONG. BUDGET OFFICE, CONG. OF THE UNITED STATES, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES* 23–24 (1998).

23. See *Members and Observers*, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Nov. 23, 2011) (providing a list of WTO members); see also TRIPS, *supra* note 2, art. 27 (requiring that inventions that meet certain criteria be granted patents).

24. See TRIPS, *supra* note 2, art. 27; see also CARLOS CORREA, *INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES II.1* (2000), available at <http://apps.who.int/medicinedocs/fr/d/Jh2963e/6.html> (“Literally interpreted, Article 27.1 does not permit the exclusion from patentability of medicines in general or, arguably, of specific groups thereof.”); JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 109 (2001) (explaining that TRIPS does not permit exclusion of pharmaceuticals from patentability).

25. Prior to TRIPS, fifty nations did not permit patenting of drugs, with some even prohibiting methods of creating drugs from patentability. *E.g.*, United Nations Conference on Trade & Dev., *THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES* 30 (1996), available at http://www.unctad.org/en/docs/ite1_en.pdf. This exclusion helped to promote access to lower cost medicine. See *e.g.*, WORLD HEALTH ORGANIZATION, *GLOBALIZATION AND ACCESS TO DRUGS—HEALTH ECONOMICS AND DRUGS SERIES*, No. 007 19–21 (1998), available at <http://apps.who.int/medicinedocs/en/d/Jwhozip35e/3.4.3.html#Jwhozip35e.3.4.3> (noting that some countries chose to exclude drugs from patentability, which enabled them to freely imitate products patented in other countries and also avoid the high cost of patented drugs).

26. TRIPS, *supra* note 2, art. 65(4) (permitting a WTO country that did not previously provide patents on products to delay doing so for an additional five years beyond the other transitional provision); see also DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 519 (3d ed. 2008) (stating that countries, such as India, had until January 1, 2005, to provide patent protection on drugs if they had not previously provided such protection).

made in countries without patent protection for the drug, such as India. In addition, a country that did not previously provide patents on drugs, such as Brazil, could legally import drugs from India without violating Brazilian or Indian patent laws.

2. Trademarks

A trademark is a word, slogan, or symbol that identifies and distinguishes the goods of an entity from those of others.²⁷ In other words, a brand name, such as Vioxx or Prozac, is a trademark.²⁸ A trademark owner has the right to prevent others from using its mark, or a similar mark, if consumers would likely be confused.²⁹ Accordingly, the owner of the trademark Prozac could prevent another company from using the word “Prozac” to market a similar drug because consumers would likely be confused. Patented drugs are often sold with a trademark, such as the trademark Rogaine, whereas unpatented drugs (including drugs where the patent has expired) are referred to as generics and generally sold using a non-proprietary chemical name.³⁰

Goods that are sold using *identical* marks as the trademark owner of the identical product are referred to as “counterfeit” trademark goods.³¹ This includes goods commonly referred to as “knock-offs,” such as relatively inexpensive watches, bags, and

27. *E.g.*, 15 U.S.C. § 1127 (2006) (defining trademark as a term that “includes any word, name, symbol, or device, or any combination thereof” that is used by a person “to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of the goods, even if that source is unknown”).

28. A trademark can also include phrases, images, or packaging, so long as it still satisfies the basic requirement of distinguishing the product from others. For example, a trademark can include distinctive packaging, such as the curved shape of a Coca-Cola bottle. COCA-COLA, Registration No. 0696147 (registered for “Bottles, jars or flasks with bulging, protruding or rounded sides; Flasks with bulging or protruding sides; Jars with bulging or protruding sides”).

29. *See, e.g.*, 15 U.S.C. § 1114 (2006).

30. For example, the term ibuprofen is the generic name for a product that contains that ingredient as the primary active ingredient, whereas Pfizer makes its own version of ibuprofen under the trademark “Advil.” While Pfizer can prevent other companies from using the term “Advil” to sell ibuprofen, it cannot prevent competitors from using the nonproprietary term ibuprofen.

31. *See, e.g.*, 15 U.S.C. § 1116(d) (2006) (defining counterfeit in the context of clarifying that courts can order the seizure of goods with counterfeit marks); 18 U.S.C. § 2320 (2006) (defining counterfeit in the context of creating criminal liability for trafficking in goods using counterfeit trademarks).

clothing sold on the street that simulate expensive, brand-name items. Similar to knock-offs of luxury consumer goods, counterfeit drugs involve the unauthorized use of one or more trademarks and are often sold for much less than the legitimate product.³²

Trademarks are enforced through two different mechanisms. Intentional and unauthorized counterfeit trademarks may be enforced through the judicial system and policed by customs officials.³³ Since a counterfeit trademark is by definition identical to a brand name, it can be easy to spot even by someone not trained in trademark law. However, when a trademark is used in a manner that is likely to cause confusion, but without rising to the level of a counterfeit use, infringement is much more difficult to determine. Traditionally, this has been the subject of unpredictable litigation.³⁴ This is especially true because even if there might be arguable confusion, there are legitimate defenses, such as “fair use” of the mark.³⁵

32. An example of a counterfeit drug would be one sold as “Vioxx,” but not made by the owner of the trademark Vioxx.

33. *E.g.*, J. THOMAS MCCARTHY, *MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION* §§ 25:10–25:11 (4th ed. 2011).

34. The “likelihood of confusion” test involves multiple factors, with no single one being dispositive, such that conclusions are considered unpredictable. *See generally* Barton Beebe, *An Empirical Study of the Multifactor Tests for Trademark Infringement*, 94 CALIF. L. REV. 1581 (2006). For example, trademark infringement is analyzed based on whether there is “likelihood of confusion.” One might assume that a well-known mark is less likely to result in confusion, but courts have sometimes concluded otherwise. *E.g.*, *Kenner Parker Toys, Inc. v. Rose Art Indus.*, 963 F.2d 350, 355 (Fed. Cir. 1992) (finding likelihood of confusion between Playdough and Fundough for similar modeling compound and not considering it persuasive that consumers are familiar with Playdough brand in finding likelihood of infringement); *McDonald’s Corp. v. Druck and Gerner, DDS.*, 814 F. Supp 1127, 1134, 1139 (N.D.N.Y. 1993) (finding trademark infringement where there was no evidence McDonald’s planned to enter defendant’s dental business, yet the Court was suspicious of defendant’s good faith in selecting “McDental” name). Trademark infringement may also involve drugs. *E.g.*, *Eli Lilly & Co. v. Natural Answers, Inc.* 233 F.3d 456 (7th Cir. 2000) (finding the herbal antidepressant name Herbrozac too similar to Prozac, and thus infringing its trademark).

35. *E.g.*, 15 U.S.C. § 1115(b) (2006) (listing some defenses to what would otherwise be infringement). In addition, a major issue with trade dress—what a consumer would normally consider product packaging—is that there is no protection if the trade dress is functional, regardless of any confusion. *See, e.g.*, *Shire US, Inc. v. Barr Labs., Inc.*, 329 F.3d 348, 350 n.2 (3d Cir. 2003); *see also* Jeremy A. Greene & Aaron S.

B. *Drugs in the Marketplace*

Now that the parameters of how drugs are protected by intellectual property rights have been delineated, this section turns to how drugs are regulated and sold in the commercial marketplace. In particular, this section both explains how the safety of drugs is governed by issues beyond intellectual property rights and also clarifies some key terms that have been repeatedly conflated in the context of in-transit seizures.

1. Drug Safety

Drug safety and efficacy are serious issues, but patents and trademarks play little role in governing these matters. Drugs may be substandard (poor quality) if they fail to meet scientific specifications, or have become contaminated. Alternatively, fake drugs contain ingredients different than indicated on the label, or no active ingredient at all. However, patent and trademark requirements are not relevant to safety issues. A patent can be granted on a drug without any evidence that it is safe or effective since the patent standards do not require evaluation of such concepts. Similarly, a trademark signifies that a product is from a particular source to help guarantee consistency, but does not guarantee safety or efficacy since these are not requirements for trademark protection.

In most developed countries, there is a domestic regulatory agency that evaluates whether drugs are safe and effective before they can be legally sold to consumers; drugs that do not go through this process are illegal and considered unsafe.³⁶ The domestic regulatory agencies, such as the United States' Food and Drug Administration, generally evaluate drugs and only approves drugs for sale that are shown to be safe and effective

Kesselheim, *Why Do the Same Drugs Look Different? Pills, Trade Dress, and Public Health*, 365 *NEW ENG. J. MED.* 83, 83 (2011).

36. Those who sell illegal drugs may be subject to criminal prosecution. *See* 21 U.S.C. § 333 (2006). However, that does not necessarily prevent all illegal drugs from reaching consumers. Indeed, to the extent that patented drugs are expensive, there is an incentive for consumers to buy illegal drugs when there is no inexpensive alternative. *See General Information on Counterfeit Drugs*, WORLD HEALTH ORG., <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> (last visited Sept. 24, 2011).

based on scientific data.³⁷ If a drug is not granted approval, it cannot be lawfully sold. The same basic standard applies to new, as well as generic drugs. However, a generic drug may be approved based on more limited tests that show it is “bioequivalent” to a previously approved (and usually patented) drug, such that it is considered equally safe and effective.³⁸

Whereas consumers in developed countries who buy legal drugs are assured that the drugs are safe and effective, this is not the case in a number of developing countries. Some poor countries lack the resources—both financially and in terms of technical expertise—to effectively analyze and monitor drug safety.³⁹ Some countries overcome this resource issue by relying on the approval of other countries. For example, India will approve drugs that have been approved in other countries, such as the EU and the United States, with minimal testing in India.⁴⁰

37. See 21 U.S.C. § 355(b) (2006) (setting “safe and effective” as basic standard for new drugs).

38. See *id.* § 355(j)(2)(A).

39. WHO *Policy Perspectives on Medicines—Effective Medicines Regulation: Ensuring Safety, Efficacy and Quality*, WORLD HEALTH ORGANIZATION (Nov. 2003), <http://apps.who.int/medicinedocs/pdf/s4921e/s4921e.pdf>. There are tremendous costs associated with drug regulation. For example, in 2010 the Food and Drug Administration (“FDA”) budget was about US\$2.4 billion. See *Food and Drug Administration: FY 2011 President’s Budget Request All Purpose Table—Total Program Level*, FOOD AND DRUG ADMIN., <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM202312.pdf> (last visited Sept. 24, 2011). This cost is underscored by the fact that roughly half the cost of drug regulation is underwritten by fees from drug companies that apply to the FDA for regulatory approval. See, e.g., *White Paper—Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications*, FOOD AND DRUG ADMIN., <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM149130.pdf> (last updated May 3, 2010). In addition, the World Health Organization (“WHO”) estimates that as many as one third of all countries have limited or no ability to regulate drugs at all. WHO *Policy Perspectives on Medicines*, *supra*, at 1.

40. Drugs & Cosmetics Act, No. 23 of 1940, INDIA CODE, ¶ 122 A(2), Schedule Y, available at <http://indiacode.nic.in>; see also Sandhya Srinivasan, *Trial by Fire*, ECON. & POL. WKLY., Aug. 29–Sept. 4, 2009, reprinted in INFOCHANGE (India) (Sept. 2009), <http://infochangeindia.org/health/analysis/trial-by-fire.html>. In addition, the World Health Organization (“WHO”) prequalifies drugs for HIV, malaria, and tuberculosis. See *Prequalification Program*, WORLD HEALTH ORG. <http://apps.who.int/prequal/> (last visited Sept. 24, 2011).

However, other countries attempt to regulate their own drugs, yet are ineffectual due to corruption.⁴¹

2. Terminology

Now that the landscape of intellectual property rights and drug safety has been outlined, this section aims to explain terminology that has been particularly confusing with respect to in-transit drugs. In particular, this section explains what the term “generic” means with respect to drugs and then how the term “generic” is different from “counterfeit.”

a. What is a Generic Drug?

What constitutes a generic drug may be confusing in the global marketplace. This can be due to the fact that the word “generic” may be used to refer either to the use of a generic trademark (such as ibuprofen), or to suggest that the drug is unpatented (yet equivalent to a previously patented drug).⁴² In addition, the same chemical compound may be patented in one country, yet available as an unpatented generic in another. This is a reflection of the fact that patents are territorially limited, such that a US drug patent has no impact on whether that drug is or is not patented in another country.⁴³ Thus, a drug to prevent strokes and heart attacks that is sold under the trademark Plavix in the United States at a premium by patent owner Sanofi Aventis⁴⁴ is available as a cheaper generic drug in

41. Corruption is identified by the WHO as a major impediment to ensuring access to quality medicine. *See, e.g.*, Guitelle Baghdadi-Sabeti & Fatima Serhan, *WHO Good Governance for Medicines Programme: An Innovative Approach to Prevent Corruption in the Pharmaceutical Sector*, WORLD HEALTH ORG. 6 (2010), <http://www.who.int/healthsystems/topics/financing/healthreport/25GGM.pdf>.

42. *See supra* Part I.A.2.

43. *See supra* notes 16–17 and accompanying text.

44. The patent owner can sell a patented drug for a premium until the patent expires, which, in the case of the drug sold as Plavix, is May 2012. *See Patent Terms Extended under 35 USC § 156*, UNITED STATES PATENT AND TRADEMARK OFFICE, <http://www.uspto.gov/patents/resources/terms/156.jsp> (last visited Sept. 25, 2011); Matthew Perrone, *FDA Extends Plavix Patent by 6 Months*, ABC NEWS, Jan. 25, 2011, <http://abcnews.go.com/Business/wireStory?id=12758125>. Although there is technically no law that prevents a patent owner from maintaining the same price, the entry of cheaper generics typically results in the patent owner substantially reducing the drug's cost.

India under the non-proprietary name clopidogrel because there is no applicable Indian patent.

This Article addresses an especially confusing and previously uncharted area of nomenclature—what to call a drug that is unpatented (and generally referred to as generic) in the country of origin and destination, but might arguably infringe a patent while in-transit. Many assume that a drug made as a generic should always be considered a generic drug. This Article will follow popular convention in referring to a drug as “generic” if made as such, but with the important caveat that this label does not mean to suggest that the “generic” drug cannot infringe while in-transit.

b. Generic vs. Counterfeit Drugs

Another frequent point of confusion in discussions of in-transit drugs involves the use of the word “counterfeit,” particularly, concerning whether a generic drug is counterfeit. The term “counterfeit” may refer to a counterfeit trademark, or alternatively, to a drug of dubious quality and safety.

As noted above, the term “counterfeit” has a special meaning for trademarks—it refers to the unauthorized use of a mark that is identical to a trademark. For example, the use of the mark “Tylenol” on a bottle of painkillers that is not made (or authorized) by the owner of the trademark Tylenol would be a counterfeit. Based on the trademark definition of the term “counterfeit,” some contend that the word “counterfeit” can never apply to generic drugs that do not purport to use any mark of the original brand owner, let alone the identical mark.

The term “counterfeit,” however, is often used more broadly. In particular, the term “counterfeit” may refer to sub-standard medicines or falsified medicine. For example, a drug may fail to contain adequate amounts of the active ingredient listed, or none of the active ingredient. While such drugs are clearly problematic from a public health perspective, they raise very different concerns than a counterfeit trademark. Some health advocates strongly oppose the use of the term “counterfeit” in connection with fake drugs and prefer to refer

to drugs as “sub-standard” or “adulterated” to avoid confusion with counterfeit trademarks and to emphasize what is at issue.⁴⁵ Some public health advocates seem to assume that the term counterfeit can *only* properly refer to counterfeit trademarks and that any other use of the term counterfeit is a purposeful attempt to blur the lines between health and intellectual property issues to justify increased intellectual property (“IP”) rights.⁴⁶

There may be an overlap in some cases. For example, an unauthorized drug could have a counterfeit trademark on its packaging.⁴⁷ However, that does not mean that all products with counterfeit trademarks are falsified. In addition, a generic name of a drug is not a counterfeit trademark. Although it is true that the only multilateral agreement on the definition of counterfeit is with respect to trademarks, it is nonetheless used more broadly. For example, both the Food and Drug Administration (“FDA”) and the World Health Organization (“WHO”) state that counterfeit drugs include branded and generic products.⁴⁸ Since generic drugs are by definition sold without a trademark,

45. See, e.g., EYE ON THE BALL: MEDICINE REGULATION—NOT IP ENFORCEMENT—CAN BEST DELIVER QUALITY MEDICINES, OXFAM 23 (2011), <http://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf> [hereinafter EYE ON THE BALL] (stating that the term “counterfeit” has little meaning in the context of public health discussions, based on the trademark definition of counterfeit); *Counterfeit, Substandard and Generic Drugs*, CAMPAIGN FOR ACCESS TO ESSENTIAL MEDS., MÉDICINS SANS FRONTIÈRES, <http://www.msaccess.org/main/access-patents/counterfeit-substandard-and-generic-drugs/> (last updated Apr. 2009).

46. See, e.g., EYE ON THE BALL, *supra* note 45, at 24; Kaitlin Mara, *Pointed Exchange of Views at WHO Briefing on Counterfeit Drugs*, IP-WATCH (Mar. 31, 2010, 2:49 PM), <http://www.ip-watch.org/weblog/2010/03/31/flare-up-in-who-briefing-on-counterfeit/>; Catherine Saez, *WHO Members to Work to Disentangle Problem of Fake Medicines, IP Issues*, IP-WATCH (Feb. 25, 2011, 12:24 AM), <http://www.ip-watch.org/weblog/2011/02/26/who-members-to-work-to-disentangle-problem-of-fake-medicines-ip-issues/>.

47. An unauthorized drug with a counterfeit trademark is not the only possibility. A falsified drug may not use any trademark, but instead be false in that it fails to contain the stated ingredient(s).

48. See, e.g., *Counterfeit Drugs Questions & Answers*, FOOD AND DRUG ADMIN., <http://www.fda.gov/Drugs/DrugSafety/ucm169898.htm> (last updated Sept. 8, 2011) (explaining what constitutes a counterfeit drug and clarifying that counterfeit drugs may include generic or brand name drugs); *Substandard and Counterfeit Medicines*, WORLD HEALTH ORG. (Nov. 2003), <http://www.who.int/mediacentre/factsheets/2003/fs275/en/> (stating that “both branded and generic products are subject to counterfeiting”).

the use of the word “counterfeit” in this Article generally refers to a sub-standard drug.⁴⁹

II. A NEW FRAMEWORK

This Part provides an analytical framework that explains why there has been confusion and conflation of facts and law concerning in-transit suspension of drugs. Although advocates are known to use issue framing and rhetoric, there may be a more fundamental phenomenon that gives rise to issue framing.⁵⁰ In particular, this Article posits that many misstatements stem from fundamentally different perspectives of patent policy. These perspectives are important both to understanding some of the statements that have been made and to understanding, predicting, and addressing future actions.

This new theory may help fill in gaps left by traditional patent theories. In particular, while there are a number of theories concerning why countries grant patents,⁵¹ those theories are largely irrelevant to the current reality in which countries set patent standards according to international agreements that have trade benefits and not because of an inherent agreement in patent theory.⁵² In addition, while some

49. The one exception to this is in the case study concerning in-transit suspensions where some parties use the term “counterfeit” in ways that are ambiguous; these references are retained as important to evaluating the patent schemas at issue.

50. The power of rhetoric and issue framing is widely recognized with respect to the development of international laws that promote patent rights. *See, e.g.*, SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW* 5–6 (Cambridge Univ. Press ed. 2003); Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 *YALE L.J.* 804, 809 (2008).

51. For example, patents can be seen as a “natural right” of inventors, or granted as a “utilitarian” tool to promote innovations. However, these general theories concerning the existence of a patent system do not provide guidance on how to fine tune a patent system to consider social goals beyond innovation, such as access to medicine.

52. Although some suggested that developing countries would benefit from enhanced patent rights, that view was, and continues to be, challenged. Rather, TRIPS was concluded *despite* the patent requirements because developing countries were keen to gain greater access to the markets of wealthy WTO members. *See generally* GERVAIS, *supra* note 26, at 336 (noting that the patent section was one of the most contentious aspects of negotiation); Arie Reich, *The WTO as a Law-Harmonizing Institution*, 25 *U. PA. J. INT'L ECON. L.* 321, 362 (2004) (suggesting that the WTO and TRIPS succeeded

scholars have suggested that patent rights should be either maximized or minimized consistent with traditional patent theories, these arguments assume that one approach is necessarily correct.⁵³ In contrast, the patent perspectives presented here, based on social science support, suggest that there may be different views of patent policy, each of which will lead to different perceptions of facts and laws.

This Part is divided into two sections. The first section provides an overview of social science information relevant to the patent perspective theory. The next section explains the patent perspectives based upon lessons from social science.

A. Social Science Foundation

1. Schemas

Social science literature repeatedly documents that people receive and understand new information based upon certain pre-existing “schemas,”⁵⁴ which are developed through direct

because it was a package deal). Developing countries opposed inclusion of patents and wanted to limit intellectual property rights to only counterfeit trademark and pirated copyright goods. *See, e.g.*, Communication from the Permanent Mission of India to the Indian Negotiating Grp., *Standards and Principles Concerning the Availability Scope and Use of Trade Related Intellectual Property Rights*, MTN.GNG/NG11/W/37, ¶¶ 2–4 (July 10, 1989).

53. In particular, patent rights and exceptions are often referred to as promoting either a “liability” or “property” rule. *See, e.g.*, Robert P. Merges, *Of Property Rules, Coase, and Intellectual Property*, 94 COLUM. L. REV. 2655, 2655 (1994). Those who support the use of compulsory licenses of patented drugs are considered to promote a liability rule whereas those who oppose such licenses are considered to promote a property rule.

54. This Article uses the term “schema” broadly to refer to any organizing principle, hypothesis, script, or prototype that functions as a mental organizing system. *See* Reid Hastie, *Schematic Principles in Human Memory*, in 1 SOCIAL COGNITION: THE ONTARIO SYMPOSIUM 39, 39–47 (Edward Tory Higgins & Mark P. Zanna eds. 1981); *see also* MARTHA AUGUSTINOS ET AL., SOCIAL COGNITION: AN INTEGRATED INTRODUCTION 68 (2d ed. 2006) (defining a schema as a “cognitive structure” which “contains general expectations and knowledge of the world”). Use of the term “schema” and related social science concepts such as “categories” and “concepts” are used differently by different social science scholars. *See, e.g.*, Ronald Chen & Jon Hanson, *Categorically Biased: The Influence of Knowledge Structures on Law and Legal Theory*, 77 S. CAL. L. REV. 1103, 1131–32 (2004) [hereinafter Chen & Hanson, *Categorically Biased*]. In addition, the terms “script” and “meta-scripts” have been used. Ronald Chen & Jon Hanson, *The Illusion of Law: The Legitimizing Schemas of Modern Policy and Corporate Law*, 103 MICH. L. REV. 1, 3–4 (2004) [hereinafter Chen & Hanson, *The Illusion of Law*]. However, one

experience, as well as communication with others.⁵⁵ Individuals rely on schemas in processing information, drawing conclusions, and generally perceiving their every day life.⁵⁶ In addition, individuals are likely to remember facts consistent with schemas.⁵⁷

Schemas often function as an unconscious lens through which information is perceived. One simple schema is a stereotype—including not only gender and racial stereotypes, but also stereotypes about occupations (such as lawyers as mercenaries).⁵⁸ A schema could also be a bias that does not rise to the level of a broadly-recognized stereotype. For example, a schema could involve a bias that perceives more complexly written articles as better.⁵⁹ Schemas may be more complex; for

unifying trend of particular pertinence to this Article is that they focus on a mental concept that serves as a lens through which future experiences are viewed.

55. See, e.g., 7 *ENCYCLOPEDIA OF PSYCHOLOGY*, 158–60 (Alan E. Kazdin ed., 2000).

56. *Id.*

57. *Id.* For example, studies consistently show that race and gender stereotypes impact memory recall and mistake. See, e.g., Alison P. Lenton et al., *Illusions of Gender: Stereotypes Evoke False Memories*, 37 *J. EXPERIMENTAL SOC. PSYCHOL.* 3, 11 (2001) (showing that subjects created false memories based on gender stereotypes); Richard L. Marsh & Gabriel I. Cook, *Gender and Orientation Stereotypes Bias Source-Monitoring Attributions*, 14 *MEMORY* 148, 157–58 (2006) (illustrating that participants misremember facts that are consistent with gender and racial stereotypes); see also Jeanine L. Skorinko & Barbara A. Spellman, *Stereotypic Crimes: How Group-Crime Associations Affect Memory and (Sometimes) Verdicts and Sentencing* (June 2006) (unpublished manuscript), cited in Justin D. Levinson, *Forgotten Racial Equality: Implicit Bias, Decisionmaking, and Misremembering*, 57 *DUKE L.J.* 345, 375 n.154, 378 (2007) (showing that subjects were more likely to accurately recall race in instances that were consistent with a racial stereotype, such as Caucasian perpetrator of the stereotypical white crime of identity fraud). In addition, memory may be impacted by non-stereotypical schemas. See, e.g., Nancy Pennington & Reid Hastie, *Evidence Evaluation in Complex Decision Making*, 51 *J. PERSONALITY & SOC. PSYCHOL.* 242, 251 (1986) (mock jurors not only forget incongruent facts, but also misremember facts that were not in evidence to support a pre-existing judgment).

58. Chen & Hanson, *Categorically Biased*, *supra* note 54, at 1125. In fact, jokes can be predicated on cultural schemas, with the punch line of the joke playing on a presumed shared schema; some such schemas include women as shoppers, and men as disinclined to commit to personal relationships. *Id.* at 1111–12.

59. See, e.g., J. Scott Armstrong, *Unintelligible Management Research and Academic Prestige*, 10 *INTERFACES* 80, 84–85 (1980) (finding that management faculty from several prestigious institutions had a bias toward more complex language that resulted in academics rating more complex conclusion sections of research as superior in quality). In addition, students and educators alike have a schema that strongly favors

example, a philosophy that values market self-regulation over government regulation can be considered a schema.⁶⁰

All individuals rely on schemas. For example, Justice Joseph P. Bradley of the United States Supreme Court evidenced a schema about the inferiority of women when he commented that “[t]he natural and proper timidity and delicacy which belongs to the female sex evidently unfits it for many of the occupations of civil life.”⁶¹ More recently, there is a growing body of literature that shows that while our society may be more egalitarian than in the 1800s, stereotypes, such as racial bias against blacks continue, albeit often at a more unconscious level. For example, a physical bump may be viewed as aggressive when done by a black actor, but innocuous when done by a white actor; this difference exists even in individuals who display no conscious animus against blacks.⁶² Such bias is shown by individuals in a variety of professions including police officers,

teacher charisma and other non-substantive content in evaluating the teacher or lecturer. A famous study of an actor posing as “Dr. Fox” suggested that even trained academics are susceptible to a common bias that ascribes weight to a teacher’s [personal traits] more than content. Donald H. Naftulin et al., *The Doctor Fox Lecture: A Paradigm of Educational Seduction*, 48 J. MED. EDUC. 630, 633-34 (1973). The “Dr. Fox” study may also demonstrate a related schema that speakers have authority if they act with authority and are given authoritative titles. This is also depicted in the movie *The Yes Men*, in which two individuals embody fake personas and make controversial points that are generally accepted without question by well-educated audiences. THE YES MEN (Yes Men Films, LLC 2003).

60. See Chen & Hanson, *The Illusion of Law*, *supra* note 54, at 87–89.

61. *Bradwell v. Illinois*, 83 U.S. 130, 141 (1872). The impact of schemas on the Court was shown in a more contemporary case in which Justices held different views of the same video of a police officer that rammed his car into a fleeing motorist. *Scott v. Harris*, 550 U.S. 372 (2007). The justices held dramatically different interpretations of the view that was of critical importance to whether to affirm a lower court’s denial of a summary judgment motion by an officer that his use of admittedly deadly force did not constitute an unreasonable seizure under the Fourth Amendment. *Id.* at 379, 395–96. A subsequent study revealed that the views likely reflected different cultural values—which can be considered a schema—that played a prominent role in perception of the same facts. See Dan M. Kahan et al., *Whose Eyes Are You Going to Believe? Scott v. Harris and the Perils of Cognitive Illiberalism*, 122 HARV. L. REV. 837, 860–61 (2009).

62. H. Andrew Sagar & Janet Ward Schofield, *Racial and Behavioral Cues in Black and White Children’s Perceptions of Ambiguously Aggressive Acts*, 39 J. PERSONALITY & SOC. PSYCHOL. 590, 593–97 (1980); see also Birt L. Duncan, *Differential Social Perception and Attribution of Intergroup Violence*, 34 J. PERSONALITY & SOC. PSYCHOL. 590, 590 (1976). The fact that individuals may subconsciously view facts differently, depending on the race of an actor, is considered *implicit* racial bias—as opposed to conscious bias against blacks. Christine Jolls & Cass R. Sunstein, *The Law of Implicit Bias*, 94 CALIF. L. REV. 969, 970 (2006).

judges, and doctors.⁶³ Although stereotypes are commonly studied, there are additional schemas that influence individuals. For example, studies have shown social science academics to favor studies consistent with their own beliefs⁶⁴ or prevailing wisdom;⁶⁵ they also perceive work from individuals at prestigious schools as more worthy of publication.⁶⁶

2. Confirmation Bias

People tend to interpret new information consistent with their schemas. For example, a teacher who believes a certain student is smart is likely to interpret subsequent performance consistent with this schema.⁶⁷ This tendency to view new

63. See, e.g., Alexander R. Green et al., *Implicit Bias among Physicians and Its Prediction of Thrombolysis Decisions for Black and White Patients*, 22 J. GEN. INTERNAL MED. 1231, 1234–35 (2007) (documenting implicit racial bias among doctors that resulted in more appropriate treatment to whites than blacks); Jeffrey J. Rachlinski et al., *Does Unconscious Racial Bias Affect Trial Judges?*, 84 NOTRE DAME L. REV. 1195, 1221 (2009) (describing implicit racial bias in judges); L. Song Richardson, *Arrest Efficiency and the Fourth Amendment*, 95 MINN. L. REV. 2035, 2060–98 (2011) (detailing implicit racial bias in police officers); Janice A. Sabin et al., *Physicians' Implicit and Explicit Attitudes about Race by MD Race, Ethnicity, and Gender*, 20 J. HEALTH CARE FOR POOR & UNDERSERVED 896, 907 (2009) (indicating that most doctors have implicit racial bias against blacks).

64. See, e.g., Andreas Hergovich et al., *Biased Evaluation of Abstracts Depending on Topic and Conclusion: Further Evidence of a Confirmation Bias Within Scientific Psychology*, 29 CURRENT PSYCHOL. 188, 188–89 (2010) (showing that psychologists reviewing abstracts of research were more likely to evaluate research as higher quality when consistent with their own beliefs); Michael J. Mahoney, *Publication Prejudices: An Experimental Study of Confirmatory Bias in the Peer Review System*, 1 COGNITIVE THERAPY AND RES. 161 (1977).

65. See, e.g., J. Scott Armstrong, *Publication of Research on Controversial Topics: The Early Acceptance Procedure*, 12 INT'L J. FORECASTING 299, 299 (1996); David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 JAMA, 1438, 1441 (1990).

66. In one study, twelve papers published by individuals from prestigious psychology departments at various colleges and universities were resubmitted to the same highly regarded journals in which the work had appeared, but with false author names and affiliations (e.g., Tri-Valley Center for Human Potential). Almost all (eight of nine) of the papers not detected as previously published work, were rejected on the basis of negative recommendations from most reviewers—even though the identical papers were previously worthy of publication. Stephen J. Ceci & Douglas P. Peters, *Peer Review Practices of Psychological Journals: The Fate of Published Articles, Submitted Again*, 5 BEHAV. & BRAIN SCI., 187, 187–255 (1982).

67. Matthew Rabin, *Psychology and Economics*, 36 J. ECON. LIT. 11, 26 (1998). Similarly, counselors in clinical settings become increasingly more confident in initial judgments, although research shows that the confidence is not correlated with

information to confirm existing schemas is referred to as “confirmation bias.”⁶⁸ Although this may seem to be inferior cognitive processing, it has also been explained as an adaptive survival skill.⁶⁹ For example, an individual who has a schema that snakes are dangerous has an “advantage” over someone who insists on testing every snake to determine its dangerousness. Even though not all snakes are dangerous, the individual with the snake danger schema will more likely avoid physical harm.⁷⁰

When information is ambiguous, it is especially likely to be interpreted consistent with confirmation bias, thereby preserving the pre-existing schema. When evidence is ambiguous, individuals emphasize the strength and reliability of confirming evidence, but deemphasize the weakness and unreliability of disconfirming evidence, such that prior views are strengthened.⁷¹ For example, in evaluating research, individuals are more likely to overlook the problem of small sample sizes if the conclusion is consistent with their beliefs, yet suggest that lack of rigor is a problem if the conclusion is contrary to their beliefs.⁷²

The confirmation bias exists even in cases where the ambiguous evidence is minimal in nature. For example, one study showed confirmation bias of pre-existing schemas concerning academic abilities of children from rich or poor backgrounds based solely on an ambiguous videotape of a child’s performance.⁷³ In the videotape, the child answered

increased accuracy. *See, e.g.*, Stuart Oskamp, *Overconfidence in Case Study Judgments*, 29 J. CONSULTING PSYCHOL. 261, 264–65 (1965).

68. The same phenomenon has alternatively been called belief perseverance, biased assimilation, conservatism, confirmational response bias, or agreement effect. *See, e.g.*, Hergovich et al., *supra* note 64, at 188. It is suggested that individuals are most susceptible to this phenomenon when the schema is easily “activated,” strong, or consistent with a “framework of related opinions and values.” Charles G. Lord & Cheryl A. Taylor, *Biased Assimilation: Effects of Assumptions and Expectations on the Interpretation of New Evidence*, 3 SOC. & PERSONALITY PSYCHOL. COMPASS 827, 831 (2009).

69. *E.g.*, Hal R. Arkes, *Costs and Benefits of Judgment Errors: Implications for Debiasing*, 110 PSYCHOL. BULL. 486 (1991); Lord & Taylor, *supra* note 68, at 831.

70. Lord & Taylor, *supra* note 68, at 831.

71. The reason this occurs is that people have an inherent need to ignore, discredit, or rationalize inconsistent information to avoid the discomfort of cognitive dissonance. *E.g.*, LEON FESTINGER, A THEORY OF COGNITIVE DISSONANCE 2–3 (1957).

72. *See* KUNDA, *supra* note 3, at 229.

73. *See* John M. Darley & Paget H. Gross, *A Hypothesis-Confirming Bias in Labeling Effects*, 44 J. PERSONALITY & SOC. PSYCHOL. 20, 20 (1983). Subjects in two groups were

questions with mixed success, but subjects came to differing conclusions based on whether they believed the child was from a wealthy or poor background. In particular, subjects who believed that a child was from a wealthy home interpreted the child's ambiguous performance to support their belief that the child had above average reading ability whereas subjects who believed the child was from a poor home interpreted the same ambiguous performance to support a belief that the child had below average reading ability.⁷⁴

In addition, individuals may become more polarized in their views after "interpreting" the same ambiguous evidence. In a study on the deterrent effects of capital punishment, subjects were randomly provided ambiguous "evidence" about the deterrent effects of capital punishment and later asked whether the evidence supported or discredited their views.⁷⁵ The subjects became more entrenched in their views; for example, those who were already positively disposed to capital punishment believed more in its deterrent effect.⁷⁶ The same effect was found in a study focused on subjects with pro- and anti-nuclear views.⁷⁷

Confirmation bias may result in ambiguous information being perceived differently by those with different group identities, such that prior schemas are maintained. A famous example of this involves the impact of school allegiance as a group identity. In particular, college students shown a film of a football game in which officials made a series of controversial decisions were viewed differently by students of two different

shown different videos of the child playing—either in a wealthy suburban area or an impoverished inner-city school. *Id.* at 23. In addition, subjects who viewed the child in the wealthy neighborhood were told that the parents were college educated with white-collar jobs whereas those who viewed the child in the poor neighborhood were told that the parents were college graduates with blue-collar jobs. *Id.*

74. *Id.* at 20.

75. Charles G. Lord et al., *Biased Assimilation and Attitude Polarization: The Effects of Prior Theories on Subsequently Considered Evidence*, 37 J. PERSONALITY & SOC. PSYCHOL. 2098, 2098 (1979).

76. *Id.*

77. S. Plous, *Biases in the Assimilation of Technological Breakdowns: Do Accidents Make Us Safer?* 21 J. APPLIED SOC. PSYCHOL. 1058, 1068 (1991) (finding that fifty-four percent of pro-nuclear subjects became more pro-nuclear and forty-five percent of anti-nuclear subjects became more anti-nuclear).

schools.⁷⁸ Students who attended the offending team's college reported seeing half as many illegal plays as did students from the opposing institution.⁷⁹ In other words, group ties had an unconscious, yet powerful effect in viewing the facts to favor their group affiliation.⁸⁰ The same effect has been found outside of experimental settings. For example, democratic and republican partisans who watched the same presidential debate each viewed their preferred candidate as performing better.⁸¹

Schemas are sufficiently powerful that they not only shape views of ambiguous evidence, but may even serve as a prism to either find ambiguity or entirely disregard inconsistent evidence. For example, despite substantial scientific support for the global warming phenomenon,⁸² some believe that the evidence is either ambiguous or supports a contrary conclusion.⁸³ Although this contemporary controversy may be difficult for some readers who consider one view or another to be "clearly" false, history can provide evidence of the impact of schemas through a now generally discarded schema. For

78. See generally Albert H. Hastorf & Hadley Cantril, *They Saw a Game: A Case Study*, 49 J. ABNORM. & SOC. PSYCHOL. 129 (1954).

79. *Id.* at 132.

80. For an additional example of this phenomenon, see generally Robert P. Vallone et al., *The Hostile Media Phenomenon: Biased Perception and Perceptions of Media Bias in Coverage of the Beirut Massacre*, 49 J. PERSONALITY & SOC. PSYCHOL. 577 (1985) (finding that pro-Arab and pro-Israeli students watching the same news coverage of a massacre of civilians viewed the coverage as consistent with their pre-existing schemas).

81. Geoffrey D. Munro et al., *Biased Assimilation of Sociopolitical Arguments: Evaluating the 1996 U.S. Presidential Debate*, 24 BASIC & APPLIED SOC. PSYCHOL. 15, 15 (2002).

82. See, e.g., JOINT SCIENCE ACADEMIES, JOINT SCIENCE ACADEMIES' STATEMENT ON GROWTH AND RESPONSIBILITY: SUSTAINABILITY, ENERGY EFFICIENCY AND CLIMATE PROTECTION (2007), http://www.nationalacademies.org/includes/G8Statement_Energy_07_May.pdf; G8+5 ACADEMIES, G8+5 ACADEMIES' JOINT STATEMENT: CLIMATE CHANGE AND THE TRANSFORMATION OF ENERGY TECHNOLOGIES FOR A LOW CARBON FUTURE (2009), <http://www.nationalacademies.org/includes/G8+5energy-climate09.pdf>; see also *The Consensus on Global Warming: From Science to Industry & Religion*, LOGICAL SCIENCE, <http://www.logicalsecience.com/consensus/consensusDI.htm> (last visited Nov. 18, 2011).

83. See, e.g., Mike Hulme, *The Science and Politics of Climate Change*, WALL. ST. J., Dec. 2, 2009, <http://online.wsj.com/article/SB10001424052748704107104574571613215771336.html>; Leslie Kaufman, *Among Weathercasters, Doubt on Warming*, N.Y. TIMES, Mar. 30, 2010, at A1; Andrew C. Revkin, *Hacked E-Mail Is New Fodder for Climate Change Dispute*, N.Y. TIMES, Mar. 20, 2009, at A1; *The Truth about Denial*, NEWSWEEK (Aug. 12, 2007, 8:00 PM), <http://www.thedailybeast.com/newsweek/2007/08/13/the-truth-about-denial.html>.

example, in the late 1800s when there was a common schema that women were inferior to men, that schema seemed to prevail even when women defied expectations. In particular, in the late 1800s, a female student who excelled at Cambridge University did not receive the same recognition as her male cohorts; whereas her male cohorts had their name published in the official class list, hers was not, prohibiting her from including the initials “B.A.” after her name.⁸⁴ In this case, the inconsistent information about a female student was simply ignored.

Moreover, the process of articulating support for a certain schema, such as a particular theory, may serve to reinforce that schema. Studies have shown this effect to exist in general and even in the extreme case where the schema was subsequently discredited.⁸⁵ This has important implications for the reinforcement of schemas in individuals in some occupations. For example, academics and judges may reinforce schemas by documenting their rationale. This may seem counterintuitive since some suggest that writing promotes careful reasoning.⁸⁶ Although the process of writing may help with the reasoning

84. Chen & Hanson, *Categorically Biased*, *supra* note 54, at 1116 (citing RITA MCWILLIAMS TULLBERG, *WOMEN AT CAMBRIDGE* 58 (1998)).

85. See, e.g., Craig A. Anderson et al., *Perseverance of Social Theories: The Role of Explanation in the Persistence of Discredited Information*, 39 J. PERSONALITY & SOC. PSYCHOL. 1037, 1039, 1041 (1980) (describing an experiment in which subjects who were told to provide a written explanation of a case study suggesting a relationship between risk taking and success as a fire fighter continued to believe in the relationship even after told that information was false); Timothy D. Wilson & Suzanne J. LaFleur, *Knowing What You'll Do: Effects of Analyzing Reasons on Self-Prediction*, 68 J. PERSONALITY & SOC. PSYCHOL. 21, 23, 26 (1995) (examining a study involving members of sororities who were asked to predict their own behavior toward future sorority members, with some randomly assigned to explain why in writing; those who “reasoned” their predictions were significantly more overconfident in their evaluations than those who did not); Lee Ross et al., *Social Explanation and Social Expectation: Effects of Real and Hypothetical Explanations on Subjective Likelihood*, 35 J. PERSONALITY & SOC. PSYCHOL. 817 (1977) (asserting that subjects who were provided a case study and were asked to explain why it reached a certain result, then were told that there was actually no information about any result, were more likely to predict the occurrence of the event they had explained than those who were not asked to give any explanation).

86. See, e.g., Chad M. Oldfather, *Writing, Cognition, and the Nature of the Judicial Function*, 96 GEO. L.J. 1283, 1284 (2008).

process in general, it may simultaneously reinforce some schemas.⁸⁷

3. Naïve Realism

The operation of schemas is further complicated by the fact that individuals are generally unaware of their own schemas, frequently referred to as biases, yet have a heightened sensitivity to the presumed biases of others; this is referred to as naïve realism.⁸⁸ For example, an individual will assume that their position on how to address the US budget deficit is based solely on an objective analysis, such that they are likely to believe that others who are objective will share the same position; those that do not will be presumed to lack essential information, intelligence, or objectivity.⁸⁹ The lack of objectivity could be attributable to multiple factors including, but not limited to, political ideology, self-interest, or other bias.⁹⁰

Individuals are not completely oblivious to possible flaws in perceptions, but when they actually perceive new information,

87. In particular, if writing is considered a form of increased thought, that may not necessarily reduce operation of schemas. See generally Duane T. Wegner et al., *Not All Stereotyping Is Created Equal: Differential Consequences of Thoughtful versus Nonthoughtful Stereotyping*, 90 J. PERSONALITY & SOC. PSYCHOL. 42 (2006) (suggesting that the process of writing down impressions does not necessarily lead to reduction of stereotype schema and may produce stereotypic perceptions with long lasting effects).

88. See, e.g., Robert J. Robinson et al., *Actual versus Assumed Differences in Construal: "Naïve Realism" in Intergroup Perception and Conflict*, 68 J. PERSONALITY & SOC. PSYCHOL. 404, 404 (1995); see also Adam Benforado & Jon Hanson, *Naïve Cynicism: Maintaining False Perceptions in Policy Debates*, 57 EMORY L.J. 499, 513-14 (2008). In addition, the same phenomenon has been observed without the use of this term. See, e.g., Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175, 1182-84 (1997) (referring to "[s]elf-[s]erving [b]ias, [u]nrealistic [o]ptimism, and [o]verconfidence" in lieu of the term "naïve realism"). Furthermore, although not identical, a related trend that most people acknowledge, albeit not in themselves, is the tendency for individuals to be overly optimistic about their own situation. For example, although entering law students know that not everyone can be at the top of their class, most students believe that they will near the top of the class. See, e.g., Ari L. Kaplan, *Would Law School Warning Labels Help?*, NAT'L L.J., Mar. 8, 2010; see also Kaplan Survey: Despite Challenging Job Market, Tomorrow's Lawyers Appear to Have a Healthy Outlook on Their Own Job Prospects, but Not Their Classmates', KAPLAN (Apr. 12, 2010), <http://www.kaplan.com/aboutkaplan/newsroom/Pages/newsroom.aspx?ID=571> (reporting that law students are more confident about their employment prospects than those of their peers).

89. See, e.g., Emily Pronin, *Perception and Misperception of Bias in Human Judgment*, 11 TRENDS IN COGNITIVE SCI. 37, 40 (2006) (using an example of bias based on position on latest welfare reform bill).

90. *Id.*

they are oblivious to possible distortions in thinking.⁹¹ Individuals are not consciously aware of bias that may impact the process of making judgments and inferences, such that they are inclined to believe that their judgments are neutral; those who disagree, on the other hand, are assumed to be biased as an explanation for a difference in opinion.⁹² Moreover, individuals can recall sometimes struggling to be objective and thus have a perception that this struggle reflects a cognitive process that is fair and balanced.⁹³ Accordingly, although individuals recognize that biases exist, they generally consider themselves less vulnerable to biases than others. For example, in one experiment where subjects were informed that all individuals suffer from a self-serving bias, subjects nonetheless believed that only other subjects, not themselves, were in fact vulnerable to such a bias.⁹⁴

The problems of naïve realism are also compounded in cases of disagreements. There is a tendency to assume that the cause of the disagreement is that the other party is subject to bias.⁹⁵ Individuals are quick to assume that the political affiliations of others bias them toward certain positions, yet deny that their own political affiliation might impact their views.⁹⁶ For example, in a study of students concerning terrorism responses after 9/11, students were more likely to view other students as biased when their views differed from their own.⁹⁷

91. See Emily Pronin et al., *Objectivity in the Eye of the Beholder: Divergent Perceptions of Bias in Self versus Others*, 111 *PSYCHOL. REV.* 781, 783–84 (2004).

92. See Emily Pronin et al., *The Bias Blind Spot: Perceptions of Bias in Self versus Others*, 28 *PERSONALITY & SOC. PSYCHOL. BULL.* 369, 378 (2002).

93. Pronin, *supra* note 91, at 784.

94. Pronin, *supra* note 92, at 378.

95. See, e.g., *id.* at 379; see also Kathleen A. Kennedy & Emily Pronin, *When Disagreement Gets Ugly: Perceptions of Bias and the Escalation of Conflict*, 34 *PERSONALITY & SOC. PSYCHOL. BULL.* 833, 834 (2008) (suggesting that the assumption that others are biased is especially relevant to disagreements).

96. Pronin, *supra* note 89, at 38 (citing Geoffrey L. Cohen, *Party over Policy: The Dominating Impact of Group Influence on Political Beliefs*, 85 *J. PERS. SOC. PSYCHOL.* 808 (2003)); Pronin, *supra* note 91, at 783 (suggesting that opposing partisans can suggest a range of biases including self interest, peer group pressure, and media brainwashing to account for the difference of opinion that is presumed to be erroneous).

97. Pronin, *supra* note 89, at 39.

B. *The Two Patent Policy Schemas*

This Article builds upon this rich literature concerning the existence and operation of schemas, confirmation bias, and naïve realism to show how two different patent schemas have impacted the interpretation of facts and laws concerning in-transit suspensions. However, before presenting the case study of these schemas in the context of in-transit suspensions, this section first presents two schemas of patent policy:⁹⁸ patents as either an uber-right or as a privilege.⁹⁹

This Section focuses on two fundamental schemas concerning patent policy that are essential to the question of the proper scope of patent rights in light of issues concerning access to affordable medicine. Although there is an arguable schema that considers all patents to be problematic and improper, the two schemas presented here both assume that patents can and

98. In addition, there may be complementary schemas at issue. For example, the privilege view may also have a schema that is suspicious of profit-making corporations that own patents; on the other hand, individuals with an uber-right view may consider anyone advocating greater access to drugs as an anti-property activist or hooligan.

99. As noted earlier, all individuals, this author included, are subject to schemas. There seems to be a schema perpetuated by the pharmaceutical industry that patents are essential to innovation and necessarily outweigh societal harm from the exclusionary power of patents. This schema is a widespread view among politicians and much of the general public. I myself held this schema and was influenced by it in writing my first article as a law professor; although some professors challenged some of my assumptions concerning the social impact of patent rights, I generally maintained my schema that patent rights were not generally a problem and found comfort in the comments of those that did not question my schema. See Cynthia M. Ho, *Patents, Patients and Public Policy*, 33 U.C. DAVIS L. REV. 601, 645–50 (2000) (arguing that the patent right to exclude is fundamental and should not be disturbed because of its possible negative impact on innovation). Although those initial comments did not immediately change my view, greater exposure to more information about how drugs are developed, as well as different approaches to patent rights and the impact of such rights has changed my views. Although I believe that I now have a more balanced perspective of patent rights, although I likely still suffer from a schema—albeit probably tilted somewhat more in the direction towards favoring exceptions to patent rights. Although my changing views are anecdotal, they are consistent with research that indicates that individuals may become less influenced by schemas as they are more cognizant of them. See, e.g., Jennifer A. Richeson & Richard J. Nussbaum, *The Impact of Multiculturalism versus Color-Blindness on Racial Bias*, 40 J. EXPERIMENTAL SOC. PSYCHOL. 417, 421 (2004) (showing that participants who learned about the virtues of multiculturalism had lower implicit racial bias than participants exposed to race-neutral information).

should exist in at least some cases.¹⁰⁰ Focusing only on schemas that assume patents should exist is most consistent with the current reality in which most nations provide patent rights, yet the scope of current patent rights may be at odds with patent schemas. In particular, although WTO member nations are required to provide patent rights pursuant to TRIPS,¹⁰¹ the scope of those rights may create tensions for countries to the extent that those rights vary in scope from a domestic patent perspective. To some degree, tensions that reflect different patent schemas are more likely now than when TRIPS was first concluded. After all, the language in TRIPS was sufficiently ambiguous such that it could be interpreted consistently with both patent policy schemas. However, the different schemas are more readily apparent when interpreting how certain TRIPS provisions apply to specific issues. As will be discussed later, the TRIPS provisions concerning border measures could be interpreted differently based on different patent perspectives.¹⁰² Before turning to the legal questions, however, this section first aims to clarify the patent schemas.

1. The Privilege Perspective

One side of the spectrum asserts that patents are a privilege, inherently subject to limitations and exceptions. As stated by Professor Brook Baker,¹⁰³ “[p]atents are not ‘property’ in the traditional sense—they are government granted rights that are intended to balance the interests of innovators and the

100. Of course, another possibility is that the schema of patents as privilege is a subset of the schema that believes all patents are improper, or that patents are improper for developing countries, without regard to what TRIPS presently requires. See generally Alan V. Deardorff, *Should Patent Protection Be Extended to All Developing Countries?*, 13 *WORLD ECON.* 497 (1990) (suggesting that developing countries be exempt from patent protection); Jean Olson Lanjouw, *Beyond TRIPS: A New Global Patent Regime*, 1 *CGD BRIEF* (Ctr. for Global Dev., Washington, DC), Aug. 2002, at 3, available at <http://www.iprsonline.org/ictsd/docs/cgdbrief003.pdf> (suggesting that companies choose between patent protection in wealthy or poor countries, but not both, in the case of global diseases).

101. TRIPS, *supra* note 2, art. 27.

102. See *infra* Part IV.A.1.

103. Professor Brook Baker is associated with Health Global Access Project, which is dedicated to eliminating barriers to access to HIV treatment.

public at large, and which are granted by governments with many express and implied conditions”¹⁰⁴ The United Nations Commissioner of Human Rights supports the idea of patents as a privilege that must be “subject to limitations in the public interest.”¹⁰⁵ In particular, the United Nations (“UN”) has suggested that certain human rights, such as the right to health, are “inalienable and universal,” and must be recognized over state-granted rights, such as patents.¹⁰⁶ Moreover, the UN Commissioner has suggested that, to the extent there is an “actual or potential conflict,” patent rights should yield to the right to public health.¹⁰⁷

The view of patents as a privilege, rather than an absolute right, suggests that the patent privilege should give way to other important social interests—such as a societal interest in promoting low-cost access to medicine. This view does not necessarily reject the idea that patent rights can promote innovation. It is a view, however, that requires a more balanced consideration of the extent to which innovation should be promoted if it negatively impacts access to medicine.

Prior to TRIPS, the patent laws of a number of countries seemed to reflect this view of patents as a privilege. In particular, even in countries that provided patent rights, a number of them excluded drugs from patentability.¹⁰⁸ This would be consistent with the patents as a privilege view that patents should be limited when necessary to promote public health. For example, India’s prior patent laws permitting patents on *methods* of

104. Brook K. Baker, *Pharma’s Seven Deadly Lies about Thai Compulsory Licenses*, CONSUMER PROJECT ON TECH. (Feb. 1, 2007, 11:14 AM), <http://www.cptech.org/blogs/ipdisputesinmedicine/2007/02/pharmas-seven-deadly-lies-about-thai.html>.

105. U.N. High Comm’r for Human Rights, Sub-Comm’n on the Promotion & Prot. of Human Rights, Intellectual Property Rights and Human Rights, ¶ 1, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (2000) [hereinafter Resolution 2000/7].

106. United Nations, Econ. & Soc. Council, Sub-Comm’n on Promotion and Prot. of Human Rights, Economic, Social and Cultural Rights, ¶ 14, U.N. Doc. E/CN.4/Sub.2/2001/13 (2001) (suggesting that rights under TRIPS, which are state-granted rather than inalienable, should, where appropriate, bow to the more universal human rights, such as the right to health); accord Resolution 2000/7, *supra* note 105, ¶ 3, (reminding “all governments of the primacy of human rights obligations over economic policies and agreements”).

107. See Resolution 2000/7, *supra* note 105, pmb. para. 11.

108. See Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI. KENT L. REV. 1469, 1511–13 (2007) (discussing the exceptions that India created to limit drug patentability, albeit subsequent to TRIPS).

creating drugs, but not the drugs themselves, fully embodies this view. This system maximized innovation in drug development while minimizing negative impacts on access to medicine. In particular, a patent on a method of creating a drug would not prevent others from developing new and improved methods. At the same time, since only the method was patented, and not the drug itself, the unpatented drug would likely be affordable.

Similarly, this view of patents as a privilege, subservient to providing low-cost drugs, is consistent with compulsory licenses of issued patents. A compulsory license is a widespread exception to traditional patent rights, which permits a nation to force a patent owner to accept a license, subject to a state-determined royalty, in certain situations that a country considers appropriate.¹⁰⁹ Countries that grant patents on food and drugs, but permit automatic compulsory licenses of such patents would be consistent with the privilege view of patents. Although automatic licenses are no longer permissible pursuant to TRIPS,¹¹⁰ more limited licenses of patented drugs to promote public access to drugs similarly reflect the view of patents as privilege. This would be especially true with respect to drugs that are considered essential, or in the case where a nation had promised universal access to essential drugs. Accordingly, those with a privilege view would strongly support and even

109. See Robert C. Bird, *Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects*, 37 J. L. MED. & ETHICS 209, 209–210 (2009) (discussing the development and importance of compulsory licenses in developing countries to promote the manufacture and sale of patented drugs within its borders); see generally Adi Gillat, *Compulsory Licensing to Regulated Licensing: Effects on the Conflict between Innovation and Access in the Pharmaceutical Industry*, 58 FOOD & DRUG L.J. 711 (2003) (explaining compulsory licenses generally and, in particular, the US approach).

110. See, e.g., GERVAIS, *supra* note 26, at 391 (stating that TRIPS does not permit categories of inventions to be automatically licensed); CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 320 (2007) (noting that licenses cannot be granted by subject matter because of the requirement for individual consideration); UNCTAD/ICTSD, *RESOURCE BOOK ON TRIPS AND DEVELOPMENT* 468 (2005) (noting that governments should avoid “blanket authorizations” for entire technologies).

congratulate nations that issued compulsory licenses to promote broader access to patented drugs.¹¹¹

The view of patents as a privilege not only suggests that patent rights should be flexible in general, but also that they should necessarily be modified to promote access to patented drugs. Opinions on the extent to which patent rights should be modified may differ, even among individuals that consider patents a privilege. For example, some may consider a right to health to necessarily include a right to any and all medical treatment that might improve health. Alternatively, others might hold a more tempered view that would only suggest modifying patent rights on drugs that are considered “essential” in some capacity. Regardless of these differences, there is a uniform belief that patented drugs necessarily impede affordable access to drugs during the patent term, such that patent rights should be modified.

The view of patents as privilege may be accompanied by related views, whether they are considered part of the overall privilege schema, or complementary schemas. For example, since patents are often owned by large companies that are seen to spend substantial amounts of money on promoting drug sales, patent rights could be considered to simply fill the coffers of greedy companies.¹¹² Suspicion of drug companies could promote naïve realism in that any actions and statements made by such companies would be assumed to be biased. In addition, there may be a related schema concerning wealthy countries where patent owners tend to reside. In particular, such countries could also be viewed sceptically as only being interested in

111. For example, in hailing Thailand’s issuance of compulsory licenses, Dr. David Wilson of Médecins Sans Frontières (“MSF”) stated that “the lives of patients have to come before the patents of drug companies,” in support of the compulsory license as an appropriate modification to the default patent rights. Press Release, Médecins Sans Frontières, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand, Campaign for Access to Essential Medicine (Nov. 29, 2006), *available at* <http://www.msfaaccess.org/our-work/hiv-aids/article/389>.

112. Patent-owning companies are frequently criticized for spending more money on the advertisement and promotion of drugs than on scientific research. *See, e.g.*, Marc-André Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS MED. 29, 32 (2008).

maximizing their own wealth and possibly doing so at the expense of other countries and their health.¹¹³

2. The Uber-Right Perspective

The alternative perspective views a patent as a very strong property right that should in fact be stronger than most property rights, such that it will be referred to as an “uber-right.”¹¹⁴ For example, Professors Richard A. Epstein and F. Scott Kieff have stated “patents are praised as a spur to innovation, which is made possible only with the predictable enforcement of rights of exclusion for the patented technology.”¹¹⁵ In other words, the uber-right perspective similarly views patents as a special type of property right, but in a very different manner than the privilege view. Patents are considered special in that they are much more limited in time, such that the strength of patent rights during that limited term is considered paramount.

The uber-right perspective of patents also has some basis in human rights norms. In particular, the Universal Declaration of Human Rights as well as the International Covenant on Economic, Social and Cultural Rights include a clause about how everyone should enjoy the benefits of scientific progress and benefit from protection of interests from any scientific

113. See Jerome Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 25 (1997) (suggesting that consumers and others are “held hostage” to the political influence of powerful industry forces that are eager to “expand market power”). In fact, some have noted that the genesis of TRIPS can be traced to a group of powerful CEOs in a range of industries (including, but not limited to, pharmaceuticals), who argued in favor of broader global protection of intellectual property rights, which would result in greater profits for them. See generally SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL POWER* (2003) (arguing that the successful conclusion of TRIPS reflects the effective efforts of private groups in framing their interests as consistent with domestic policies in the global economy); Peter Drahos & John Braithwaite, *INFORMATION FEUDALISM: WHO OWNS THE KNOWLEDGE ECONOMY* 7 (2002) (arguing that a small group of multinational companies conceived of and orchestrated the creation of TRIPS as a matter of self-interest).

114. This view of patents as an uber-right is proposed to exist in general, although it has more specific implications for the issue of access to affordable medicine.

115. Richard A. Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71, 72 (2011).

production of which she is the author.¹¹⁶ These statements have been used to suggest that if patent rights are minimized, the author is improperly deprived of the protection of his or her interests.¹¹⁷

The uber-right view also considers balance of interests an important part of patent rights, although what is balanced is inherently distinct from the privilege view of patents. In particular, the uber-right perspective considers strong patent rights as paramount to promote innovation. Although the uber-right may recognize that patent rights have the potential to create challenges to accessing patented drugs in the short-term, these challenges are considered less important than maintaining long-term innovations.¹¹⁸ Exceptions to patent rights are considered a threat to crucial incentives needed to develop new drugs that involve “huge, lengthy and risky investments” of over a billion dollars per drug.¹¹⁹ For those with an uber-right perspective, short-term access issues can and should be resolved outside the patent system because reduced patent protection necessarily compromises long-term innovation. Accordingly, those with an uber-right view frequently suggest that access to

116. See Universal Declaration of Human Rights, G.A. Res. 217 (III) A, art. 27(2), U.N. Doc. A/RES/217(III), (Dec. 10, 1948) (“Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.”); International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI) A, U.N. Doc. A/RES/2200(XXI), art. 15(1) (Dec. 16, 1966).

117. The same article, however, has been read to support the perception of patents as a privilege—that consumers are entitled to enjoy the results of scientific progress in drug discovery such that they have actual access to medicine, not merely theoretical access based upon economic conditions beyond their control. See HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES 112 (2007) (stating that ICESCR article 15(1)(b) supports access to medicine); see also Philip Cullet, *Patents and Medicines: The Relationship between TRIPS and the Human Right to Health*, 79 INT’L AFFAIRS 139, 150–51 (2003) (suggesting that the ICESCR is focused on end user access).

118. E.g., AIDE MÉMOIRE, COMPULSORY LICENSES IN THAILAND ON PHARMACEUTICALS UNDER PATENT PROTECTION, available at http://www.keionline.org/misc-docs/1/swiss2thailand_cl.pdf (stating that patents are part of the solution to “long term access” to medicine and suggesting that mechanisms to increase short term access may negatively impact long term development, as well as access).

119. Epstein & Kieff, *supra* note 115, at 78. Others with an uber-right view similarly acknowledge the high cost of patented drugs, but tend to emphasize that drug discovery is lengthy and expensive. See, e.g., Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 JAMA 1886, 1886 (2001); Bird, *supra* note 109, at 216.

affordable medicine is not precluded by patents, but by poverty.¹²⁰

Although an uber-right view of patents recognizes that access to affordable medicine may be limited during the patent term by prices set by patent owners, they suggest that strong patent rights nonetheless benefit all. Professor Martin Adelman has suggested that the question of access to medicine often overlooks the fact that “without patents there would be far fewer drugs around for people to access. One cannot have access to something that does not exist.”¹²¹ Similarly, Fred Hassan, Chairman and CEO of major pharmaceutical company Schering Plough, suggests patent protection is the important first step toward low-cost generics by considering generics to be the “direct result of IP-fuelled innovation.”¹²²

Those who view patents as an uber-right may consider any exceptions to this right as not only improper, but in fact “stealing.” For example, the traditionally recognized and internationally sanctioned doctrine of compulsory licenses have nonetheless been characterized as “stealing” or “piracy” by those with an uber-right perspective.¹²³ In addition, those that impose compulsory licenses are referred to as “anti-property hooligans” or free-riders who want to benefit from innovations encouraged by the patent system without paying their due.¹²⁴

The uber-right view of patents may consider any modification of patent rights to not only be improper, but also to inappropriately destroy incentives to create new drugs. The importance of a strong patent right may be considered so

120. See, e.g., Richard P. Rozek, *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 3 J. WORLD INTELL. PROP. 889, 896–99 (2000) (pointing to other barriers to access to affordable medicine).

121. Martin J. Adelman, *Compulsory Licensing of Drugs: TRIPS Context*, INT’L ASS’N FOR ADVANCEMENT TEACHING & RES. INTELL. PROP. (Aug. 4, 2003), http://www.atrip.org/Content/Activities/s02-Adelman_art.doc.

122. Caroline Joiner, *Building a Better World through Innovation*, CHAMBERPOST (Oct. 8, 2008), <http://www.chamberpost.com/2008/10/building-a-bett/>.

123. See, e.g., Christopher C. Horner, *Thailand Stealing out of WTO?*, WASH. TIMES, May 17, 2007, at A15; Ronald A. Cass, *Drug Patent Piracy*, WALL ST. J., May 7, 2007, at 15.

124. Editorial, *Bangkok’s Drug War Goes Global*, WALL ST. J. ASIA, Mar. 7, 2007, at 13; Ronald A. Cass, Op-Ed., *Patent Remedy*, WALL ST. J. ASIA, Aug. 28, 2007, at 13.

sacrosanct to the uber-right that any potential limit of patent rights is considered equivalent to no patent rights at all. Notably, those with an uber-right view tend to suggest that there will be no innovation without patents in response to the suggestion to modify, but not eliminate patent rights.¹²⁵ However, evidence does not unequivocally support this schema. After all, there are notable inventions that were created without any patent incentive, such as the Polio vaccine.¹²⁶

The uber-right view of patents (or a complementary schema) may believe so strongly in the power of patents to promote socially productive innovation that broad patent rights for all countries are assumed as necessarily desirable. In other words, the uber-right view advocates not just patent rights for wealthy countries, but also advances the idea that patent rights in developing countries will necessarily promote wealth in those countries. Indeed, in promoting global patent standards under TRIPS, some suggested that requiring developing countries to provide patents on all inventions would promote foreign direct investment from wealthy countries as well as spur local innovation despite more modest evidence.¹²⁷ Although TRIPS

125. This frequently occurs in the context of compulsory licenses. *See, e.g.*, Cass, *supra* note 124, at 13 (asserting that Thailand's compulsory licenses threaten the worldwide system for the protection of innovation); *see also A Gathering Storm*, *ECONOMIST*, June 7, 2007, <http://www.economist.com/node/9302864> (quoting Fred Hassan of Schering-Plough saying "without intellectual property there is no innovation"). In addition, the same phenomenon occurs in defending laws that provide stronger patent rights. *See, e.g.*, *GSK's Position on the Anti-Counterfeiting Trade Agreement (ACTA)*, GLAXOSMITHKLINE (Dec. 10, 2010), <http://www.gsk.com/policies/GSK-Public-Position-on-ACTA.pdf> (in a statement supporting the Anti-Counterfeiting Trade Agreement, GlaxoSmithKline (GSK) asserted "[w]ithout IP laws, GSK would not be able to fund new R&D and to provide new innovative products" even though the discussion was not about eliminating IP laws, but only about the extent to which such laws should be further strengthened) (emphasis added).

126. *See, e.g.*, Melody Petersen, *Our Daily Meds: How the Pharmaceutical Companies Transformed Themselves into Slick Marketing Machines* ch. 6 (2009); *About Jonas Salk*, SALK INSTITUTE, http://www.salk.edu/about/jonas_salk.html (last visited Nov. 23, 2011); *see also* François Bompard et al., *Innovative Public-Private Partnerships to Maximize the Delivery of Anti-Malarial Medicines: Lessons Learned from the ASAQ Winthrop Experience*, 10 *MALARIA J.* 143, 143 (2011) (describing a successful collaboration that resulted in the development of the anti-malarial ASAQ without patent protection by DnDI).

127. *See, e.g.*, Martin J. Adelman & Sonia Balda, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 *VAND. J. TRANSNAT'L L.* 507, 517, 530 (1996) (suggesting that patent provisions of TRIPS will spur India to innovation); Michelle McGrath, *The Patent Provisions in TRIPS: Protecting Reasonable Remuneration for Services Rendered—Or the Latest Development in Western Colonialism?*, 18 *EUR. INTELL.*

has not clearly had this impact, those who believe in an uber-right view of patents may nonetheless continue to hold this view since they continue to promote ever-increasing global standards of patent protection.¹²⁸ This could be consistent with social science evidence concerning schemas, even when there is no evidence that patents promote progress, any possible ambiguity is still interpreted in favor of the schema of strong patent rights as a necessary good. For example, US officials have repeatedly stated that increased patent rights in Jordan have encouraged foreign direct investment and stimulated local research, consistent with the uber-right view that these are benefits of strong patent protection.¹²⁹ However, although Jordan has developed its own medicines, providing more patent rights has not increased innovation or resulted in greater collaboration

PROP. REV. 398, 400 (1996); Mariko Sakakibara & Lee Branstetter, *Do Stronger Patents Induce More Innovation? Evidence from the 1988 Japanese Patent Law Reforms*, 32 *RAND. J. ECON.* 77, 78 (2001).

128. Studies concerning whether increased patent rights increase foreign direct investment are not conclusive. See, e.g., Darnita York Akers & Sencer Ecer, *The TRIPS Agreement and Its Effects on the R&D Spending of US-Owned Multinational Companies in Developing Countries*, 43 *J. WORLD TRADE* 1173, 1174 (2009); Pamela J. Smith, "How Do Foreign Patent Rights Affect U.S. Exports, Affiliate Sales, and Licenses?" 55 *J. OF INT'L ECON.* 411, 411 (2001); see also Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 *DUKE J. COMP. & INT'L L.* 109, 118 (1998) (noting the large amount of foreign investment in Latin American countries, in part due to tax and operating advantages). Moreover, as pointed out by Professor Carlos Correa, countries such as Brazil and Thailand have received substantial foreign direct investment at times when they had low levels of patent protection. CARLOS M. CORREA, *INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS* 27 (2000); see also Arman S. Kirim, *Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry*, 13 *WORLD DEV.* 219 (1985) (finding that foreign direct investment in Korea increased after patents were eliminated on pharmaceuticals).

129. See *US-Bahrain FTA: Fact Sheet on Access to Medicines*, OFFICE OF THE U.S. TRADE REPRESENTATIVE (Sept. 2004), <http://www.ustr.gov/trade-agreements/free-trade-agreements/bahrain-fta> (asserting that Jordan has developed its own medicine since the enactment of Free Trade Agreement ("FTA") with the United States as evidence that stronger patent protection helps developing countries); Marilyn Chase & Sarah Lueck, *In New Trade Pacts, U.S. Seeks to Limit Reach of Generic Drugs*, *WALL. ST. J.*, July 6, 2004, at A1 (quoting USTR spokesperson that Jordan had a blossoming of its pharmaceutical industry after implementation of the FTA with the United States).

with multinational pharmaceutical companies.¹³⁰ This is another example of rejecting information that is inconsistent with a schema.

III. EXPOSING THE IMPACT OF PERSPECTIVES ON FACTS

This Part shows how the competing patent perspectives may view facts concerning suspensions of generic drugs in-transit differently. In particular, this Part begins by providing background on the legal framework permitting such suspensions, as well as facts concerning the actual suspensions. Then, the facts are re-considered through two vignettes written from the lens of each perspective.

A. Background

This Section begins with the EU Regulation that gave rise to suspensions of in-transit drugs on the ground of patent infringement. Then, it describes the actual suspensions. Finally, it discusses more current international developments that further threaten global trade in generic drugs, focusing in particular on the recently-concluded ACTA.

1. EU Regulation

The EU Regulation permitting suspension of goods that allegedly infringe patents is a relatively recent expansion of a regulation first designed to address counterfeit trademarks that entered into free circulation in Member States.¹³¹ It was subsequently expanded to address not only pirated copyrighted goods,¹³² but also both counterfeit and pirated goods in

130. Hamed El-Said & Mohammed El-Said, *TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement*, 10 J. WORLD INTELL. PROP. 438, 438–57 (2007).

131. See Council Regulation No. 3842/86/EEC on Laying Down Measures to Prohibit the Release for Free Circulation of Counterfeit Goods, 1999 O.J. L 27/1; see also Commission of the European Communities, *Combating Counterfeiting and Piracy in the Single Market: Green Paper*, COM (98) 569 Final (Oct. 1998) (identifying a need to address counterfeiting and piracy).

132. See Council Regulation No. 3295/94/EC on Laying Down Measures to Prohibit the Release for Free Circulation, Export, Re-Export or Entry for a Suspensive Procedure of Counterfeit and Pirated Goods, 1994 O.J. L 341/8.

transit.¹³³ In addition, the regulation was expanded to permit customs officials to take action on their own initiative without awaiting a specific request from the right holder.¹³⁴

The expansion to include patent infringements was made in 1999¹³⁵ and may have been in response to industry interest in including them.¹³⁶ Extending the scope to patented inventions was also justified as important to “safeguarding innovation” and permitting European products to be internationally competitive;¹³⁷ although safeguarding innovation does not appear to have previously played a prominent role in the history of the regulation.¹³⁸ However, this inclusion was admitted to be an “experiment” in that identifying patent infringement was admittedly more difficult than identifying counterfeit trademarked or pirated copyrighted goods.¹³⁹

Under the current EU Regulation, customs officials may act either on behalf of a specific application by a rights-holder or on their own initiative in suspending goods that infringe an intellectual property right based on local right. In other words, although the Regulation applies to all EU member countries, whether an intellectual property right is being violated is a function of national law. For example, German customs officials

133. *See id.*

134. *See id.* The ex officio provisions were included in 1994. There are, however, mechanisms in the regulation intended to prevent abuse of the system. For example, the owner should be able to obtain release by either objecting to a patent owner’s request to destroy the goods or by notifying the customs office that legal procedures have been initiated to evaluate whether patent infringement is occurring. *See* Customs Action Regulation, *supra* note 4, arts. 13–14, at 12.

135. Council Regulation No. 241/1999/EC Amending Regulation (EC) No 3295/94 Laying Down Measures to Prohibit the Release for Free Circulation, Export, Re-Export or Entry for a Suspensive Procedure of Counterfeit and Pirated Goods, 1999 O.J. L 27/1.

136. *See* Proposal for a Council Regulation (EC) Amending Regulation (EC) No. 3295/94 Laying Down Measures to Prohibit the Release for Free Circulation, Export, Re-Export or Entry for a Suspensive Procedure of Counterfeit and Pirated Goods, 1998 O.J. C 108/63, ¶ 7.1 [hereinafter Amending Regulation].

137. *Id.*

138. Innovation was not previously mentioned in the 1986 nor the 1994 regulations.

139. Amending Regulation, *supra* note 136, ¶¶ 6.4–6.5.

apply German patent law to assess whether in-transit goods infringe patent laws.¹⁴⁰

However, there is a wrinkle in assessing local patent infringement of in-transit goods. In particular, no EU member state has patent laws that specifically include in-transit goods as goods that violate the patent owner's right to exclude imports. Nonetheless, Dutch courts have interpreted the EU regulation to create a similar effect. In particular, recital 8 of the Regulation suggests that infringement is assessed based on whether the goods would infringe *if made* in the Member State.¹⁴¹ Based on this recital, Dutch courts have held that in-transit products can infringe Dutch patents based on an admitted legal fiction that the products were made in the Netherlands.¹⁴² In other words, although Dutch patent law does not consider in-transit goods to be imported, the Dutch interpretation of the EU regulation considers in-transit goods to nonetheless infringe its patent law for purposes of permitting customs to suspend the drugs based on a fiction that the in-transit products are made in the Netherlands.

The Dutch case law has been criticized as inappropriate and inconsistent with the EU regulation, as well as prior jurisprudence of the Court of Justice of the European Union ("Court of Justice").¹⁴³ The Dutch law, however, has not been specifically overruled. While there are some cases before the Court of Justice that challenge the application and

140. Customs Action Regulation, *supra* note 4, art. 10.

141. *See id.*, pmb. recital 8 ("Proceedings initiated to determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights.").

142. *See, e.g.*, Rechtbank 's-Gravenhage 18 juli 2008, 311378/KG ZA 2008, 08-617 m.nt. (Sosecal/Sisvel) (Neth.), ¶ 4.14.

143. *See, e.g.*, Henning Grosse Ruse-Khan & Thomas Jaeger, *Policing Patents Worldwide? EC Border Measures against Transiting Generic Drugs under EC and WTO Intellectual Property Regimes*, 40 INT'L REV. INTELL. PROP. & COMPETITION L. 502, (2009); Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WORLD INTELL. PROP. ORG. J. 43 (2009). In particular, some suggest that *Montex Holdings Ltd. v. Diesel SpA*, a trademark case that precluded seizure of in-transit goods without evidence of likely diversion into the EU markets, suggests that there can be no infringement of in-transit goods without evidence of likely diversion *E.g.*, Abbott, *supra*, at 47–48; *see also* *Montex Holdings Ltd. v. Diesel SpA*, Case C-281/05, [2006] E.C.R. I-10,881.

interpretation of the EU Regulation, they do not directly challenge the Dutch suspension of in-transit goods based on patent infringement.¹⁴⁴ There is one pending case before the Court of Justice that does question whether an analogous provision should be interpreted to avoid the legal fiction.¹⁴⁵ The Court of Justice might eventually find that in-transit goods should not be considered to infringe copyrights, the intellectual property right at issue, such that perhaps in-transit infringement of patents would also cease to be an issue in the EU.¹⁴⁶ However, even if that were to occur, the basic principle of suspending in-transit goods on grounds of patent or trademark infringement is possible in the international realm under the ACTA, as discussed in a later section.¹⁴⁷

2. EU Seizures

Although EU customs officials were permitted to suspend alleged patent infringements in 1999, actual suspension of goods did not happen for another decade. In 2008, EU customs officials began using their authority to detain drugs that allegedly infringed patent rights.¹⁴⁸ Over a period of about eighteen months, almost twenty shipments were detained, with

144. See *Koninklijke Philips Elecs. NV v. Lucheng Meijing Indus. Co.*, Joined Cases C-446/09 & C-495/09, [2011] E.C.R. I ___ (delivered Feb. 3, 2011).

145. See *id.* ¶ 113.

146. See *id.* Although the Court of Justice of the European Union (“Court of Justice”) has not yet ruled, the Advocate General (“AG”) has advised that the provision that relates to the problematic recital be interpreted as meaning that member states should not discount the transitory status of goods and in particular, should not apply the legal fiction that the good was manufactured in the transitory state. *Id.* Even before the AG opinion, some had suggested that existing Court of Justice jurisprudence should compel the same conclusion despite the fact that no Court of Justice case involved patents. See *supra* note 143 and accompanying text.

147. See *infra* Part IV.B.

148. See *e.g.*, XAVIER SEUBA, INT’L CTR. FOR TRADE AND SUSTAINABLE DEV., FREE TRADE OF PHARMACEUTICAL PRODUCTS: THE LIMITS OF INTELLECTUAL PROPERTY ENFORCEMENT AT THE BORDER, ISSUE PAPER NO. 27 at 1 (2010); THOMAS JAEGER ET AL, MAX PLANCK INST. FOR INTELL. PROP., COMPETITION & TAX L., STATEMENT OF THE MAX PLANCK INSTITUTE FOR INTELLECTUAL PROPERTY, COMPETITION AND TAX LAW ON THE REVIEW OF EU LEGISLATION ON CUSTOMS ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS, RESEARCH PAPER NO. 10-08 para. 3 (2010), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1622619.

many delayed for months and some even destroyed.¹⁴⁹ Most shipments originated from India, where they were legally made as unpatented generics.¹⁵⁰ The shipments were predominantly destined for developing countries where the drugs were also considered unpatented generics.¹⁵¹ The drugs were most often suspended in the Netherlands, where courts have construed the EU regulation to consider in-transit goods to infringe Dutch patent rights based on an admitted legal fiction.¹⁵² However, there were also suspensions of generic goods in France and Germany.¹⁵³

The seized drugs treated a variety of conditions including HIV, heart disease, dementia, and schizophrenia.¹⁵⁴ Some of the seized drugs were major profit-makers for patent owners. For example, Sanofi-Aventis aggressively enforces its patent on the heart medication it sells as Plavix,¹⁵⁵ which is a blockbuster drug.¹⁵⁶ In addition, the antipsychotic drug olanzapine, sold as

149. See, e.g., Request for Consultations by India, *European Union and a Member State—Seizure of Generic Drugs in Transit*, WT/DS408/1, at 1 (May 19, 2010) (noting nineteen confirmed shipments).

150. See *id.*

151. See *id.*, Annex (noting shipments to Brazil, Columbia, Nigeria, and Peru).

152. *Id.*

153. The suspension in Germany was actually based upon an inappropriate assumption of trademark infringement, as discussed later in this section. However, the suspension in France was for a generic anti-platelet drug called clopidogrel (the generic form of what is sold as Plavix) from India destined for Venezuela; a shipment was suspended at the Paris airport in October 2009. See, e.g., *Macleod's Clopidogrel Generic Pills Consignment Seized at Paris: Reports*, DANCE WITH SHADOWS (Nov. 3, 2009, 3:12 PM), <http://www.dancewithshadows.com/pillscribe/macleods-clopidogrel-generic-pills-consignment-seized-at-paris-reports/>. Although the French have not historically interpreted the EU Regulation as considering in-transit drugs as violative of patent rights, this shipment was suspended nonetheless.

154. Letter from J. van der Vlist, Mgmt. Team Member, Neth. Ministry of Fin., to S. Bloemen, Health Action Int'l Eur. (HAI) (May 7, 2009) [hereinafter HAI Letter from Netherlands], available at [http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20\(EN\).pdf](http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20(EN).pdf).

155. See, e.g., IMS Health, *Top 10 Global Products—2007*, IMS HEALTH (last updated Feb. 26, 2008), available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Top10GlobalProducts.pdf (noting indicating that Plavix was the second most profitable drug in global sales in 2007); Peter Loftus & Shirley S. Wang, *Bristol Posts a Profit As Drugs Make Gains*, WALL ST. J., Jan. 28, 2009, at B3 (noting that Plavix brought in US\$1.47 billion in fourth-quarter sales in 2009).

156. In the pharmaceutical industry, a blockbuster drug is one that has annual world wide sales exceeding US\$1 billion. E.g., STAN FINKELSTEIN & PETER TEMIN,

Zyprexa by Eli Lilly, is a global best-seller.¹⁵⁷ Similarly, Rivastigmine, a dementia treatment sold under the trademark Exelon by Novartis, is considered a top-performing drug for Novartis,¹⁵⁸ and Losartan potassium, a high blood pressure treatment sold by Merck under the trademark Cozaar, is a similarly profitable drug for Merck.¹⁵⁹

Many of the suspended drugs never reached their final destination. About half of the seized drugs were destroyed.¹⁶⁰ The destruction was often due to the lack of response from the manufacturer to a notification of the seizure; pursuant to the EU regulation, authorization to destroy goods is presumed if there is no response.¹⁶¹ While full details are not known about each case, in at least one case, the shipment was abandoned because the estimated cost of litigation was deemed to exceed the cost of the shipment.¹⁶²

REASONABLE RX: SOLVING THE DRUG PRICE CRISIS 6 (2008); European Commission, *Pharmaceutical Sector Inquiry: Preliminary Report* 17 (DG Competition Staff, Working Paper, Nov. 28, 2008). Companies substantially rely on sales of blockbuster drugs since they have large profit margins and also focus research and development efforts on such drugs. *E.g.*, FINKELSTEIN & TEMIN, *supra*, at 5–6; *see also* European Commission, *supra*, at 33 (noting that companies rely substantially on blockbuster drugs for profits).

157. John W. Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J., Aug. 6, 2009, <http://lists.essential.org/pipermail/ip-health/2009-August/014110.html>.

158. *See, e.g.*, Financial Report, NOVARTIS INT'L AG, 7, 14, <http://www.annualreports.com/HostedData/AnnualReports/PDFArchive/nvs2009.pdf> (reporting that global Exelon sales were over US\$900 million); Daniela Sigrist, *Novartis Posts 32 Percent Rise in 3Q Net Profit*, USA TODAY (Oct. 20, 2008, 3:10 PM), http://www.usatoday.com/money/economy/2008-10-20-715205609_x.htm (naming Exelon as a top-performing drug contributing to net profits).

159. *See* Press Release, Merck, Merck Reports Second Quarter 2008 Financial Results (July 21, 2008), *available at* http://www.merck.com/newsroom/press_releases/financial/2008_0721a.html (noting global sales of Merck's antihypertensive medicines COZAAR (losartan potassium) and HYZAAR (losartan potassium and hydrochlorothiazide) were US\$941 million for the second quarter of 2008).

160. *E.g.*, Miller & Anand, *supra* note 157; Daniel Pruzin, *Brazil Cites Growing Instances of 'Illegal' Dutch Generic Medicine Seizures*, 2009 PAT., TRADEMARK & COPYRIGHT L. DAILY (BNA) (Mar. 4, 2009).

161. Customs Action Regulation, *supra* note 4, art. 11, at 12.

162. *E.g.*, *Cipla Export Consignment Too Seized at Amsterdam*, MONEYCONTROL.COM (Feb. 4, 2009) http://www.moneycontrol.com/news/business/cipla-export-consignment-too-seized-at-amsterdam_383598-1.html. In general, the known value of shipments ranges from US\$50,000 to US\$100,000. *See, e.g.*, Jyothi Datta, *Amsterdam*

The grounds for seizing the drugs are often confusing as they conflate issues, or at least loosely use the term “counterfeit” when referring to generic drugs. For example, in the first reported seizure of in-transit drugs, Sanofi-Aventis informed the company anticipating a shipment of generic heart medication (comparable to Sanofi-Aventis’ Plavix-brand drug) that the goods were seized on suspicion that they were “counterfeit.”¹⁶³ However, subsequent correspondence refers to the problem as one of patent infringement.¹⁶⁴ In a different situation, patent owner Eli Lilly did not go so far as to call generic versions of its antipsychotic drug olanzapine counterfeit, but nonetheless suggested that the generic Indian versions “may not be safe or effective” because they were not made by Eli Lilly.¹⁶⁵ Similarly, the European Federation of Pharmaceutical Industries and Associations (“EFPIA”), which represents pharmaceutical companies in Europe, stated that EU Member States have the right to stop products suspected of being counterfeit and that customs authorities play an important role in “protecting patients from the danger of counterfeit medicine.”¹⁶⁶ In addition, an EU official was quoted as stating that “[m]any countries actually should be grateful to European customs, who most likely have saved lives and certainly in developing countries, because fake medicines are more spread in

Authorities Release Ind-Swift Exports, HINDU BUS. LINE, May 23, 2009, <http://www.thehindubusinessline.com/2009/05/23/stories/2009052350971500.htm> (stating that the Ind-Swift consignment of clopidogrel was worth US\$50,000).

163. Eli Lilly Letter, *supra* note 8.

164. The letter explains that infringement exists under Netherlands law because of case law that finds goods in transit destined for countries outside the EU to nonetheless be considered infringing if they would have been infringing if manufactured in the Netherlands—with full acknowledgment that this is a legal fiction. *Id.*

165. Sanofi Letter 2, *supra* note 7.

166. Press Release, Eur. Fed’n of Pharm. Indus. and Ass’ns, *Customs Seizures of In-Transit Medicines* (Mar. 13, 2009) [hereinafter EFPIA Press Release], available at <http://www.efpia.eu/content/default.asp?PageID=559&DocID=6574>. The membership of the European Federation of Pharmaceutical Industries and Associations (“EFPIA”) includes Eli Lilly, March, and Sanofi—all companies that have been involved with in-transit seizures. *EFPIA Membership*, EFPIA, <http://www.efpia.eu/Content/Default.asp?PageID=353> (last visited Aug. 25, 2011).

developing countries than developed countries.”¹⁶⁷ However, in no case were the suspended drugs in-fact fake.¹⁶⁸

Although most of the suspended drugs were held on grounds of alleged patent infringement, there was one instance where generic drugs were suspended for alleged trademark infringement. On May 5, 2009, a shipment of amoxicillin, the non-proprietary name for a generic antibiotic used to treat a wide range of infections, was suspended in the Frankfurt airport on grounds that it might infringe the trademark antibiotic sold as Amoxil by GlaxoSmithKline (“GSK”).¹⁶⁹ When contacted, GSK clarified that there was no trademark problem and the goods were ultimately released to their final destination in Vanuatu, a least-developed country.¹⁷⁰ Although GSK did not initiate the suspension and in fact timely indicated that there were no intellectual property problems,¹⁷¹ the shipment was nonetheless delayed for four weeks—a time period that may have delayed effective treatment. This suspension prompted further calls for change.¹⁷²

There have been no seizures since Brazil and India brought a formal challenge to the WTO in May 2010. However, unless and until there is a change in the laws, there remains a threat to trade in generic drugs because of legal uncertainty. Even before the formal challenge, some Indian companies had rerouted

167. *Fight over Generic Drug Seizure Takes Centre Stage at TRIPS Council Meeting*, 13 INT’L CENTRE FOR TRADE AND SUSTAINABLE DEV. (2009), 1–2, <http://ictsd.org/i/news/bridgesweekly/42823/>.

168. *See id.*

169. *See, e.g.,* Khomba Singh, *Row over Generic Drugs Intensifies after Seizure in Germany*, ECON. TIMES (India), June 8, 2009; Kaitlin Mara, *Drug Seizures in Frankfurt Spark Fears of EU-Wide Pattern*, IP-WATCH (June 5, 2009), <http://www.ip-watch.org/weblog/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/print/>.

170. *Id.*

171. Glaxo is reported to have informed German customs authorities that there was no trademark infringement within seven days of notification. Press Release, Health Action Int’l et al., *Another Seizure of Generic Medicines Destined for a Developing Country, This Time in Frankfurt* (June 5, 2009), *available at* <http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf>.

172. *See, e.g., id.* (quoting Sophie Bloemen, from Health Action International—Europe (“HAI”), as saying “this suggests that the detainment of legitimate generics in transit “is not just a Dutch issue, but rather a European problem”).

their global trade to avoid the EU, even though that meant shipping costs were twice as expensive.¹⁷³ This action is likely a function not only of the Dutch law, but also the actions of patent owners. For example, in at least one case, a European patent owner requested an Indian manufacturer of generic drugs that had been suspended to sign a declaration that it would “not send other consignments containing products which infringe.”¹⁷⁴

3. The ACTA and Beyond

Even if the EU regulation, or its interpretation, is modified to eliminate in-transit infringement of patents, the problematic result may be exported to other countries through an international agreement that the EU helped negotiate.¹⁷⁵ In particular, concurrent with suspensions of in-transit drugs in Europe, some countries negotiated the ACTA. As will be later explained, the ACTA requires members to police certain types of infringement at its borders that may result in suspensions of in-transit drugs.

B. A Case Study of Patent Perspectives

This Section considers how the views of patents as either a limited privilege or uber-right may play a role in conflicts concerning the relevant facts of the EU seizures, as well as subsequent agreements, such as the ACTA. This Section focuses primarily on factual issues, although some information concerning whether the facts represent extraterritorial

173. *E.g.*, Miller & Anand, *supra* note 157.

174. Eli Lilly Letter, *supra* note 8.

175. The EU recently proposed amendments to the regulation at issue here. Commission of the European Communities, Proposal for a Regulation of the European Parliament and of the Council Concerning Customs Enforcement of Intellectual Property Rights, COM (11) 285 Final (May 2011). However, the amendments do not prevent in transit generic drugs from being suspended for patent infringement. *See* Catherine Saez, *Proposed EU Customs Regulation May Not Dispel Fear of Wrongful Drug Seizures*, IP-WATCH (May 31, 2011), <http://www.ip-watch.org/weblog/2011/05/31/proposed-eu-customs-regulation-may-not-dispel-fear-of-wrongful-drug-seizures/>; Letter from Peter Maybarduk, Access to Meds. Program Dir., Public Citizen, to the Directorate-Gen. for Taxation and Customs Union, Eur. Comm’n (May 25, 2010), available at <http://www.citizen.org/documents/Public%20Citizen%20comments%20submitted%20to%20DG%20TAXUD%20on%201383.pdf>.

applications of law or are inconsistent with TRIPS are included as a preview of a later discussion of the impact of perspectives on legal interpretations. This section is written as a case study with vignettes representing the privilege versus uber-right views of patents. While some liberties were taken to create cohesive statements from a variety of different documents over several years, each vignette should overall represent what has been actually stated, as clarified by the quotes in the accompanying footnotes.

1. The Privilege View

The EU is putting public health at risk by its aggressive and abusive implementation of its EU Regulation. Any law that permits seizure of in-transit generic drugs presents a serious risk to public health as treatment delays are not merely undesirable, but potentially life-threatening. Indeed, the UN Special Rapporteur recently expressed concern that the seizures jeopardize achievement of human rights norms.¹⁷⁶ Accordingly, the seizures must be condemned as unacceptable and the EU Regulation promptly reviewed and altered.¹⁷⁷

The EU Regulation creates barriers to the export of quality, low-cost generic drugs. Patients in the developing world are deprived of access to affordable life-saving drugs due to the EU Regulation.¹⁷⁸ Generic drugs from India have been a “lifeline for

176. See *Intervention by India, June 2009, supra* note 5.

177. See, e.g., Press Release, Health Action Int’l et al., Seizure of UNITAID/Clinton Foundation Anti-Retroviral Medicines by Dutch Customs Authorities “Unacceptable” (Mar. 6, 2009), [http://www.haiweb.org/06032009/6%20Mar%202009%20Press%20release%20More%20generic%20medicines%20intercepted%20in%20the%20Netherlands%20\(English\).pdf](http://www.haiweb.org/06032009/6%20Mar%202009%20Press%20release%20More%20generic%20medicines%20intercepted%20in%20the%20Netherlands%20(English).pdf) [hereinafter HAI, Dutch Seizure of Drugs] (“Oxfam International, Health Action International and Knowledge Ecology International condemn the unacceptable seizure of legitimate generic antiretroviral medicines in transit from India to Nigeria by Dutch customs officials, and call on the European Commission to immediately review and modify its regulations . . . to allow lawful trade of generic medicines.”).

178. See Radhicka Pandeya, *Dr. Reddy’s Consignment of Drugs to Brazil Seized*, LITEMINT.COM (Jan. 15, 2009, 12:09 AM), <http://www.livemint.com/2009/01/14220926/dr-reddy8217s-consignment-o.html> (quoting MSF attorney Leena Menghaney, who stated that “[t]he fallout will be on patients’ lives in the developing world who will not be able to access affordable life-saving drugs from India”).

countries” that cannot afford patented drugs—a lifeline that is now in jeopardy.¹⁷⁹ Trade in legitimate medicines is critical to ensuring access to medicines for millions.¹⁸⁰

The EU is repeatedly placing embargos on medicines at the behest of drug company “bullies” under a law they masterminded to give them authority to harass generic drug companies.¹⁸¹ The EU Regulation allows “corporate criminals”¹⁸² to act with impunity when making frivolous intellectual property rights claims concerning goods.¹⁸³ These claims have no legal basis. If the goods were intended for actual sale in any EU Member State, there might be grounds for patent infringement. However, all the seized goods were merely part of the regular and legitimate flow of products in transit that do not infringe patents.¹⁸⁴ The fact that some suspended drugs have been released after protracted delay simply underscores that the patent allegations are baseless.¹⁸⁵

179. See Miller & Anand, *supra* note 157 (quoting Sophie Bloemen of HAI).

180. See Priyanka Golikeri, *EU Seizes Another Generic Package*, DAILY NEWS & ANALYSIS (Nov. 3, 2009, 2:13 PM), http://www.dnaindia.com/money/report_eu-seizes-another-generic-package_1306411 (quoting an official from an Indian pharmaceutical company, who stated that “trade in legitimate medicines between countries is fundamental to ensuring access to medicines for millions”).

181. See Brook K. Baker, *Pointing the Finger at Big Pharma—Dutch Seizure of Generic Medicines*, PROGRAM ON INFO. JUST. & INTELL. PROP. (Feb. 10, 2009), <http://www.wcl.american.edu/pijip/go/blog-post/pointing-the-finger-at-big-pharma-dutch-seizure-of-generic-medicines>.

182. See *id.* (“[T]oo little attention has been directed at these corporate criminals who are acting with impunity to thwart lawful generic competition even in countries where their patents and marketing rights have no effect.”).

183. See *id.* (noting that the EU Regulation “gives impunity to Big Pharma to make frivolous claims of its ‘suspicion’ that the products ‘might’ violate intellectual property rights in the Netherlands”).

184. See *id.* (noting that the shipment would infringe on patent-holder rights if intended for sale in the Netherlands but neglecting to mention any Dutch patent law that would consider in-transit goods an infringement); see also Michael Day, *WHO Angry at Seizure by Dutch of HIV Drug Shipment*, PHARMATIMES (Mar. 12, 2009), <http://www.eatg.org/eatg/Global-HIV-News/Access-to-treatment/WHO-angry-at-seizure-by-Dutch-of-HIV-drug-shipment> (noting that the WHO has condemned the shipment’s suspension as “farcical”); *UNITAID Statement on Dutch Confiscation of Medicines Shipment*, UNITAID, <http://www.unitaid.eu/en/resources/news/156-unitaid-statement-on-dutch-confiscation-of-medicines-shipment.html> (last visited Sept. 7, 2011) (stating that a seized shipment did not infringe on any form of intellectual property).

185. See *Intervention by India, June 2009*, *supra* note 5 (stating that India takes “serious exception to such unsubstantiated and wild allegations [that seized drugs were counterfeits, fake drugs, patent violations, et cetera]. The fact that the drugs were

The EU repeatedly conflates generic drugs with counterfeit and suggests that it is somehow protecting the public against dangerous counterfeit drugs.¹⁸⁶ However, the EU is confusing multiple issues. Counterfeit drugs are ones that improperly use the trademark of another; they may pose health risks if they are substandard drugs, but the word *counterfeit* by itself does not mean that the drug is of poor quality.

Even if the EU were genuinely concerned about counterfeit trademark drugs, its procedure is seriously flawed as EU customs officials seem unable to distinguish legitimate generic drugs from counterfeit products. There was at least one shipment of drugs that was improperly suspended on the grounds of a purported counterfeit trademark.¹⁸⁷ The supposed counterfeit trademark—amoxicillin—was in fact the internationally recognized nonproprietary (i.e., non-trademark) name of the drug. Notably, counterfeit trademarks *should* be easy to identify, as that is one of the reasons they have been considered appropriate for customs officials to police. The inability of EU customs officials to distinguish between a nonproprietary name from a counterfeit trademark—a supposed “easy” task—is not reassuring to generic drug manufacturers. To the contrary, this suggests that EU customs officials are seriously misguided in their enforcement attempts.

The EU is evidencing a deep—yet wrongly held—belief that violation of intellectual property rights, including patent rights,

subsequently released are [sic] a proof that the allegations were baseless”) (emphasis omitted).

186. See Kaitlin Mara, *Medicines Access Again Captures Attention at WTO as Progress Urged in Round*, IP-WATCH (Oct. 30, 2009, 12:52 PM), <http://www.ip-watch.org/weblog/2009/10/30/medicines-access-again-captures-attention-at-wto-as-progress-in-round-urged> (quoting India’s statement that “[u]nderlying the drug seizures is also a deliberate mixing up of the issue of spurious/sub-standard drugs . . . with [intellectual property rights ‘IPRs’]”) (internal quotation marks omitted); Sanjay Suri, *EU Blocking Medicines for the Poor*, IPS, Oct. 20, 2009, <http://ipsnews.net/news.asp?idnews=48935> (quoting Sophie Bloemen from HAI who stated that although “[t]he EU has argued it needs to check for counterfeits as these are dangerous for public health,’ . . . ‘counterfeits actually relate to a trademark infringement, not a patent infringement’”).

187. See *Intervention by Brazil, June 2009*, *supra* note 5, at 2.

must necessarily involve potentially dangerous substances.¹⁸⁸ Such a linkage is not only overly simplistic, but just wrong.¹⁸⁹ Generic medicines neither infringe on intellectual property nor are dangerous.¹⁹⁰ Generic medicines are “not substandard or illegal.”¹⁹¹ Rather, generic drugs are by definition legal drugs that have been properly evaluated and certified as being equivalent in safety and efficacy to the original brand name version.

EU claims about saving lives are a transparent attempt to misrepresent the facts; in none of the cases of seized drugs was quality an issue.¹⁹² This underscores that the EU is not truly worried about quality; rather, their concern is in overzealous enforcement of EU patents.¹⁹³ The EU Regulation is a thinly disguised trade barrier that protects the European pharmaceutical industry while undermining the Indian generics industry.¹⁹⁴

The EU seizures violate the concept of territoriality that is a “key stone in the edifice of the TRIPS Agreement” as well as a “widely understood and accepted principle.”¹⁹⁵ Only the country of final destination should be involved in enforcing its own patent laws. It is “farfetched” to claim that the in-transit country will understand the laws of a destination country and have the authority to enforce them; each country should only enforce its

188. See *Intervention by India, June 2009*, *supra* note 5 (“It seems that it has been ingrained very deeply within the EC authorities that *IP violative products are synonymous with potentially dangerous substances.*”).

189. See *id.* (“This clearly is an untenable logic.”).

190. See *id.* (“[W]e are talking about generic medicines, which neither infringe IPRs nor are they ‘potentially dangerous.’”).

191. *Intervention by Brazil, June 2009*, *supra* note 5, at 1.

192. See *id.* at 2 (“This is a blatant attempt to confound the issue. . . . In none of the cases . . . was there any issue with the quality of the drugs.”); see also *Intervention by India, June 2009*, *supra* note 5.

193. See *id.*

194. See Pallavi Aiyar, *No Cure in Sight for India-EU Drug Seizure Controversy*, BUS. STANDARD, Nov. 14, 2009, at 8 (suggesting that India “maintains that European countries are creating trade barriers against Indian drug companies to protect the interests of their firms”); Miller & Anand, *supra* note 157 (quoting Rajeev Kher, Joint Secretary of Commerce in India, who stated that the country views the in-transit seizures “as an attack on the Indian generics industry”).

195. *Intervention by India, June 2009*, *supra* note 5 (emphasis omitted).

own laws.¹⁹⁶ The EU Regulation thus constitutes an improper extraterritorial enforcement of patent rights.¹⁹⁷ Moreover, such action simply cannot be reconciled with the Doha Declaration, which requires member states to promote access to medicine.¹⁹⁸

The EU seizure of goods, as well as its broader international efforts to associate generics with counterfeit medicines, go beyond TRIPS and negate steps that the international community—including the EU—has taken or promised to take to promote access to medicine.¹⁹⁹ For example, the EU Regulation that authorizes seizures of generic goods threatens a global accord (recognized by the EU) that permits compulsory licensing of goods for export to developing countries.²⁰⁰ In

196. See *id.* (“[S]overeign functions of the country of destination should be exercised by the country itself and other countries may assist in enforcement of their law if requested. It may be farfetched to claim that the country of transit will have sound understanding of the IPR laws of country of destination or origin and will have the authority to enforce them during transit.”).

197. See *Intervention by Brazil, WTO General Council*, IP WATCH, para. 7 (Feb. 3–4, 2008), available at <http://www.ip-watch.org/files/RemediosIntervencao-do-Brasil-Conselho%20Geral-03%2002%202008.doc> [hereinafter *Intervention by Brazil, Feb. 2009*] (“Brazil is gravely concerned with the setting of a precedent for extraterritorial enforcement of IP rights.”); *Intervention by Brazil, June 2009*, *supra* note 5, at 3 (“[T]he TRIPS Agreement does not allow the detention of goods in transit. The seizure of goods in transit on grounds that they may be violating IP rights in the country of transit violates the principle of territoriality, a keystone of the international IP system.”).

198. See *Intervention by Brazil, Feb. 2009*, *supra* note 197, para. 8 (“Extraterritorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration . . .”).

199. See, e.g., *Intervention by India, WTO General Council*, IP WATCH (Feb. 3, 2008), <http://www.ip-watch.org/files/India%20Statement%20to%20General%20Council%20Jan2009.doc> [hereinafter *Intervention by India, Feb. 2008*] (noting that the intellectual property maximalist trend, including efforts to link generics with counterfeit medicines, circumscribes TRIPS flexibilities and is “counter to the spirit of the TRIPS Agreement which is a minimum standards agreement”).

200. See, e.g., *Intervention by India, June 2009*, *supra* note 5 (“It is ironical that while on one hand WTO has taken steps to promote access to affordable medicines and remove obstacles to proper use of TRIPS flexibilities, on the other hand some Members seek to negate the same by seizing drug consignments in transit and creating barriers to legitimate trade.”); see also William New, *Concern Erupts over WTO System and Medicines Shipments: TRIPS Talks Rekindling*, IP WATCH (Feb. 3, 2009, 11:16 PM), <http://www.ip-watch.org/weblog/2009/02/03/concern-erupts-over-wto-system-and-medicines-shipments-trips-talks-rekindling/> (noting that the in transit suspensions in the Netherlands could undermine the WTO agreement to permit countries lacking manufacturing ability to import needed medicines from other countries under a

addition, the seizures are inconsistent with a recent resolution adopted by members of the World Health Assembly—again including the EU—suggesting that public health be considered when adopting rules that exceed the minimums required under TRIPS.²⁰¹ Moreover, the same resolution declared a commitment to improving access to health products and overcoming access barriers; commitments that are clearly undermined by the EU seizures.²⁰²

The EU seizures are not only unacceptable, but they set a dangerous precedent in the global arena.²⁰³ Patent holders and those who support them are promoting a coordinated and global approach toward maximizing intellectual property rights while simultaneously threatening the delicate balance under TRIPS.²⁰⁴ The in-transit seizures in the EU are a mere symptom of a much larger and more dangerous phenomenon that involves creating new laws to control generic drugs and unduly confusing low-cost, but high-quality generics with counterfeit medicine that is substandard.²⁰⁵ Such actions are inconsistent with the spirit of the TRIPS Agreement, which sets minimum

compulsory cross-licensing arrangement). The global accord that removes an obstacle to use of the TRIPS flexibility of compulsory license is a WTO measure that creates an exception to one of the usual TRIPS rules for compulsory licenses based on broad consensus that this was necessary. See Doha Public Health Declaration, *supra* note 1, ¶ 6 (indicating a need to address the fact that countries without manufacturing capacities for pharmaceuticals could not effectively use compulsory licenses to promote access to cheaper patented drugs); Council for TRIPS, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003). The EU has already modified its domestic laws to effectuate this measure. See Council for TRIPS, *Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* ¶ 5, IP/C/42, (Nov. 2, 2006).

201. See NGO Letter to Chan, Feb. 2009, *supra* note 5, at 3 (citing WHO resolution WHA61.21).

202. See Statement, *Access to Medicines*, WHO (Mar. 13, 2009), <http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/index.html>.

203. See *Intervention by Brazil*, Feb. 2009, *supra* note 197, para. 4 (noting that the Dutch seizure was unacceptable and sets a dangerous precedent).

204. See *Intervention by India*, KNOWLEDGE ECOLOGY INT'L (Mar. 3, 2009), <http://keionline.org/node/309> (noting the trend “to implement the protection and enforcement of IPRs in a maximalist manner and thereby upset the delicate balance between rights of IPR holders and the public policy objectives under the TRIPS Agreement”).

205. See *Intervention by India*, Feb. 2008, *supra* note 199, at 2 (arguing that seizure is clearly an unfounded attempt to “enlarge the definition of counterfeits” beyond its accepted definition under TRIPS).

standards,²⁰⁶ and have disastrous implications for access to medicine.²⁰⁷ Moreover, as the EU well knows, drug quality is controlled by laws directly regulating such drugs and not by intellectual property laws. However, the EU has shown no efforts to aid in promoting stronger regulatory systems in developing countries and instead improperly suggests that stronger intellectual property rights will somehow protect consumers from poor quality medicines.

The negotiation of the ACTA is only the latest example of its improper action. While the EU was asserting that there was no problem with in-transit suspensions in the EU, it was simultaneously negotiating the ACTA, and one issue during the negotiation was the scope of border measures, which would include whether member countries could suspend in-transit goods for patent infringement in a manner similar to the EU Regulation.²⁰⁸ The EU never honestly addressed how the ACTA would impact in-transit goods in the context of addressing questions by those who criticized the EU Regulation and sought

206. *See id.* (noting that the actions “run counter to the spirit of the TRIPS Agreement which is a minimum standards agreement”); *Intervention by India, June 2009*, *supra* note 5 (“Enforcement of IPRs in disregard of [TRIPS] Objectives and Principles and efforts to enshrine new, maximalist TRIPS plus enforcement provisions in other multilateral forums will seriously undermine the delicate balance in the TRIPS Agreement . . .”).

207. *See* HAI, *Dutch Seizure of Drugs*, *supra* note 177 (quoting Sophie Bloemen from HAI saying that “the European Commission . . . ‘must modify the way it applies IP enforcement globally, because it is even demanding exactly the same provisions of IP enforcement in developing countries through free trade agreements. This could prove to be disastrous for access to medicines in their regions’”).

208. As noted earlier, the in-transit suspensions happened in 2008–09 and the ACTA was simultaneously negotiated in that time frame. *See, e.g.*, European Commission, *THE ANTI-COUNTERFEITING TRADE AGREEMENT (ACTA) FACT SHEET*, available at http://trade.ec.europa.eu/doclib/docs/2009/january/tradoc_142039.pdf (indicating that ACTA negotiations began in 2007 and were still ongoing in 2009); Ctr. Int’l Env’tl. L., *The Dangers of Including Patent Infringements in ACTA: Some Implications for Access to Medicines*, *Intellectual Property Law Quarterly*, Second Quarter, 2008, available at http://www.ciel.org/Publications/IP_Update_2Q08.pdf; *see also* PETER MAYBARDUK, *ACTA’S SCOPE AND ACCESS TO MEDICINE* (2010), available at <http://www.citizen.org/documents/ACTAScopeAccessbyPublicCitizen.pdf> (noting continued discussion in 2010 of whether the ACTA should include patents within the scope of border measures).

a clear answer on the ACTA.²⁰⁹ In fact, the EU repeatedly asserted that trade in generic medicines would not be impacted by the ACTA even when draft provisions did not foreclose this possibility.²¹⁰

209. See *European Communities Statement to TRIPS Council*, IPEG (June 8–9, 2009), <http://www.ipeg.eu/blog/wp-content/uploads/EU-comments-on-use-of-BDO-against-seized-medicines.pdf> [hereinafter *EC Statement, June 2009*] (stating that “the EU does not intend to hamper trade in generic medicines” in the context of defending the EU regulation permitting suspension of in-transit drugs, but without mention of pending ACTA negotiations); *Explanatory Note on the Application of Council Regulation (EC) No 1383/2003 Concerning Customs Action against Goods Suspected of Infringing Certain Intellectual Property Rights and the Measures to be Taken against Goods Found to Have Infringed Such Rights*, HUNG. INTELL. PROP. OFFICE 1, 1–4 (July 13, 2009), http://www.sztnh.gov.hu/hirek/kapcsolodo/Explan_note_1383_2003_EN.pdf [hereinafter *EU Explanatory Note, July 2009*] (clarifying and defending application of EU Regulation (EC) No 1383/2003 without any mention of international issues beyond compliance with the Doha Public Health Declaration); *EC Statement, June 2009, supra*, at 4 (defending EU Regulation (EC) No 1383/2003 and its application by customs officials and stating that it is “fully in line with WTO/TRIPS requirements,” but not mentioning the pending ACTA discussions); see also Letter from Christian Wagner-Ahlf, BUKO PHarma-Kampagne, et al. to Pascal Lamy, Dir.-Gen., WTO (Feb. 18, 2009), http://www.keionline.org/misc-docs/seizures/WTO_seizures_18feb.pdf; Letter from Pascal Lamy, Dir.-Gen., WTO, to Christian Wagner-Ahlf, BUKO Pharma-Kampagne, et al. (Mar. 4, 2009), <http://www.keionline.org/misc-docs/seizures/dglamyresponse.pdf> (acknowledging a letter from public health advocates concerning suspensions of generic drugs from India and asserting that the EU has “reiterated its commitment to the efforts being made to facilitate access to medicines,” but failing to address the letter’s specific concern that ACTA negotiations might challenge the goal of “providing medicine to all” pursuant to the Doha Declaration”).

210. For example, in the August 2010 draft of the ACTA, the section on border measures indicates that it could apply to goods infringing any intellectual property right covered by TRIPS, which would include patents. See *Anti-Counterfeiting Trade Agreement: Informal Predecisional/Deliberative Draft*, art. 2.X(2) (Aug. 25, 2010) [hereinafter *ACTA Draft, Aug. 2010*], available at <http://publicintelligence.net/anti-counterfeiting-trade-agreement-acta-august-2010-draft/>. Granted, this same draft suggested that parties “may” decide to exclude patents, but patents were definitely at play. *Id.* (stating that members may exclude rights “other than trademarks, copyrights and GIs;” the key intellectual property right that could be excluded is patents). However, despite the fact that broader measures to include patents were under discussion, the EU, and other countries, suggested that the ACTA would not impact trade in generic medicine. *E.g.* Press Release, Negotiation Participants, Joint-Statement on Anti-Counterfeiting Trade Agreement (ACTA), IP/10/437 (Apr. 16, 2010) [hereinafter *Press Release, IP/10/437*] (“ACTA will not address the cross-border transit of legitimate generic medicines”); FFII, *ACTA Undermining Access to Medicines (E-4292/2010)*, FFII ACTA BLOG (Oct. 22, 2010), <http://acta.ffii.org/?p=131> (“The Commission can assure the Honourable Members that there are no provisions in the Anti Counterfeiting Trade Agreement (ACTA) text being currently negotiated that could directly or indirectly affect the legitimate trade in generic medicines.”); James Love, *Part 2: Notes on the August 25, 2010 Version of the ACTA Consolidated Text*, KNOWLEDGE ECOLOGY INT’L (Sept. 8, 2010, 1:50 PM), <http://www.keionline.org/>

2. The Uber-Right View

There has been great confusion and many overstatements made concerning a few shipments of drugs that were temporarily detained.²¹¹ There is a critical need to put these limited situations into their proper perspective rather than have them continue to be misconstrued.²¹²

The EU has been improperly and incorrectly criticized by overly zealous healthcare advocates and misguided news reporters as “seizing” drugs. The EU does not seize goods.²¹³ Rather, small shipments of goods are merely temporarily detained. It is incorrect and unfair to characterize the EU as seizing generic drugs when it is only temporarily detaining them for further investigation.

In addition, the number of shipments that have been detained is miniscule compared to the number of counterfeit drugs that have been seized;²¹⁴ the detained generic drugs are likely only a “nano-percentage” of medicine passing through the EU.²¹⁵ Moreover, most of the detained drugs are not essential ones, so claims that the detentions created life-threatening

node/937 (noting that only Australia, Canada, and New Zealand have argued against including patents in border measures while the EU, among others, favor permitting countries to decide for themselves what types of IP rights to include).

211. See EFPIA Press Release, *supra* note 166 (acknowledging “a certain amount of media coverage” concerning detained in-transit drugs).

212. See *id.* (stressing that “[i]t is important that these events are not misconstrued”).

213. See *Intervention by the European Communities, WTO General Council*, IP WATCH, ¶ 4 (Feb. 3, 2009), available at http://www.ip-watch.org/files/WTO_GENERAL_COUNCIL.doc [hereinafter *Intervention by EC, Feb. 2009*]. In an official statement to the WTO, the EU stated that “Dutch authorities temporarily detained (which does not mean *seize, confiscate or destroy*) a small shipment of drugs” in a Dutch airport and underscored that this was consistent with TRIPS. See *id.*

214. See, e.g., EFPIA Press Release, *supra* note 166 (characterizing the number of detentions as “minuscule relative to the massive flow of medicines . . . transiting through the EU” while noting that the number of “counterfeit pharmaceutical items” seized numbers over thirty-four million).

215. See Catherine Saez, *WTO Forum: Bypassing International Agreements May Hamper Medicines Access*, IP WATCH (Oct. 11, 2009), <http://www.ip-watch.org/weblog/2009/10/11/wto-forum-bypassing-international-agreements-may-hamper-medicines-access/> (quoting Luc Devigne of the European Commission trade directorate).

delays to treatment are simply unwarranted.²¹⁶ The detained drugs include treatments for dementia and schizophrenia, which are not life-threatening conditions. In addition, not all treatments are for life-threatening illnesses—a substantial number are for lifestyle conditions.²¹⁷ Although some drugs were for heart treatments, unpatented and affordable alternatives existed. For example, aspirin has been used as a substitute for the heart drug sold as Plavix by its patent owner.

Objections to the temporary delays are an “over-exploitation” of limited instances.²¹⁸ If there were an actual problem with the EU Regulation permitting suspensions, all EU Member States would have continuously stopped medicines since the Regulation was enacted. To the contrary, goods have only been detained in a handful of countries that elected to consider in-transit goods as violating patent laws.²¹⁹ Moreover, the few instances all occurred a number of years ago, such that they are no longer relevant.²²⁰ This is especially true since European patent owners have clarified that although they recognize they have the legal authority to stop goods in some EU countries, it is not their policy or practice to detain legitimate generic drugs intended for shipment to customers in developing countries.²²¹

216. Although there were two instances of HIV treatments being temporarily detained in 2008, they comprised a mere eleven percent of all goods detained in the EU. *See* HAI Letter from Netherlands, *supra* note 154, Annex 1 (noting that two out of seventeen drugs were AIDS inhibitors). Moreover, one of the HIV shipments was destined for Brazil, which has its own generic drug industry such that it could have easily made the desired drug. *See, e.g.*, Daniel Pruzin, *Brazil Cites Growing Instances of ‘Illegal’ Dutch Generic Medicine Seizures*, 2009 PAT., TRADEMARK & COPYRIGHT L. DAILY (BNA), Mar. 4, 2009, *available at* 2009 WL 524673.

217. In 2008, there were five life-style drugs seized out of a total of seventeen suspended shipments; in other words, twenty nine percent were for life style conditions. HAI Letter from Netherlands, *supra* note 154, Annex 1.

218. *See, e.g.*, Jonathan Lynn, *Developing States Attack EU on Generic Drug Seizure*, REUTERS, Feb. 4, 2009, *available at* <http://in.reuters.com/article/idINIndia-37821420090203> (noting that EU ambassador Eckart Guth warned WTO members not to blow the Dutch seizure case out of proportion).

219. *See* EU Explanatory Note, July 2009, *supra* note 209 (noting that in several member states, patent rights do not extend to goods in transit).

220. *See* Saez, *supra* note 215 (mentioning that Luc Devigne of the European Commission trade directorate noted that there were only a few cases of detention in 2008, creating “much noise about nothing”).

221. *See* EFPIA Press Release, *supra* note 166 (“[I]t is neither the policy nor practice of [EFPIA] members to encourage Member States to use the powers of

Indian companies and organizations have loudly protested detention of drugs from India, yet failed to note their own complicity in any unnecessary delay of drugs to developing countries. In at least one case after a temporarily detained shipment was released, the Indian company returned the shipment to India rather than continuing it on the original route.²²² In other cases, Indian companies have abandoned their shipments after those shipments have been released.²²³

Even some of the examples that advocates put forth as being illustrative of a problem suggest otherwise. For example, public health advocates strongly protested the temporary detention by German customs of a shipment of antibiotics from India destined for Vanuatu.²²⁴ However, the shipment was detained for suspected infringement of *trademark* rights, so this event has no bearing on the issue of trade in generic drugs based on patent rights.²²⁵ Moreover, once customs received information that there was no trademark infringement, the goods were promptly released and reached their final destination.²²⁶

The EU has an interest in safeguarding the health of its own citizens, as well as all the citizens of the world. Counterfeit drugs pose serious risks to health and constitute a major problem. Customs officials are acting properly when they detain drugs that may be counterfeit.²²⁷ The EU has no intent to

detention available to them to prevent the flow of legitimate generic products from manufacturer to customer outside the EU. This applies even where goods transit through EU countries where intellectual property legislation could be applied.”).

222. See *Intervention by EC, Feb. 2009*, *supra* note 213 (indicating that the owner of the released generic drug returned the shipment of the hypertension drug losartan potassium to India rather than continuing on to Brazil).

223. See, e.g., *id.*; *Cipla Export Consignment Too Seized at Amsterdam*, *supra* note 162 (noting that Cipla abandoned a shipment that was suspended while in transit because litigation costs were considered “disproportionate to the value of the consignment”).

224. See, e.g., Aiyar, *supra* note 194.

225. See *EC Statement, June 2009*, *supra* note 209, at 2 (“This shipment was suspected to infringe a trademark, not a patent. Therefore, it did not involve the issue of generics, which is a patent matter in the present context.”).

226. See *id.* (characterizing the issue as “solved quite swiftly” since the shipment was initially detained on May 5 and released by May 28).

227. See *id.* (suggesting that customs officials act within their authority to control goods in transit to address “global trade in counterfeit products”).

hamper legitimate trade in generic drugs, and its laws do not have this effect.²²⁸ The EU supports the goal of promoting low-cost drugs to developing countries.²²⁹ However, counterfeit drugs are not beneficial to anyone. EU customs authorities play an important role in addressing the global trade in counterfeit products, especially fake medicines whose effects disproportionately impact developing countries.²³⁰ In fact, fake medicines are often shipped to developing countries through Europe and forty percent of the seventy-six million counterfeit and pirated goods stopped in the EU in a single year were in-transit goods.²³¹

Accordingly, EU customs officials have played an important role in protecting consumers from dangerous counterfeit medicines such that consumers should be grateful to the EU for its laws and policies.²³² Contrary to repeated allegations, the EU is not confused concerning the distinction between generic medicines and fake medicines.²³³ Although generics may be distinct from fakes, “EU customs probably saved lives around the world by stopping fakes” pursuant to the EU Regulation.²³⁴

The EU Regulation does not constitute extraterritorial enforcement of patent rights—and all claims to the contrary are

228. See, e.g., *Intervention by EC, Feb. 2009*, *supra* note 213.

229. See, e.g., European Parliament Resolution on the TRIPS Agreement and Access to Medicines, C 175 E/591.

230. See *EC Statement, June 2009*, *supra* note 209, at 2 (noting that “it is important to continue to allow the Customs Authorities to control goods in transit and ensure that measures can be taken against global trade in counterfeit products, and in particular fake medicines whose effects mainly hit developing countries”); see also *id.* (“EU customs statistics for 2007 have revealed a significant increase—compared to 2006—in trade of fake medicines (+51%). Although customs controls of this kind of goods are often difficult, their role is crucial to prevent the flow of fake medicines in transit from reaching the populations of EU and other countries, in particular developing countries.”).

231. See *id.* (“[M]any dangerous goods, such as fake medicines, are shipped to developing countries, often via European ports and airports. In 2007, out of seventy-six million counterfeit and pirated goods stopped by the European customs, 40 percent were goods in transit.”).

232. See, e.g., EFPIA Press Release, *supra* note 166.

233. See *EC Statement, June 2009*, *supra* note 209, at 2–3 (“[T]o respond to what has been said I want to insist that we do not make any confusion between generic medicines, which are legitimate quality products, and fake medicines, which are too often sub-standard products aiming at confusing the consumer about its quality.”).

234. Saez, *supra* note 215 (quoting Luc Devigne of the European Commission trade directorate).

erroneous.²³⁵ Any goods seized must be in violation of domestic laws.²³⁶ In addition, the EU Regulation provides procedures to protect against overzealous enforcement. EU customs officials do not make any final decision on whether goods infringe intellectual property rights.²³⁷ Customs officials merely detain goods if there is a suspicion of infringement of an intellectual property right, and it is up to the right holder to pursue the matter in national courts.²³⁸ Moreover, if goods are found to be improperly detained, compensation is provided.²³⁹ These procedures are fully in compliance with TRIPS. TRIPS permits border measures to cover patent infringements, including in-transit infringement.²⁴⁰ In addition, border enforcement by customs is expressly contemplated by both the WTO and the World Customs Organization.²⁴¹ Although the EU believes that its actions have always been consistent with domestic and international laws, it has nonetheless clarified that customs authorities should avoid actions that would delay or unnecessarily disrupt legitimate trade in generic drugs.²⁴²

The EU remains committed to combating counterfeit drugs that pose deadly dangers to consumers and especially consumers in developing countries. The EU's commitment is reflected in its leading role in establishing a new international framework under the ACTA to "combat more effectively the proliferation of counterfeit and pirated goods" that not only undermine

235. *EC Statement, June 2009, supra* note 209, at 4 (noting that "regarding the principle of territoriality let me reassure you that the EU Customs Regulation has no extra-territorial effect").

236. *See EC Statement, June 2009, supra* note 209, at 3 (noting that the final decision of whether goods suspended by customs constitute infringement is decided under national laws).

237. *See id.*

238. *See id.*

239. *See id.*

240. *See id.* ("TRIPS foresees that border enforcement measures may apply not only to imports of goods infringing any IPR, including patents, but also to goods introduced into the customs territory or leaving that territory, including transit.").

241. *See id.*

242. *See EU Explanatory Note, July 2009, supra* note 209, at 2 (noting that "[c]ustoms [a]uthorities . . . are invited to pay particular attention when controlling pharmaceutical products in transit in order to avoid actions that would delay or cause unnecessary disruption of legitimate trade in generic drugs.").

legitimate trade but also pose serious health risks.²⁴³ Trade in illegitimate goods is not only inconsistent with legitimate trade, but may also contribute to organized crime and increased numbers of dangerous fake products.²⁴⁴ The ACTA will not interfere with fundamental rights and liberties.²⁴⁵ In particular, the ACTA is consistent with TRIPS and the Doha Declaration, but it will not hinder global trade in legitimate generic drugs since patents are not covered in the section on border measures.²⁴⁶

3. Reflections on the Perspectives

As the vignettes above illustrate, different perspectives on patents can lead to dramatically different portrayals of the same facts. Just as citizens of a Presidential debate may come to different conclusions concerning whose candidate “won” after watching the same debate, so too advocates on different “sides” of the in-transit trade in drugs have come to differing conclusions concerning recent events. This section aims to recap how different views of the same facts are consistent with social science evidence concerning the operation and power of schemas.

The vignettes repeatedly show that the same information may be viewed differently by both sides. For example, to the privilege view, all suspended drugs are a problem. This is consistent with a broad privilege view that wants to modify patent rights to accommodate access to any medication. However, those with an uber-right view are less inclined to find a problem when the drugs are for “lifestyle conditions.” As noted earlier, the uber-right does not believe that patent rights should

243. See, e.g., Press Release, European Union, Anti-Counterfeiting Trade Agreement (ACTA) Moves Forward, No. 25/09 (June 12, 2009) <http://www.eurunion.org/eu/2009-News-Rlleases/EU/NR-25/09-ANTI-COUNTERFEITING-TRADE-AGREEMENT-ACTA-MOVES-FORWARD.html> (“Trade in these illegitimate goods undermines legitimate trade and the growth of the world economy, and in some cases, may contribute to funding organized crime and exposing American consumers to dangerous fake products.”).

244. *Id.*

245. Press Release, IP/10/437, *supra* note 210 (“ACTA will not interfere with a signatory’s ability to respect its citizens’ fundamental rights nad liberties.”)

246. See, e.g., *id.* (“ACTA will not address the cross-border transit of legitimate generic medicines.”).

ever be altered to promote access to affordable medicine at all. The only situation in which the uber-right has acknowledged that patent rights might be modified is in the case of an epidemic involving an infectious disease; drugs for lifestyle conditions would be the exact opposite situation.²⁴⁷ That is still, however, a limited situation. Accordingly, the different views of the impact of the suspended drugs are consistent with the patent perspectives.

In addition, the vignettes are consistent with social science evidence that individuals tend to ignore facts inconsistent with schemas and selectively use facts that support their schema. For example, the most extreme privilege view of patents ignores the existence of Dutch law that permits suspensions of in-transit drugs for patent infringement.²⁴⁸ In addition to ignoring the Dutch law that conflicts with the privilege schema, selected facts are also relied upon to support the privilege view conception of what the Dutch law should be. For example, since some suspended drugs have been released, the privilege view considers these releases to prove that there were no viable legal claims regarding in-transit drugs.²⁴⁹ However, release of the

247. See, e.g., Roger Bate, Editorial, *Thailand's Patent Attack*, N.Y. SUN, Feb. 13, 2007, <http://www.nysun.com/opinion/thailands-patent-attack/48499> (asserting that heart disease and leukemia are not epidemics, such that Thailand's compulsory license was not justified).

248. See *supra* notes 103–13 and accompanying text (describing the privilege view of patents); *supra* notes 141–42 and accompanying text (showing that Dutch law finds that in-transit products can interfere with Dutch patents). However, not all groups with similar interests will necessarily share the same schema or be similarly impacted by the same schema. For example, the European Generic Medicines Association, which generally promotes generic drugs, did not make the mistake of some with a privilege view in completely dismissing relevant law. Rather, it stated that “the EU is entitled under TRIPS to detain products under alleged patent infringement,” although it nonetheless urged caution to avoid public health risk. See Letter from Greg Perry, Dir. Gen. of Eur. Generic Meds. Ass'n, to Mr. László Kovács, Eur. Comm'r for Taxation & Customs Union (Feb. 20, 2009), available at <http://www.ip-watch.org/weblog/wp-content/uploads/2009/03/rotterdam-seizure-letter-to-customs-commissioner-09.pdf>.

249. Interestingly, although there is a decision from the Court of Justice of the European Union that suggests trademark rights do not encompass in-transit goods, the most extreme privilege view does not consider this since it may be easier to simply ignore the undesirable Dutch law rather than to acknowledge its existence and advocate for an extension from an analogous area of law. However, scholars who may have a privilege view may conclusively determine that the Dutch law is inconsistent with

goods does not mean that there are no rights that are violated—they may be released despite legal authority to suspend them. This is especially true if there is public pressure and controversy.

Moreover, the lack of acknowledgement of the Dutch law may reveal an additional nuance to the patents as privilege schema. Some additional nuance is probably expectable since the basic privilege view of patents focuses only on exceptions to patent rights within a single country. However, the issue with in-transit suspensions is that countries have an interest in the scope of patent rights beyond their borders; for example, India does not want Dutch patent law to suspend drugs made in India destined for a third country. The privilege view of in-transit drugs appears to be that a drug made as a generic must necessarily continue to be generic in global trade—at least when it is destined for a market that would similarly consider the drug generic. This conclusion would be consistent with the general privilege view that patents should be limited to permit access to affordable medicine. At the same time, it is an expansion on that basic principle to suggest that global patent rights should be interpreted to enable trade in generic drugs. Accordingly, as noted in the vignettes, some have asserted that a drug not sold in the Netherlands cannot violate patent law without regard for the actual Dutch law that would hold otherwise. Although this view deviates from the Dutch law, it is consistent with the complementary schema that patent laws must be construed to promote global trade in drugs that are generic where made and at their final destination.

The vignettes also suggest an additional schema to complement the traditional uber-right schema concerning patents. As discussed above, the uber-right traditionally focuses on promoting patent rights in the name of innovation while suggesting that public health issues are beyond the patent system. However, in discussions concerning in-transit drugs, the

law of the Court of Justice, even though there is no specific case on in-transit patents. *See, e.g.,* Ruse-Khan & Jaeger, *supra* note 143, at 518–19 (although admitting that the Court of Justice has not specifically ruled in this area, concluding that there is no reason to assume analogous case law “should not be applicable to patents”); *see also* SEUBA, *supra* note 148, at 18. (suggesting that the Dutch law “contravenes” Court of Justice jurisprudence). This is admittedly a much smaller deviation from ignoring the Dutch law entirely.

uber-right view emphasizes the importance of policing counterfeit drugs that are suspected to be unsafe. Another complementary schema to the traditional uber-right narrative may be that the only truly safe and effective drugs are those made by the original patent owner, regardless of whether a national regulatory agency has found a generic to be bioequivalent.²⁵⁰

These vignettes are also consistent with the phenomenon of naïve realism.²⁵¹ Each side assumes that the other—and only the other—is biased. For example, those with a privilege view assume that the EU is acting at the behest of “corporate criminals” whereas those with an uber-right view assert that public health advocates are over-stating the facts by focusing on a “nanopercentage” of drugs. These views are not only consistent with naïve realism but also with other social science evidence suggesting that divergent views on the same socially-charged topic may cause increasing polarization.²⁵² This has important implications not only for the issues concerning in-transit suspensions of generic drugs, but for the broader topic of how to address access to medicine when there are clearly polarized views.

IV. *THE LEGAL FRAMEWORK*

This Part explains the legal framework that applies to whether countries can or must police in-transit goods for infringing patent or trademark rights. In particular, this Part explains the legal framework under both TRIPS and the ACTA. This Part provides an important backdrop to understanding and

250. See, for example, Eli Lilly Letter, *supra* note 8, in which Eli Lilly’s attorney contacted a generic Indian manufacturer whose tablets had been suspended by Dutch customs authorities for violating Eli Lilly’s patent, stating that “the [t]ablets are not genuine Eli Lilly products and they have not been produced by Eli Lilly or any of its licensees worldwide. As such, the [t]ablets may not be safe or effective.”

251. See *supra*, Part II.A.3.

252. See Pronin, *supra* note 89, at 41; see also Dan M. Kahan, *The Cognitively Illiberal State*, 60 STAN. L. REV. 115, 130–42 (2007) (showing that when individuals perceive others to be the only group distorting facts, this breeds resentment and distrust, which leads to further entrenchment regarding a variety of controversial topics, such as sodomy, guns, smoking, nuclear energy, and global warming).

evaluating the extent to which patent perspectives diverge from the proper legal interpretation, as further explained in Part V.

A. TRIPS

This Section first explains the basic requirements and then considers whether members can properly exceed these minimum requirements by considering in-transit goods to infringe patent rights while temporarily in a country. As explained below, although members can generally exceed the minimum requirements of TRIPS, they can only do so to the extent that would not “contravene” another provision of TRIPS.

1. TRIPS Border Measures—Articles 51 and 52

The fundamental provision under TRIPS concerning border measures is Article 51. This provision states as follows:

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.²⁵³

In essence, Article 51 only requires member states to suspend goods intended to be imported into a country for free circulation if they are counterfeit, trademark, or pirated copyrighted goods. However, pursuant to the second sentence, members *may* also suspend imported goods that violate other intellectual property rights, such as patents and non-counterfeit

253. TRIPS, *supra* note 2, art. 51 (citations omitted).

trademarks.²⁵⁴ Moreover, although not required, members may also suspend goods in transit. In particular, a footnote to Article 51 states that “there shall be no obligation to apply such procedures . . . to goods in transit.”²⁵⁵ In the context of a minimum obligation treaty such as TRIPS, the lack of an obligation does not mean that exceeding minimum obligations is prohibited. To the contrary, this clarifying footnote seems to suggest that applying suspensive procedures to in-transit goods is expressly contemplated.²⁵⁶

However, Article 51 alone does not define which in-transit goods member states can police. After all, Article 51 only permits customs authorities to act “in conformity with the provisions set out below,” which refers to the related TRIPS provisions, such as Article 52. Article 52 is of critical importance because it refers to the relevant proof to establish infringement. Article 52 states: “Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder’s intellectual property right”²⁵⁷

The critical question with respect to in-transit goods is what constitutes infringement “under the laws of the country of importation.” Although the Article 51 footnote clarifies that in-transit goods may be suspended, that footnote is of no assistance to evaluate *which* country’s laws should apply in assessing whether infringement has occurred. This is a critical issue for global trade in generic goods because a drug may be considered generic at the points of origin and destination, but not where it

254. *See id.* (stating explicitly that members may apply the same procedures to “goods which involve other infringements of intellectual property rights”).

255. TRIPS, *supra* note 2, art. 51 n.13 (“It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.”).

256. While one commentator has argued that in-transit goods should not be within the scope of Article 51 because such goods are not generally “released” by customs, see SEUBA, *supra* note 148, at 13–14, a coherent reading of the entirety of Article 51, including the clarifying footnote, suggests that TRIPS intended to permit such action whether or not customs officials formally “release” goods.

257. TRIPS, *supra* note 2, art. 52.

is in transit. This was true for each of the drug shipments suspended in the Netherlands—although patent owners had rights in the Netherlands, there were no patent rights in the country of origin (India) or final destination (mostly South American countries). Accordingly, the key question is whether “country of importation” should refer to the final destination—in which case there would be no infringement—or whether it should refer to an in-transit country.

According to traditional tools of treaty interpretation, the proper starting place for interpretation is with the ordinary meaning of terms.²⁵⁸ In this case, the issue is the ordinary meaning of the phrase “law of the country of importation.” In particular, the issue is what constitutes “importation.” This word is broad enough to include both goods that are imported permanently for sale as well as in-transit goods.²⁵⁹ Indeed, some countries have occasionally interpreted in-transit goods—that are not sold in transit—to be imports that violate domestic intellectual property laws.²⁶⁰

258. See Vienna Convention of the Law of Treaties art. 31(1), May 23, 1969, 1155 U.N.T.S. 331 (“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to terms of the treaty in their context and in the light of its object and purpose.”).

259. See *Import*, OXFORD DICTIONARIES, http://oxforddictionaries.com/definition/import?region=us#m_en_us1257355.015 (last visited Sept. 7, 2011) (defining the word import as to “bring (goods or services) into a country from abroad”); BLACK’S LAW DICTIONARY 647 (9th ed. 2009) (defining import as to bring merchandise from a foreign source, without specifically requiring a sale).

260. For example, in *Gramophone Co. of India v. Pandey*, the Indian Court found that the right of a copyright owner to exclude imports included the case of an import within Indian territory en route to Nepal. See *Gramophone Co. of India v. Pandey*, (1984) 2 S.C.C. 534, ¶ 32 (India). In addition, in a trademark case, a US court concluded that merchandise was adequately imported for the purpose of applying trademark laws banning trafficking in counterfeit goods, even though the merchandise was not intended to enter for free-circulation; the goods were considered to have been imported into the United States even though duties were not assessed or paid. See *United States v. Watches, Watch Parts, Calculators & Misc. Parts*, 692 F. Supp. 1317, 1321, 1322 (S.D. Fla. 1988). In addition, the World Customs Organization’s (“WCO”) model legislation recommends that customs officials take action against goods in transit. See WCO, MODEL PROVISIONS FOR NATIONAL LEGISLATION TO IMPLEMENT FAIR AND EFFECTIVE BORDER MEASURES CONSISTENT WITH THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS art. 1(1) (2007) (“A rights holder may submit applications to Customs, in accordance with the procedures and under the conditions set out in this law, for the suspension of the customs clearance and the detention of imported goods, goods *destined for exportation and goods in transit*.” (emphasis added)); see also WCO, PROVISIONAL STANDARDS EMPLOYED BY CUSTOMS FOR

However, the ordinary meaning of terms must also be considered in light of the broader interpretive TRIPS context.

The TRIPS provision on enforcement of intellectual property rights in general provides some context that might suggest that “country of importation” should mean the country of final destination. In particular, Article 41 requires that enforcement of intellectual property rights should not be a barrier to “legitimate trade.”²⁶¹ Arguably, if global trade in generic drugs constituted “legitimate trade,” then “country of importation” should be interpreted to prevent border measures from disrupting such legitimate trade. While those sympathetic to global trade in generic drugs may consider this argument intuitive and obvious, it is not the only possibility. After all, this would depend on the meaning of “legitimate trade,” which is again an important, yet undefined term. In addition, intellectual property rights generally inhibit trade, so it is unclear how to interpret this term.²⁶² Moreover, if countries may only suspend in-transit goods that infringe at the point of final destination, this would seem at odds with the traditional territorial limits of patent protection since the in-transit country would be enforcing foreign law.

There is another part of the TRIPS context that may also lend support to interpreting “country of importation” as the final destination. The TRIPS Council has created a mechanism permitting drugs to be made under a compulsory license in one country for export to a country unable to make its own low-cost generic drugs.²⁶³ Arguably, this mechanism cannot be effective if drugs made for export never reach the final destination because of in-transit infringement. Accordingly, the successful use of this

UNIFORM RIGHTS ENFORCEMENT (SECURE) ¶ 10 (2007) (recommending customs enforcement action against any goods under custom supervision, which would include transshipment, as well as free zones).

261. See TRIPS, *supra* note 2, art. 41.

262. See Henning Grosse Ruse-Khan, *A Trade Agreement Creating Barriers to International Trade?: ACTA Border Measures and Goods in Transit*, 26 AM. U. INT’L L. REV. 645, 696–97 (2011).

263. See Decision of the General Council of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 2, WT/L/540 (Sept. 2, 2003).

mechanism could suggest that “country of importation” should be interpreted as the country of final destination. However, this mechanism technically only applies to a very narrow subset of global trade in generic drugs; thus far, there has only been a *single* time this has happened.²⁶⁴ An important interpretive question is whether the existence of this TRIPS mechanism should mean that “country of importation” under Article 52 should be interpreted as the country of final destination only for trade initiated under this mechanism, or under all cases. If applied to all cases, customs officials would once again be applying the laws of other countries; this application extends beyond the traditional norms of territoriality inherent in patent rights.

Another part of the broader interpretive context that could be consulted is the Doha Public Health Declaration (“Declaration”).²⁶⁵ Although the Declaration does not address in-transit goods, it does suggest that public health interests are important to countries. There may be a tendency to assume that this Declaration necessarily weighs in favor of interpreting “country of importation” to mean the final destination so that public health is promoted. However, the Declaration could be read differently. In particular, the Declaration generally supports the rights of countries to make their own decisions concerning the scope of intellectual property rights at their borders; most of the provisions concern the sovereign ability of countries to decide how to apply exceptions to patent rights.²⁶⁶ None of the specific provisions of the Declaration discuss the basic scope of patent rights or potential limits to patent rights. Importantly, nothing in the Declaration suggests that a nation such as India should be able to decide how a nation such as the Netherlands defines the scope of its patent rights. Any such

264. See Catherine Saez, *Patentable Subject Matter, IP Waiver for Health Discussed at WTO*, IP WATCH (Mar. 2, 2011), <http://www.ip-watch.org/weblog/2011/03/02/patentable-subject-matter-ip-waiver-for-health-discussed-at-wto/> (noting that delegations have expressed concern that the mechanism has only ever been used once since 2003 and that when it was used it took about three years for a Canadian generic manufacturer to deliver drugs effectively to Rwanda).

265. See generally Doha Public Health Declaration, *supra* note 1.

266. See Doha Public Health Declaration, *supra* note 1, ¶ 5(b)–(d) (clarifying the ability of nations to decide the basis for issuing compulsory licenses, as well as whether to permit international exhaustion of intellectual property rights).

suggestion is inconsistent with the territorial limits of patent rights.

As noted above, TRIPS Articles 51 and 52 do not clearly explain when a nation can suspend in-transit goods at its borders. Under Article 51 of TRIPS, it seems that nations can enact laws that consider in-transit goods to infringe patent and non-counterfeit trademarks. However, what constitutes infringement under Article 52 is far from clear; infringement could be based on either infringement in the in-transit country or in the country of final destination.

2. TRIPS Ceiling?—Article 1

According to Article 1 of TRIPS, member states may exceed the minimum standards in TRIPS but only to the extent that other “provisions” of TRIPS are not “contravene[ed].”²⁶⁷ In other words, even if Articles 51 and 52 may suggest that nations can suspend in-transit goods for patent infringement, Article 1 may provide an independent basis to preclude such action—if other provisions are contravened.

An initial inquiry must be what it means to “contravene” a “provision” of TRIPS. As with many other critical terms under TRIPS, neither term is defined. The Oxford English Dictionary defines contravene as something that is “counter to” or “in conflict with.”²⁶⁸ Although these definitions do not clearly resolve what it means to “contravene,” when they are considered together with the ordinary definition of a “provision,” things are a bit clearer. The Oxford Dictionary definition of “provision” includes “a condition or requirement in a legal document.”²⁶⁹ Given that a treaty, such as TRIPS, is a legal document, a “condition or requirement” would suggest some type of obligatory part of TRIPS. In addition, given that the customary interpretation includes the preamble and objects and purposes as the appropriate context, it would seem redundant to also

267. See TRIPS, *supra* note 2, art. 1.

268. *Contravene*, THE OXFORD ENGLISH DICTIONARY 847 (2d ed. 1989).

269. See *Provision*, OXFORD DICTIONARIES, <http://oxforddictionaries.com/definition/provision?region=us> (last visited Sept. 4, 2011).

include them in the definition of “provisions” of TRIPS. Since general principles of treaty interpretation require favoring interpretations that give meaning to all provisions and avoiding redundancy, the phrase “other provisions” should refer to other substantive articles of TRIPS that provide affirmative requirements on member states.²⁷⁰ Accordingly, to “contravene” a provision of TRIPS should refer to actions that are inconsistent with affirmative obligations under TRIPS rather than actions that are inconsistent with general principles and policies. Importantly, although the Doha Public Health Declaration contains some positive statements concerning the importance of public health, it does not contain a clear affirmative obligation that can be expressly violated.

There are affirmative obligations under TRIPS that could be contravened. In fact, two aspects of TRIPS discussed earlier as possibly supporting an interpretation of “country of importation” to mean the country of final destination could alternatively be TRIPS provisions that would be contravened. In particular, Article 41 of TRIPS, which requires that enforcement of intellectual property rights not be a barrier to “legitimate trade,” as well as the TRIPS Council mechanism for providing generic drugs to countries, could both be considered TRIPS provisions that might be contravened if member states exceeded the minimum TRIPS border measures.²⁷¹ In particular, although these provisions did not clearly determine how to define “country of importation,” when these provisions are considered in light of the Article 1 prohibition against contravening provisions of TRIPS they may suggest that member states should not be permitted to consider in-transit goods to infringe. In other words, although the TRIPS border measures arguably permit countries to suspend in-transit goods for infringing patent rights, which could be interpreted to mean patent rights of the in-transit country, Article 1 may nonetheless suggest that this is impermissible.

270. In addition, even if it were not redundant to consider such provisions, it would be difficult to “contravene” general principles and policies since such principles under TRIPS often assert *competing* principles that cannot be simultaneously promoted. *See, e.g.*, TRIPS, *supra* note 2, arts. 7–8. Also, these provisions are couched as things that should be promoted, which makes them more difficult to contravene.

271. *See* TRIPS, *supra* note 2, art. 41; Decision of the General Council of 30 August 2003, *supra* note 263, ¶¶ 4–5.

Although this application of Article 1 of TRIPS would provide a powerful limit to exceeding the minimum standards of TRIPS, as well as an important resolution of the otherwise ambiguous interpretation of the border measures, there is still some ambiguity. Although Article 41 and the TRIPS Council mechanism both easily qualify as “provisions” that can be contravened, there are still some interpretive difficulties. As noted earlier, it is not clear that trade in drugs that are generic at point of origin and destination always constitute “legitimate trade.” The TRIPS Council mechanism suggests that at least in one case, where goods are made under compulsory license for export, such drugs are legitimate.

B. *The ACTA*

This Section explains the relevant ACTA provisions concerning policing of intellectual property infringement to provide a foundation for later analysis of how the ACTA has been interpreted based on patent perspectives. This Section first explains that border measures include basic trademark infringement, with patent infringement possible but not required. The Section then explains that the ACTA clearly permits—but does not require—Member States to police in-transit goods that violate trademark or patent rights based on the law of the in-transit country. Finally, this Section discusses the implications of the ACTA border measure provisions for trade in generic goods.

1. Scope of Intellectual Property Rights Covered

The basic ACTA provision concerning the scope of border measures provides as follows:

In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of *intellectual property rights*, a Party should do so in a manner that does not discriminate unjustifiably between intellectual property

rights and that avoids the creation of barriers to legitimate trade.²⁷²

As highlighted above, the border measure requirements apply to intellectual property rights, defined in the ACTA to include intellectual property rights under TRIPS, which would generally include patents and trademarks.²⁷³

Although patents are a type of intellectual property right under TRIPS, there is a footnote that states: “The Parties agree that patents . . . do not fall within the scope” of Section 3.²⁷⁴ In other words, although patents would ordinarily be included as an intellectual property right, members need not extend border measures to patents. However, since the ACTA is a minimum standards agreement, like TRIPS, the lack of an obligation does not necessarily preclude a country from *exceeding* that minimum.²⁷⁵

An important question to proponents of global trade in generic drugs is whether the ACTA can prevent member states from extending border measures to patents—despite the minimum standard framework of the ACTA. According to the Vienna Convention on the Law of Treaties, treaty terms—such as the aforementioned ACTA footnote—are to be interpreted “in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”²⁷⁶ Here, there is a question concerning the “ordinary meaning” of the footnote that says that patents are not within the scope of the section. In particular, the question is whether this footnote not only excludes patents from the minimum ACTA standard, but *precludes* member states from extending border measures to include patents. The language notably does not use any word similar to “preclude” to suggest that members are prohibited.

Additional interpretive context for the meaning of the patent footnote to the border enforcement section might be found in comparing this footnote to the footnote of the civil

272. ACTA, *supra* note 10, art. 13 (emphasis added).

273. *See id.* art. 5(h) (defining intellectual property as all categories under TRIPS Pt. II, §§ 1–7).

274. *Id.* art. 13 n.6.

275. *See id.* art. 2(1).

276. *See* Vienna Convention on the Law of Treaties, *supra* note 257, art. 31(1).

enforcement section. Whereas the border enforcement section states that patents “do not fall within the scope” of the section, the civil enforcement section states that parties “may exclude patents.”²⁷⁷ The different language suggests that the footnotes have differing meaning. The ordinary meaning of “may exclude patents” in the civil enforcement section suggests that parties can, but need not, apply the ACTA civil enforcement provisions to patents. The different wording for the border measures could be interpreted to suggest that patents are intended to be precluded rather than merely excluded. However, that would seem inconsistent with the generally accepted wisdom that parties can exceed stated minimums, especially when the language does not clearly prohibit exceeding the minimums. As noted above, drafters could have stated something to the effect that “border measures can not be applied to patents” for more clarity.

Even if the border section footnote does not clearly preclude members from policing patent infringement, additional interpretive context within the ACTA could suggest that members are barred from policing such infringement. Although the ACTA is a minimum standard agreement, more extensive enforcement cannot “contravene” provisions of the agreement. In addition, the border measures section explicitly states that border enforcement should “avoid[] the creation of barriers to legitimate trade.”²⁷⁸ This could be interpreted to argue that trade in generic drugs should not be barred. However, as discussed with respect to TRIPS, this could be interpreted differently, depending on whether generic drugs are considered “legitimate” trade. The argument for considering global trade in generic drugs as legitimate may be weaker in the context of the ACTA since the border provisions explicitly define infringement to be based on the laws of the in-transit country, as discussed below.

Arguably, the meaning of the patent footnote in the border measures section is not clear based on a textual interpretation.

277. See ACTA, *supra* note 10, § 2, n.2.

278. See *id.*, art. 13; see also *id.*, art. 6(1).

Accordingly, resorting to “supplementary means” of interpretation, such as preparatory work of the treaty, would be appropriate. Prior drafts of the ACTA included suggestions to both explicitly include in-transit patent infringement as well as to exclude in-transit patent infringement from the scope.²⁷⁹ In rejecting language that either clearly included or excluded patents from the scope of border measures, perhaps the most appropriate interpretation is that the final language permits countries to include patents among border measures but is intended to clarify that there is no obligation to do so, such that it embraces the desires of all countries. This would be consistent with statements from negotiating parties that they did not intend for the ACTA to prevent trade in global generic drugs.

2. In-Transit Policing

A second issue is the procedures the ACTA requires its member states to have at their borders. Member states are required to police all imports and exports that infringe on the applicable intellectual property rights.²⁸⁰ In addition, members may, but need not, similarly police goods that merely pass through “in transit” to a final destination.²⁸¹ In particular, the ACTA states as follows:

A Party *may* adopt or maintain procedures with respect to suspect *in-transit goods* . . . under which: (a) its customs authorities may act upon their own initiative to suspend the release of, or to detain, suspect goods; and (b) where

279. See, e.g., Anti-Counterfeiting Trade Agreement: Public Predecisional/Deliberative Draft, § 2, art. 2.X(2) (Apr. 21, 2010) [hereinafter ACTA Draft, Apr. 2010], available at http://trade.ec.europa.eu/doclib/docs/april/tradoc_146029.pdf (“Parties may decide to exclude from the scope of this section, certain rights other than trade marks, copyrights and GIs . . .”). In the August 2010 draft, the last version that did not have a footnote stating that parties agreed patents were not encompassed, some countries proposed different language. For example, whereas some countries suggested that the border measures should be applied to trademark counterfeiting and copyright piracy, a few countries suggested adding the language “at least” and also stating explicitly that countries may provide border measures “to be applied in other cases of infringement of intellectual property rights.” See ACTA Draft, Aug. 2010, *supra* note 210, § 2, art. 2.X(2).

280. See ACTA, *supra* note 10, art. 16(1) (referring to “import and export shipments” when discussing each member state’s ACTA-mandated border requirements).

281. See *id.* art. 16(2) (referring to “in-transit goods” when discussing each member state’s ACTA-permitted border requirements).

appropriate, a right holder may request its competent authorities to suspend the release of, or to detain, suspect goods.²⁸²

Although it is clear that member states may police in-transit goods that infringe intellectual property rights, there is a critical issue for global trade in generic goods concerning which country's law applies to assessing infringement. Article 17 of the ACTA, entitled "Application by the Right Holder," states:

Each Party shall provide that its competent authorities require a right holder that requests the procedures described in subparagraphs 1(b) and 2(b) of Article 16 (Border Measures) to provide adequate evidence to satisfy the competent authorities that, *under the law of the Party providing the procedures*, there is *prima facie* an infringement of the right holder's intellectual property right²⁸³

By specifying that the relevant law to assess *prima facie* infringement is the law "of the party providing the procedures," this suggests that in the case of a country that permits policing of in-transit goods, the in-transit country would use its own laws to assess infringement. Importantly, this would mean that a good that did not infringe at point of origin or final destination could nonetheless be legitimately stopped by border officials for infringement of in-transit goods. In addition, this would not be a mere delay. If the goods infringe within the in-transit country, the ACTA requires that "competent authorities have the authority to order the destruction of [the] goods."²⁸⁴

3. Impact on Global Trade in Generic Drugs

The ACTA has more serious repercussions for trade in generic goods than TRIPS. There are two important issues with respect to the border provisions. First, although the ACTA members do not have to adopt border measures for in-transit

282. *Id.*

283. *Id.* art. 17(1) (first emphasis added).

284. *See id.* art. 20(1).

goods, the ACTA clearly permits this.²⁸⁵ In addition, although members are not required to police patent infringement at their borders, the ACTA does not preclude them from doing so. In fact, as a minimum standard agreement, members should generally be able to exceed the standards in the ACTA—so long as they do not contravene any other provision. In addition, whereas there is arguable ambiguity concerning which country's law applies to find in-transit infringement under TRIPS, the ACTA clearly permits the in-transit country to use its own laws.

However, even if members did not police in-transit patent infringement, there would be major problems if they policed in-transit trademark infringement—as permitted under the ACTA. Whereas TRIPS only required member states to police counterfeit (virtually identical) trademarks, the ACTA requires policing of goods for basic trademark infringement (based on mere likelihood of confusion) if a country elects to extend border provisions to in-transit goods.²⁸⁶

A major challenge for trade in generic drugs is that the nonproprietary generic name may be somewhat similar to the trademark—at least based on a cursory inspection by customs officials. As noted earlier, there was one shipment of drugs in the EU that was suspended for suspected counterfeit trademark because of its use of the word amoxicillin that was actually a nonproprietary name for a drug sold by the brand owner as Amoxil.²⁸⁷ Importantly, the generic name “amoxicillin” is the international nonproprietary name (“INN”) for the drug. INNs are by definition not owned by any single company and intended to facilitate easy identification of drugs world-wide without trademark problems.²⁸⁸ Although the WHO, which designates global INNs, has suggested that companies not choose brand names that are similar to INNs, it nonetheless

285. *See id.* art. 16(2) (“A [p]arty may adopt or maintain procedures with respect to suspect in-transit goods . . .”).

286. *See supra* notes 253–54, 273–74 and accompanying text.

287. *See supra* notes 169–71 and accompanying text.

288. *See* WHO, GUIDELINES ON THE USE OF INTERNATIONAL NONPROPRIETARY NAMES (INNs) FOR PHARMACEUTICAL SUBSTANCES §§ 1.1, 2.2, WHO Doc. WHO/PHARMS/NOM 1570 (1997).

occurs, as underscored by the similarities between amoxicillin and Amoxil.²⁸⁹

V. *EXPOSING THE IMPACT OF PERSPECTIVES ON THE LAW*

This Part shows how patent perspective schemas impact how laws are interpreted. As noted earlier, schemas are particularly important when information is ambiguous. This Part extends this principle to the interpretation of law. In particular, although there are canons of treaty interpretation, they are basic principles that do not always yield clear answers, as noted in Part IV. This Part shows how interpretations of TRIPS and the ACTA may be especially influenced by schemas to result in conclusions that are not firmly supported by proper means of treaty interpretation. This Part is an important complement to the prior Part concerning the operation of schemas to perceptions of facts concerning in-transit suspensions. In particular, whereas factual interpretations highlighted schemas beyond the traditional patent perspectives, legal interpretations of TRIPS and the ACTA emphasize the traditional patent perspectives.

A. *Privilege View*

The view that patents are a privilege that should be modified to ensure access to affordable medicine may play a strong role in some asserted interpretations of TRIPS that may appear to lack firm grounding in TRIPS provisions that are interpreted according to customary principles of international law. This Section first addresses interpretations of the specific TRIPS border measures and then considers the contextual provisions such as the TRIPS preamble, TRIPS articles relating to the “objectives and purposes,” of TRIPS and the Doha Public Health Declaration.

289. See, e.g., World Health Assembly Res. WHA46.19, ¶ 1(3), in WHO, GUIDELINES ON THE USE OF INTERNATIONAL NONPROPRIETARY NAMES (INNs) FOR PHARMACEUTICAL SUBSTANCES, WHO Doc. WHO/PHARMS/NOM 1570 (1997) (discouraging trademarks based on INNs).

1. TRIPS

This Section focuses on the two fundamental TRIPS provisions governing member obligations to police intellectual property violations at their borders. In particular, this section focuses on how the requirements of Articles 51 and 52 of TRIPS have been interpreted from a privilege view.

a. TRIPS Article 51

As explained earlier, although TRIPS does not *require* member states to suspend goods for allegedly infringing patents, there is a footnote that explicitly contemplates in-transit goods. Nonetheless, those who hold a privilege view may reach conclusions that seem to contradict the clear text.

b. TRIPS Article 51 Footnote

The best example of the impact of how a privilege view may lead to incorrect interpretations of Article 51 of TRIPS is a listserv post by Daya Shanker, a scholar in the area of international business. He correctly stated that the footnote to Article 51 “specifically mention[s] that there shall be no obligation to apply such provision to [suspend] the goods in transit.”²⁹⁰ However, he then asserts that “use of the term ‘shall be’ does not leave any doubt that the provision of Article 51 is *not to be applied to the case of goods in transit.*”²⁹¹ In other words, he is suggesting that the “shall be” reference means that countries are precluded from policing in-transit goods.²⁹² Such an

290. See Daya Shanker, *Re: Can India, Brazil Take on EU over Regulation?*, IP-HEALTH (Feb. 8, 2009, 2:35 PM), <http://lists.essential.org/pipermail/ip-health/2009-February/013452.html>. Daya Shanker is a lecturer at Deakin University. See Dr. Daya Shanker, Deakin University, <http://www.deakin.edu.au/buslaw/management-marketing/staff/profiles/shanker.php> (last visited Oct. 26, 2011).

291. See Shanker, *supra* note 290; see also Nirmalya Syam, *Seizures of Drugs in Transit: Why Europe’s Law and Actions are Wrong*, S. BULL. (S. CTR., GENEVA, SWITZ.), Sept. 22, 2009, at 3 (stating that the footnote “clearly obliges WTO Members . . . not to apply border measures to goods in transit”); NGO Letter to Chan, Feb. 2009, *supra* note 5, at 2 (relying on footnote thirteen of Article 51 of TRIPS to state that “[u]nder some legal traditions and consistent with WTO rules,” goods in transit are exempt from normal restrictions associated with IPR when in transit).

292. This interpretation is confirmed by the fact that the states that the footnote makes it “clear” that the ability to police intellectual property goods besides counterfeit trademarks and pirated copyrights “shall not be applicable in the case of losartan which

interpretation would be inconsistent with the fact that TRIPS is generally a “minimum standards” agreement.²⁹³ In other words, while the footnote does say that members are not required to police in-transit goods, member states may do so since TRIPS generally permits member states to provide more extensive protection than its minimums.²⁹⁴ Shanker’s contrary reading could reflect a fundamental misunderstanding of the fact that TRIPS provides minimum standards that countries can exceed. However, given that Shanker is a scholar in the area of international business, it is unlikely that he misunderstands a fundamental concept of TRIPS.

A more plausible interpretation is that despite his understanding of the minimum standards framework of TRIPS, he nonetheless arrived at an inconsistent reading of the footnote because he has a view of patents as a privilege, which may result in reading TRIPS in a way that is most consistent with his world view that patents—and provisions implicating patents—should be narrowly construed to promote access to health. This would be consistent with the social science literature that individuals perceive information in a way most consistent with their pre-existing views. This could be true even if he does not explicitly endorse a privilege view of patents, since social science literature suggests that some “biases” are in fact not conscious.²⁹⁵

A privilege view of patents may alternatively lead to a different yet still questionable interpretation of the same Article 51 footnote. For example, Professor Frederick Abbott, a noted

was in transit in Amsterdam.” See Shanker, *supra* note 290, at 2. Similarly, he later states that the EU regulation permitting suspension of goods infringing all intellectual property rights, including patents, “is in direct violation of the TRIPS agreement.” See *id.* at 4.

293. See TRIPS, *supra* note 2, art. 1(1) (“Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.”); see also *Intervention by India, Feb. 2008*, *supra* note 199 (describing TRIPS as a “minimum standards agreement”).

294. See TRIPS, *supra* note 2, art. 1(1) (establishing TRIPS as a minimum standards agreement); *id.* art. 51 n.13.

295. See Pronin, *supra* note 92, at 378.

scholar in international intellectual property law, states that “[i]t places too much weight on footnote 13 to suggest that it was intended to authorize the seizure of patented goods in transit when the practice was almost certainly outside the contemplation of the drafters of the TRIPS Agreement.”²⁹⁶ He seems to suggest that while the footnote does not explicitly bar members from considering in-transit goods, this should be the effect nonetheless. This is at odds with the fundamental tenet of treaty interpretation that gives controlling weight to the final language rather than whether the language was consistent with accepted practice. Moreover, Professor Abbott’s belief that there was no contemplation of in-transit infringement is not consistent with contemporaneous documents concerning TRIPS negotiations.²⁹⁷ His comments are perhaps better explained as revealing not only a view of patents as privilege, but a schema that a drug created as a generic should always be a non-infringing generic, regardless of domestic or international laws. As discussed above, schemas persist because individuals are prone to focus only on confirming evidence. In addition, disconfirming evidence—such as the contemporaneous documents—could be forgotten as information that is not consistent with a desired schema.

c. TRIPS Article 52

The privilege perspective is clearly seen in interpretations of what constitutes the “country of importation” upon which prima facie infringement must be established under Article 52 of TRIPS . As noted earlier, interpretation of this term is far from clear or simple. Nonetheless, there have been statements and assumptions that the country of importation must necessarily be the final destination. For example, during the

296. Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 2009 WORLD INTELL. PROP. ORG. J. 43, 46.

297. See Secretariat, *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods*, ¶ 51, MTN.GNG/NG11/17 (Jan. 23, 1990); Submission from Hong Kong, *GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods*, ¶¶ 22, 34, MTN.GNG/NG11/W/54 (Dec. 7, 1989); GATT Secretariat, *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods*, ¶¶ 30(9.a), 30(10), 31, MTN.GNG/NG11/13 (Aug. 16, 1989).

ACTA negotiations, some suggested that the language “country of importation” be used in the ACTA provisions of border measures based on the assumption that this language must necessarily mean the country of final destination.²⁹⁸ This interpretation would be consistent with a privilege schema that would interpret ambiguous information—such as the undefined term “country of importation”—consistent with a pre-existing schema. In this case, country of importation is assumed to necessarily mean the country of final destination since that would promote global trade in generic drugs. Importantly, those operating under this schema believe so strongly in it that they do not see that there is ambiguity and assume that there can only be a single proper interpretation.

In addition, some statements made by India and Brazil assume that the country of importation is the final destination.²⁹⁹ For example, India asserted that it was “farfetched” to claim that the in-transit country will understand the laws of a destination country.”³⁰⁰ Moreover, the Indian Joint Secretary of Commerce asserted that “international law says you can’t stop anything in transit if there’s no evidence that the products aren’t destined for those countries,” without citing any actual supporting law.³⁰¹ Brazil similarly asserted without any specific authority that under TRIPS, medicines are generic under the law of market in which they are meant to be commercialized.³⁰² Moreover, Brazil asserted that “[w]hether or not the medicines were generic under the law of the country of

298. See, e.g., Sean Flynn, *Amend ACTA: Defining Terms by Country of Importation*, PROGRAM ON INFO. JUST. & INTELL. PROP. (Sept. 9, 2010), <http://www.wcl.american.edu/pijip/go/blog-post/amend-acta-defining-terms-by-country-of-importation>.

299. This is admittedly an assumption since India and Brazil cited no specific provisions of TRIPS. However, Article 52 of TRIPS is the most plausible TRIPS provision to support their assertion that the country of importation is the final destination, especially in light of the fact that this would be consistent with the stated schema to consider a drug generic based on where it is made and sold only.

300. See *Intervention by India, June 2009*, *supra* note 5.

301. See Miller & Anand, *supra* note 157 (internal quotation marks omitted).

302. See *Intervention by Brazil, Feb. 2009*, *supra* note 197, ¶ 6; see also Day, *supra* note 184 (“Aid agencies note that under World Trade Organisation rules, intellectual property rights only apply at a shipment’s point of origin and its destination.”).

transit is an irrelevant question.”³⁰³ In both cases, there is no relevant provision that directly supports these interpretations. TRIPS never uses the term “generic;” TRIPS simply requires members to provide patent rights and leaves it up to members to decide what is patent infringement.³⁰⁴ In addition, the footnote to the TRIPS border provisions explicitly permits suspension of in-transit goods but does not clearly state how to assess infringement; as noted earlier, infringement is based on the ambiguous phrase “country of importation.” The statements by Brazil and India assume that “country of importation” must necessarily mean the final destination, despite the fact that this is ambiguous. Similarly, Brazil’s claim that whether a drug is generic under the law of country is irrelevant is only one possible view of the ambiguous term “country of importation.” Nonetheless, these interpretations are consistent with the schema that a drug is generic based on where it is made and sold.

d. TRIPS Articles 1 & 41

Those with a privilege view may also be inclined to assume that Article 1 of TRIPS read in conjunction with Article 41 must necessarily prohibit suspensions of in-transit generic drugs. However, as discussed above, this is not a foregone conclusion; to the contrary, it hinges on the interpretation of key terms, such as what constitutes “legitimate trade” as well as a “barrier” to such trade. To those with a privilege view, a drug that is made and sold as generic is necessarily legitimate trade. Indeed, some have claimed that such trade is “not contested at all.”³⁰⁵ However, the fact that the EU repeatedly expresses an interest in

303. See *intervention by Brazil, Feb. 2009*, *supra* note 197, ¶ 6.

304. See TRIPS, *supra* note 2, arts. 28, 52.

305. See, e.g., Xavier Seuba, *Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit* 9 (Int’l Ctr. For Trade & Sustainable Dev., Working Paper, June 2009) (on file with author and the International Centre for Trade and Sustainable Development); see also *Intervention by Brazil, June 2009*, *supra* note 5, at 1 (“[T]rade in generic medicines is perfectly legal from the intellectual property point of view.”); Shammad Basheer, *India’s “TRIPS” Case Against the EU: How Strong is it?*, SPICY IP (Jan. 30, 2009, 11:39 PM), <http://spicyipindia.blogspot.com/2009/01/indias-trips-case-against-eu-how-strong.html> (asserting that drugs that are not patented in country of export or import “easily qualify as ‘legitimate trade’”).

promoting “legitimate trade in generic medicines,” yet defends its regulation permitting in-transit suspension of generics suggests that there is more than one view.³⁰⁶

e. TRIPS Context—Doha (Over-Reliance)

Those with a privilege view seem to also place undue reliance on other contexts, especially the Doha Public Health Declaration. For example, some have suggested that the EU Regulation permitting suspension of drugs for alleged in-transit patent infringement is “clearly inconsistent” with or a “direct violation” of Doha.³⁰⁷ Similarly, Professor Abbott stated in an early article that the Doha Declaration “should preclude” member states from suspending goods that allegedly infringe patents in transit.³⁰⁸ Although Professor Abbott is correct that the Doha Declaration is an interpretive agreement, his

306. See, e.g., *Intervention by EC, Feb. 2009*, *supra* note 213 (stating that “the EU has absolutely no intention to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries, nor have our measures had this effect”); *EC Statement, June 2009*, *supra* note 209, at 3–4 (stating that “the EU does not intend to hamper trade in generic medicines” while simultaneously defending the EU regulation permitting suspension of in-transit drugs).

307. See, e.g., NGO Letter to Chan, Feb. 2009, *supra* note 5, at 2; see also *Intervention by Brazil, Feb. 2009*, *supra* note 197, para. 8 (asserting that “[e]xtraterritorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration” and that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health” (internal quotation marks omitted)); HAI, *Dutch Seizure of Drugs*, *supra* note 177 (quoting Rohit Malpani from Oxfam International as stating that the seizures are a “nonsensical encroachment . . . on the WTO’s Doha Declaration on TRIPS and Public Health, which ensures that intellectual property rules should not interfere with the ability of developing countries to protect and promote public health” (emphasis added)).

308. See Frederick M. Abbott, *Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil*, 13 BRIDGES (Int’l Ctr. For Trade & Sustainable Dev., Geneva, Switz.) Feb.–Mar. 2009, at 13, available at http://www.frederickabbott.com/uploads/Abbott_-_Worst_Fears_Realized_-_Pages_from_Bridges-vol13-no1.pdf; see also Abbott, *supra* note 296, at 49 (referring to the suspension of drugs in transit as a “frontal assault by the EU on the object and purpose of the Doha Declaration”). Professor Abbott maintains that it is improper to consider the TRIPS footnote to permit suspension of goods that allegedly infringe patents in transit, but relies more on the fact that there was no practice of suspending goods in transit for patent infringement at the time TRIPS was adopted. See *id.* at 44, 46. In addition, he focuses primarily on arguing that in-transit infringement violates the principle of limited territoriality of patents.

subsequent assertion that the EU Regulation conflicts with Brazil's "right . . . to protect the public health of its citizens and to promote access to medicines for all of them" borders on an overbroad interpretation of what the Doha Declaration provides.³⁰⁹ As noted earlier, the Doha Declaration does not guarantee nations the ability to take any action to promote the public health of their citizens; after all, it simultaneously acknowledges TRIPS requirements.³¹⁰ At some level, Professor Abbott seems to acknowledge that the Doha Declaration does not provide a *carte blanche* to nations to take any action that is supportive of public health. Indeed, he correctly recognizes that TRIPS does not explicitly bar the EU regulation, although he nonetheless states that the regulation is "beyond that required" by TRIPS and is "not 'supportive' of public health."³¹¹ However, the belief that the Doha Declaration provides broader support for public health may reflect not only the importance of the privilege schema but also a recollection of originally proposed language for the Declaration that was not adopted.³¹²

309. See Abbott, *supra* note 308, at 13.

310. The complete context states as follows:

"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/W/2, art. 4 (2001). Although the last clause about promoting access to medicine for all may be tempting to focus on, neither this clause nor the sentence in its entirety sets forth a condition that can be easily violated.

311. See Abbott, *supra* note 308, at 13. In addition, he states in the same document that the in-transit seizures may present an opportunity for Brazil and India to claim that their benefits under TRIPS are nullified or impaired because they had a legitimate expectation that products unpatented in their territories could be freely traded. See *id.* at 14. Although the facts may present a good case for this argument, it is nonetheless not a permissible one at this time. There is presently a moratorium on so-called "non-violation" claims under TRIPS, which he duly recognizes. See *id.* However, the fact Professor Abbott mentions a non-violation claim suggests that he knows there is no direct violation of the TRIPS border provisions.

312. See World Trade Organization, Draft Ministerial Declaration: Proposal from a Group of Developing Countries, ¶ 1, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) (affirmatively stating that "nothing in the TRIPS Agreement shall prevent Members from taking measures to protect public health" without any caveats to this principle).

f. TRIPS Context—Articles 7 and 8

Another example of the power of schemas is evident in claims that TRIPS' Articles 7 and 8—the objectives and principles—would prohibit suspension of in-transit goods despite the fact that these Articles do not clearly prohibit such suspension and in fact do not even mention in-transit goods. For example, Brazil asserted that “the TRIPS Agreement does not allow the detention of goods in transit” because it is counter to the objectives and purposes of TRIPS as stated in Articles 7 and 8.³¹³ Brazil cites Article 7 as stating that enforcement of rights must be done “in a manner conducive to social and economic welfare” while Article 8 “upholds members’ rights to ‘protect public health and nutrition.’”³¹⁴ However, Article 7 actually states that enforcement of rights should contribute to social and economic welfare; not only is “should” not a mandatory requirement, but it is also ambiguous what would contribute to “social and economic welfare.”³¹⁵ Most likely, “social and economic welfare” would be interpreted differently by those with a privilege versus uber-right view. Similarly, Article 8 does not provide member states an unfettered right to take any action that promotes public health; to the contrary, an essential caveat to Article 8 is that measures to protect public health must be “consistent” with TRIPS.³¹⁶ In other words, Article 8 does not provide a complete loophole from TRIPS obligations. At a minimum, Articles 7 and 8 are not as clearly breached as Brazil’s statement seems to suggest.

Brazil’s focus on Articles 7 and 8 is consistent with the fact that individuals interpret information consistent with schemas and selectively focus on information that supports those schemas. To the extent that the footnote to Article 51 of TRIPS does not support the schema that a drug is generic based on where it is made and sold—such that it could not conceivably infringe in-transit—Brazil ignores this footnote. This is

313. See *Intervention by Brazil, June 2009*, *supra* note 5, at 3.

314. See *id.*

315. See TRIPS, *supra* note 2, art. 7.

316. See *id.* art. 8.

consistent with social science evidence that individuals ignore disconfirming evidence. Moreover, Brazil's over-emphasis of the importance of ambiguous language in Articles 7 and 8 is similarly consistent with social science evidence that schemas appear when there is ambiguity.

g. TRIPS "Context"—Territoriality

Along similar lines, the privilege view may result in arguments that suspensions of in-transit goods for patent infringement under TRIPS violate territoriality or are extraterritorial. For example, India has said that the in-transit seizures violate territoriality principles that are the "key stone in the edifice" of TRIPS, without citing a specific provision of TRIPS or explaining the territorial violation.³¹⁷ Similarly, Brazil has asserted that "TRIPS "does not allow the detention of goods in transit" because it "violates the principle of territoriality, a keystone of the international IP system," again without citing a specific provision of TRIPS that is being violated.³¹⁸

Although there are territorial limits to patent protection, both as a historical matter and under TRIPS it is an overstatement to suggest that suspension of in-transit goods necessarily violates territorial principles. While each nation must comply with the minimums of TRIPS, each has the discretion to decide how to do so; thus, TRIPS can be seen as consistent with the traditional principle of territoriality that patents granted by individual nations are independent of each other.³¹⁹ However, the issue with in-transit goods is more nuanced. As noted earlier,

317. See *Intervention by India, Feb. 2009*, *supra* note 199; see also Preneet Kaur, Indian Minister of State for External Affairs, Address to High-Level Segment of the Economic and Social Council at Special Event on Africa and the Least Developed Countries: Partnerships and Health (July 8, 2009), available at <http://www.keionline.org/blogs/2009/07/08/india-ecosoc-seizures> (noting the "seizures contravene the concept of 'territoriality' enshrined in the TRIPS Agreement").

318. See *Intervention by Brazil, June 2009*, *supra* note 5, at 3; see also *Intervention by Brazil, Feb. 2009*, *supra* note 197, para. 8 (stating that "[e]xtraterritorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration on TRIPS and Public Health").

319. See TRIPS, *supra* note 2, at art. 2 (requiring compliance with provisions of the Paris Convention); see also Paris Convention, *supra* note 17, at art. 4 bis (1) (stating that patents in separate countries are independent of each other, which is consistent with the concept of territorial limits to patent protection).

TRIPS requires each member state to provide certain patent rights, including the right to exclude imports of the patented invention; however, TRIPS does not define what constitutes an “import.”³²⁰ The issue raised by in-transit goods is whether a nation can consider “import” to be a good that is only temporarily within the its borders.³²¹ As a general matter, member states have the right to self-define terms that are undefined under TRIPS.³²² Applying this basic rule suggests that a country could define “import” to include goods that are imported only in the customs area. While most nations have not defined importation in this way, this does not mean that such a definition would necessarily violate territoriality principles under TRIPS. At a minimum, such an action is not an extraterritorial extension of patent rights. Indeed, while there is no clear precedent under patent laws, nations have previously considered in-transit goods to be imported and thus impermissible infringements of the rights of copyright as well as trademark owners.³²³

Holders of the privilege perspective may view the national right to determine patent scope as inviolate so as to disregard the ability of other countries to consider in-transit goods as

320. See TRIPS, *supra* note 2, art. 28.

321. The Dutch law that permits suspension of in-transit goods for patent infringement actually does so based on a fictional assumption that the in-transit goods were “made” in the Netherlands. See *supra* notes 141–44 and accompanying text (discussing case law in the Netherlands where in-transit products were found to infringe on Dutch patents based on the legal fiction that the products were made in the Netherlands). Although nations can define TRIPS patent rights, including the right to “make” an invention within a country, considering in-transit goods to infringe would seem to more logically be considered a type of “import” that would violate patent rights. However, in either event, the same principle applies—TRIPS permits countries to define terms that it leaves undefined.

322. See TRIPS, *supra* note 2, art. 1(1); see also Reichman, *supra* note 113, 30–35 (suggesting that developing countries could choose and interpret the TRIPS patent requirements concerning the novelty and inventive step consistent with their goals); UN CONF. ON TRADE & DEV. & INT’L CTR. FOR TRADE AND SUSTAINABLE DEV., RESOURCE BOOK ON TRIPS AND DEVELOPMENT 358 (2005) (noting that members have “considerable leeway” in defining the undefined TRIPS criteria of patentability).

323. See *supra* note 260 (reviewing various instances in which member states have interpreted in-transit goods to be imports that violate domestic intellectual property laws).

infringing patent rights. After all, the action of other countries, such as the EU, could effectively preempt the ability of other nations, such as Brazil and India, to take a different view of patent rights. Not only may this reflect the privilege view's assumptions about national rights but it may reflect a schema previously mentioned—that a drug made as a generic and destined for a country where it is considered generic must necessarily always be generic. Although this schema does not reflect basic tenets of patent law that permit individual nations to determine the scope of patent rights, the schema is sufficiently strong that some claim a violation of territoriality that is inconsistent with the facts.

2. The ACTA—Privilege View

Some of the discussion of the ACTA's border provisions reinforce the prior point that ambiguity—including legal ambiguity—provides more room for schema-based interpretations. Whereas TRIPS border provisions were arguably ambiguous concerning which country's laws were used to determine in-transit infringement, the ACTA's border provisions clearly refer to the country where in-transit procedures are initiated.³²⁴ Although this clarity would not work in favor of global trade in generic medicines, those with a privilege view seem to understand that the ACTA permits countries to apply the law of the in-transit country.³²⁵ This could suggest that where language is clear and unambiguous even inconsistent schemas will not distort the text. However, there is an alternative possibility. In particular, those with a privilege view may believe that member states cannot suspend in-transit goods for patent

324. See *supra* notes 283-84 and accompany text (discussing the ACTA's border provisions under Article 17 and positing that if a country permits policing in-transit goods, the in-transit country can use its own laws to assess infringement).

325. See Jimmy Koo, *ACTA December (Final) Draft—Section by Section Analysis* INFOJUSTICE.ORG (Jan. 28, 2011), <http://infojustice.org/archives/2912> (noting that Article 16 is “dangerous” in that it could result in more in transit suspensions, which would be consistent with an understanding that Article 16 permits in-transit countries to decide whether goods infringe); Sean Flynn, *Note on ACTA and Access to Medicines*, PROGRAM INFO. JUST. INTELL. PROP., <http://www.wcl.american.edu/pijip/go/blog-post/note-on-acta-and-access-to-medicines> (last visited Nov. 15, 2011) (in discussing a draft of the ACTA with the same language, it is noted that the border measure language suggests that the law violated is the law of the in-transit country, not the destination country).

infringement in general, regardless of what law would apply. Although the ACTA does not explicitly state this, there is a footnote indicating that “patents are excluded” from the border measures section.³²⁶ As discussed earlier, a proper interpretation of this footnote should be that Member States are not required to, but nonetheless, may police in-transit goods for patent infringement.³²⁷ However, this interpretation would be contrary to the schema that a good is generic, if generic where manufactured and sold.

In addition, there are other opportunities for interpreting the ACTA consistent with certain schemas. In particular, although the ACTA permits member states to suspend in-transit goods for the lesser infraction of trademark infringement, there has nonetheless been the suggestion that the ACTA should be interpreted in a way to exclude such infringement where it would impact public health.³²⁸ For example, a group of European academics concluded that the ACTA “requires rewording or, at least, a narrow interpretation” to prevent members from excluding trademark infringement based on mere confusion and to ensure global trade in generic medicines.³²⁹ However, as noted earlier, this reflects a schema that a drug that is considered generic at point of origin and destination is necessarily legitimate trade—a point that not all will concede. Further evidence of the strength of the schema is that the European academics recognized some ambiguity, yet characterized an alternative interpretation as “misuse.”³³⁰ This is consistent with naïve realism in that others are assumed to be biased in their interpretations.

326. See ACTA, *supra* note 10, art. 13 n.6 (“The [p]arties agree that patents . . . do not fall within the scope of this [s]ection.”).

327. See *supra* notes 271–76 and accompanying text (describing the ACTA’s provisions for policing of in-transit goods by the in-transit country); see also Ruse-Khan, *supra* note 262, at 668–69.

328. See Roberto D’Erme et al., *Opinion of European Academics on Anti-Counterfeiting Trade Agreement*, 2 J. INTELL. PROP. INFO. TECH. & ELECTRONIC COM. L. 65, 65, 67 (2011).

329. See *id.* at 67.

330. See *id.*

B. *Uber-Right View*

The uber-right view of patents also plays an important role in how laws are interpreted. The impact of uber-right view on in-transit suspensions is more difficult to document since most of the critique and analysis seem to reflect the views of those with a privilege view. However, that does not mean that an uber-right view does not exist with respect to in-transit goods. To the contrary, considering in-transit goods to infringe in the first instance would be consistent with an uber-right view that advocates maximum patent rights to promote improved innovation and social welfare. In addition, treaty provisions that promote an uber-right view are less likely to prompt discussion from those with an uber-right view because such provisions would be consistent with this view.³³¹ Nonetheless, there are still some examples of how the uber-right view may influence interpretation as well as negotiation of international agreements.

1. TRIPS Border Measures

An uber-right perspective may be relevant to the EU's consistent view that its border measures Regulation complies with TRIPS.³³² As noted earlier, interpretation of the relevant TRIPS provisions on border measures is difficult. To date, however, the EU has not provided a comprehensive explanation of how its Regulation complies. While the EU has noted that the procedures for detaining goods are consistent with TRIPS, it has never explicitly addressed the critical interpretative question of what constitutes a "country of importation." Its actions suggest that it believes that the country of importation should be

331. In contrast, there is more discussion from the uber-right when treaty provisions are less consistent with their view. For example, the uber-right perspective is inclined to distort the TRIPS requirements concerning compulsory licenses to favor their preferred view of patents so that in some cases they contradict even clear text. See Cynthia M. Ho, *Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1081–88 (2009).

332. See, e.g., *EC Statement, June 2009, supra* note 209, at 4 (stating that the Regulation "is fully in line with WTO/TRIPS . . . TRIPS foresees that border enforcement measures may apply not only to imports of goods infringing any IPR, including patents, but also to goods . . . [in] transit"); World Trade Organization, General Council, *Minutes of Meeting*, ¶ 94, WT/GC/M/118 (2009) (asserting that suspensions are consistent with Article 51 of TRIPS).

interpreted as the in-transit country. However, it notably never articulated this in response to claims from Brazil and India that this was impermissible under TRIPS.

An uber-right view may also have a different view of what constitutes an extraterritorial application of laws. As noted earlier, those with a privilege view suggest that the Dutch law constitutes an extraterritorial application of the laws.³³³ The EU has denied any extraterritorial effect of its customs Regulation.³³⁴ This seems consistent with the EU's view that each EU member state decides whether to consider in-transit goods to infringe and thus be potentially suspended under the EU Regulation.³³⁵ Pursuant to this view, even when suspensions occur, there is no extraterritorial application of the law because no country is applying the laws of another country. For example, the Dutch border officials are applying Dutch law and not the law of a distant nation such as Brazil or India.

An uber-right perspective may also be relevant to interpreting Article 1 of TRIPS, which allows member states to exceed TRIPS requirements only to the extent that they do not contravene TRIPS. As noted above, there are reasonable grounds for considering that domestic laws that consider in-transit drugs to infringe patent (or trademark) rights to violate the requirement under Article 41 of TRIPS that enforcement procedures not create barriers to legitimate trade.³³⁶ The EU's repeated statements that it is not interested in disturbing "legitimate trade in generic drugs" suggests that there may be a view that drugs that infringe while in transit are perhaps not

333. See *supra* note 248 and accompanying text (discussing the privilege view's refusal to recognize the Dutch law that considers in-transit goods to infringe on Dutch patent rights under the fiction that the in-transit products were made in the Netherlands).

334. See, e.g., *EC Statement, June 2009, supra* note 209, at 4 (claiming that the EC Regulation has "no extra-territorial effect").

335. See *EU Explanatory Note, July 2009, supra* note 209, at 1 (stating that national courts determine infringement and that different patent laws may result in differing conclusions among different member states).

336. See *id.* at 1–2.

actually legitimate generics to the extent they might infringe in-transit.³³⁷

In addition, an uber-right view of Article 1 of TRIPS might discount the relevance of the clause that suggests that additional protection should not contravene other provisions. Countries known to promote uber-right views, including the United States and the EU, have suggested language that would have had no limitations on stronger rights; both suggested that “nothing . . . shall *prevent* contracting parties” from granting more extensive protection without the current caveat in Article 1 concerning contravening other provisions.³³⁸ Those with an uber-right view may believe so strongly in the correctness of their view that they improperly assume that TRIPS reflects their beliefs. While there is no clear evidence of this with respect to Article 1 of TRIPS, an uber-right view has resulted in interpretations of other TRIPS provisions that are contrary to TRIPS text and erroneously rely on past negotiating language rather than on clear text.³³⁹

An uber-right view of patents may also result in a different view of what international obligations are consistent with the Doha Public Health Declaration,³⁴⁰ which relates to

337. See, e.g., *EC Statement, June 2009, supra* note 209 (stating that “the EU does not intend to hamper trade in generic medicines” while simultaneously defending the EU regulation permitting suspension of in-transit drugs); *Intervention by EC, Feb. 2009, supra* note 213 (stating that “the EU has absolutely no intention to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries, nor have our measures had this effect”).

338. See GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights: Communication from the United States*, 3, MTN.GNG/NG11/W/70 (May 11, 1990) (emphasis added); GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Draft Agreement on Trade-Related Aspects of Intellectual Property Rights: Communication from the European Communities*, 2, MTN.GNG/NG11/W/68 (Mar. 29, 1990) (emphasis added).

339. See Ho, *supra* note 331, at 1081–88 (discussing the influence of patent perspectives on TRIPS compulsory license requirements and presenting specific examples of the uber-right’s distortion of clear TRIPS language); CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY 76-80, 341 (2011) (interpreting TRIPS provision on data protection and explaining why an uber-right view, as propagated by the US Trade Representatives Office as well as by patent owners, is incorrect).

340. Similarly, an uber-right view may believe that stronger rights can only bring social benefits, such that there is no need to address Article 1 of TRIPS concerning stronger rights that contravene other provisions.

interpretation of TRIPS as well as the ACTA.³⁴¹ Governments that have tended to advocate an uber-right view, such as the United States and sometimes the EU, have consistently claimed that rights exceeding the minimums of TRIPS are consistent with the Doha Declaration.³⁴² However, that consistency seems to be premised on a very narrow view of the Doha Declaration. In particular, the uber-right view of the Doha Declaration seems to be that countries fully compliant as long as one paragraph of the Declaration is complied with—the part relating to waiving one of the usual compulsory license requirements to enable generic drugs to be made for poor countries.³⁴³ Although health advocates have suggested that domestic laws permitting suspension of drugs for alleged infringement in transit are inherently inconsistent, an uber-right view may find no problem unless a shipment was actually made pursuant to the Declaration, which has yet to happen. In fact, in the EU's explanation and defense of its Regulation, it suggested its

341. See Draft Anti-Counterfeiting Trade Agreement pmble., Dec. 3, 2010, available at <http://www.actawatch.org/blog/final-acta-text-december-3-2010> (“Recognizing the principles set forth in the Doha Declaration on the TRIPS Agreement and Public Health . . .”).

342. See, e.g., *EU Explanatory Note, July 2009*, supra note 208, at 2 (asserting that decision of EU pharmaceutical industries not to exercise right under EU regulation to suspend “legitimate generic” drugs is consistent with Doha Declaration).

343. See, e.g., *EU-India FTA Negotiations and Access to Medicines Q&A*, EUROPEAN COMM'N TRADE (May 26, 2010), available at http://trade.ec.europa.eu/doclib/docs/2010/may/tradoc_146191.pdf (showing that in responding to a question concerning how the proposed Free Trade Agreements will limit access to affordable medicines, the EU focused solely on the provision permitting compulsory licenses for export while ignoring the possibility that nations can interpret TRIPS provisions to limit patentability of drugs and thus promote more generics). Although there are US laws requiring that the United States negotiate trade agreements consistent with the Doha Declaration, not all agree that agreements in fact are consistent. See, e.g., H.R. COMM. ON GOV. REFORM—MINORITY STAFF SPEC. INVESTIGATIONS DIV., *TRADE AGREEMENTS AND ACCESS TO MEDICATIONS UNDER THE BUSH ADMINISTRATION* 18 (2005), available at <http://democrats.oversight.house.gov/images/stories/documents/20050609094902-11945.pdf> (stating that US trade agreements “undermine” Doha); Letter from Henry A. Waxman, Cong. Rep., et al., to Susan Schwab, U.S. Trade Rep. (Mar. 12, 2007), available at <http://www.forumdemocracy.net/downloads/Congress%20to%20USTR%20on%20Trade%20in%20Medicines.pdf> (urging reconsideration of Free Trade Agreements negotiated with the United States to comply with the Doha Declaration).

Regulation was consistent with the Doha Declaration.³⁴⁴ However, given that there has only been a *single* shipment of drugs pursuant to this procedure—and none that were suspended in the EU—there would be no conflict from an uber-right perspective.

2. The ACTA and Beyond

The views of the uber-right are better highlighted in developments beyond TRIPS. The genesis of TRIPS, as well as the continued proliferation of bilateral and multilateral agreements requiring stronger patent rights, is consistent with an uber-right view that more patent rights are better to promote innovation and other social benefits. In addition, the border measures under the ACTA may also illustrate an important issue. Where existing agreements are susceptible to interpretations inconsistent with an uber-right view, there may be an incentive to create new agreements that more explicitly embrace the uber-right view. For example, in the case of border measures, whereas TRIPS is ambiguous concerning which country's laws are relevant to assessing infringement for border measures and those with a privilege view repeatedly suggested that it must mean the country of final destination, this could have led to different language under the ACTA. As noted earlier, the ACTA more clearly states that infringement of in-transit goods is to be assessed by the in-transit country.

An uber-right view may also consider the ACTA to not pose any serious problem for global trade of generic problems.³⁴⁵ For example, when a draft of the ACTA was first publicly released in April 2010,³⁴⁶ the EU stated that the ACTA would be consistent with TRIPS and that it “will not address the cross-border transit of legitimate generic medicines.”³⁴⁷ At the time of this

344. See *EU Explanatory Note, July 2009, supra* note 209, at 2–4 (suggesting that details of the EU regulation actually minimize problems).

345. Australia, Canada, and New Zealand apparently favored a clear exclusion of patents from border protection, whereas others, such as the United States, while not advocating mandatory suspension based on patent infringement, seemed to be open to this possibility.

346. ACTA Draft, Apr. 2010, *supra* note 279.

347. See Press Release, IP/10/437, *supra* note 210; see also Press Release, European Commission, EU Welcomes Conclusion of Negotiations on Russia's WTO Accession (April 21, 2010), available at <http://europa.eu/rapid/pressReleasesAction.do?>

statement, however, the draft text did not prevent members from considering in-transit drugs as infringing on local patent rights. To the contrary, the draft made clear that enforcement of patent rights against in-transit goods was explicitly being considered.³⁴⁸ While some health advocates may believe that the EU statement was made in bad faith, an alternative explanation is possible when viewed through the uber-right lens. In particular, an uber-right view might consider the term “legitimate generic medicines” to only constitute medicines that do not infringe a patent at any point, including even where it is only in the customs area of a nation while in-transit. The EU has never stated this. However, this is consistent with its actual statements, as well as an uber-right view of patents. After all, if patents are strong rights, the borders of a country where patents exist are a natural extension of where patents should be enforced.

CONCLUSION

This Article provides an important understanding of patent policy perspectives that operate as key schemas in discussions concerning the balance between patent rights and access to affordable medicines. The case study demonstrates that patent schemas operate similar to other schemas as a lens through

reference=IP/11/1334; Letter from Ambassador Ron Kirk, U.S. Trade Rep., to Ron Wyden, U.S. Sen. (Jan. 28, 2010), *available at* http://keionline.org/sites/default/files/ustr_acta_response.pdf (stating that the ACTA would be consistent with TRIPS and would respect the Doha Declaration, yet failing to articulate what steps the United States would take despite the question). Similarly, in July 2010, the EU issued a press release on ACTA negotiations and again stated that the ACTA would be consistent with TRIPS. Negotiating participants not only reiterated that “ACTA will not hinder the cross-border transit of legitimate generic medicines,” but also that “patents will not be covered in the [s]ection on [b]order [m]easures.” *See* Press Release, European Commission, Anti-Counterfeiting Trade Agreement, Report on the 9th Round of Negotiations (July 2, 2010), *available at* <http://trade.ec.europa.eu/doclib/press/index.cfm?id=588&serie=352&langId=en>.

348. *See* ACTA Draft, Apr. 2010, *supra* note 279, § 2.6; *see also id.* § 2.X(3) (“Parties shall provide for the provisions related to border measures to be applied [at least] in cases of trade mark counterfeiting and copyright piracy. [Parties may provide for such provisions to be applied in other cases of infringement of intellectual property rights.]” (alteration in original)).

which individuals interpret information. This Article builds upon prior social science work to establish that such schemas play a critical role in how laws are interpreted. Although some have previously noted that schemas impact evaluation of facts that may be relevant to subsequent legal interpretations, this Article shows how schemas may impact the process of treaty interpretation—a process that has previously been considered to be objective and not inherently subject to bias. Moreover, because of the combination of schemas and naïve realism, individuals may not only interpret treaty provisions consistent with their schemas but also assume that their view is correct and only others are biased. Although all individuals—including this author—are subjects to schemas and bias, hopefully the examples shown here help expose the significance of patent perspective schemas and naïve realism in furthering conflict.

The existence of these perspectives may play a prominent role in how parties approach specific solutions that attempt to promote access to medicine. Currently, adherents of each view propose solutions consistent with their schemas while dismissing proposals of the other side as inadequate and biased. Although social scientists have not studied conflicts concerning access to medicine, they have studied conflicts in other areas of social conflict that consistently suggest that due to the operation of naïve realism, individuals tend to not only assume that the other side is more biased, but also holds more extreme positions than they in fact do, which can lead to further polarization and animosity. This seems to perfectly describe discussions concerning access to medicine. This knowledge can thus lay the groundwork for subsequent inquiry into how to address perspectives to promote an improved balance between patent rights and affordable access to health.