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# Compulsory License Case Study: An Introduction to Competing Patent Perspectives

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## UNVEILING COMPETING PATENT PERSPECTIVES

*Cynthia M. Ho\**

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## I. INTRODUCTION

Compulsory licensing has been a lightening rod of controversy in the global arena. Recent compulsory licenses issued by Thailand and Brazil expose very different views from patent-owning pharmaceutical companies versus developing countries and their sympathizers. For example, while one headline trumpets “Brazil, Thailand Override Big Pharma Patents,” another reads “Pharma’s Seven Deadly Lies about Thai Compulsory Licenses.”<sup>1</sup> Patent owners primarily argue that compulsory licenses will inevitably kill the goose that lays the

1. Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 SCIENCE 816 (2007); Posting of Brook K. Baker, *Pharma’s Seven Deadly Lies About Thai Compulsory Licenses*, to IP Disputes in Medicine (Feb. 1, 2007, 11:14 EST), <http://www.cptech.org/blogs/ipdisputesinmedicine/2007/02/pharmas-seven-deadly-lies-about-thai.html>. There are, of course, also intermediate positions. For example, sometimes an article will refer to a compulsory license as “breaking” patents, while simultaneously acknowledging that such an action is “completely legal.” Jonathan Head, *Thailand Takes on Drugs Giants*, BBC NEWS, Apr. 26, 2007, <http://news.bbc.co.uk/2/hi/asia-pacific/6587379.stm>.

golden egg, on the assumption that patent profits are required to fund research and development costs. Patent owners often minimize discussion of whether such licenses are legal. On the other hand, developing countries and their sympathizers usually ignore innovation issues and instead emphasize the literal language of TRIPS, the international agreement that explicitly permits compulsory licenses.<sup>2</sup>

Many seem inclined to believe that there is a single correct answer. Public discussions of compulsory licenses not only include quick dismissals of opposing views, but outright hostility and name calling. Patent-owning pharmaceutical companies are called greedy corporations that place profits above life,<sup>3</sup> whereas public health advocates are decried as anti-property activists and patent hooligans.<sup>4</sup> The one commonality between these positions is that they believe that only one view can be true. However, considering that there are intelligent people on both sides, including attorneys that should understand the law, the polarized positions raise a question of whether there are alternative phenomena at issue.

The seeming deadlock in views suggests that there is a need to look for new insight to better understand and get beyond the deadlock. This Article does just that. This Article suggests that there are two competing perspectives that each provide a different lens through which to view whether compulsory licenses are consistent with TRIPS. Each lens may be consistent within the previously known categories of the rights-maximalist or rights-minimalist approach to patent law. However, unlike most scholarship that advocates a single approach—whether it is to maximize or minimize rights—this Article suggests that neither is per se correct. Rather, this Article posits that the more important phenomenon is *how* a particular perspective impacts

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2. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter TRIPS].

3. At one point, a website critical of the pharmaceutical company Abbott Laboratories' actions against Thailand existed at <http://www.abbottsgreed.com>. Although the website is no longer live, an archived version is available at [http://web.archive.org/web/20080424010611rn\\_2/www.abbottsgreed.com](http://web.archive.org/web/20080424010611rn_2/www.abbottsgreed.com).

4. See, e.g., 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 (stating that those who endorse compulsory licenses "oppose protection of property rights in general and IP rights in particular"). In addition, a website critical of Thailand was created at <http://www.thailies.com>. Although that website is no longer active, an archived version is available at <http://web.archive.org/web/20070909172311/http://www.thailies.com>.

how laws are interpreted and understood. Moreover, this Article seeks to demonstrate that recognizing the existence of these differing perspectives is critical because each serves as a powerful prism that impacts how laws, such as TRIPS, are interpreted and understood. Given that there is widespread discord not only on the appropriateness of compulsory licenses, but on the broader question of the appropriate balance between patents and public health, a better understanding of the impact of these competing perspectives could have significant implications for an improved understanding of current controversies and more viable solutions.

The basic thesis is that there is a spectrum of views on patents benchmarked by two distinct and seemingly irreconcilable perspectives. One perspective of patents is that they are a mere privilege granted by a nation and are inherently subject to limitations to accommodate other societal goals, such as access to medicine. This view is referred to as the “privilege view” of patents. The alternative perspective views patents as a type of super-property right that should seldom, if ever, be subject to exception. This Article refers to this perspective as an “uber-right” view in contrast to the traditional conception of property rights that necessarily includes limitations and exceptions. The privilege view of patents can find some roots in the historical genesis of patents because patents were once a privilege conveyed by the crown and also often had restrictions on where the patented invention was used.<sup>5</sup> On the other hand, the patents as a super-property view may reflect a more modern conception by some.<sup>6</sup>

This Article suggests that these differing perspectives are at least as important as a proper interpretation of international

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5. See Oren Bracha, *The Commodification of Patents 1600–1836: How Patents Became Rights and Why We Should Care*, 38 LOY. L.A. L. REV. 177, 183–86 (2004) (discussing early patents as a “creature of royal prerogative” because there were no criteria for patentability, or even scope of patent privilege); Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S.–Brazil Patent Dispute*, 27 YALE J. INT’L L. 365, 370–73 (2002) (noting that patents were originally designed not to protect inventors, but to protect domestic interests, such that early patent laws often required patents to be forfeited if they were not used in the granting territory); see also CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* 53–54 (2006) (discussing early grants of privilege as they relate to modern day patents). But see Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context*, 92 CORNELL L. REV. 953, 992, 1012 (2007) (challenging the traditional view that American patents are special legal privileges).

6. See, e.g., SUSAN K. SELL, *PRIVATE POWER*, PUBLIC LAW 5 (2003) (suggesting that increasing use of the term “rights” with respect to intellectual property suggests that they must be upheld).

law. After all, the current controversy exists against a backdrop of legal rules that permit compulsory licensing.<sup>7</sup> Some clear rules, such as what subject matter may be licensed, have been distorted to reflect a desired (uber-right) perspective of patents.<sup>8</sup> In addition, both perspectives are responsible for injecting a number of non-issues into the discussion that serve as a smoke screen that blocks attention to issues in need of true resolution under TRIPS.<sup>9</sup> The extent of the distortions and non-issues suggests that the controversies must be explained by more fundamental phenomena than simple rhetoric and issue-framing. Granted, these tools can be very powerful in shaping the creation and interpretation of law.<sup>10</sup> However, the perspectives outlined here may reflect fundamental beliefs that precede more conscious rhetoric and issue-framing.

The competing perspectives may provide an enriched understanding of the negotiation of TRIPS, as well as subsequent controversies beyond compulsory licenses. In particular, the competing perspectives may provide an alternative narrative for why developing countries agreed to TRIPS. The broad language under TRIPS may have permitted each side to believe that the agreement adequately reflected its views. Subsequent controversies can be viewed as instances where divergent perspectives are exposed. Thus far, the perspectives have been lurking below the surface. However, if more explicitly acknowledged, they could perhaps be more directly addressed in future conflicts when WTO panels are commissioned to resolve TRIPS issues.

In addition, a better understanding of competing perspectives may provide an important foundation for viable global solutions concerning the intersection of patents and public health. There have been several instances thus far where countries have attempted to clarify the intersection of patents and public health under TRIPS, including when compulsory licenses are permissible. For example, in 2001 all WTO countries agreed to the Doha Public Health Declaration, which affirms the ability to provide compulsory licenses.<sup>11</sup> However, the unanimity behind adoption of the Declaration has dissolved into divergent perspectives with regard to text that would otherwise seem clear,

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7. TRIPS, *supra* note 2, art. 31.

8. *See infra* Part IV.B.

9. *See infra* Part IV.C.

10. *See, e.g.,* SELL, *supra* note 6, at 26–29.

11. World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 5, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Public Health Declaration].

as will be later discussed.<sup>12</sup> Similarly, although all countries agreed that some type of exception to TRIPS was required to provide access to low-cost drugs for the poorest countries, the solution seems to satisfy no one and also not be effective.<sup>13</sup> Perhaps if the competing perspectives are better understood, problems can be anticipated and potentially addressed in the proposal stage.

While this Article aims primarily to document the sometimes dramatic impact of each perspective on how laws are interpreted, the phenomena can also be understood against the broader context of social cognition research. In particular, there is rich literature in that field that supports the idea that prior knowledge and beliefs may substantially impact how new information is processed. In particular, such literature supports the fact that existing “schemas,” such as a perspective, would be resistant to change even in the face of contradictory evidence. While this Article does not attempt to provide a thorough discussion of this literature, this Article will briefly address how the perspectives are consistent with this literature and its implications. After all, insights from other bodies of knowledge may help to reframe issues to get beyond blaming and move towards problem solving.

This Article proceeds in five parts following this Introduction. Part II provides a brief explanation of the two patent perspectives that will be explored in further depth throughout the Article. Part III provides a case study of competing perspectives concerning several compulsory licenses in Thailand. Part IV takes a “behind the scenes” look at the differing perspectives in comparison to the rule of law under TRIPS. This Part begins by providing and explaining the relevant TRIPS provision at issue for compulsory licenses. Then, it documents and explains some dominant misconceptions

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12. See *infra* Part IV.B–C.

13. See World Trade Organization, General Council Decision of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTL/540 (Sept. 2, 2003) [hereinafter 2003 General Council Decision]. However, to date this “solution” has only been utilized once to provide drugs to Rwanda. See, e.g., Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 938 (2007). In addition, the company that was licensed to provide the drugs has since stated that it would be reluctant to do so again because of undue complexity. Press Release, Apotex, CAMR Federal Law Needs to Be Fixed if Life-Saving Drugs for Children Are to Be Developed (May 14, 2009), <http://www.apotex.com/global/about/press/20090514.asp> (quoting Jack Kay, President of Apotex, as stating that “in its current form, [CAMR is] not workable for us and, it appears, it doesn't work easily for developing countries”).

concerning TRIPS, followed by non-issues that are frequently raised that mask legitimate TRIPS issues in need of interpretation. Part V first provides alternative explanations to the perspectives phenomena, but rebuts each one. In addition, Part V explains the importance of the perspectives phenomena for an accurate understanding of the history of TRIPS, as well as more recent conflicts. This Part concludes with a discussion of how the perspectives theories are further supported by social science research. Part VI concludes the Article.

## II. THE COMPETING PERSPECTIVES

This Part posits that no single unifying view of patents is correct. Rather, it suggests that there is a spectrum of views on patents benchmarked by two very distinct and seemingly irreconcilable perspectives. On one end, patents are a “mere” privilege granted by a nation and are inherently subject to limitations to ensure that patents do not impede other socially desirable goals. At the other end of the spectrum, patents are viewed as strong property rights that should seldom, if ever, be encroached. This view of patent rights assumes that patents, and greater patent rights, will necessarily lead to greater social goods. The goal of this Part is not to choose a single view. Rather, this Part aims to show that even the most extreme views can be understandable—at least when viewed in isolation. As explained in subsequent Parts, it may be difficult, if not impossible, for competing perspectives to co-exist in the international spectrum regardless of the existence of international laws. However, in this Part, the focus is simply to sketch the outlines of the competing perspectives. Parts III and IV will provide more detail through a close examination of differing perspectives on compulsory licenses.

### A. *Patent as Mere Privilege—A Moldable Tool*

On one side of the spectrum of views is the conception that patents are a tool inherently subject to limitations. While many—including those with an uber-right view—may concur that patents are a utilitarian tool to promote innovation by providing an incentive or reward for new innovations, those who view patents as a privilege do not necessarily place innovation as a priority over all other social interests. Rather, promoting innovation is only one goal amongst other competing societal goals that inherently contemplate the need for balance. Regardless of whether patents are legally considered property rights, they may be viewed as a special type of property to those



who see patents as a privilege. As stated by Professor Baker, who is also associated with the Health Global Access Project,<sup>14</sup> which is dedicated to eliminating barriers to access to HIV treatment: “Patents are not ‘property’ in the traditional sense—they are government granted rights that are intended to balance the interests of innovators and the public at large, and which are granted by governments with many express and implied conditions . . . .”<sup>15</sup>

The U.N. Commissioner for Human Rights supports the idea of patents as a privilege that must be “subject to limitations in the public interest.”<sup>16</sup> In particular, the United Nations has suggested that certain human rights, such as the right to health, are “inalienable and universal” rights that must be recognized over state-granted rights such as patents.<sup>17</sup> Moreover, the U.N. Commissioner has suggested that to the extent that there are “actual or potential conflicts,” patent rights should yield to the right to public health.<sup>18</sup>

If patents were conceived as a tool to promote innovation as one among many societal goals, exceptions to ensure that the patent purpose is served would seem reasonable. In particular, while patents are assumed to provide an incentive to innovate, to the extent that patents fail to provide appropriate incentives, or actually interfere with additional innovation, modifications are necessary. Accordingly, under the view of patents as privilege, a nation would limit or craft exceptions to typical patent remedies if doing so would promote greater innovation, such as the use of patented inventions by researchers.

In the area of health care and access to medicine, the idea that patents are a privilege has particularly dramatic consequences. One possible view is that “the lives of patients

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14. The organization states that “[w]e believe that the human right to life and to health must prevail over the pharmaceutical industry’s excessive profits and expanding patent rights.” Health GAP Global Access Project, <http://www.healthgap.org/hgap/about.html> (last visited Nov. 21, 2009).

15. Baker, *supra* note 1.

16. U.N. Office of 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 (Aug. 17, 2000) [hereinafter Resolution 2000/7].

17. U.N. Econ. & Soc. Council, Sub-Comm’n on Promotion & Prot. of Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, ¶ 14, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 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 16, ¶ 3 (reminding “all Governments of the primacy of human rights obligations over economic policies and agreements”).

18. See Resolution 2000/7, *supra* note 16, pmbl., ¶ 3.

have to come before the patents of drug companies,”<sup>19</sup> such that substantial modifications of patents are appropriate, particularly if a nation places a premium on the right to health through programs such as universal access to essential drugs, including HIV treatment for all citizens. Accordingly, possible limitations on a patent right to accommodate public health interests might include limits on the scope of patentability, shorter patent terms, and compulsory licenses.

The view of patents as a privileged tool does not necessarily advocate abolishing all patents. However, considering patents and the scope of their rights as a privilege injects more hesitation into whether they should be granted in the first place. For example, countries such as India and China could be seen as embracing a view of patents as a privilege in their national approaches to patents prior to TRIPS because they provided patents on *methods* of making drugs, but not on drugs themselves.<sup>20</sup> The rationale of providing a patent incentive to increase new methods of creating drugs, but not monopoly rights on needed drugs, seems to fit with a view of patents as a tool to promote progress in advancing other social interests, such as broad access to low-cost drugs. Another example of a nation viewing patents as privilege would be Canada. Until a trade agreement with the United States required Canada to change its laws,<sup>21</sup> Canada broadly granted compulsory licenses on drugs to increase access to medicine.<sup>22</sup>

The view of patents as a privilege is also consistent with the historical requirement of many nations to require a patent owner to “work” the patent locally. Although there is currently some question as to whether such a requirement would be consistent

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19. Press Release, Campaign for Access to Essential Medicines, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand (Nov. 30, 2006), [http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx\\_ttnews\[tt\\_news\]=20&cHash=f8040f62f5](http://www.msfaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews[tt_news]=20&cHash=f8040f62f5) (quoting Dr. David Wilson of Médecins Sans Frontières).

20. See Ying Zhan, *Patent Protection for Biotechnology in China: The Current Legislation and the Proposed Third Amendment*, 5 J. INT'L BIOTECH. L. 34, 34 (2008); Xiaolu Wei, *Drugs and Intellectual Property Rights*, LAW@MIT, Fall 2006, at 2, <http://web.mit.edu/lawclub/www/lawjournal.html>; *infra* text accompanying note 202 (providing an explanation for India's prior approach to patents).

21. See North American Free Trade Agreement art. 104, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993).

22. However, although more constrained by international rules, Canada can still be seen to take a privilege approach to its patent laws. For example, until a recent challenge within the WTO, Canada allowed generic manufacturers of drugs to make and stockpile drugs during the patent term to enable true competition with the patent owner—and lower costs—on the very day of patent expiry. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, ¶ 4.14, WT/DS114/R (Mar. 17, 2000).

with TRIPS,<sup>23</sup> a number of countries have historically limited—or entirely eliminated—patent rights if a patent owner failed to use the patent in the nation that granted it. The requirement to make the product locally was intended to help transfer the technology to local citizens.<sup>24</sup> The sanction for failure to work has included total forfeiture of a patent or compulsory licensing, as a less onerous punishment than complete patent forfeiture.<sup>25</sup>

The privilege view would take a cautious approach towards requiring patent rights globally. Because patents are seen as a tool to promote innovation, and because there is literature to support that patents alone are not adequate to support such innovation, increasing patents globally would not be encouraged.<sup>26</sup> Rather, those who believe that patents are a privilege would advocate allowing each nation to decide when and whether to grant patents and how to define their scope. Accordingly, those who view patents as a privilege would be opposed to an international agreement that mandates patents. However, to the extent that an international agreement was required, those who view patents as a privilege would likely be more amenable to an agreement that permitted national discretion to recognize competing interests. Indeed, some of the language in TRIPS can be seen as the handiwork of those who

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23. The United States challenged Brazil's local working requirement. Request for the Establishment of a Panel by the United States, *Brazil—Measures Affecting Patent Protection*, WT/DS199/3 (Jan. 9, 2001); Request for Consultations by the United States, *Brazil—Measures Affecting Patent Protection*, WT/DS199/1 (June 8, 2000). However, the parties came to a mutually agreed settlement, such that there has been no official WTO analysis of whether local working is required or barred under TRIPS. Notification of Mutually Agreed Solution, *Brazil—Measures Affecting Patent Protection*, WT/DS199/4 (July 19, 2001); see also DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 359–61 (3d ed. 2008). In addition, the negotiation history of TRIPS reveals a huge divide in viewpoints that do not seem to have ever been reconciled. See, e.g., Champ & Attaran, *supra* note 5, at 373–80 (discussing conflict between the United States, the EU, and developing countries regarding local working of patents).

24. Champ & Attaran, *supra* note 5, at 370–71.

25. Compare Paris Convention for the Protection of Industrial Property art. 5, Mar. 20, 1883, 25 Stat. 1372 (“The patentee . . . shall be subject to the obligation of working his patent conformably to the laws of the country into which he has introduced the patented articles.”), with Paris Convention for the Protection of Industrial Property art. 5, Mar. 20, 1883, as revised at The Hague Nov. 6, 1925, 47 Stat. 1789 (permitting revocation for failure to use only “if the granting of compulsory licenses shall not suffice to prevent such abuses”); see also, e.g., Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licensing at International Law*, 35 OSGOODE HALL L.J. 243, 266–67, 285 (1997).

26. E.g., COMM’N ON INTELLECTUAL PROP. RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 79–89 (3d ed. 2003) (suggesting that increased patent rights may not be optimal for developing countries); Carlos M. Correa & Sisule F. Musungu, *The WIPO Patent Agenda: The Risks for Developing Countries* 23 (Trade-Related Agenda, Dev. & Equity, Working Paper No. 12, 2002).

view patents as a privilege: Articles 7 and 8 of TRIPS talk about balancing patent rights, and Article 30 explicitly considers the rights of third parties in limiting the rights of the patent holder.<sup>27</sup>

*B. Patents as an Uber-right*

The alternative perspective views patents not as a privilege, but rather, as a *privileged* property right, or an *uber-right* that is stronger than other property rights. All rights have exceptions, including property rights.<sup>28</sup> Nonetheless, those who subscribe to the uber-right view likely see any possible limitation on patent rights as extremely suspect. While they recognize that property rights may be limited, they nonetheless analogize legal exceptions such as compulsory licensing to stealing. They suggest that limits on patents should be exercised with caution because the nature of the patent right is based entirely in the right to exclude.

Those who see patents as an uber-right believe that patents deserve an exalted status because they provide the necessary reward to fuel innovation that benefits all of society. The high costs of patented drugs are acknowledged, but most often in the context of emphasizing the high costs and long path towards drug discovery.<sup>29</sup> To the extent that high costs of patented drugs may impede access, proponents of uber-patent rights suggest that the problem is one of poverty, such that any possible solution lies outside patent law.<sup>30</sup>

Although they recognize that access is limited during the patent term by prices set by patent owners, they suggest that patents benefit all. For example, Fred Hassan, Chairman and CEO of major pharmaceutical company Schering-Plough,

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27. TRIPS, *supra* note 2, arts. 7–8, 30.

28. For example, the traditional property right may be limited by the nuisance doctrine, as well as by takings.

29. 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, 216 (2009) (suggesting that consumers in developing countries do not understand that the high cost of drugs reflects the less visible, but nonetheless high costs of research and development in a broader discussion against use of compulsory licensing).

30. See Richard P. Rozek, *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 3 J. WORLD INTELL. PROP. 889, 896–97 (2000) (pointing to other barriers to access). In addition, uber-right sympathizers are inclined to suggest that problems related to the exclusivity of patent rights may pale in comparison to other factors that increase the cost of medicine, such as tariffs and taxes that some countries impose on imported drugs. *E.g.*, Roger Bate, *Death and Taxes: Why Taxes and Tariffs on Medicines in Developing Nations Is a Fatal Policy*, MED. PROGRESS TODAY, May 5, 2005, [http://www.medicalprogresstoday.com/spotlight/spotlight\\_indarchive.php?id=752](http://www.medicalprogresstoday.com/spotlight/spotlight_indarchive.php?id=752).

suggests that patent protection is actually responsible for low cost generics:

IP protection for pharmaceutical innovation creates a wonderful cycle. It rewards and incentivizes the huge investments needed to create new medicines. Then, on expiration of the patent, the innovation becomes freely available to all. Generic drugs are thus the direct result of IP-fueled innovation. They would not exist without IP. And without IP, we would not see new advances in medicines that in turn would become generic drugs.<sup>31</sup>

Similarly, Professor Martin Adelman has suggested that the question of access to medicine often overlooks the simple 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.”<sup>32</sup>

The uber-right perspective has invoked human rights norms to support their position. In particular, they argue that inventors have a right to benefit from the fruits of their invention based upon language in the Universal Declaration of Human Rights as well as the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>33</sup> While neither document refers explicitly to either patents or intellectual property rights, both include a clause about how everyone should enjoy the benefits of scientific progress and benefit from protection of interests from any scientific production of which he is the “author.”<sup>34</sup> The basic argument is that if patent rights are minimized, the author (inventor) is deprived of the protection of his interests.<sup>35</sup>

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31. Fred Hassan, Chairman & CEO, Schering-Plough Corp., Keynote Address at U.S. Chamber of Commerce 5th Annual Intellectual Property Summit, Fueling Innovation: To Be Our Best for a Better World (Oct. 8, 2008), [http://www.phrma.org/about\\_phrma/ceo\\_voices/fueling\\_innovation\\_to\\_be\\_our\\_best\\_for\\_a\\_better\\_world](http://www.phrma.org/about_phrma/ceo_voices/fueling_innovation_to_be_our_best_for_a_better_world). This quote also illustrates a false dichotomy—the choice presented is patents versus no patents, without considering the possibility of promoting innovation while simultaneously providing access to cheaper generic medication.

32. Martin J. Adelman, *Compulsory Licensing of Drugs: TRIPS Context* 1, Paper Presented at ATRIP Annual Meeting in Tokyo, Japan (Aug. 4, 2003), available at [http://www.atrip.org/upload/files/activities/tokyo2003/s02-Adelman\\_art.doc](http://www.atrip.org/upload/files/activities/tokyo2003/s02-Adelman_art.doc).

33. See Universal Declaration of Human Rights, G.A. Res. 217A (III), at 71, art. 27(2), U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948) [hereinafter UDHR] (“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. 2200A (XXI), art. 15(1), U.N. GAOR, 21st Sess., Supp. No. 16, U.N. Doc. A/6316 (Dec. 16, 1966) [hereinafter ICESCR].

34. UDHR, *supra* note 33, art. 27(2); ICESCR, *supra* note 33, art. 15(1).

35. However, the same article has been read to support the perception of patents as privilege—that consumers are entitled to enjoy the results of scientific progress in drug discovery, such that they have actual access to medicine, and not merely theoretical

If patents are uber-rights, they should be given more protection than other rights. For example, although injunctions are equitable remedies that typically require a court to consider and balance a variety of factors including harm to the plaintiff, the defendant, and the public interest, an uber-right perspective may take a more extreme approach. In particular, the uber-right view would hold that if a patent is found to be infringed, a permanent injunction should be nearly automatic.<sup>36</sup>

The uber-right perspective would want to limit any and all exceptions to patent rights. Compulsory licenses would be considered anathema to an uber-right perspective and only permissible in the narrowest of circumstances.<sup>37</sup> In particular, a compulsory license would likely be considered valid only if the patent owner was incapable of providing an adequate supply.<sup>38</sup>

Extending the global reach of patents would also be consistent with patents as an uber-right. In particular, some of the arguments made in support of mandatory international minimum rights for patents reflect this perspective. Prior to the conclusion of TRIPS—the first international agreement setting forth minimum patent rights—some suggested the need for strong patent laws to promote innovation and prosperity.<sup>39</sup> In addition, they argued that strong patent systems would improve the economic status of nations by promoting foreign direct investment.<sup>40</sup>

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access based upon economic conditions beyond their control.

36. This view has been espoused for years by the Federal Circuit. *See, e.g.*, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988); *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987) (“In matters involving patent rights, irreparable harm has been presumed when a clear showing has been made of patent validity and infringement.” (citing *Smith Int’l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir. 1983))). This presumption derives in part from the finite term of the patent grant. The U.S. Supreme Court, however, has held that this view is an incorrect reading of the law, at least with respect to copyright infringement. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 392–93 (2006). Even so, that may not necessarily change existing perspectives.

37. *See, e.g.*, Rozek, *supra* note 30, at 890, 904.

38. *See e.g.*, Adelman, *supra* note 32, at 2.

39. *E.g.*, CARLOS M. CORREA, *TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT* 91 (2007) (noting that proponents of TRIPS emphasized the importance of promoting intellectual property rights to incentivize innovation); Negotiating Group of Trade-Related Aspects of Intellectual Property Rights, *Including Trade in Counterfeit Goods*, Meeting of 25 March 1987, ¶ 4, MTN.GNG/NG11/1 (Apr. 10, 1987) (noting that greater protection of intellectual property rights was necessary to provide incentives to innovate).

40. *See, e.g.*, Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 *VAND. J. TRANSNAT’L L.* 689, 698 n.16 (explaining the argument that increased intellectual property protection may increase economic development, while simultaneously critiquing its lack of empirical basis). *But see* Michelle McGrath, *The Patent Provisions in TRIPS:*

Proponents of the uber-right perspective would argue for strong international patent norms with minimal exceptions. They would want to minimize as much as possible exceptions such as compulsory licenses. Moreover, to the extent that prevailing global norms seem to permit too many exceptions, those who believe in uber-rights would want to change the norms, such as by negotiating free trade agreements that create stronger patent rights with narrower exceptions.

Those who believe in patents as an uber-right tend to not see a conflict between strong patent rights and competing interests, such as public health. The view is that because patent rights necessarily promote innovation, possible long-term benefits trump any current access problems. Moreover, the strong belief in the value of patent rights is maintained in the face of evidence that patent rights do not compel innovation in all areas; for example, it is widely documented that patent rights do not promote research into so-called “neglected diseases” that primarily afflict poor countries that cannot afford to pay a patent premium.<sup>41</sup> Nonetheless, when there are discussions of limiting patent rights, those who believe in patents as an uber-right suggest that any limitations will sacrifice research into these neglected diseases. For example, in response to Brazil’s compulsory license of the HIV medication efavirenz, the major pharmaceutical company Merck stated that “[t]his expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world, potentially hurting patients who may require new and innovative life-saving therapies.”<sup>42</sup>

### III. A CASE STUDY IN COMPETING PERSPECTIVES: THAILAND’S COMPULSORY LICENSES

This Part illustrates competing perspectives of patents through the lens of recent conflicts concerning compulsory

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*Protecting Reasonable Remuneration for Services Rendered—Or the Latest Development in Western Colonialism?*, 18 EUR. INTELL. PROP. REP. 398, 400 (1996) (asserting that “experience disproves the alleged connection between strict IP protection and foreign investment”).

41. COMM’N ON INTELLECTUAL PROP. RIGHTS, INNOVATION & PUB. HEALTH, WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 13 (2006) (noting how diseases that disproportionately affect developing countries receive “essentially no commercially based R&D in the rich countries”).

42. Press Release, Merck & Co., Statement on Brazilian Government’s Decision to Issue Compulsory License for STOCRIN™ (May 4, 2007), [http://www.merck.com/newsroom/press\\_releases/corporate/2007\\_0504.html](http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html).

licenses issued by Thailand. This Part begins with a chronological background to Thailand's actions. This Part then presents separate vignettes to present the story of Thailand versus PhRMA. The vignettes were not created by either party, but should represent their beliefs because the information is distilled from a ninety-page "white paper" issued by Thailand, as well as numerous news articles and corporate press releases.<sup>43</sup>

### A. *Background*

Since 2002, Thailand, a lower middle-income country, has offered its citizens universal access to medicine and has provided access to antiretrovirals (ARVs) for patients with HIV since 2003.<sup>44</sup> International agencies, including the World Health Organization (WHO) and the World Bank, have recognized Thailand's success in providing treatment for those infected with HIV.<sup>45</sup> Thai HIV patients are similar to HIV patients globally; they eventually need newer treatments as they build resistance

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43. See THAI MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND (Vichai Chokevivat ed., 2007), available at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> [hereinafter WHITE PAPER]; THAI MINISTRY OF PUB. HEALTH & NAT'L HEALTH SEC. OFFICE, THE 10 BURNING QUESTIONS REGARDING THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND (2008), available at <http://www.moph.go.th/hot/White%20paper%20CL%20II%20FEB%2008-ENG.pdf> [hereinafter TEN BURNING QUESTIONS ON CANCER DRUGS]; see also Roger Bate, *Thailand and the Drug Patent Wars*, HEALTH POL'Y OUTLOOK, Apr. 2007, at 6, <http://www.aei.org/outlook/25890> [hereinafter Bate, *Thailand and the Drug Patent Wars*] (discussing history of Thailand compulsory licensing and implications for Thai people and government); Roger Bate, Op-Ed., *Thai-ing Pharma Down*, WALL ST. J. ASIA, Feb. 9, 2007, at 13 [hereinafter Bate, *Thai-ing Pharma Down*] (discussing effects of 2007 compulsory licensing for Thailand); Julian Froehner, *Compulsory Licensing: Inevitable Failures of the Thailand Strategy in the Global Fight Against HIV/AIDS* (July 20, 2007) (unpublished manuscript, on file with Author).

44. National Health Security Act, B.E. 2545 § 5 (2002) (Thail.); see also Constitution of the Kingdom of Thailand, B.E. 2550 § 51 (2007), reprinted in CONSTITUTIONS OF THE COUNTRIES OF THE WORLD: THE KINGDOM OF THAILAND (Rüdiger Wolfrum & Rainer Grote eds., 2008) ("A person shall enjoy an equal right to receive standard public health service . . .").

45. WHO & THAI MINISTRY OF PUB. HEALTH, EXTERNAL REVIEW OF THE HEALTH SECTOR RESPONSE TO HIV/AIDS IN THAILAND 35 (2005), available at [http://www.searo.who.int/LinkFiles/News\\_and\\_Events\\_ThailandProgrammeReviewNEW.pdf](http://www.searo.who.int/LinkFiles/News_and_Events_ThailandProgrammeReviewNEW.pdf) [hereinafter EXTERNAL REVIEW] (noting Thailand's achievement of national treatment target from 2001 to 2004 of treating more than 50% of those in need of antiretroviral treatment); ANA REVENGA ET AL., WORLD BANK, THE ECONOMICS OF EFFECTIVE AIDS TREATMENT: EVALUATING POLICY OPTIONS FOR THAILAND 38 (2006) (reporting success from 2002 to 2004 in increasing health care coverage and use while reducing household out-of-pocket expenditures). Similarly, Doctors Without Borders described Thailand as having "one of the gold standard treatment programmes for the developing world." Amy Kazmin & Andrew Jack, *Thailand Breaks Patent for AIDS Drug to Cut Costs*, FIN. TIMES, Nov. 30, 2006, at 9 (quoting Nathan Ford of Doctors Without Borders).



to older drugs. However, newer treatments tend to be patented and much more expensive.<sup>46</sup>

A looming budget problem for Thailand's continued treatment of its HIV patients had previously been forecast, with the idea of compulsory licensing explicitly mentioned as a possible mechanism to provide cost-effective treatment by the World Bank. At the same time, the World Bank noted that such an approach would require "high-level political resolve."<sup>47</sup>

Thailand issued compulsory licenses to achieve its mandate of providing access to essential drugs after years of negotiation with patent owners failed to yield price cuts beyond the level of currency appreciation. The licenses were issued to cover only Thai citizens who are supported by government-funded insurance and not the small percent of Thai citizens who are capable of paying the premium patent prices for the drugs.<sup>48</sup> Wealthy Thai citizens would be required to purchase their own drugs at the price set by patent owners.<sup>49</sup>

Thailand issued three compulsory licenses over a period of several months. Two were for patented drugs used in the treatment of HIV and the third was for a heart disease medication.<sup>50</sup>

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46. First-line treatments are available cheaply as generic drugs, primarily from India, which before 2005 did not provide patents on drug compounds. *See, e.g.*, MÉDECINS SANS FRONTIÈRES, WILL THE LIFELINE OF AFFORDABLE MEDICINES FOR POOR COUNTRIES BE CUT? CONSEQUENCES OF MEDICINES PATENTING IN INDIA 2–3 (2005), <http://msf.fr/drive/2005-02-01-msf.pdf>.

47. *See* REVENGA ET AL., *supra* note 45, at 169–70.

48. WHITE PAPER, *supra* note 43, at 6.

49. *Id.*

50. The first license was issued on November 29, 2006, for Merck's patented drug efavirenz (sold by Merck under the brand name Stocrin). DEP'T OF DISEASE CONTROL, THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT UNDER DRUGS AND PHARMACEUTICALS PRODUCTS PATENT (2006), *reprinted in* WHITE PAPER, *supra* note 43, at 38, 39–40 [hereinafter EFAVIRENZ LICENSE]. Efavirenz is an effective first-line treatment for HIV that has fewer adverse side effects than generic HIV drugs. *Id.* at 39. Most developed countries treat all new patients with efavirenz. WHITE PAPER, *supra* note 43, at 13. The second licensed antiretroviral was issued on January 24, 2007, for Abbott's patented combination drug lopinavir and ritonavir, sold under the brand name Kaletra, which is commonly used to treat HIV patients that build resistance to older drugs. DEP'T OF DISEASE CONTROL, THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT UNDER DRUGS AND PHARMACEUTICALS PRODUCTS PATENT FOR COMBINED FORMULATION OF LOPINAVIR AND RITONAVIR (2007), *reprinted in* WHITE PAPER, *supra* note 43, at 41, 42–43 [hereinafter KALETRA LICENSE]. Abbott sold Kaletra in Thailand at a price of \$2,200 per patient per year—a cost that exceeds the \$1,600 yearly income of the average Thai citizen. Paul Cawthorne et al., *Access to Drugs: The Case of Abbott in Thailand*, 7 LANCET: INFECTIOUS DISEASES 373, 373–74 (2007). The third license was issued on January 25, 2007, for Sanofi-Aventis's heart disease drug Plavix, which the license notes is relevant to treating one of the top three causes of death in Thailand; without the license, only 20% of government-insured patients could access the drug, which is inconsistent with the

In February 2007, Thailand issued a ninety-page white paper, entitled “Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand,” including supporting documents to defend its three compulsory licenses. Although the white paper was meant to support Thailand’s position, some statements likely induced additional concern. In particular, the document telegraphed Thailand’s intent to consider issuing additional licenses on up to 15% of patented drugs and that it would consider a license warranted when the market price was considered too high to achieve Thailand’s goal of universal access to essential drugs.<sup>51</sup>

Companies and countries began to react. Switzerland, home to patent owner Novartis, published an “Aide Mémoire” in late February 2008 in which it acknowledged that TRIPS provides for compulsory licenses, but emphasized that they “should be used only as a last resort” given that “[p]atents are of paramount importance for the research and development of new pharmaceuticals.”<sup>52</sup> Abbott responded to the compulsory license of its drug by withdrawing several drugs from the Thai marketplace in March 2007, including a heat-stable form of Kaletra, particularly well suited for the Thai climate.<sup>53</sup> The U.S. Trade

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universal coverage of essential medicines. THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT UNDER DRUGS AND PHARMACEUTICALS PRODUCTS PATENT FOR CLOPIDOGREL (2007), *reprinted in* WHITE PAPER, *supra* note 43, at 44, 44–46 [hereinafter PLAVIX LICENSE].

51. WHITE PAPER, *supra* note 43, at 12. The criteria for issuing a compulsory license includes a listing on the National Essential Drug List; a need to solve public health problems, emergencies, or epidemics; or a need to save lives where the price of the drug is too high to be affordable by the government. *Id.* at 11. Thailand attempted to stem concern by noting that “lifestyle” drugs, such as those to treat baldness, acne, or erectile dysfunction would not be considered for compulsory licenses. *Id.* at 12; *see also* Sinfah Tunsarawuth, *20 More Drugs in Pipeline for Possible Compulsory Licenses*, INTELL. PROP. WATCH, Nov. 2, 2007, <http://www.ip-watch.org/weblog/index.php?p=806> (noting that Thailand would probably only issue ten licenses out of twenty considered).

52. Aide Mémoire: Compulsory Licences in Thailand on Pharmaceuticals Under Patent Protection (Feb. 25, 2008) (on file with Houston Law Review), *available at* [http://www.keionline.org/misc-docs/1/swiss2thailand\\_cl.pdf](http://www.keionline.org/misc-docs/1/swiss2thailand_cl.pdf).

53. Erika Check, *Abbott’s AIDS Fight-back*, NATURE, July 5, 2007, at 14; *see also* Editorial, *Putting Meaning Back into TRIPS*, BANGKOK POST, Mar. 22, 2007, *available at* <http://www.aegis.org/news/bp/2007/BP070308.html> (arguing compulsory licensing is an exercise of Thai citizens’ rights under TRIPS); Nicholas Zamiska, *Abbott Escalates Thai Patent Rift*, WALL ST. J., Mar. 14, 2007, at A9 (reporting Abbott withdrew a new version of Kaletra that would be more convenient to take). In addition, patent owner Sanofi-Aventis has threatened legal action against the Indian drug company Cadila that was to supply low-cost versions of Plavix to Thailand. Rupali Mukherjee, *Pharma Firms Under US Pressure to Stop Generic Sale*, TIMES INDIA, Feb. 13, 2008, *available at* <http://timesofindia.indiatimes.com/articleshow/2777692.cms>; C.H. Unnikrishnan, *Sanofi in Talks with Thai Govt to Protect Its Patent Right*, LIVEMINT.COM, Mar. 13, 2008,

Representative (USTR) elevated Thailand to Priority Watch status on its Special 301 list, which may lead to unilateral trade sanctions, as well as pressure to agree to a regional trade agreement that increases patent protection.<sup>54</sup>

Thailand continued to explore additional compulsory licenses amidst the criticism. In June 2007, Thailand established two exploratory committees to consider possible compulsory licenses on cancer medications.<sup>55</sup> At the same time, Thailand was pressured against perceived broad use of compulsory licenses by EU Trade Commissioner Peter Mandelson, as well as by the U.S. Ambassador to Thailand, Ralph Boyce.<sup>56</sup>

After initially promising negotiations stalled,<sup>57</sup> Thailand issued licenses on four cancer drugs in January 2008 on the eve of a change in government administration.<sup>58</sup> Thailand asserted

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<http://www.livemint.com/2008/03/13164842/Sanofi-in-talks-with-Thai-govt.html>.

54. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2007 SPECIAL 301 REPORT 27 (2007); *see also* OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2008 SPECIAL 301 REPORT 36–37 (2008) (maintaining Thailand's status on the Priority Watch List because of concerns of inadequate and ineffective protection of patent medicines along with concerns over piracy and counterfeiting).

55. Posting of Ed Silverman, *Thailand May Break Patents on Cancer Meds*, to Pharmed (June 22, 2007, 7:22 EST), <http://pharmed.com/2007/06/thailand-may-break-patents-on-cancer-meds>.

56. Letter from Peter Mandelson, Eur. Union Trade Comm'r, to Krirk-krai Jirapaet, Thai Minister of Commerce (July 10, 2007), *available at* [http://www.wcl.american.edu/pijip\\_static/documents/mandelson07102007.pdf](http://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf) (noting concern about Thailand's use of compulsory licenses and asserting that "[n]either the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licences wherever medicines exceed certain prices"); Letter from Ralph L. Boyce, U.S. Ambassador to Thailand, to Surayud Chulanont, Thai Prime Minister (July 20, 2007), *available at* <http://lists.essential.org/pipermail/ip-health/2007-August/011610.html> (noting concern about potential issuance of additional compulsory licenses).

57. Thailand began negotiations for lower prices on patented cancer drugs in October 2007, but these negotiations eventually broke down in December 2007. TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 3–4.

58. On January 4, 2008, licenses were issued on Docetaxel, the breast and lung cancer drug by Sanofi-Aventis; Erlotinib, a drug for treating lung, pancreatic, and ovarian cancer by Roche; Imatinib, a cancer drug patented and sold by Novartis as Glivec; and Letrozole, a breast cancer medicine made by Novartis AG. THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT ON PHARMACEUTICALS PRODUCTS PATENT FOR DOCETAXEL (2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 22, 22–23 [hereinafter DOCETAXEL LICENSE]; THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT ON PHARMACEUTICALS PRODUCTS PATENT FOR ERLOTINIB (2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 26, 26–27; THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT ON PHARMACEUTICALS PRODUCTS PATENT FOR LETROZOLE (2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 24, 24–25; THAI MINISTRY OF PUB. HEALTH, EXERCISING OF RIGHT UNDER DRUGS AND PHARMACEUTICALS PRODUCTS PATENT FOR IMATINIB (2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 28, 28–29; *see also* Sinfah Tunsarawuth, *New Thai Minister May Review Compulsory Licences on Cancer Drugs*, INTELL. PROP. WATCH, Feb. 8, 2008, <http://www.ip-watch.org/weblog/2008/02/08/new-thai-minister-may-review-compulsory-licences-on-cancer-drugs> (reporting that Thailand's new

that they were necessary because cancer is currently the number one cause of death in Thailand, and most effective cancer treatments are patented and thus inaccessible to most citizens because of undue expense.<sup>59</sup>

On February 7, 2008, the first day of taking office, the new Thai Public Health Minister announced that he would reevaluate the decision to issue licenses on the cancer drugs.<sup>60</sup> Ultimately, Thailand decided not to revoke any of the compulsory licenses despite being told that the continued imposition of licenses threatened to impact Thailand's international trade.<sup>61</sup> Some suggested that canceling the licenses would be inconsistent with the Thai constitution and other laws requiring the government to provide low-cost drugs. Thailand has also resisted the suggestion that it promise to forgo the option of compulsory licenses in the future, arguing that to do so would be "a neglect of duty or failure to exercise the rights established by the law to safeguard public interest and public health."<sup>62</sup>

### *B. Thailand's (Patent as Privilege) Perspective*

Thailand is committed to the health of its citizens, even if such commitment requires taking bold steps in the international arena and potentially prompting the ire of more powerful countries.<sup>63</sup> Thailand is required to provide all Thais with access to essential medicines, including drugs to treat HIV.<sup>64</sup> Thailand's

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Public Health Minister may review compulsory licenses issued by previous government).

59. Letter from Sanguan Nitayarumphong, Chair of the Subcomm. on Selecting the Essential Drugs with Access Problems Under the Nat'l Health Ins. Schemes, to Mongkol Na Songkhla, Minister of Pub. Health (Sept. 25, 2007), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 15, 17.

60. Editorial, *Bangkok's Drug War, Round Two*, WALL ST. J. ASIA, Feb. 27, 2008, at 13.

61. Nopporn Wong-Anan, *Thailand Will Override Cancer Drug Patents*, REUTERS, Mar. 10, 2008, <http://www.reuters.com/article/healthNews/idUSBKK14764720080310>.

62. TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 11–12.

63. See WHITE PAPER, *supra* note 43, at 4 (stating that compulsory licenses for essential drugs are "clear evidence of the government's commitment to put the right to life above the trade interest"). Specifically regarding the economic impact of potential international sanctions, the Thai Ministry of Public Health has noted the following:

[A]t least two-thirds of our economy depends on exporting of our goods and services. . . . If the US government applies retaliation measures on our exports which results in 10 percent reduction of exports to the US market, it will mean a one to 1.2 per cent loss of economy and several hundred thousands job losses. So this is a very sensitive issue. Unless there is very important need for the people supported by solid evidences, we will not make these decisions.

*Id.* at 16.

64. Since 2002, Thailand has had a mandate to achieve universal access to essential medicines for all its citizens, with access to ARVs included since 2003. *Id.* at 1–2.

commitment to health care has been recognized by international agencies such as the World Bank and the World Health Organization.<sup>65</sup> Thailand believes in a public interest orientation to patent rights with the view that patients must come before profits.<sup>66</sup>

Increasing drug costs have outstripped Thailand's ability to truly provide universal access to all necessary drugs. As recognized by the World Bank and the WHO, Thailand needs to use TRIPS flexibilities as HIV patients develop tolerance to cheaper first-line ARVs. AIDS will become a death sentence, rather than a long-term disease for patients who cannot obtain second-line treatment. However, until Thailand's bold action, many patients were denied these essential drugs because they are generally patented and priced beyond reach. For example, Abbott set the annual price of Kaletra, a good second-line drug, at \$2,200 per Thai patient, where the average annual wage in Thailand is only \$1,600 per year.<sup>67</sup> In addition, heart disease and cancer are major sources of death in Thailand and no less serious than AIDS.<sup>68</sup> Without compulsory licenses on cancer drugs, patients and their families will suffer either severe economic hardship, including bankruptcy, or certain death.<sup>69</sup>

Thailand carefully considered the implications of granting compulsory licenses before doing so. In fact, Thailand attempted to negotiate with each patent owner to reduce prices for *years* prior to the actual licenses, but to no avail.<sup>70</sup> While Thailand

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65. EXTERNAL REVIEW, *supra* note 45, at 35; REVENGA ET AL., *supra* note 45, at 4; Letter from Tom Allen et al., Members of Congress, to Susan C. Schwab, U.S. Trade Rep. (Jan. 10, 2007), available at <http://www.cptech.org/ip/health/c/thailand/congressional-schwabletter-thailand-10jan06.pdf> ("Thailand's HIV/AIDS treatment initiative has been recognized as among the most successful in the developing world.").

66. Mongkol Na Songkhla, *Preface* to WHITE PAPER, *supra* note 43 ("The Thai Ministry of Public Health firmly believes in a moderate and public interest oriented approach to implement the intellectual property right. We are convinced and committed to the view that 'Public Health interest and the life of the people must come before commercial interest.'").

67. Cawthorne et al., *supra* note 50, at 373-74; see also Open Letter, Christopher Fournier, Int'l President, Médecins Sans Frontières, MSF's Response to *Wall Street Journal* Editorial on Compulsory Licenses in Thailand (Mar. 12, 2007), available at <http://doctorswithoutborders.org/publications/article.cfm?id=1957&cat=open-letters> (noting that second-line ARV medications cost "at best 5 times the price of current first-line treatments and, in countries like Thailand, as much as 22 times!").

68. BRIEF REPORT OF THE OUTPUT FROM THE AD HOC WORKING GROUP FOR PRICE NEGOTIATION OF THE PATENTED ESSENTIAL DRUGS, *reprinted in* WHITE PAPER, *supra* note 43, at 71, 71.

69. DOCETAXEL LICENSE, *supra* note 58, at 22; TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 2.

70. WHITE PAPER, *supra* note 43, at 5; see also Robert Weissman, Op-Ed., *Compulsory Licenses Are the Right Medicine*, NATION (Bangkok), Feb. 23, 2008,

could have continued to attempt such negotiations, past experience indicates that companies are much more willing to negotiate after a license has issued rather than before.<sup>71</sup> Thailand did not even need to undertake such negotiations. After all, TRIPS clearly states that prior negotiations may be skipped not only when there is a public health crisis, but also when the license is for public noncommercial use, as Thailand's clearly is because the drugs are distributed for noncommercial public use.<sup>72</sup>

Contrary to the bluster of pharmaceutical giants, compulsory licenses are an essential part of national and international laws.<sup>73</sup> The WTO rules allow member states to issue compulsory licenses to protect public health according to their own criteria; indeed, the Doha Public Health Declaration clearly affirms that each country has the "freedom to determine the grounds upon which [compulsory] licences are granted."<sup>74</sup> No emergency is required, nor is compulsory licensing limited solely to ARV drugs. To the contrary, the Declaration, which was unanimously adopted by all WTO member states in 2001, provides that members "agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health."<sup>75</sup> Accordingly, it is puzzling that legal licenses have been improperly characterized as theft and breaking of patents.<sup>76</sup>

Thailand is opening up a new market for pharmaceutical companies rather than compromising existing markets. In particular, the compulsory licenses simply enable more Thai citizens to have access to essential drugs; those who can afford

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[http://www.nationmultimedia.com/2008/02/23/opinion/opinion\\_30066217.php](http://www.nationmultimedia.com/2008/02/23/opinion/opinion_30066217.php) ("[T]here is no question that the government undertook extensive negotiations before issuing the recent licences on cancer products.").

71. WHITE PAPER, *supra* note 43, at 6.

72. In accordance with the Doha Declaration on the TRIPS Agreement and Public Health, each license is issued for noncommercial use to protect public health and to provide wider access to medicines in the case of emergency. *E.g.*, EFAVIRENZ LICENSE, *supra* note 50, at 39; KALETRA LICENSE, *supra* note 50, at 42; PLAVIX LICENSE, *supra* note 50, at 45.

73. Cawthorne et al., *supra* note 50, at 374.

74. Doha Public Health Declaration, *supra* note 11, ¶ 5(b); *accord* Letter from Margaret Chan, WHO Dir.-Gen., to Mongkol Na Songkhla, Thai Minister of Pub. Health (Feb. 7, 2007), *available at* <http://www.cptech.org/blogs/ipdisputesinmedicine/2007/02/dr-margaret-chan-to-dr-mongkoi-na.html> ("The decision whether to issue a compulsory license for a pharmaceutical product is a national one.").

75. Doha Public Health Declaration, *supra* note 11, ¶ 4; *see* Roger Bate & Richard Tren, *The WTO and Access to Essential Medicines: Recent Agreements, New Assignments*, HEALTH POL'Y OUTLOOK, Feb. 2006, at 1, [http://www.aei.org/docLib/20060216\\_19636HPO200604\\_g.pdf](http://www.aei.org/docLib/20060216_19636HPO200604_g.pdf) (viewing the unanimously agreed-upon Doha Declaration as a temporary fix for access to essential medicines until tariffs are lowered).

76. *See, e.g.*, Editorial, *Theft in Thailand*, WALL ST. J., Feb. 10, 2007, at A8.

the retail price will continue to pay that price from the patent owner.<sup>77</sup> Even though the compulsory licenses provide patent owners with less profit than their preferred price, the patent owners will still receive greater net profit than without the compulsory licenses.

Thailand should not be punished for being more committed to the health of its citizens than to the profits of multinational pharmaceutical companies.<sup>78</sup> In addition, Thailand's budget is not reduced with the compulsory licenses; such licenses simply increase the number of citizens who receive access, rather than reducing financial costs to Thailand. In fact, in some cases, more money will be spent.<sup>79</sup> In addition, the Thai drug market is less than 0.5% of the global drug market, so the compulsory licenses should have an insignificant effect on the profits of pharmaceutical companies.<sup>80</sup>

Thailand's ability to use compulsory licenses to provide its citizens with access to essential drugs is internationally recognized. International organizations including the Clinton Foundation and Doctors Without Borders have supported Thailand's actions; as President Clinton stated, "No company will live or die because of high price premiums for AIDS drugs in middle-income countries, but patients may."<sup>81</sup> Moreover, the

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77. WHITE PAPER, *supra* note 43, at 17 ("[I]t should be reiterated that the Government Use of Patent does not touch on the out of pocket payment market, the current market of the patented drugs. The Government Use only opens new market for those who never have access to these drugs before.").

78. See, e.g., Press Release, Médecins Sans Frontières, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand (Nov. 29, 2006), <http://doctorswithoutborders.org/press/release.cfm?id=1905&cat=press-release&ref=tag-index> (quoting Dr. Wilson of Médecins Sans Frontières in Thailand as stating that "Thailand is demonstrating that the lives of patients have to come before the patents of drug companies, and this policy needs to be expanded to essential drugs that are expensive and in short supply, such as the AIDS drug lopinavir/ritonavir, which currently costs over 7,000 baht a month (US\$194) and is far too expensive for Thailand.").

79. See WHITE PAPER, *supra* note 43, at 13, 15.

80. *Id.* at 17 ("[T]he size of the Thai drug market is less than 0.5 per cent of the global drug market. It is even less for the market of patented drugs. So there should not be significant effect on the market and return of the research based drug companies.").

81. Marwaan Macan-Markar, *Holding Big Pharma's Feet to the Fire*, ASIA TIMES ONLINE, May 17, 2007, [http://www.atimes.com/atimes/Southeast\\_Asia/IE17Ae02.html](http://www.atimes.com/atimes/Southeast_Asia/IE17Ae02.html); see also Letter from Peter Piot, Executive Dir., UNAIDS, to Mongkol Na Songkhla, Thai Minister of Pub. Health (Dec. 26, 2006), reprinted in WHITE PAPER, *supra* note 43, at 84, 84 (commending Thailand for its "strong and steadfast efforts to provide access to antiretroviral treatment"); Letter from Martin Khor, Dir., Third World Network, to Mongkol Na Songkhla, Thai Minister of Pub. Health (Feb. 23, 2007), reprinted in WHITE PAPER, *supra* note 43, at 87, 88 ("We share the belief that life and health are the most important priority, and that providing the public with medicines (especially the poor who cannot afford it otherwise) at affordable cost is a duty of government. We therefore congratulate your actions to make use of the flexibilities of TRIPS . . .").

WHO has stated that it supports use of TRIPS flexibilities by developing countries to ensure access to affordable drugs.<sup>82</sup> In addition, over twenty U.S. congressmen supported the Thai position in a letter asking the USTR to not exercise trade pressure on Thailand.<sup>83</sup>

Thailand's licenses are consistent with the practice of many nations. Over twenty-five countries have issued, or have considered issuing, compulsory licenses.<sup>84</sup> Wealthy countries, including the United States and European countries, have issued compulsory licenses and engaged in government use of patents.<sup>85</sup> The United States routinely issues compulsory licenses as a remedy for anticompetitive actions and has threatened to issue compulsory licenses in a variety of situations, including to supply generic ciprofloxacin, and to permit government use of wireless mobile devices commonly referred to as BlackBerries.<sup>86</sup> If wealthy countries are permitted to grant such licenses, Thailand should not be denied the same right.

Thailand recognizes that its actions will subject it to political pressure and vilification. However, Thailand strongly believes that it must stand up to pressure from pharmaceutical companies and the United States.<sup>87</sup> Thailand is a world leader in securing better treatment for its patients.

### C. *PhRMA's (Patent as Uber-right) Perspective*

Thailand has overruled the international patent system by breaking patents on numerous medicines.<sup>88</sup> Thailand's military

82. Letter from Margaret Chan, *supra* note 74.

83. Letter from Tom Allen et al., *supra* note 65 (urging the United States to respect the Thai compulsory license of efavirenz).

84. See generally JAMES PACKARD LOVE, KNOWLEDGE ECOLOGY INT'L, RECENT EXAMPLES OF THE USE OF COMPULSORY LICENSES ON PATENTS (2007), available at [http://www.keionline.org/misc-docs/recent\\_cls\\_8mar07.pdf](http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf).

85. WHITE PAPER, *supra* note 43, at 4 ("Thailand is not the first country to apply compulsory licensing or the Government Use of patent, developed countries including the USA, European countries, and other developing countries have previously attempted and implemented compulsory licensing and Government Use of Patents."); see also Raymond C. Offenheiser, Letter to the Editor, WSJ.COM, Mar. 14, 2007, <http://online.wsj.com/article/SB117382283064835964.html> ("[T]he United States has been a major user of compulsory licensing . . ."); Robert Weissman, *U.S. Compulsory Licensing and Government Use 1*, Paper Presented at the International Conference on Compulsory Licensing (Nov. 22, 2007) (on file with Houston Law Review) ("The United States is probably the single greatest user of compulsory licensing in the world.").

86. LOVE, *supra* note 84, at 3.

87. See Macan-Markar, *supra* note 81 (quoting Jiraporn Limpananont, associate professor in pharmaceutical science at Chulalongkorn University, as stating that "[w]e have to stand up to the pressure from the pharmaceutical companies and the US").

88. See Nirmal Ghosh, *Thailand Breaks Patents for Heart and AIDS Drugs*, STRAITS



government is trampling the global patent system and expropriating intellectual property as its own, rather than paying its proper share.<sup>89</sup>

Thailand is threatening a well-established global system for innovation.<sup>90</sup> Everyone knows that “without intellectual property there is no innovation,”<sup>91</sup> yet Thailand has “decided not to support innovation by breaking the patents.”<sup>92</sup> Although strong patents benefit everyone, public debates improperly pit ignorant passion against profit.<sup>93</sup> Such activists blindly believe that the pipeline of drugs will continue even if there is less funding—seemingly oblivious to the fact that each new drug costs about a billion dollars to develop.<sup>94</sup>

In addition to being “very shortsighted,” Thailand’s actions are selfish and will ironically compromise the health of everyone, including its own citizens.<sup>95</sup> The costs of research and development must be borne by someone. If Thailand is not willing to contribute its share, then the rest of the world, including countries at even lower stages of development, will be required to shoulder the burden unnecessarily and in contravention of a prior global accord to increase access to the poorest countries. Higher prices for everyone besides Thailand are simply unfair. As a middle-income country, Thailand should be respecting patents to promote innovation and investment opportunities. It is shocking that a country ranked 34 out of 181

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TIMES (Sing.), Jan. 31, 2007, *available at* [http://app.mfa.gov.sg/pr/read\\_content.asp?View,6405](http://app.mfa.gov.sg/pr/read_content.asp?View,6405), (beginning news story with the assertion that “Thailand has overruled the international patents system”); Darren Schuettler, *Angered U.S. Firm Excludes Thailand from New Drugs*, REUTERS, Mar. 14, 2007, <http://www.reuters.com/article/companyNewsAndPR/idUSBKK26805820070314> (quoting an Abbott spokesman stating that “Thailand has chosen to break patents on numerous medicines, ignoring the patent system”).

89. Cass, *supra* note 4 (characterizing Thailand’s actions as “trampling patents”); see Editorial, *supra* note 76; Adelman, *supra* note 32, at 3–4; Letter from Kenneth L. Adelman, Exec. Dir., USA for Innovation, to Members of Congress (May 9, 2007), *available at* <http://lists.essential.org/pipermail/ip-health/2007-May/011154.html> (characterizing licenses as “attacks on American intellectual property”).

90. See Cass, *supra* note 4 (referring to licenses as a threat to the “world’s system of protections for innovation”).

91. *A Gathering Storm*, ECONOMIST, June 9, 2007, at 71 (quoting Fred Hassan of Schering-Plough).

92. Zamiska, *supra* note 53 (quoting Jennifer Smoter, spokeswoman for Abbott).

93. See Ronald A. Cass, Op-Ed., *Drug Patent Piracy*, WALL ST. J. ASIA, May 7, 2007, at 15 (stating that “IP protection benefits everyone” and that “[u]nfortunately, public debates on IP rights are skewed to pit passion against profit”).

94. *Id.* (asserting that activists opposed to IP rights “blindly assert that the drug companies won’t stop inventing just because they will make less money”).

95. Zamiska, *supra* note 53 (quoting Teera Chakajnarodom, president of Thailand’s Pharmaceutical Research and Manufacturing Association).

countries based on GDP would expect any public sympathy for stealing patents—especially when it knowingly diverted funds from health care to defense spending.<sup>96</sup> Moreover, Thailand's reckless action will negatively boomerang against any further economic growth.<sup>97</sup> Why would any company be willing to invest in Thailand after it has shown such reckless disregard of property rights?

Compulsory licenses are antithetical to patent rights and accordingly are granted rarely and under only very narrow circumstances. Compulsory licenses are rarely employed by any country, even if permitted under global rules.<sup>98</sup> Such extreme action is only permitted in extraordinary circumstances, such as when a critical patent is not being used to produce essential goods or when the patent owner cannot provide adequate quantities of a drug in the event of a health emergency.<sup>99</sup> However, such situations are very rare.<sup>100</sup> Moreover, such licenses should be very limited because they inevitably provide a patent owner with far less than a reasonable economic return.<sup>101</sup> Accordingly, global rules require that compulsory licenses be used only as a last resort.<sup>102</sup>

Sympathizers to Thailand's position are simply opposed to protection of all property rights.<sup>103</sup> Thailand's action is not

96. Cass, *supra* note 93.

97. *Id.*

98. See Editorial, *supra* note 4 (“[N]o serious government has contemplated using compulsory licensing, even if it's allowed to do so under WTO rules.”).

99. Cass, *supra* note 4.

100. Activists like to emphasize that provisions for compulsory licensing commonly appear in U.S. statutes, but these characterizations are improper because such statutes regulate a variety of activities that have nothing to do with the licensing of patented drugs. See, e.g., Posting of Sidney Rosenzweig, *Bogus Reliance on the Clean Air Act's Compulsory Patent Licensing*, to Progress & Freedom Foundation (Mar. 17, 2009, 14:20 EST), [http://blog.pff.org/archives/2009/03/jamie\\_loves\\_bogus\\_reliance\\_on\\_the\\_clean\\_air\\_acts\\_c.html](http://blog.pff.org/archives/2009/03/jamie_loves_bogus_reliance_on_the_clean_air_acts_c.html) (observing that the Clean Air Act's compulsory licensing provision for air pollution control technology has never been invoked in its forty-year history). Moreover, licenses issued as part of a remedy for actual anticompetitive conduct are similarly irrelevant to the health care context. Finally, a denial of a permanent injunction is not a compulsory license; while activists may try to equate the two as having comparable effect, everyone knows that a compulsory license is something issued not by a court, but by a government according to statute. *E.g.*, Adelman, *supra* note 32, at 3.

101. Cass, *supra* note 93 (“[C]ompulsory licenses—like any one-sided deal that doesn't require consent from the person whose property is taken—almost always leave the rights holder with far less than a reasonable economic return.”).

102. *E.g.*, *A Gathering Storm*, *supra* note 91 (noting that Jon Pender of British pharmaceutical giant GlaxoSmithKline insisted that a compulsory license was only to be used “as a last resort”); Editorial, *Drugs in Thailand*, *FIN. TIMES*, Jan. 31, 2007, at 14 (“WTO rules say compulsory licenses should be a last resort.”).

103. See Cass, *supra* note 4 (stating that those who endorse compulsory licenses “oppose protection of property rights in general and IP rights in particular”).

surprising because authoritarian governments and social activists take what is not theirs.<sup>104</sup> Such sympathizers are just the usual crowd of anti-patent hooligans that fails to understand that without patents, there would be no drugs for anyone. These anti-patent activists have tried hard to alter the meaning of TRIPS and were behind the 2001 Declaration that permits governments to deal with health emergencies posed by epidemics of HIV in sub-Saharan Africa.<sup>105</sup> However, that Declaration does not support the compulsory license of any drug patent for any reason, especially when a relatively developed country with no epidemic, such as Thailand, simply wants to save costs by stealing the property of another.<sup>106</sup>

Thailand's purported interest in fostering public health is suspect. After all, Thailand's recent compulsory licenses were issued after a military-imposed government suspiciously raised the defense budget by over \$30 billion in recent years.<sup>107</sup> Any purported budget crisis should be viewed with skepticism considering that the military-imposed Thai government gave itself a huge pay increase, together with a substantial increase in defense spending, while at the same time reducing the health care budget.<sup>108</sup> Why should pharmaceutical investment worldwide suffer just because Thailand has elected to fund its defense budget, rather than legitimately pay for drugs it uses? In addition, why should Thailand's medical budget be underwritten by all other countries?

Thailand's extraordinary bad faith in issuing the compulsory licenses is evident at multiple junctures. First of all, Thailand did not undertake any serious negotiations with patent owners. Although Thailand repeatedly invokes TRIPS, it seems to gloss over the fact that TRIPS requires patent owners to be consulted

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104. See, e.g., Ronald A. Cass, Op-Ed., *Thai Patent Turmoil*, WALL ST. J. ASIA, Mar. 13, 2007, at 13 (referring to "the free lunch crowd").

105. See Cass, *supra* note 4 ("While the system of IP protections has worked well to encourage investment in innovations, some groups oppose protection of property rights in general and IP rights in particular. Over the past decade, these groups have worked hard to alter the meaning of the TRIPS agreement and to encourage any government that will listen to use compulsory licensing to break IP protections.").

106. *Id.* (characterizing the Doha Declaration as a "small victory" for groups opposed to protection of all property rights).

107. Roger Bate, *Thailand's Creaking Health System*, AMERICAN, June 9, 2008, available at <http://www.american.com/archive/2008/april-04-08/thailand2019s-creaking-health-system>; Don Pathan, *Military Spending to Soar a Further 24%*, NATION (Bangkok), June 28, 2007, [http://www.nationmultimedia.com/2007/06/28/politics/politics\\_30037960.php](http://www.nationmultimedia.com/2007/06/28/politics/politics_30037960.php).

108. Bate, *supra* note 107 (asserting that health spending in Thailand is now 3% of GDP—down from 3.5% a few years ago—and that if Thailand simply spent an additional 1% of GDP, it would have more than \$2 billion to spend on health care).

prior to the imposition of a compulsory license.<sup>109</sup> To the contrary, patent owners were shocked to have their patents broken without an attempt to first negotiate a reasonable price.<sup>110</sup>

Thailand's asserted health commitment is a sham. Thailand only promulgated a universal access to health program as a populist measure.<sup>111</sup> Moreover, the licenses are issued to the Government Pharmaceutical Organization (GPO), which is not only historically corrupt, but also a state-owned monopoly for profit.<sup>112</sup> In addition, any drugs made by Thailand's GPO will be inferior to the actual patented product because the GPO facilities have never met WHO standards.<sup>113</sup> Poor products may lead to drug resistance, or may be ineffective, which would only further exacerbate costs. Any purported HIV resistance in Thailand is likely due to its reliance on inferior drugs manufactured by its own GPO.<sup>114</sup>

The alleged need for HIV treatment in Thailand is similarly a sham. There is no HIV epidemic in Thailand. Thailand has relatively low rates of HIV infection, with less than 1% of the population infected—a far cry from countries such as sub-Saharan Africa where 20% of the population may be afflicted.<sup>115</sup> If Thailand has truly contained its HIV numbers, there is no need

109. TRIPS, *supra* note 2, art. 31(b).

110. *E.g.*, Harvey E. Bale, Jr., Letter to the Editor, WSJ.COM, Mar. 14, 2007, <http://online.wsj.com/article/SB117382283064835964.html> (quoting Dr. Harvey Bale, Director General of IFPMA, as stating that Thailand had “no serious contacts” with patent owners prior to the imposition of the license); Schuettler, *supra* note 88.

111. *See* Head, *supra* note 1 (“The nationwide health scheme was first introduced in 2001 by then-Prime Minister Thaksin Shinawatra, who had a gift for coming up with populist policies that would keep getting him elected.”).

112. *See* Bate, *Thai-ing Pharma Down*, *supra* note 43 (“The only winner will be Thailand's historically corrupt Government Pharmaceutical Organization, or GPO, the state-owned pharmaceutical monopoly.”); Editorial, *Patently Wrong*, WALL ST. J. ASIA, Feb. 9, 2007, at 12 (stating the licenses are a “boon” for the GPO).

113. *E.g.*, Bate, *Thai-ing Pharma Down*, *supra* note 43 (reporting that GPO drugs “are at best approximate copies” and that even with lax WHO standards, 18 different “WHO approved” HIV treatments have been withdrawn in 2005 due to lack of proof that the drugs actually worked); Editorial, *supra* note 76.

114. Bate, *Thai-ing Pharma Down*, *supra* note 43 (“Drugs that are not pre-qualified [WHO approved] may not directly kill people, but they could foster resistance to AIDS drugs.” (quoting Lembit Rago, WHO coordinator of drug quality & safety)). Bate states that a 2005 study by Thailand's Mahidol University found that GPO-vir, an HIV treatment produced by GPO, had between 39.6% and 58% resistance, which is perhaps the worst case of HIV drug resistance in the world. *Id.*

115. Christopher C. Horner, *Thailand Stealing out of WTO?*, WASH. TIMES, May 17, 2007, at A15; Editorial, *supra* note 76; *see also* Cass, *supra* note 104 (“Thailand today has a relatively low rate of HIV/AIDS compared to much of the developing world, has enjoyed notable success in reducing the rate of new infections (cutting the annual increase to about 13% of its level a decade before), and has seen a dramatic decrease in its AIDS death rate since 2000.”).

for compulsory licenses of drugs. Moreover, to the extent that HIV is a problem, it is one that is fostered by Thailand's own lucrative sex trade.<sup>116</sup>

The argument that there could be any emergency that justifies breaking the patent on Plavix is completely laughable and also highlights Thailand's extremely inappropriate action. There is clearly no threat of an epidemic based on heart disease because it is not an infectious or contagious disease.<sup>117</sup> Moreover, to the extent that Thai citizens suffer from heart disease, the "problem" they suffer from is simply that they are wealthy enough to buy and consume large quantities of unhealthy foods.<sup>118</sup> Citizens with such wealth should be able to pay the fair price for medication. Alternatively, they should take better care of their health. Breaking a patent is completely unjustified in the case of a condition like heart disease that reflects an unhealthy choice of lifestyle undertaken by affluent citizens.

In addition, patents are not the problem; poor health systems are a much bigger problem than the prices of drugs. Besides, drugs are already provided free or at low cost to countries around the world when they are truly needed. However, Thailand's economy is in no way comparable to the countries that receive such low-cost drugs, such as sub-Saharan Africa.<sup>119</sup> Thailand is cutting the wrong corners; instead of breaking patents, it should address corruption in the health services industry and provide better health training.<sup>120</sup>

Thailand's actions are not only suspicious, but also inconsistent with TRIPS. TRIPS only permits such licenses in limited circumstances, such as a national health emergency, and even then only after legitimate and lengthy efforts have been

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116. See, e.g., Bate, *Thailand and the Drug Patent Wars*, *supra* note 43, at 2 (noting that Thailand's AIDS epidemic is "fueled by its notorious sex industry").

117. See Bate, *Thai-ing Pharma Down*, *supra* note 43 (opining that "it's hard for anyone to argue that heart disease meets" the criteria of a health emergency); Roger Bate, Op-Ed., *Thailand's Patent Attack*, N.Y. SUN, Feb. 13, 2007, at 9, available at <http://www.nysun.com/opinion/thailands-patent-attack/48499> (asserting that heart disease and leukemia are not epidemics).

118. See Ghosh, *supra* note 88 (asserting that heart disease afflicts the affluent).

119. See CIA, *The World Factbook*, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2001rank.html> (last visited Nov. 21, 2009) (comparing each country's GDP).

120. See Bate, *supra* note 107 (alleging that other problems beyond drug costs are a problem, including poorly paid medical workers and corruption in the health care industry that are exacerbated by limited government funding); Bate, *Thai-ing Pharma Down*, *supra* note 43 ("[T]he real risk to the poorest of the ill, and HIV sufferers in particular, is not drug prices but bad health systems and poor training of medical professionals.").

made to negotiate with the patent owner.<sup>121</sup> There is no specific provision in TRIPS that permits Thailand to issue licenses on drugs that treat conditions that are not epidemics. Thailand has clearly violated the spirit, if not the letter, of TRIPS by taking such extreme action in exploiting the vaguely worded TRIPS agreement to simply balance its budget.<sup>122</sup> There is no mention in TRIPS that licenses can be used to get more drugs than a nation can legitimately pay for. After all, everyone knows that the goal of TRIPS was to ensure that patents were given increased, rather than reduced, protection.<sup>123</sup> Otherwise, innovation will fail and there will be no drugs to supply to the Thai market or any market in the world.

The inappropriateness of Thailand's action is broadly recognized in the international community. As stated by Switzerland, "patents are part of the solution to long term access to innovative medicines in Thailand," such that compulsory licenses must be used "only in emergencies and other exceptional cases" or else the entire patent system will be undermined, and with it, the "incentive to invest in research and development of new and more effective medicines."<sup>124</sup> Similarly, the EU Commissioner of Trade has repeatedly written to Thailand to clarify that compulsory licenses are inappropriate to use as a standard business practice because that will inevitably be detrimental to the development of new medicines and to insist that Thailand stop such inappropriate use.<sup>125</sup> Even the Director-General of the WHO has recognized that patent protection is critical and that compulsory licenses must be pursued cautiously.<sup>126</sup>

Thailand's repeated stealing of drugs must be condemned. Abbott's decision to withdraw new drugs from the Thai market is very reasonable because Thailand has indicated that it will take others' property if given the opportunity.<sup>127</sup> It is completely

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121. TRIPS, *supra* note 2, art. 31(b).

122. Editorial, *supra* note 76; *Lonely Thailand*, WALL ST. J. ASIA, May 23, 2007, at 11.

123. TRIPS, *supra* note 2, arts. 7–8.

124. Aide Mémoire, *supra* note 52.

125. Letter from Peter Mandelson, EU Trade Comm'r, to Krirkkrai Jirapaet, Thai Minister of Commerce (Sept. 10, 2007), *available at* <http://www.vittorioagnoletto.it/uploads/file/Mandelson4.pdf>.

126. Editorial, *supra* note 76 (quoting WHO's Director-General as stating, "I'd like to underline that we have to find a right balance for compulsory licensing . . . We can't be naive about this. There is no perfect solution for accessing drugs in both quality and quantity.").

127. See Zamiska, *supra* note 53 ("Pharmaceutical executives say the Thai government's decision, which they say effectively steals the drugs from the companies

inappropriate for a middle-income country to steal from companies.

Thailand's actions also destroy a fragile global framework. Companies currently provide a tiered pricing system. They already provide drugs at higher costs to wealthy countries so that they can provide drugs at low or no cost in poorer markets.<sup>128</sup> However, this is only sustainable if it can provide some profits in middle-income countries that can afford to pay. If other middle-income countries follow Thailand's bad example, the entire structure of subsidizing drugs to poor countries will collapse. Not only will this result in less access to drugs for poor countries, but it will also reduce incentives for all drug development, including drugs that address the needs of developing countries.<sup>129</sup>

#### IV. IMPACT OF PERSPECTIVES ON COMPULSORY LICENSING CONTROVERSY

Although the prior Part provided a holistic flavor of how perspectives color Thailand's licenses, this Part endeavors to provide a deeper description of how perspectives have influenced the dialogue. In particular, this Part focuses on how perspectives have played a key role concerning discussion of whether Thailand's actions are proper under TRIPS.

What may not be evident from the vignettes is the tremendous emphasis on different issues by the privilege versus uber-right perspective. The privilege perspective generally begins all discussions with an emphasis on the legality of Thailand's actions under TRIPS. The uber-right, on the other hand, often gives short shift to even discussing TRIPS and instead argues that the stealing of patent rights will doom innovation to the detriment of all. The privilege perspective predictably interprets any ambiguity in TRIPS provisions in favor of justifying Thailand's actions. However, the uber-right's de-emphasis of the rule of law is somewhat surprising—except as a reflection on the importance of entrenched perspectives. The importance of such a perspective may account for the fact that many editorials promoting an uber-right perspective do not even discuss TRIPS,

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that own them, has left the industry with little choice.”).

128. Roger Bate & Kathryn Boateng, *Drug Pricing and Its Discontents: At Home and Abroad*, HEALTH POL'Y OUTLOOK, Aug. 2007, at 1–2, <http://www.aei.org/outlook/26622>.

129. See, e.g., Bate, *Thai-ing Pharma Down*, supra note 43 (“If other countries follow Thailand's lead and demand no-profit African pricing, then the incentives for further drug development are weakened, especially for diseases uniquely affecting the Asian region, such as dengue fever and leishmaniasis.”).

or, alternatively, refer to TRIPS vaguely as a legal technicality that does not merit any discussion.<sup>130</sup>

This Part will demonstrate how the competing perspectives have introduced confusion into clear text and raised red herrings that detract from issues in need of actual attention. While some would simply accuse patent-owning pharmaceutical companies of obfuscation, this Part suggests an alternative explanation that is consistent with the perspective theory. The first section shows how the strength of the uber-right perspective has produced interpretations of TRIPS that seem to defy its clear text. The second section highlights non-issues that have been raised that mask legitimate TRIPS issues in need of interpretation.

#### A. *Legal Framework: TRIPS Article 31*

TRIPS generally requires all member countries to provide patents to inventions that are new, useful, and nonobvious.<sup>131</sup> In addition, countries must generally provide patent owners with the right to exclude others from their inventions.<sup>132</sup> However, TRIPS also provides exceptions to the usual patent rights.<sup>133</sup> The relevant TRIPS exception that permits compulsory licensing is Article 31,<sup>134</sup> which states:

Where the law of a Member allows for other use [than that permissible under TRIPS Article 30] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain

130. *E.g.*, Benjamin Krohmal, Knowledge Ecology Int'l, Notes from March 16th 2007 U.S. Capitol Briefing on Thailand's Compulsory Licenses (Mar. 16, 2007), <http://keionline.org/print/book/export/html/426> (referring to a statement by PhRMA's Richard Kjeldgaard that his speech "would not focus on the legal technicalities of compulsory licensing").

131. TRIPS, *supra* note 2, art. 27.1.

132. *Id.* art. 28.1.

133. *Id.* arts. 30–31.

134. Although this provision does not use the term "compulsory licenses," it is widely acknowledged to govern the proper use of compulsory licenses. *See, e.g.*, CORREA, *supra* note 39, at 313 (suggesting that Article 31 covers compulsory licenses even without express use of that term); GERVAIS, *supra* note 23, at 390 ("[Article 31] deals with what are traditionally referred to as compulsory or non-voluntary licences."); UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 460 (2005) (using the term "compulsory licenses" in the heading of the chapter focused on Article 31).



authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized . . . ;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
- (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after

judicial or administrative process to be anti-competitive. . . .<sup>135</sup>

While a complete analysis of this provision is beyond the scope of this Article, some highlights will be summarized here as a backdrop to analyzing the competing perspectives.<sup>136</sup> Article 31 *permits*, but does not require, member states to issue compulsory licenses; however, if they do so, they must follow a number of procedural requirements. There is no limitation to use of compulsory licenses by poor countries; Article 31 applies whenever the laws of any WTO country provides for compulsory licenses.<sup>137</sup> Although many assume that TRIPS limits the subject matter available for compulsory licensing, that is not the case. Rather, TRIPS focuses on ensuring that proper procedures take place, such as considering the “individual merits” of each compulsory license, rather than providing blanket licenses of entire categories of subject matter.<sup>138</sup> Similarly, TRIPS requires providing “adequate remuneration” to the patent owner for use of the patent, and generally requires prior negotiation with the patent owner before issuing a compulsory license, although there are three situations where prior negotiation may be waived: a national emergency, a situation of extreme urgency, or public noncommercial use.<sup>139</sup> In addition, although an early draft suggested that compulsory licenses should be generally minimized,<sup>140</sup> the final text contains no such limitation. The only restriction to the scope of compulsory licenses is on the level of individual patents—the scope and duration of individual licenses are to be limited to the authorized purpose.<sup>141</sup>

Subsequent to TRIPS, all WTO members at the Doha Ministerial Conference agreed to a Declaration on Public Health

135. TRIPS, *supra* note 2, art. 31.

136. For a more complete analysis of Article 31, including whether Thailand's licenses comply with Article 31, see Cynthia M. Ho, *Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 387–411 (2009).

137. TRIPS, *supra* note 2, art. 31. There are other provisions of TRIPS that apply only to developing countries. See, e.g., *id.* art. 65 (providing transitional provisions for a “developing country”). The absence of the qualifier “developing country” in Article 31 thus suggests that there was no intent to limit this provision to such countries.

138. Compare TRIPS, *supra* note 2, art. 31(a) (requiring licenses be considered on “individual merits”), with Patent Act, 1923 S.C., ch. 23, art. 24 (Can.) (allowing the Commissioner to grant compulsory licenses for any invention by a public servant that relates to the nature of his employment).

139. TRIPS, *supra* note 2, art. 31(b), (h).

140. For example, a 1990 draft suggested that parties “shall minimise the grant of compulsory licences in order not to impede adequate protection of patent rights.” Draft of July 23, 1990, W/76, reprinted in GERVAIS, *supra* note 23, at 387.

141. TRIPS, *supra* note 2, art. 31(c).

that provides further clarification on Article 31.<sup>142</sup> The Declaration is not an amendment to TRIPS. However, that does not mean that it is not relevant. To the contrary, the relevant rules for interpreting international laws give primary weight to the “ordinary meaning” of the text of a treaty in its appropriate context, which includes subsequent agreements between all parties to the treaty.<sup>143</sup> Most scholars who have analyzed this issue have concluded that the Declaration is in fact a subsequent agreement.<sup>144</sup> Patent owners, on the other hand, tend to discount the Declaration as merely a political statement of no consequence.<sup>145</sup> The Declaration will be discussed here as a relevant interpretative device.

However, even if the Declaration were not utilized, the interpretation of TRIPS Article 31 should be the same because the Declaration simply makes explicit principles already set forth under TRIPS. For example, the Declaration plainly states that “[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences

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142. Compare Doha Public Health Declaration, *supra* note 11, ¶ 5(a)–(c), with TRIPS, *supra* note 2, art. 31(b).

143. Vienna Convention on the Law of Treaties art. 31.1, Mar. 21, 1986, 1155 U.N.T.S. 331 (“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”); *id.* art. 31.3(a) (noting that the context should include “any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions”).

144. See, e.g., CARLOS M. CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 45 (2002), available at [http://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf); Denis Borges Barbosa, Margaret Chon & Andrés Moncayo von Hase, *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 131–32; Steve Charnovitz, *The Legal Status of the Doha Declarations*, 5 J. INT’L ECON. L. 207, 211 (2002); Susy Frankel, *WTO Application of “the Customary Rules of Interpretation of Public International Law” to Intellectual Property*, 46 VA. J. INT’L L. 365, 400–01 (2006); Carmen Otero García-Castrillón, *An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health*, 5 J. INT’L ECON. L. 212, 212 (2002); James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 314–16 (2002).

145. See, e.g., U.S. GOV’T ACCOUNTABILITY OFFICE, U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION 3–4 (2007); Press Release, PhRMA, WTO Doha Declaration Reaffirms Value of Intellectual Property Protection (Nov. 14, 2001), available at <http://www.aegis.com/NEWS/PR/2001/PR011126.html>. However, not everyone sympathetic to patent rights has dismissed the Declaration. For example, Professor Alan Sykes noted that while ministerial declarations under the WTO are not legally binding for dispute resolution purposes, the Doha Public Health Declaration “is primarily interpretative of imprecise obligations in TRIPS, and does not appear to contradict any textual provision. As such, it is likely to be persuasive authority . . . in the event of a dispute.” Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT’L L. 47, 54 (2002).

are granted.”<sup>146</sup> However, there is nothing in Article 31 that would contradict this statement because Article 31 simply provides provisions that should be respected by countries granting compulsory licenses, without requiring the approval of any other country or entity. Although Article 31 permits compulsory licenses to be challenged, the challenge occurs within the country granting the license.<sup>147</sup> In addition, the Doha Declaration further states that “[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”<sup>148</sup> Again, this statement is consistent with Article 31, although it does provide additional clarification; in particular, TRIPS states that a national emergency or circumstances of extreme urgency are possible grounds for waiving the usual requirement to first negotiate with the patent owner, but TRIPS does not define when such terms occur.<sup>149</sup> Under general principles of interpretation, undefined terms in TRIPS permit member states to self-define. What the Doha Declaration adds is a broader consensus of examples of particular diseases that should fit this definition.<sup>150</sup> However, the general principle that member nations have the right to define the undefined key terms of national emergency and extreme urgency is inherent in TRIPS.

#### *B. Distorted TRIPS Interpretations Fostered by an Uber-right Perspective*

This section highlights the most extreme impact of patent perspectives to a proper understanding of TRIPS. It is important

146. Doha Public Health Declaration, *supra* note 11, ¶ 5(b).

147. TRIPS, *supra* note 2, art. 31(i).

148. Doha Public Health Declaration, *supra* note 11, ¶ 5(c).

149. TRIPS, *supra* note 2, art. 31(b).

150. However, there remains debate as to whether these are the *only* diseases permissible for compulsory licenses. In particular, the United States has contended that these are the *only* possible emergencies, while developing countries have argued for a broader interpretation. *See, e.g.*, MARY MORAN, MÉDECINS SANS FRONTIÈRES, RENEGING ON DOHA (2003), available at <http://www.cptech.org/ip/wto/p6/msf052003.pdf>; Chakravarthi Raghavan, *TRIPS Consultations on Implementing Doha Recessed*, THIRD WORLD NETWORK, Nov. 29, 2002, <http://www.twinside.org.sg/title/5246a.htm>; Brook K. Baker, Doha Redux—U.S. Enters New Phase of Bad Faith Bargaining (July 2, 2003), <http://www.cptech.org/ip/wto/p6/hgap07022003.html>; Deadlock over Scope of Diseases Threatens to Kill Solution (Nov. 27, 2002), <http://www.cptech.org/ip/wto/p6/ngos11272002.html>.

to first recall that the prior section noted that TRIPS provides no limits to what patents may be licensed, as well as no restrictions to countries that can use compulsory licenses. Moreover, the Doha Public Health Declaration has reinforced these rules. Nonetheless, these rules have been repeatedly contradicted and distorted by patent owners and others holding an uber-right view. This section is not intended to demonize those perspectives. Rather, the goal is to show the power of perspectives in convincing adherents to adopt positions inconsistent with clear text.

1. *Mythical Emergency Limitation.* There are two variations propagated by the uber-right perspective concerning the extent to which an emergency is relevant to a compulsory license. First, there are statements suggesting that a compulsory license is only appropriate if a national emergency or health crisis exists. This is false because TRIPS only mentions national emergencies as relevant when issuing a compulsory license without prior negotiation.<sup>151</sup> As noted above, TRIPS does not restrict what subject matter may be licensed, and the Doha Public Health Declaration affirms that each member state has the “freedom to determine the grounds upon which such licences are granted.”<sup>152</sup> Second, some acknowledge that a national emergency is not always required, but still misstate TRIPS rules by omitting public noncommercial use as a ground for issuing a compulsory license without prior negotiation. Examples of each of these are shown below.

a. *Clear Misstatements that an Emergency Is Always Required.* Those holding an uber-right view have repeatedly suggested that compulsory licenses must be limited to a narrow class of cases. For example, Roger Bate, a fellow of the conservative think tank American Enterprise International (AEI), stated that compulsory licenses are permissible if “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions have failed, or in cases of national emergency.”<sup>153</sup> Along similar lines, Tim Wilson, Director of the conservative think tank Institute of Public Affairs, stated that “Section 31(b) of the TRIPS agreement allows for compulsory licensing of patented technologies in cases of national emergency or other circumstances of extreme urgency or in cases

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151. TRIPS, *supra* note 2, art. 31(b).

152. Doha Public Health Declaration, *supra* note 11, ¶ 5(b).

153. Roger Bate, *Thailand's Drug Wars*, AMERICAN, Mar. 12, 2008, <http://www.american.com/archive/2008/march-02-08/thailand2019s-drug-wars> (internal quotation marks omitted).

of public non-commercial use.”<sup>154</sup> By failing to state that these conditions are only relevant when prior negotiation with the patent owner is waived and omitting all other criteria, the reader is left with the impression that these are the actual grounds for issuing a license.

The perceived “requirement” of an emergency extends beyond patent owners to all that maintain an uber-right perspective. For example, a U.S. report on Foreign Trade Barriers states that “[t]he United States acknowledges Thailand’s ability to issue compulsory licenses to address public health emergencies,” which may sound permissive, but actually suggests that an emergency is *required* for a compulsory license—in conflict with the Doha Declaration’s clear statement that member states get to decide the appropriate grounds.<sup>155</sup> Similarly, a letter from several senators to U.S. Trade Representative Schwab states:

We strongly support WTO rules that recognize the rights of countries to consider actions, including compulsory licensing, to address *urgent* public health needs, such as those resulting from HIV/AIDS, tuberculosis, malaria and other pandemics. But *we do not believe* that WTO members intended those rules to be used to allow compulsory licenses on any medicine whatsoever . . . .<sup>156</sup>

However, nothing in TRIPS states that compulsory licensing is limited to urgent health needs. As pointed out by a different group of congressmen, “TRIPS does not limit compulsory licenses to ‘emergencies,’” and instead grants each nation the ability to assess when licenses should be granted.<sup>157</sup> Perhaps even the congressmen with an uber-right approach to patents realize that their view does not comport with the actual interpretation of TRIPS, such that they specifically emphasized their *belief* of what WTO members intended, instead of noting that proper interpretation of international law requires that the text primarily controls.

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154. TIM WILSON, INST. OF PUB. AFFAIRS, UNDERMINING MITIGATION TECHNOLOGY 4 (2008), *available at* [http://www.ipa.org.au/library/publication/1219192134\\_document\\_wilson\\_mitigationtechnology.pdf](http://www.ipa.org.au/library/publication/1219192134_document_wilson_mitigationtechnology.pdf) (internal quotation marks omitted).

155. OFFICE OF THE U.S. TRADE REPRESENTATIVE, 2008 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS: THAILAND (2008), *available at* [http://www.ustr.gov/sites/default/files/uploads/reports/2008/NTE/asset\\_upload\\_file823\\_14611.pdf](http://www.ustr.gov/sites/default/files/uploads/reports/2008/NTE/asset_upload_file823_14611.pdf).

156. Letter from Joseph I. Lieberman et al., Members of Congress, to Susan Schwab, U.S. Trade Rep. (Mar. 20, 2007) (emphasis added), *available at* <http://www.keionline.org/misc-docs/liebermanplus4.pdf>.

157. Letter from Henry A. Waxman et al., Members of Congress, to Susan Schwab, U.S. Trade Rep. (Apr. 9, 2008), *available at* [http://waxman.house.gov/UploadedFiles/Letter\\_to\\_US\\_Trade\\_Representative\\_Susan\\_Schwab\\_Urging\\_Focus\\_on\\_Access\\_to\\_Medicines.pdf](http://waxman.house.gov/UploadedFiles/Letter_to_US_Trade_Representative_Susan_Schwab_Urging_Focus_on_Access_to_Medicines.pdf).

Another example of the force of an uber-right perspective lies in the writings Juliano Froehner, an assistant professor at the University of São Paulo Brazil, who states that although “negotiators did authorize signatory nations to decide what constitutes a public health emergency that would warrant a CL[,] . . . it was and is understood that compulsory licenses are intended to be used rarely and in response to genuine emergencies.”<sup>158</sup> He argues that compulsory licenses should be limited to cases of “‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics,’ which represent a ‘national emergency or other circumstances of extreme urgency.’”<sup>159</sup> While the quoted material accurately reflects a statement in the Doha Public Health Declaration, the entirety of the statement fails to capture the broader message that those examples are merely illustrative of what constitutes an emergency *if* prior negotiation with the patent owner is waived. The more important statement under Doha—that nations have the right to determine the grounds of compulsory licenses—is importantly omitted.

*b. Mistake by Omission—An Emergency Is Not the Only Time When Prior Negotiation with the Patent Owner May Be Waived.* A less distorted, but nonetheless incomplete, characterization of TRIPS is the belief that the only condition authorizing a country to issue a compulsory license without prior negotiation is that there is a national emergency—or perhaps a case of extreme urgency. This is in clear contradiction to the actual text of TRIPS, which permits waiver of prior negotiation in the case of extreme urgency or public noncommercial use.<sup>160</sup>

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158. Froehner, *supra* note 43, at 5. Whether Professor Froehner continues to hold these views is an open question because the quoted material has since been removed from its earlier location on the web.

159. See, e.g., Froehner, *supra* note 43, at 2 (quoting Doha Public Health Declaration, *supra* note 11, ¶ 5(c)) (“CLs are permitted by the World Trade Organization in exceptional circumstances . . . According to the WTO, circumstances in which they are appropriate include ‘public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics,’ which represent a ‘national emergency or other circumstances of extreme urgency.’” (quoting Doha Public Health Declaration, *supra* note 11, ¶ 5(c))). Similarly, the Doha Declaration has been selectively quoted to give the impression that these are the only situations where licenses are permissible. For example, the uber-rights perspective will quote from the Doha Declaration that countries have the “right to determine what constitutes a national emergency or other circumstances of extreme urgency.” See, e.g., WILSON, *supra* note 154, at 5. However, what is omitted from the discussion is that the prior sentence of the same document explicitly states that “[e]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” Doha Public Health Declaration, *supra* note 11, ¶ 5(b) (emphasis added).

160. TRIPS, *supra* note 2, art. 31(b).

However, the misconception is repeatedly emphasized by those with an uber-right perspective not only in the mainstream media<sup>161</sup>—although they could potentially be simply parroting the vocal uber-right—but in academic presses as well.<sup>162</sup> For example, the Economist quotes Jon Pender of GlaxoSmithKline as saying that “although compulsory licensing is legal, TRIPS rules allow it only under limited circumstances, such as national health emergencies, and only after lengthy efforts to negotiate prices with firms.”<sup>163</sup> Although the article clearly notes the source and that GlaxoSmithKline is a “British drugs giant,” thus suggesting some self-interest, there is nothing in the article to contradict this position as possibly inaccurate.<sup>164</sup>

Another article acknowledges that Article 31(b) is about prior negotiation, yet still provides an incorrect reading. In particular, the article provides a block quote of Article 31(b), which clearly states that prior negotiation “may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”<sup>165</sup> However, in the very next sentence, it is stated that a compulsory license without initial negotiation is permissible “only in situations of national emergency or other circumstances of extreme urgency.”<sup>166</sup> This concluding sentence manages to ignore the very text it cites in excluding noncommercial uses as a permissible basis to waive the usual requirement of prior

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161. See, e.g., PHARM. RESEARCH & MFRS. ASS'N, PARTNERING FOR BETTER HEALTH: AN INDUSTRY PERSPECTIVE 26 (2007), available at [http://www.qplushost.com/portfolio/prema/upload/publications/PReMAWhitePaper\\_Thai\\_English.pdf](http://www.qplushost.com/portfolio/prema/upload/publications/PReMAWhitePaper_Thai_English.pdf) (suggesting by omission that the Doha Public Health Declaration only affirms the right to use flexibilities for health crises and emergencies); Bate, *supra* note 153 (neglecting to mention public noncommercial use as a possible grounds for issuing a license without prior negotiations); Bate & Boateng, *supra* note 128, at 4; Editorial, *supra* note 60; Nicholas Zamiska, *Thai Move to Trim Drug Costs Highlights Growing Patent Rift*, WALL ST. J., Jan. 30, 2007, at A8 (“World Trade Organization rules allow a government to unilaterally declare an emergency and make or sell patented drugs without the permission of the drug companies.”).

162. E.g., MAY & SELL, *supra* note 5, at 171 (noting an exception for a “national emergency” only); Kristina M. Lybecker & Elisabeth Fowler, *Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules*, 37 J.L. MED & ETHICS 222 (2009) (omitting any discussion of noncommercial use); Sykes, *supra* note 145, at 56.

163. *A Gathering Storm*, *supra* note 91.

164. *Id.*

165. Christopher E. Chalsen & Lawrence T. Welch, *Growing Hostility Toward Intellectual Property?* 8, Paper Presented at 1st IPO-JIPA Asian Practice International Congress (Sept. 14, 2005) (quoting Article 31(b) of TRIPS) (emphasis added), available at <http://www.ipo.org/AM/Template.cfm?Section=Home&Template=/CM/HTMLDisplay.cfm&ContentID=14899>.

166. *Id.* (emphasis added).



negotiation. This omission may reflect the uber-right view that compulsory licenses should be granted only in emergencies, regardless of the actual law.

Similarly, Stanford Law Professor Alan Sykes stated that Article 31 “limits compulsory licensing without prior negotiation to genuinely extreme circumstances,” but mentions only a “national emergency.”<sup>167</sup> He seems to entirely overlook the possibility that a country could issue a compulsory license without prior negotiation in a situation beyond a national emergency, and instead tries to characterize what would likely be a public noncommercial use as a twisted situation of national emergency. However, he is not alone. A recent article co-authored by a professor of economics asserts that “countries do have the option to waive the negotiation with the patent holder in cases of extreme urgency or national emergency,” without any mention of the possibility of waiver in the case of public noncommercial use.<sup>168</sup> In fact, the article later suggests that Thailand acted improperly because it “simply announced the ‘public use’ of the patent without discussing the matter with Merck & Co. first.”<sup>169</sup>

Interestingly, Professor Sykes seems to have concern about waiver of prior negotiation even in his limited circumstances. In particular, he is skeptical that a developing country should be able to “unilaterally determine that they are unable to afford pharmaceuticals at current prices, declare that a ‘national emergency’ results, and then implement policies that leave patent holders with rents near zero.”<sup>170</sup> This statement may reflect an uber-right view of patents that leads him to assume a contorted interpretation of what constitutes a national emergency and overlook that TRIPS plainly permits public noncommercial use without prior negotiation. Alternatively, perhaps the idea that any patent could be licensed for public noncommercial use is so terrifying that framing the issue as a clearly improper emergency seems more appropriate—even if this happens at an unconscious level. Similarly, an article co-authored by Professor Lybecker suggests that while “it *may* be reasonable to utilize compulsory licensing for national emergencies . . . there is a need to distinguish legitimate compulsory licensing regimes from abusive ones.”<sup>171</sup> Although

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167. Sykes, *supra* note 145, at 56.

168. Lybecker & Fowler, *supra* note 162, at 224.

169. *Id.* at 228.

170. Sykes, *supra* note 145, at 56.

171. Lybecker & Fowler, *supra* note 162, at 225 (emphasis added).

“abusive” compulsory licenses are not defined, there is a suggestion that compulsory licenses can only be supported to “address a humanitarian *crisis*,” further suggesting that there should be some urgent or emergency situation to justify a compulsory license.<sup>172</sup>

2. *Mythical Exclusion of Some Countries.* Although discussion of the perceived lack of emergency in Thailand seems to overshadow most other topics, there are a couple of other areas where the influence of the uber-right perspective seems to result in new requirements not within the literal text of TRIPS. Two examples exist with respect to which countries may qualify to use compulsory licensing. As noted above, TRIPS permits any member state to issue a compulsory license. Nonetheless, there have been suggestions that licenses be denied to middle-income countries, or militarily governed countries. For example, an article in an academic publication recently asserted that compulsory licensing “is intended . . . for developing countries.”<sup>173</sup> There is no citation to TRIPS for this assertion—nor can there be because TRIPS is not so limited.<sup>174</sup>

Critics repeatedly suggest that Thailand should not have been permitted to issue compulsory licenses because it is a middle-income country.<sup>175</sup> However, nowhere in TRIPS Article 31 is there a limitation on compulsory licenses based on the economic status of the country. Many of the criticisms are also tied to the general premise that middle-income countries can afford to pay full price. This factual premise may be disputed, considering at least 25% of the Thai population lives on less than \$2 per day.<sup>176</sup> More importantly, there is nothing in TRIPS that requires a country to demonstrate financial incapacity, or to be below a certain income level before being able to utilize compulsory licenses. Any suggestion otherwise may reflect an uber-right perspective that reads in additional limitations to justify the position that exceptions such as compulsory licenses must be limited.

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172. *Id.* (emphasis added). The article further asserts that humanitarian crises are more supportable than the “industrial policy objective” of a country. *Id.* However, what would constitute an illegitimate policy objective is not stated.

173. *Id.* at 223.

174. *Id.* at 223 & n.5 (implying that TRIPS intended for compulsory licensing to be used in developing countries but failing to cite any section of TRIPS for support).

175. *E.g.*, Cass, *supra* note 4; Kazmin & Jack, *supra* note 45.

176. *See* U.N. DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2007/2008, at 238 (2007), available at [http://hdr.undp.org/en/media/HDR\\_20072008\\_EN\\_Complete.pdf](http://hdr.undp.org/en/media/HDR_20072008_EN_Complete.pdf).

Another issue that is sometimes raised with respect to Thailand is that the licenses were imposed by a military-installed government, as if this were a relevant factor. However, just as with the economic status of a country, the type of government is not a relevant issue under TRIPS with respect to issuing a compulsory license. There is nothing under the terms of TRIPS Article 31 referring to the type of government entitled to use a compulsory license, let alone any suggestion that use of licenses by a military-based government should be subject to increased scrutiny.<sup>177</sup>

*C. Non-issues Raised Versus Real Issues in Need of Resolution*

This section focuses yet again on the impact of patent perspectives on compulsory licenses, but from a different angle. Whereas the prior section provided examples of the power of perspectives in distorting clear language of TRIPS, this section highlights a more subtle, yet nonetheless significant impact of perspectives. In particular, this section focuses on the fact that perspectives may result in the propagation of non-issues under TRIPS that mask fundamental questions about TRIPS terms that are in actual need of interpretation. The competing perspectives are posited as responsible for the misplaced discussion because each perspective may yield differing, yet valid interpretations. This section attempts to pair the non-issues raised with the real issues under TRIPS jurisprudence that in fact need attention.

1. *No Emergency Versus Public Noncommercial Use: Is There an Emergency or an Epidemic?* Critics have spent a great deal of time addressing the issue of whether there is an appropriate epidemic that would justify any of Thailand's licenses.<sup>178</sup> Some have criticized Thailand's licenses as improper for lack of any public emergency regarding AIDS, let alone heart disease or cancer.<sup>179</sup> Moreover, the comments seem to suggest that what constitutes an emergency should be qualified in contrast to the plain language of the Doha Public Health

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177. In fact, other provisions of Article 31 suggest that discretion is given to the national authority without regard to how it is organized. For example, the decision of what constitutes permissible subject matter is one that is within the province of the national government. TRIPS, *supra* note 2, art. 31.

178. See, e.g., Lybecker & Fowler, *supra* note 162, at 233; Cass, *supra* note 4 (stating that Thailand is a "relatively developed nation facing no epidemic").

179. See, e.g., Lybecker & Fowler, *supra* note 162, at 233 (disputing claim of adequate emergency where only 300,000 patients are inflicted with heart disease and only 15,000 with lung and liver cancer).

Declaration, which states that each nation is entitled to decide what constitutes a national emergency, *including HIV*.<sup>180</sup>

A great deal of the comments criticizing Thailand's lack of an emergency would seem relevant to an uber-right view that wants to limit exceptions. In particular, perhaps an uber-right view is willing to permit compulsory licenses in the case of an emergency, but *not* for public noncommercial use, such that all the arguments are framed within the emergency context. Moreover, the attempt to further limit what counts as an emergency when the Doha Public Health Declaration reserves this issue for the national authorities also suggests the imprint of the uber-right view that exceptions be very limited.

The relevant TRIPS issue that may be masked by the discussion of whether there is an adequate emergency is what constitutes "public noncommercial use." As noted above, this is one of several grounds upon which a nation may issue a compulsory license without prior negotiation with the patent owner. Thailand has assumed that it clearly qualifies. Although a few critics have suggested that only a cynical distortion of TRIPS would possibly encompass Thailand's actions, there has been relatively little discussion of this term. However, all of Thailand's licenses were issued on this ground.<sup>181</sup>

It may be more appealing to paint Thailand's actions as failing to meet the requirement of an emergency—even if this is not an issue—rather than address the more difficult question of what constitutes public noncommercial use.<sup>182</sup> However, some of the comments that attempt to fit criticism concerning the license of Plavix as an inappropriate emergency could be easily replaced by criticism against an overbroad interpretation of public noncommercial use. For example, the Plavix license has been sharply criticized as the first step on a slippery slope towards licensing any and all patents if heart disease were considered an emergency.<sup>183</sup> However, it would seem equally *apropos* for the pharmaceutical industry to say that if public noncommercial use

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180. Doha Public Health Declaration, *supra* note 11, ¶ 5(c) (emphasis added).

181. EFAVIRENZ LICENSE, *supra* note 50, at 38–39; KALETRA LICENSE, *supra* note 50, at 41–42; PLAVIX LICENSE, *supra* note 50, at 44–45.

182. This is a challenging question under TRIPS because what uses are considered noncommercial, as well as for the benefit of the public, have been thorny questions in national laws with respect to what should be a legitimate research exception in patent law, as well as a legitimate fair use in copyright law. Even if a TRIPS interpretation focused more on dictionary definitions, rather than the vagaries of these terms under national law, there is likely still much room for discussion concerning what constitutes a public noncommercial use.

183. Cass, *supra* note 104.

were a permissible ground for compulsory license, it would be a slippery slope towards licensing any and all patents. Perhaps the public noncommercial use is the true slippery slope that terrifies patent owners such that they have displaced their concerns on the emergency criteria instead.

There are a few critical articles that address the question of what constitutes public noncommercial use, but they generally take a very dismissive and conclusive approach. For example, some state that because the licenses were issued to a government agency that is for-profit, the licenses presumably must be for profit.<sup>184</sup> Others assert that for Thailand to assert the application of public noncommercial use would be simply “taking advantage of vague language.”<sup>185</sup> However, it is unclear whether the term “public noncommercial use” is really any more vague than other terms that lack definition in TRIPS; after all, when other terms are undefined, countries have been given freedom to define these terms themselves. In addition, to the extent that this term should have a uniform meaning, these dismissive comments fail to foster a productive conversation about the scope of public noncommercial use. While the existing comments about how heart disease is not an adequate emergency to justify a compulsory license of Plavix can be easily dismissed as legally irrelevant, there is an outstanding issue of whether Thailand or any other country could broadly license any and all drug patents without any negotiation with the patent owner based on the ground of public noncommercial use.

2. *No Research/Innovation Versus Adequate Remuneration.* There is a disproportionate amount of commentary suggesting that the compulsory licenses are wrong or improperly issued because they will negatively impact research, rather than discussion of whether the licenses comply with TRIPS requirements. Out of the many articles criticizing the Thai licenses, almost none mention the amount of remuneration, whereas most suggest that the licenses would negatively impede innovation.<sup>186</sup> While innovation is relevant,

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184. See *id.* (stating that public noncommercial use “comprehends uses such as public research programs, not monopoly provision by a for-profit government agency”); Christopher Horner, *Thailand Stealing out of WTO?* WASH. TIMES, May 17, 2007, at 1 (presuming that the GPO will use the licenses for commercial sale based on its past work with private companies); see also Editorial, *Good Medicine for Thailand*, WALL ST. J. ASIA, May 29, 2008, at 13 (suggesting that the GPO is in competition with the pharmaceutical industry, such that a license to the GPO cannot be for noncommercial use).

185. Editorial, *The Thai Flu*, WALL ST. J., Mar. 14, 2007, at A14.

186. E.g., Aide Mémoire, *supra* note 52 (“Switzerland is convinced that patents are

TRIPS does actually address this issue by mandating that the patent owner be provided “adequate remuneration.”<sup>187</sup> This term is not defined under TRIPS. However, as some scholars have noted, if the remuneration is truly adequate, the pipeline of new drugs would not suffer. Moreover, in addition to the uneven discussion of adequate remuneration, none of the patent owners brought a legal challenge to the amount of remuneration provided by Thailand, although that avenue was available to them.

The uber-right may believe that compulsory licenses are inherently inconsistent with the principle of adequate remuneration, such that it is not worth even discussing that term. In the few instances where remuneration is mentioned, it seems clear that an uber-right perspective would deem any amount below the usual market value to be inadequate. For example, one editorial states that reasonable royalties “almost always leave the rights holder with far less than a reasonable economic return,” thus suggesting that *any* compulsory license would be unacceptable.<sup>188</sup> No alternative amount of remuneration

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part of the solution to long term access to innovative medicines in Thailand.”); Ashley M. Heher, *Abbott, Thailand Face off in AIDS Drug Patent Stalemate*, AEGIS NEWS, June 6, 2007, <http://www.aegis.com/news/ap/2007/AP070616.html> (quoting PhRMA president as stating that Thailand’s “misguided focus” would have “long-term cost, potentially limiting important incentives”); Kristina M. Lybecker, Op-Ed., *Compulsory Drug Licensing Disastrous*, DENVERPOST.COM, Mar. 19, 2008, [http://www.denverpost.com/guestcommentary/ci\\_8616902](http://www.denverpost.com/guestcommentary/ci_8616902) (suggesting that compulsory licenses will negatively impact innovation in the area of neglected diseases); Sally Pipes, *Sanction Nations Selling Generic Versions of Drugs?*, CHARLOTTE OBSERVER, Mar. 31, 2008, at 13A (suggesting that Thailand’s action sets a “dangerous precedent that will stifle medical innovation and endanger the health of millions”). This is even true of articles published in academic journals. One of the most recent articles discussing the Thai situation repeats the pharmaceutical perspective that compulsory licenses harm innovation, and while generally critical of the Thai licenses, this article fails to discuss whether the licenses provide inadequate remuneration. See Lybecker & Fowler, *supra* note 162, *passim*. Most articles suggest that innovation in general will be crippled if compulsory licenses occur, although some also suggest that compulsory licenses will harm innovation for neglected diseases that predominantly impact poor countries. For example, one article generally sympathetic to the uber-right noted that the pharmaceutical industry argument that compulsory licenses reduce incentives for research of neglected diseases is weakened by the lack of current research, but that it was nonetheless a viable argument because “*any* obstacle to research on neglected diseases should be removed to increase the likelihood of innovation in these areas.” *Id.* at 232. Similarly, some have suggested that stricter criteria for patentability will necessarily discourage innovation into neglected diseases. See Roger Bate, *India and the Drug Patent Wars*, HEALTH POL’Y OUTLOOK, Feb. 2007, at 4, [http://www.aei.org/docLib/20070207\\_200702HPOg.pdf](http://www.aei.org/docLib/20070207_200702HPOg.pdf) (suggesting that if Novartis is denied a patent for its beta crystal version of Glivec, it will lack incentive to develop drugs to address diseases unique to the Indian market, such as dengue fever, for which Novartis is the leader in the search for a cure).

187. TRIPS, *supra* note 2, art. 31(h).

188. Cass, *supra* note 93.

is proposed; rather, the only alternative discussed is simply not imposing a license.<sup>189</sup>

Despite the lack of discussion of adequate remuneration thus far, this could be a very important issue. After all, if a compulsory license could be imposed with a remuneration amount deemed adequate to patent owners, compulsory licenses would theoretically lose a major objection.<sup>190</sup> Indeed, based on that theory, some academics have suggested that compulsory licenses ensure that patent owners get appropriate value and that it is a mere myth that compulsory licenses should result in cost-savings.<sup>191</sup> If that were the case, a compulsory license would be of little value to countries attempting to use “TRIPS flexibilities” to enhance access to medicine as the Doha Public Health Declaration suggests is possible.

3. *Factual Dispute on Prior Negotiation Versus Defining Prior Negotiation.* Another non-issue is the seemingly factual question of whether Thailand negotiated with patent owners before issuing compulsory licenses. While this may seem to be a relevant factual dispute with a single correct answer, the real problem is that the “facts” seen are a function of how differing patent perspectives define “prior negotiation,” yet another important, but undefined, term under TRIPS. Whereas Thailand asserts that it is not required to negotiate with patent owners prior to exercising a compulsory license for public noncommercial use, but in fact did attempt to negotiate for years,<sup>192</sup> critics of its licenses generally contend that Thailand failed to negotiate such that patent owners were shocked to find out about the licenses.<sup>193</sup>

The prior negotiation controversy highlights the impact of patent perspectives on undefined TRIPS terms. The privilege

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189. See Bate & Boateng, *supra* note 128, at 7 (arguing that prices set by drug companies are required for continued research and development, such that compulsory licenses constitute theft); Bate, *Thailand and the Drug Patent Wars*, *supra* note 43, *passim* (suggesting that Thailand’s licenses were inconsistent with TRIPS because there was no emergency but failing to address the issue of remuneration); Cass, *supra* note 4 (arguing that compulsory licenses are only permitted under “extraordinary circumstances” and suggesting that Thailand failed to comply without mentioning any specific violation, let alone any discussion of what amount of remuneration would be adequate).

190. There may still be fears of parallel imports, although some academics have suggested that the fears are disproportionate to actual evidence. *E.g.*, Kevin Outtersson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 261–62 & n.304 (2005).

191. *E.g.*, Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 155–56 (2007).

192. See TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 43, at 3–6.

193. See, *e.g.*, Lybecker & Fowler, *supra* note 162, at 228; Bale, *supra* note 110.

view of patents may view any negotiation as prior negotiation, even if conducted years before the compulsory license is granted. After all, there was some negotiation and it was prior to the license. If patents are viewed as a privilege, the extent of negotiation would not seem important, nor would giving notice to the patent owner of an imminent imposition of a compulsory license be important because a patent is only a privilege, and not a right. However, judging from the response of patent owners that they were shocked that the licenses were imposed with *no negotiation* at all, it seems that an uber-right view may take a different view of what constitutes prior negotiation. Perhaps the uber-right requires prior negotiation to occur immediately before the license is imposed and perhaps with explicit mention of an impending license, rather than general negotiations years in advance of a license.

The importance of prior negotiation to the uber-right may have resulted in at least one misstatement of the TRIPS rule. TRIPS plainly provides an exception to prior negotiation in the case of an emergency, public urgency, as well as public noncommercial use.<sup>194</sup> Nonetheless, Professor Froehner alleged that “[e]ven in a legitimate emergency . . . the owner of the IP rights that are confiscated is entitled under WTO rules to consultation before the decision is made.”<sup>195</sup> While this statement is inaccurate as to the actual law, it may accurately reflect what the uber-right views as essential, such that it becomes their reality.

4. *Factual Dispute of Frequency of Compulsory Licenses.* The final non-issue shows some exaggeration by both the uber-right, as well as the privilege views.<sup>196</sup> In particular, whereas the privilege perspective asserts that compulsory licenses occur

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194. TRIPS, *supra* note 2, art. 31(b) (“This requirement [of prior negotiation with the patent owner] may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.”).

195. Froehner, *supra* note 43, at 5.

196. Although this is the final “non-issue” discussed in this article, there are other non-issues that could be addressed. For example, as shown in the contrasting narratives, the uber-right seems to second-guess whether Thailand is acting in the interest of public health, although this is not technically required by TRIPS. *See supra* text accompanying notes 107–108 (noting the suspicions raised by Thailand’s having issued the compulsory licenses after an increase in the defense budget and a decrease in the health care budget); *see also* Lybecker & Fowler, *supra* note 162, at 228 (suggesting that Thailand’s motivation to protect public health is suspect). This could be another situation where the uber-right would *prefer* compulsory licenses to be limited to health crises, such that they may seize any opportunity to suggest that the licensor country does not have a legitimate health interest.



frequently in a variety of countries,<sup>197</sup> the uber-right perspective asserts that compulsory licenses are rare.<sup>198</sup> This seems like another situation where there must be only one correct answer. However, the differing perspectives may once again fill ambiguities under TRIPS. The dispute here focuses not only on how often compulsory licenses are issued, but on what constitutes a compulsory license in the first place. However, that is actually a red herring because TRIPS does not even use the term compulsory license. Rather, TRIPS refers to uses not authorized by the patent owner.<sup>199</sup> This term is considered to encompass not only the type of compulsory license issued by Thailand, but also “government use” of patents commonly practiced by the United States whereby use of patented inventions by government contractors are subject only to remuneration, but never injunctions.

In this case, although how frequently compulsory licenses are issued may on its face seem pertinent to whether they should be permitted or granted, that is a non-issue in the context of what is permissible under TRIPS. Granted, frequency of compulsory licenses may seem like a relevant policy consideration, but to the extent that TRIPS states the rule of law, that would seem the relevant metric. So, what does each side have to gain by focusing on this non-issue?

One hypothesis for the posturing concerning what counts as compulsory licensing and how frequently it occurs is that the accusations are intended to mask the other issues. In particular, if the uber-right, for example, can show that the privilege view on the number of compulsory licenses granted is an exaggeration, they can perhaps attempt to suggest that all statements concerning the privilege view are suspect. On the other hand, the privilege view may be attempting to indirectly tackle the non-issue of whether compulsory licenses impact innovation by suggesting they occur frequently. This could be an admission by the privilege view that policy is relevant on some level beyond what is permitted under TRIPS.

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197. Offenheiser, *supra* note 85 (“The intellectual property safeguards that Thailand ‘exploited’ have been invoked by many countries, not only for medicines but for many fields of technology. In fact, the United States has been a major user of compulsory licensing . . .”); see also LOVE, *supra* note 84 (discussing global use of compulsory licenses).

198. E.g., Sidney A. Rosenzweig, *The False Connection Between Strong Patent Rights and Global Inequity: A Response to Professor Stiglitz*, PROGRESS ON POINT, March 2009, at 1, 19–20, <http://www.pff.org/issues-pubs/pops/2009/pop16.8patentstiglitz.pdf>; Editorial, *supra* note 4 (“[N]o serious government has contemplated using compulsory licensing, even if it’s allowed to do so under WTO rules.”).

199. TRIPS, *supra* note 2, art. 31.

## V. EXAMINING THE IMPORTANCE OF PATENT PERSPECTIVES

This Part addresses the importance of the patent perspective theory. Prior Parts have mostly focused on the relatively narrow, albeit contentious issue of compulsory licenses of patents. This Part both anticipates challenges to the general theory, as well as considers broader implications. For example, this Part considers implications of the perspective theory for an enhanced narrative of TRIPS history, as well as a better understanding of future negotiations in both domestic and global arenas.

A. *Anticipating Challenges*

The competing patent perspectives theory is important both because it is real and because it has not been previously recognized. Like all new theories and observations, challenges are anticipated. Accordingly, this section attempts to anticipate and address possible challenges to the competing perspectives theory set forth above.

1. *Fake Phenomena?* One potential objection to the competing views presented here may be that the two poles of patent perspectives articulated do not accurately represent true views, or at most, represent mere rhetoric. However, the intensity of debates concerning compulsory licenses, including name-calling and full page advertisements to support differing positions, suggests that there is in fact something real to discuss.<sup>200</sup> Moreover, even if some statements are rhetoric, when similar positions are evidenced by news media and academics, it seems less likely that they are all engaged in simple posturing. Also, patent perspectives may be the source of rhetoric because rhetoric does not arise in a vacuum.

In addition, although compulsory licenses have been used as a case study to showcase patent perspectives, they are not the only illustration of the role of perspectives in viewing patents.

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200. Full page advertisements criticizing Thailand's actions were taken out by a group called USA for Innovation in the *Wall Street Journal* and in the Thai media. See, e.g., The USA for Innovation Story, <http://www.2bangkok.com/07/news07apr.shtml> (last visited Oct. 22, 2009); Press Release, USA for Innovation, USA for Innovation Announces Advertising Campaign in Thailand (May 10, 2007), <http://www.thaipr.net/nc/readnews.aspx?newsid=2FF823462E1DE002F0DBA754EE0ABCC3>. In addition, there were competing ads that supported Thailand's actions. See, e.g., Macan-Markar, *supra* note 81 (highlighting efforts by AIDS activists in support of Thailand's decision); National AIDS Treatment Advocacy Project, US Website Attacks Thai Government's Breaking of AIDS/HIV Drug Patents (May 15, 2007), [http://www.natap.org/2007/newsUpdates/052407\\_05.htm](http://www.natap.org/2007/newsUpdates/052407_05.htm) (documenting specific government and international health organization responses).

Another example lies in India's unique patent laws that limit the scope of patentability for compounds that are similar to existing compounds; in such cases, India requires that there be increased efficacy.<sup>201</sup> India's narrow approach to patentability is consistent with a view of patents as privilege; indeed, the explanation given for this provision is a desire to foster true innovation, and avoid a popular pharmaceutical practice of "evergreening" patents with very small, yet patentable modifications.<sup>202</sup> It is also consistent with India's recent history of denying patents on all pharmaceutical products in the interest of promoting access to drugs, until it was required to modify its laws to comply with TRIPS.<sup>203</sup> However, to patent owners and those who subscribe to the uber-right view, India's law can be seen as stealing from innovators and casting a death knell on innovation.<sup>204</sup>

This is not to suggest that the competing perspectives provide the only reason for discord. There are also other legitimate issues that may be at play, including, but not limited to, the fear that compulsory licenses will lead to other problems for patent profits even in countries where no such licenses issue. This could happen, for example, because low-cost drugs made under compulsory license could become parallel imports in another country where they undercut the price of the patent owner. Alternatively, the price of drugs made under a compulsory license may result in pressure to reduce prices in other markets either because some nations use reference pricing based on what other countries pay, or because of public pressure to offer

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201. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 3(d).

202. See, e.g., Adarsh Ramanujan & Rajarshi Sen, *Pruning the Evergreen Tree: Section 3(d) of the Indian Patents Act 1970*, 31 EUR. INTELL. PROP. REV. 135, 137 (2009).

203. The Patents Act, 1970, No. 39, Acts of Parliament, 1970, § 5 (providing that for inventions in the area of food, medicine, drugs, or chemical substances, only patents on methods or processes of manufacture could be obtained); see also Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 INDIAN J.L. & TECH. 15, 17–19, 34 (2005) (explaining the rationale for prior patent law and the ability of the amended laws to limit patents on incremental pharmaceutical innovations). For an extensive history on India's patent law, see Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491 (2007).

204. See, e.g., Janice M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicine*, 356 NEW ENG. J. MED. 541, 541 (2007) ("According to Novartis, there is 'no faster way to kill access to the latest life-saving drugs for people in India than to avoid offering patent protection.'"); Press Release, Int'l Fed'n of Pharm. Mfrs. & Assocs., Chennai Court Ruling: India's Innovative Potential Continues to Be Stifled by Its Poor Patent Law (Aug. 6, 2007), <http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=7860> (noting that the clause "severely restricts innovation" and that "India has the potential to be a global leader in biomedical R&D, but its current patent legislation condemns it to lag behind").

discounted prices. However, the existence of these other factors does not mean that perspectives do not exist.

2. *All About Property.* Another possible objection to the competing views presented is that they simply reflect different views of property—namely, that the observations are not unique to patent law. It is indeed possible that there are differing views on personal ownership of property. However, that might actually suggest that the competing perspectives have broader application. In addition, there should be some similarity between patents and other property in general because by law, patents are often considered property.<sup>205</sup> On the other hand, patents also have unique characteristics that make them distinguishable from real and personal property. One very important issue is that patents can impede access to medicine—something that real and personal property rights normally do not do. In addition, while matters of life and death may occasionally be at issue with real property—for example, if passage through real property was necessary in the case of an emergency—there tends to be less controversy than when exceptions are made to patent rights. Part of this may be due to the fact that patents routinely impede access to medicine whereas real property does not routinely stand in the way of health and safety. Some may suggest that patents are a bargain struck by society—that the limited access to patents during the patent term is a proper trade for encouraging more innovation. However, the privilege perspective would seem to expect additional exceptions to patent rights despite this bargain.

Alternatively, perhaps controversy over any property, whether real or intellectual, is more a function of a disconnect between expected and actual rights. In particular, to the extent that compulsory licenses are not expected, patent owners may be rightfully surprised about their rights being taken away. Similarly, when the rights of private property are seemingly disturbed, as happened when the U.S. Supreme Court permitted a broad reading of what property could be taken, rights holders may react strongly.<sup>206</sup> Although there may be a similar reaction in both cases, they can also each be alternatively characterized as a disagreement between rights (whether property or patent) as an uber-right, or as a privilege, subject to exception.

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205. *E.g.*, 35 U.S.C. § 261 (2006) (declaring that “patents shall have the attributes of personal property”).

206. *See* David Fagundes, *Property Rhetoric and the Public Domain*, 94 MINN. L. REV. (forthcoming 2010) (discussing the public reaction to *Kelo v. City of New London*, 545 U.S. 469 (2005)).

In addition, even if there are similarities between real and intellectual property, disputes concerning patents and implications of differing privileges may be more important because of some distinctions between patents versus real property. One important difference is that the legal boundaries of real property are generally much clearer than with patent rights. Unlike the clear boundaries of real property, the legal boundaries of patents are notoriously unclear unless and until litigated.<sup>207</sup> This lack of clarity might be at least partially responsible for patent owners craving more certainty in other areas, such as limiting exceptions to patent rights.

In addition, there is no international agreement analogous to TRIPS that attempts to dictate how all nations respect property rights. Accordingly, it may be easier for nations to have different views of property rights when each sovereign nation may make its own decision. Moreover, there are important differences between patents versus real property in that they each raise distinct issues. Although rights in patents and real property are both granted under national law, real property typically has no international analogs, whereas a patent owner often has similar patents in a number of countries. Accordingly, the issue of differing perspectives on real property would not be a global issue because real property does not as easily cross borders. This does not mean that there may not be conflict concerning property rights within a nation. However, the conflicts within a nation may be less severe given that there is more likely to be a shared culture. Moreover, as mentioned earlier, conflicting perspectives on patents raise special concern because conflicts over real property entitlements are unlikely to be the same death knell as exclusion from patented drugs.

3. *Wishful Thinking.* The view that compulsory licenses should be limited to declared national emergencies could be based on an assumption that TRIPS reflects what was proposed or desired. After all, TRIPS was the brainchild of U.S. companies seeking to protect their global interest in intellectual property, and most agree that the final language in TRIPS often reflects the desires of developed countries such as the United States.<sup>208</sup> In

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207. See, e.g., JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE 46–68 (2008).

208. See, e.g., Duncan Matthews, *Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organization*, LAW SOC. JUSTICE & GLOBAL DEV., June 4, 2004, at 4, [http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004\\_1/matthews](http://www2.warwick.ac.uk/fac/soc/law/elj/lgd/2004_1/matthews) (stating that the final version of TRIPS “was perceived to closely reflect the demands of developed countries and their industries”).

the context of compulsory licenses, the United States did suggest that licenses should be limited to these two situations.<sup>209</sup> In addition, the Brussels draft on compulsory licensing—the last draft before the final text of TRIPS was concluded—does not include public noncommercial use amongst the categories of situations under which prior negotiation with the patent owner may be waived; although there is a separate paragraph suggesting that public noncommercial use by the government, or authorized by the government, need not comply with any of the procedural requirements.<sup>210</sup> And, as noted by another scholar, the U.S. government has continued to represent its *proposed* view as to what TRIPS states.<sup>211</sup> In addition, while TRIPS places no restrictions on which countries can use compulsory licenses, there is a perpetual belief by the uber-right that this should be the case.<sup>212</sup> That seems clear not only from criticisms of Thailand, but also from other discussions about solutions to providing poor countries with access to medicine.

The presumption that TRIPS contains all provisions originally desired may be further complicated by the fact that in a number of international agreements a member can claim a breach if expected benefits are not conferred, even if those benefits are not expressly stated as a requirement. Under the GATT, which has been superseded by the WTO, a member can bring a nonviolation complaint when the negotiated balance of concessions is upset by application of a measure, even if the measure is not inconsistent with the literal text of the agreement.<sup>213</sup> However, in the area of TRIPS, parties agreed to place an initial moratorium on nonviolation complaints, which has yet to be lifted.<sup>214</sup> In addition, it has been stated that

209. See Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights: Communication from the United States* art. 27, MTN.GNG/NG11/W/70 (May 11, 1990).

210. Brussels Draft of the TRIPS Agreement subsecs. (b), (o), *reprinted in* GERVAIS, *supra* note 23, at 385–87.

211. See JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 320 (2001).

212. See, e.g., Head, *supra* note 1 (“The drug companies have always *assumed* that the [TRIPS] exception would only be used for a dire emergency, like HIV/Aids or avian flu.” (emphasis added)).

213. General Agreement on Tariffs and Trade art. XXIII.1(b), Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194.

214. TRIPS initially provided a moratorium on such disputes; the 2005 WTO Ministerial Convention (Hong Kong) extended the moratorium. TRIPS, *supra* note 2, art. 64(2) (noting a five year moratorium on nonviolation complaints); World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 11.1, WT/MIN(01)/17 (Nov. 20, 2001) (stating that members shall not initiate such complaints while the TRIPS

“virtually all the experts” believe that such types of claims should not apply to TRIPS disputes.<sup>215</sup>

4. *Genuine Confusion.* An alternative explanation to patent perspectives may be that they simply reflect real confusion. Even among intellectual property scholars—including those familiar with the patent provisions of TRIPS—there is frequently an assumption that an emergency is required, or at least that only an emergency or other situation of extreme urgency could provide the grounds for waiving prior negotiation.<sup>216</sup> While there may indeed be some legitimate confusion, that confusion could be stoked by those with an uber-right view propagated by the media.<sup>217</sup>

Confusion regarding compulsory licenses is exacerbated by the fact that the requirements of compulsory licenses relevant to Thailand are not the ones that have been most discussed in the popular press, as well as in scholarly literature. Rather, what may be exacerbating the confusion is a complicated procedure for waiver of one of the usual TRIPS requirements *not* at issue in the Thai licenses—that compulsory licenses be predominantly for

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Council continues to study the issue); World Trade Organization, Ministerial Declaration of 18 December 2005, ¶ 45, WT/MIN(05)/DEC (Dec. 22, 2005) (noting a continued moratorium on nonviolation complaints while the TRIPS Council continues to study the issue); see also GERVAIS, *supra* note 23, at 115–18 (explaining nonviolation complaints).

215. Haochen Sun, TRIPS and Non-violation Complaints: From a Public Health Perspective 5 (Nov. 2002), available at <http://www.cid.harvard.edu/cidtrade/Papers/Sun-TRIPS.pdf>.

216. For example, a recent article discussing the history of TRIPS characterizes Article 31 as requiring prior negotiation except “in the event of a national emergency or other circumstances of extreme urgency,” without any mention of public noncommercial use. Matthews, *supra* note 208, at 5. Rather, the article states that “on the face of it, compulsory licenses could be granted by a developing country without prior negotiation with the holder of rights to key pharmaceutical patents *in the case of a public health crisis of epidemic proportions*.” *Id.* (emphasis added).

217. Media reports read by the public, including academics, frequently reflect an uber-right perspective and seem to give it credence. For example, Ron Cass has written a number of editorials critical of Thailand’s licenses in the *Wall Street Journal*. *E.g.*, Cass, *supra* note 93. His editorials definitely fall within the uber-right mold, but are given a sense of legitimacy because he is often referred to as former Dean and Professor of Boston University, as well as associated with the authoritative sounding “Center for the Rule of Law,” which is in fact a conservative group. Cass, *supra* note 4. His views—or at least, his views together with similar views in the *Wall Street Journal*—may be influential even among those who would not necessarily subscribe to an uber-right view. Although I have not done a full-fledged empirical study, in presenting earlier iterations of this paper, I have been surprised by the number of legal academics who questioned whether Thailand’s actions could be proper because the *Wall Street Journal* repeatedly criticized its actions. Granted, most who asked this question did not specialize in the field of international patent law, but I was still surprised that legal academics would necessarily assume that a claim in the *Wall Street Journal* that those sympathetic to Thailand were necessarily “activists” would have garnered more skepticism.

domestic use. In 2001, member states came to the unanimous consensus that poor countries with inadequate manufacturing capacities could not realistically use compulsory licenses under TRIPS because even if they issued such a license, they had no ability to make cheap drugs because of lack of infrastructure.<sup>218</sup> Moreover, countries with infrastructure to make generic drugs could not necessarily make and ship those drugs under a compulsory license because TRIPS required licenses to be limited to predominantly domestic use.<sup>219</sup> For several years there was a global discussion concerning how to address this issue until the WTO announced a complicated procedure to permit waiver of the domestic use requirement in 2003.<sup>220</sup> This proposal stirred further debate, culminating in 2005 with proposed Article 31*bis*, which is essentially the identical waiver provision proposed as a formal amendment to TRIPS.<sup>221</sup> This waiver provision contains a number of limitations that seem to have been incorporated into the uber-right view of compulsory licenses in general, even though the procedure is only applicable to compulsory licenses issued to supply countries without adequate manufacturing capacities. For example, Article 31*bis* is stated to always apply to any least-developed member country, perhaps giving credibility to the assumptions of some that all compulsory licenses should be limited to such countries.<sup>222</sup> In addition, a number of countries agreed to only use the procedure in case of national emergency or other circumstances of extreme urgency, perhaps giving rise to confusion about whether an emergency is required.<sup>223</sup> Also, the confusion about whether only patents for some subject matter

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218. See Doha Public Health Declaration, *supra* note 11, ¶ 6.

219. TRIPS, *supra* note 2, art. 31(f); see also Matthews, *supra* note 208, at 5 (discussing the consequences of the domestic use limitation for those countries with pharmaceutical industries incapable of local production).

220. 2003 General Council Decision, *supra* note 13 (detailing the requirements of prospective exporter and importer countries seeking a waiver of the domestic use limitation, and their respective obligations when acting under such a waiver).

221. World Trade Organization, Decision of the General Council of 6 December 2005, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005).

222. *Id.* at 4 (defining “eligible importing member”). Other countries may also use the provision if they have inadequate manufacturing capacity to meet their needs in a given circumstance beyond that controlled by the patent owner. *Id.* at 7.

223. Certain members agreed to use the system as importers only, pending their accession to the European Union. General Council Chairperson’s Statement, *Excerpt from the Minutes of the General Council Meeting 30 August 2003 (Paragraph n°29)*, WT/GC/M/82 (Nov. 13, 2003), available at [http://www.wto.org/english/tratop\\_E/TRIPS\\_e/gc\\_stat\\_30aug03\\_e.htm](http://www.wto.org/english/tratop_E/TRIPS_e/gc_stat_30aug03_e.htm). Other members that would only use the system in the case of an emergency include Hong Kong, China, Korea, and Mexico. *Id.* Some other countries, such as the United States, Switzerland, Canada, and Japan, promised not to use the procedure at all. *Id.*



may be licensed could also derive from discussion of whether the waiver provision was limited to the conditions listed in the original Doha Declaration, such as HIV and malaria. The waiver itself does not explicitly state that it is limited to certain diseases, but some have nonetheless made that contention.<sup>224</sup>

### B. Next Steps

Although this Article has focused primarily on documenting how perspectives can have a dramatic impact on how a single provision of TRIPS is viewed, the existence of perspectives has additional support and implications. This section aims to use the perspectives to provide a richer understanding through two avenues. First, this section provides further evidence of the implication of perspectives for the history of TRIPS as well as current conflicts. Second, this section places the perspectives theory posited here in the broader context of social science research. Finally, this section provides some thoughts about possible implications, as well as points for further research.

#### 1. Additional Illustrations of Perspectives in Action.

a. *TRIPS Revisited—Papering over Perspectives.* Most agree that the conclusion of TRIPS was considered a major and surprising accomplishment given that many countries had been opposed to a global regime of intellectual property rights.<sup>225</sup> Scholars have suggested a number of theories thus far for why agreement was reached on TRIPS. A common view is that because TRIPS was a package deal, developing countries willingly bargained away sovereignty over patent (and other intellectual property) rights in exchange for broader access to markets.<sup>226</sup> Others suggest that while TRIPS can be viewed as a contract, it is more a contract of adhesion that developing countries had little choice to sign.<sup>227</sup> Still others suggest that the

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224. The United States, in particular, has suggested that the list of diseases stated in Doha is exclusive, rather than illustrative. *See supra* notes 148–150 and accompanying text.

225. *See generally* WATAL, *supra* note 211, at 22–41 (documenting the negotiating process of TRIPS).

226. *See, e.g.,* Arie Reich, *The WTO as a Law-Harmonizing Institution*, 25 U. PA. J. INT'L ECON. L. 321, 362 (2004).

227. *E.g.,* PETER DRAHOS & JOHN BRAITHWAITE, *INFORMATION FEUDALISM* 141 (2002) (“The inequalities of resources and expertise, not to mention US unilateralism on intellectual property, would make it easy for anyone wishing to do so to depict TRIPS as an unconscionable bargain.”); Ruth L. Gana, *The Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL’Y 315, 334 (1996) (“[T]he TRIPS Agreement accomplishes, through the potential threat of economic

conclusion of TRIPS was aided by its minimal framework and many undefined terms.<sup>228</sup> What the perspectives focus adds is that the supposed consensus was based on papering over competing perspectives; each country could believe that its goals were met under TRIPS if the language was broad enough to reflect competing perspectives.

The entire TRIPS framework can be seen as consistent with the existence of competing perspectives. Many key terms in TRIPS are undefined, such as what constitutes an “invention,” as well as what inventions are sufficiently “new” that they must be patentable.<sup>229</sup> The traditional view is that the lack of definitions leaves countries “flexibility” to define these terms as they see fit.<sup>230</sup> The perspectives approach supplements this view by explaining why TRIPS was originally seen as compatible with all perspectives, though now subject to conflict. For example, if the term “invention” is undefined, the uber-right may assume that TRIPS requires a broad scope of subject matter to count as invention whereas a privilege view may assume something much narrower. These different views can coexist until a country implements a law that illustrates the discord. One recent example would be India’s patent law requiring increased efficacy as a prerequisite for patenting a compound similar to a preexisting compound.<sup>231</sup> While this seems reasonable under the privilege view, it is alternatively viewed as unprecedented and improper by the uber-right because it deviates from traditional patent norms.<sup>232</sup>

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ostracism, what could not be accomplished through negotiations independent of the international economic framework.”); Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT’L ECON. L. 681, 724–38 (2006).

228. See, e.g., WATAL, *supra* note 211, at 7 (contending the ambiguous language of the TRIPS Agreement helped resolve bitter disputes between countries with competing interests because its terms could be interpreted flexibly depending on the party’s circumstances).

229. TRIPS, *supra* note 2, art. 27.1.

230. See, e.g., CORREA, *supra* note 39, at 317; see also Jerome H. Reichman, *Securing Compliance with the TRIPS Agreement After US v India*, 1 J. INT’L ECON. L. 585, 597 (1998) (“*US v India* confirms that the developing countries are free to adopt their own laws and policies with respect to all the intellectual property issues that were *not* expressly harmonized in the TRIPS standards themselves.”).

231. The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, § 3(d) (declaring that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance” is not an invention within the meaning of law).

232. The collision of these two views resulted in Novartis’s challenge to the law. *Novartis v. Union of India*, 2007 A.I.R. 24759 (Madras H.C.) (India), *available at* <http://judis.nic.in/chennai/qrydisp.asp?tfnm=11121> (arguing section 3(d) of India’s amended Patents Act violates Article 27 of the TRIPS agreement declaring all “inventions” patentable, by narrowing the definition of “invention”). Novartis persisted in

Competing perspectives are also reflected in ongoing debates about the meaning of the Doha Public Health Declaration. For example, the privilege view of patents sees the Declaration as broadly supporting a health-based approach to patents, citing Paragraph 4 which states that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health,”<sup>233</sup> as well as Paragraph 5(b) which provides that “[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”<sup>234</sup> On the other hand, the uber-right view sees Paragraph 4 as merely hortatory text of no real meaning—after all, how can patent rights be possibly reconciled with members taking any measure to protect public health if patents exist on drugs? In addition, the uber-right view would point to Paragraph 3, which states that “[w]e recognize that intellectual property protection is important for the development of new medicines,”<sup>235</sup> as support for narrowly limiting exceptions to patent rights. Moreover, the uber-right view would interpret all aspects of Doha from the narrow framework of diseases listed in Paragraph 1—“HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>236</sup> The privilege view repeatedly emphasizes that this initial clause more broadly begins by stating, “We recognize the gravity of the public health problems afflicting many developing and least-developing countries,” and that the listed diseases are only examples, as indicated by the provision’s use of the word “especially.”<sup>237</sup> In addition, the privilege view would point again to Paragraph 4 as reflecting a consensus that “we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS

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its challenge despite repeated pressure by governments and nongovernmental organizations to drop the case. *See, e.g.,* Bate, *supra* note 186, at 3; Tove Iren S. Gerhardesen, *Opposition Gains Support Against Novartis Patent Lawsuit in India*, INTELL. PROP. WATCH, Feb. 15 2007, <http://www.ip-watch.org/weblog/index.php?p=535&res=1024> (detailing the global outcry against Novartis’s case against the Indian government); Letter from Anne Ferreira et al., Members of the European Parliament, to Daniel Vasella, CEO, Novartis (Feb. 9, 2007), *available at* <http://www.cptech.org/ip/health/c/india/meps02092007.html> (predicting that Novartis’s success in the litigation would compromise India’s ability to export affordable medicines to developing countries); Letter from Henry Waxman, Chairman, Comm. on Oversight & Gov’t Reform, to Daniel Vasella, CEO, Novartis (Feb. 13, 2007), *available at* <http://oversight.house.gov/images/stories/documents/20070213183300-13686.pdf> (expressing concern that Novartis’s “attempt to influence domestic Indian law could have a severe impact on worldwide access to medicines”).

233. Doha Public Health Declaration, *supra* note 11, ¶ 4.

234. *Id.* ¶ 5(b).

235. *Id.* ¶ 4.

236. *Id.* ¶ 1.

237. *Id.*

Agreement, which provide flexibility for this purpose [of protecting public health],” which is given further meaning in Paragraph 5.<sup>238</sup>

The ability of each side to find some language to support its position may reflect the international reality that to achieve consensus, language is adopted that is capable of reflecting multiple viewpoints. However, this simply seems to defer conflicts to a later date. Indeed, even on one issue that all countries agreed needed resolution—the futility of compulsory licensing provisions for countries with inadequate manufacturing capacity to make their own generic drugs—conflicts abound. On one level, this should have been a very easy situation because all agreed that such countries deserved lower-cost drugs, unlike the controversy over middle-income countries such as Thailand. However, there was a great deal of haggling over whether there should be a limit to the types of diseases, as well as applicable countries.<sup>239</sup> Even after the WTO produced a “solution,” in the form of a proposed amendment to TRIPS, problems remain as the amendment lacks the necessary two-thirds agreement of members to be enacted.<sup>240</sup>

*b. Current Conflicts.* Competing perspectives may also help explain some current conflicts and controversies in the international landscape. Several scenarios are outlined here that reflect how perspectives operate beyond the Thailand case study. First, there are competing perspectives concerning the interpretation of TRIPS in a new situation—the seizure of drugs for alleged infringement in a country where they are only in-transit to a final destination. Second, the uber-right perspective may be existent, yet seemingly dormant in some discussions due to a complex web of international interactions. Third, both perspectives play a role in domestic and global consideration of patent law and policy.

238. *Id.* ¶¶ 4–5.

239. *See supra* note 150 (describing the debate over which diseases constitute public health emergencies for the purpose of compulsory licenses); *see also* Abbott & Reichman, *supra* note 13, at 936–37 (noting objections to the scope of covered diseases).

240. *Compare* World Trade Organization, Members Accepting Amendment of the TRIPS Agreement, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (last visited Nov. 21, 2009) (providing list of 26 member states accepting agreement), *with* World Trade Organization, Members and Observers, [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (last visited Nov. 21, 2009) (noting 153 members). The original deadline for adoption of the amendment was extended from 2007 to 2009, with another extension likely necessary. World Trade Organization, Ministerial Decision of 18 December 2007, WT/L/711 (Dec. 21, 2007). In addition, agreement to the amendment is not the only hurdle. For example, although the United States consented to the TRIPS amendment, it has yet to pass any domestic legislation that would enable the United States to export drugs under compulsory licenses for designated countries.

The competing perspectives are clearly evident in discussions surrounding recent in-transit seizures of legally made generic drugs. In particular, customs officials in Europe have seized a number of drugs<sup>241</sup> pursuant to an EU regulation that permits seizure of goods that infringe a patent.<sup>242</sup> The current debate centers on whether the seizures are consistent with TRIPS.<sup>243</sup>

An uber-right view would say that TRIPS permits seizure of in-transit patented goods because TRIPS only provides a minimum level of protection and even seems to contemplate extending protection to this particular instance.<sup>244</sup> This in fact is the position taken by the EU.<sup>245</sup> Similarly, the EU takes the

241. *E.g.*, Sanjay Suri, *Health: EU Blocking Medicines for the Poor*, INTER PRESS SERVICE, Oct. 20, 2009, available at <http://www.ipseurope.org/news/news.php?key1=2009-10-21%2018:02:24&key2=1>; Kaitlin Mara, *Generic Drug Delay Called "Systemic" Problem at TRIPS Council*, INTELL. PROP. WATCH, June 9, 2009, <http://www.ip-watch.org/weblog/2009/06/09/generic-drug-delay-called-%E2%80%9Csystemic%E2%80%9D-problem-at-trips-council>; Posting of thiru, *NGO Views: World Health Organization (WHO) Voice on Issue of Medicines in Transit to Developing Countries?*, to Knowledge Ecology International (Mar. 13, 2009, 3:51 EST), <http://www.keionline.org/blogs/2009/03/13/who-silence-goods-in-transit>; see also *Fight over Generic Drug Seizure Takes Centre Stage at TRIPS Council Meeting*, INTELL. PROP. PROGRAMME, Mar. 11, 2009, <http://ictsd.net/i/news/bridgesweekly/42823> [hereinafter *Fight over Drug Seizure*] (detailing the dispute over the European Commission's IP enforcement provisions).

242. Council Regulation 1383/2003, arts. 1–2, 4, 2003 O.J. (L 196) 7, 8–9 (EC) (authorizing customs authorities to detain goods suspected of violating an intellectual property right).

243. In particular, India and Brazil have suggested that the EU action is in violation of TRIPS and have signaled that they may bring a formal dispute before the WTO. *E.g.*, Pallavi Aiyar, *No Cure in Sight for India-EU Drug Seizure Controversy*, BUS. STANDARD, Nov. 14, 2009, <http://www.business-standard.com/india/news/no-cure-in-sight-for-india-eu-drug-seizure-controversy/376436>; John W. Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J. ASIA, Aug. 6, 2009, at 1; Kaitlin Mara, *India May Be Nearing Dispute Settlement with EU Over Generic Drug Seizures*, INTELL. PROP. WATCH, Aug. 28, 2009, <http://www.ip-watch.org/weblog/2009/08/28/india-may-be-nearing-dispute-settlement-with-eu-over-generic-drug-seizures>. The relevant TRIPS provision requires member states to adopt procedures to enable custom officials to seize counterfeit trademark or copyright goods, whereas patents may, but need not be, subject to similar enforcement. TRIPS, *supra* note 2, art. 51. Also, TRIPS states that "there shall be no obligation to apply such procedures to . . . goods in transit." *Id.* art. 51 n.13. To further complicate matters, rights holders initiating the border enforcement are required under TRIPS to show prima facie infringement "under the laws of the country of importation." *Id.* art. 52. But what is the relevant country—is it the in-transit country or the country of final destination? This ambiguity leaves an opening to be filled by competing perspectives. In addition, there is an open question concerning whether the seizures violate GATT Article V concerning freedom of goods. *E.g.*, Frederick M. Abbott, *Worst Fears Realized: The Dutch Confiscation of Medicines Bound from India to Brazil*, INTELL. PROP. PROGRAMME, Mar. 2009, <http://ictsd.org/i/news/bridges/44192>.

244. See TRIPS, *supra* note 2, art. 1 ("Members may . . . implement in their law more extensive protection than is required by this Agreement . . ."); see also *id.* art. 51 n.13 (noting that goods in transit need not be subject to border enforcement, but also not prohibiting such action).

245. See Posting of thiru, *Intervention by the European Communities (EC) at WTO General Council on the Seizure of Losartan by Dutch Customs Authorities*, to Knowledge

position that it is the law of the in-transit country, rather than the final intended destination that applies to whether there is infringement of the in-transit goods, such that it can deem goods temporarily in the Netherlands as infringing upon a Dutch patent. In addition, the uber-right view may be responsible for conflation of issues by the EU as well as right holders. For example, in a letter to an Indian generic drug manufacturer, patent owner Eli Lilly stated that the generic drugs “are not genuine Eli Lilly products and . . . [a]s such, the Tablets may not be safe or effective.”<sup>246</sup> However, safety and efficacy are issues beyond the scope of patent law—those issues are solely for a regulatory agency and, by definition, generic drugs are considered the bioequivalent of their patented counterpart. Another example of conflation of issues is a statement by an EU representative that “countries actually should be grateful to European customs” for stopping counterfeit medicines because doing so has “most likely . . . saved lives,”<sup>247</sup> even though goods that infringe patents are not counterfeit—that is a term that refers to trademark violations—and generic drugs are not unsafe.

The privilege perspective, on the other hand, seems to underlie a number of interpretations that do not seem justified by the actual TRIPS text. For example, some have asserted that in-transit goods cannot infringe if they are legally manufactured and permissible at the point of final destination. However, they do not cite a specific TRIPS provision for support.<sup>248</sup> In addition, the privilege perspective is evident in statements that place undue emphasis on one clause in the Doha Public Health Declaration that says TRIPS “can and should be interpreted and implemented in a manner supportive of the right to protect

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Ecology International (Feb. 5, 2009, 9:03 EST), <http://www.keionline.org/blogs/2009/02/05/ec-intervention-at-wto> (detailing the EC intervention at the WTO General Council defending the Dutch seizure of medicines en route from India to Brazil).

246. Letter from Eli Lilly & Co. to Cipla (Dec. 9, 2008), *available at* <http://online.wsj.com/public/resources/documents/eudrugs2009letter3.pdf>.

247. *Fight over Drug Seizure*, *supra* note 241.

248. Intervention by Brazil, WTO General Council Meeting Feb. 3–4, 2008, ¶ 6, *available at* <http://www.ip-watch.org/files/RemediosIntervencao-do-Brasil-Conselho-Geral-03-02-2008.doc> (asserting that medicines are generic under the law of the market where they are commercialized based on TRIPS, although not citing any actual TRIPS provisions); Michael Day, *Aid Agencies Condemn Drug Confiscation*, 338 BRIT. MED. J. 1002 (2009) (noting that aid agencies assert that under WTO rules, intellectual property rights only apply at a shipments’ point of origin and destination); John W. Miller & Geeta Anand, *India to Fight EU Drug Delays in WTO Complaint*, WALL ST. J., Aug. 6, 2009, at B4; *see also* Intervention by Brazil, TRIPS Council Meeting June 8–9, 2009, *available at* <http://www.ip-watch.org/weblog/wp-content/uploads/2009/06/brazil-statement-trips-june-09.pdf> (asserting that the “TRIPS Agreement does not allow the detention of goods in transit,” without citing a specific TRIPS provision that directly supports this proposition).

public health” to suggest that any action inconsistent with public health—such as seizure of in-transit drugs—is improper. While this quote is accurate, this statement does not provide an affirmative right—unlike the provisions of TRIPS at issue. Moreover, the cited provision omits the broader context of the quote, which first states that members “reiterat[e] our commitment to the TRIPS agreement.” Accordingly, it would seem that public health considerations can only be relevant to the extent that they are consistent with TRIPS.

Interestingly, not every issue involving a conflict between the interests of patent owners and patients prompts statements reflecting the uber-right. For example, when Ecuador recently announced that it would consider issuing compulsory licenses for “priority medicines,” drug companies not only declined to condemn Ecuador—unlike their response to Thailand—but actually seemed to embrace Ecuador’s decision.<sup>249</sup> In particular, patent-owning drug companies are reported to have stated that “[w]e accept the democratic decision . . . to use this extraordinary legal measure . . . . No legal right of any kind can take precedence over the interests of public health.”<sup>250</sup> This strong statement seems to reflect more of a privilege view of patents, rather than an uber-right view. However, whether it reflects an *actual* shift in position or simply a calculated public relations move is an important, yet unanswered, question.<sup>251</sup>

It is possible that patent-owning companies continue to maintain an uber-right view, but have simply elected to take actions that would promote this view, without specifically telegraphing its existence, in order to avoid public criticism. In particular, the uber-right perspective views TRIPS as providing inadequate protection, such that stronger agreements that better reflect the uber-right perspective are required. Free trade agreements negotiated by powerful countries such as the United States and the European countries often mandate such stronger rights and are thus aptly referred to as “TRIPS-plus agreements.” Given this scenario, there may be no need to criticize potential compulsory licenses if the ability to grant them

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249. This is surprising because both countries are lower-middle-income countries and the drugs Ecuador is considering licensing—second-generation HIV drugs and cancer treatments—prompted great controversy when licensed by Thailand.

250. Jeanneth Valdivieso, *Ecuador to Make Cheap Versions of Patented Drugs*, BUSINESSWEEK, Oct. 28, 2009, <http://www.businessweek.com/ap/financialnews/D9BKAV5G0.htm>.

251. Interestingly, this bold statement is reported in the press, but not on any of the websites of companies that participated in this announcement.

will be limited by such TRIPS-plus agreements.<sup>252</sup> Even in TRIPS-plus agreements that do not specifically limit compulsory licensing, other provisions may make compulsory licenses a moot point because they limit the ability of a potential generic manufacturer to obtain regulatory approval for the proposed generic drug based on existing studies completed by the patent owner.<sup>253</sup> In addition, the currently negotiated Anti-Counterfeiting Trade Act, more commonly known as ACTA, could similarly impede access to medication through yet a different route—by deeming goods in transit to constitute patent infringement, even if they do not infringe at the point of origin or destination. In other words, ACTA could extend the current EU Regulation to a broader scope of countries. The details are difficult to confirm because the agreement has largely been negotiated under a veil of secrecy.<sup>254</sup> However, it is nonetheless worth mentioning as additional evidence of a continued uber-right perspective through actions, rather than public statements.

The differing perspectives also have relevance for approaches to reforming and refining patent law on both domestic and global levels. To the uber-right, patent rights should be strong and have limited exceptions. However, to the privilege perspective, more exceptions to patent rights seem necessary. This may be reflected in recent national legislation to broaden compulsory licenses,<sup>255</sup> as well as proposals to limit the

252. Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 CHI.-KENT L. REV. 1469, 1499–1500 (2007).

253. These provisions are referred to as “data exclusivity” and provide a different method for drug companies to protect their drugs from competition beyond the patent system. Although such provisions have been criticized for their public health consequences, they nonetheless often appear in free trade agreements. Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Agrochemical Products Under Free Trade Agreements*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES 97, 100, 122–23 (Pedro Roffe et al. eds., 2006); Meir Perez Pugatch, *Intellectual Property, Data Exclusivity, Innovation and Market Access*, in NEGOTIATING HEALTH, *supra*, at 81, 84–91.

254. *ACTA Text Revealed to 42 Select Insiders*, INTELL. PROP. WATCH, Oct. 15, 2009, <http://www.ip-watch.org/weblog/2009/10/15/acta-text-revealed-to-42-select-insiders>.

255. For example, France extended compulsory licensing to cover diagnostic patents in 2004 in response to concerns about the high cost and restrictive licensing practices of patent owner Myriad Technologies. LOVE, *supra* note 84, at 9–10; Esther van Zimmerman & Gilles Requena, *Ex-Officio Licensing in the Medical Sector: The French Model*, in GENE PATENTS AND PUBLIC HEALTH 123, 132–33 (Geertrui van Overwalle ed., 2007) (highlighting this case’s central role in raising global awareness of “the potential undesirable effects on research and clinical services of restrictive licensing practices in the field of genetic diagnostics”). In addition, Belgium has adopted a new law to permit compulsory licenses in the interest of public health. Jerome H. Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 250 (2009). Although neither nation has yet utilized these provisions, their existence nonetheless reflects a privilege view of patents. *Id.*



scope of patentability.<sup>256</sup> Moreover, the privilege view likely believes that patents are not solely responsible for innovation and thus may endorse current movements to consider alternative means of promoting innovation. Rather, they are likely to note that patents are an incomplete solution because patents only promote research into the most lucrative areas, but not the areas that are in most need, predominantly those afflicting countries with little ability to pay hefty profit margins.<sup>257</sup> For example, the current charge of the World Health Organization to find alternative means to promote innovation, such as through prizes and faster regulatory approval for priority conditions, would be consistent with the privilege view of patents.<sup>258</sup>

## 2. *Support from Social Science.*

a. *Perspectives as Schema.* The perspectives presented here may also be viewed as consistent with social science literature that documents imperfect information processing. In particular, such research suggests that people rely on prior schemas or heuristics that are essentially unconscious biases in receiving and understanding new information.<sup>259</sup> A schema has been defined as a “mental structure which contains general expectations and

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256. See, e.g., Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 106 (2007) (proposing to exclude genes from patentability).

257. Examples of this phenomenon are that existing patent rights seem to encourage firms to look for “block-buster” drugs that garner huge profits, as well as many “me-too” drugs that treat the same condition. See, e.g., MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES* 74–79 (2004) (proposing drug companies be made to show the FDA their new products work better than existing treatments, as opposed to being merely “effective”). Moreover, such proponents might also note that although patent rights have been expanding in scope and strength, the pipeline of new drugs has actually been decreasing. See, e.g., U.S. GOV’T ACCOUNTABILITY OFFICE, *SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS* 34 (2006) (detailing the ways in which intellectual property protections enable pharmaceutical companies to continue profiting off existing drugs by making negligible changes to the drugs’ dosage or form, or developing new uses for them).

258. Sixty-First World Health Assembly, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* ¶¶ 35–36, WHA61.21 (May 24, 2008), available at [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf).

259. 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, 1125 (2004); see also SUSAN T. FISKE & SHELLEY E. TAYLOR, *SOCIAL COGNITION* 97–99 (2d ed. 1991) (providing an introduction to the area of social cognition); ZIVA KUNDA, *SOCIAL COGNITION: MAKING SENSE OF PEOPLE* 17–19 (1999) (“[W]e take part in shaping our own reality; the concepts we impose on events determine the meaning we extract from them.”). Both schemas and heuristics are mental rules of thumb that can create errors in judgment. KUNDA, *supra*, at 56. Schemas are discussed more in the area of cognitive science, whereas heuristics are discussed within the field of behavioral law and economics. See *id.* at 36, 106–07.

knowledge of the world.”<sup>260</sup> Although schemas are recognized as essential to enable individuals to cope with the large amounts of information that is present in everyday life, they have also been identified as a possible source of bias. Indeed, one example of a schema is a stereotype.<sup>261</sup> Moreover, while some may believe that biases such as stereotypes are only for the uneducated, cognitive biases and imperfect decisionmaking can occur regardless of education or sociocultural background.<sup>262</sup> Not surprisingly, the lessons of social science have been applied to a variety of areas to both break obvious deadlocks as well as reveal new phenomena.<sup>263</sup>

Each perspective can thus be seen as a schema through which individuals receive and understand information, such as TRIPS. While much of legal analysis assumes that individuals may be completely impartial, this is not consistent with social science research. However, existing frameworks for analysis, such as the framework for interpreting TRIPS, seem to assume that there can be a single and consistent meaning. Even if an individual could hypothetically do so, the existing research on the existence and power of prior schemas—such as patent perspectives—suggests that attempts to interpret TRIPS will be done through the lens of the preexisting perspective. The distorted TRIPS interpretations and non-issues documented here seem entirely consistent with the lessons of schemas. Granted, schemas have more often been discussed in connection with fundamental beliefs or stereotypes.<sup>264</sup> However, views of patents seem to also fit within the same model in that there seem to be fundamental beliefs that are so intractable that their adherents go to great lengths to try to persuade others through the creation of websites, full-page advertisements, campaigns to Congress, and beyond.

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260. MARTHA AUGOUSTINOS & IAIN WALKER, *SOCIAL COGNITION: AN INTEGRATED INTRODUCTION* 32 (1995).

261. Chen & Hanson, *supra* note 259, at 1125–26.

262. Stephanie Stern, *Cognitive Consistency: Theory Maintenance and Administrative Rulemaking*, 63 U. PITT. L. REV. 589, 589 (2002); *see also* Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175, 1183 (1997) (noting how “people in most social categories” exhibit signs of “unrealistic optimism”).

263. *See, e.g.*, Jerry Kang, *Trojan Horses of Race*, 118 HARV. L. REV. 1489, 1494–95 (2005) (applying implicit bias theory from social cognition literature to show how the FCC relaxation of ownership orders may exacerbate implicit racist biases); L. Song Richardson, *When Human Experimentation Is Criminal*, 99 J. CRIM. L. & CRIMINOLOGY 89, 94 (2009) (suggesting that implicit biases may result in doctors being given more lenient criminal treatment); Stern, *supra* note 262, at 590–91 (contending cognitive consistency theory as applied to notice and comment rulemaking limits public participation in federal rulemaking).

264. *See, e.g.*, FISKE & TAYLOR, *supra* note 259, at 97–99; KUNDA, *supra* note 259, at 17.

Another important issue with schemas or any prior opinion is that they may be resistant to change. Sometimes referred to in the area of psychology as the concept of cognitive consistency, there is research to show that people will maintain preexisting beliefs out of proportion with actual correctness, even when subsequent evidence reveals that the initial information was incorrect.<sup>265</sup> The general theory is that people have an inherent need to ignore, discredit, or rationalize inconsistent information to avoid the discomfort of cognitive dissonance.<sup>266</sup> Those who view patents as an uber-right may thus ignore TRIPS provisions if they do not comport with the view that patents should be uber-rights and instead focus on innovation. Similarly, a view of patents as privilege could persist in the face of competing evidence that strong patent rights are relevant to support at least some types of innovation. This is consistent with research that suggests a tendency to minimize or trivialize inconsistencies.<sup>267</sup>

*b. Implications.* Even with this brief introduction to social science literature, it should become apparent that perspectives are not easily modified. Accordingly, any proposed solution that aims to find a middle ground between the two competing perspectives may actually be doomed to fail as individuals with differing perspectives each reject the middle ground. This may initially suggest that perspectives have no bearing on future solutions. However, that is not necessarily the case; it may simply be that further investigation into the existence of perspectives, as well as social cognition, is necessary. For example, some have suggested that beliefs are a function of culture and that a better understanding of the underlying cultural worldviews may be helpful in addressing controversies.<sup>268</sup>

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265. See, e.g., RICHARD NISBETT & LEE ROSS, HUMAN INFERENCE 169 (1980); Craig A. Anderson, Mark R. Lepper & Lee Ross, *Perseverance of Social Theories: The Role of Explanation in the Persistence of Discredited Information*, 39 J. PERSONALITY & SOC. PSYCHOL. 1037, 1041–42 (1980); Kari Edwards & Edward E. Smith, *A Disconfirmation Bias in the Evaluation of Arguments*, 71 J. PERSONALITY & SOC. PSYCHOL. 5, 18 (1996); Helen C. Harton & Bibb Latané, *Information- and Thought-Induced Polarization: The Mediating Role of Involvement in Making Attitudes Extreme*, 12 J. SOC. BEHAV. & PERSONALITY 271, 289 (1997); Charles G. Lord, Less Ross & Mark R. Lepper, *Biased Assimilation and Attitude Polarization: The Effects of Prior Theories on Subsequently Considered Evidence*, 37 J. PERSONALITY & SOC. PSYCHOL. 2098, 2098–99, 2105–06 (1979); Arthur G. Miller et al., *The Attitude Polarization Phenomenon: Role of Response Measure, Attitude Extremity, and Behavioral Consequences of Reported Attitude Change*, 64 J. PERSONALITY & SOC. PSYCHOL. 561, 564 (1993).

266. LEON FESTINGER, A THEORY OF COGNITIVE DISSONANCE 2–3 (1957).

267. E.g., Linda Simon, Jeff Greenberg & Jack Brehm, *Trivialization: The Forgotten Mode of Dissonance Reduction*, 68 J. PERSONALITY & SOC. PSYCHOL. 247, 250 (1995).

268. See, e.g., Donald Braman & Dan M. Kahan, *Overcoming the Fear of Guns, the*

Further exploration of these questions may be necessary now that these perspectives have been highlighted.

## VI. CONCLUSION

The principal aim of this Article was to uncover and document the power of competing perspectives, using the Thai compulsory licenses as an illustration. The implications, however, of such perspectives are much broader. The divergent views on the Thai licenses are symptomatic of many disputes concerning the proper balance of patents and public health, including, but not limited to, controversies under TRIPS.

The competing perspectives help to explain current difficulties addressing disputes concerning the extent to which TRIPS provides nations with flexibility to address public health needs. In a pre-TRIPS world, a nation that believed patents on drugs unduly limited access to medication could restrict patentability or, alternatively, provide broad exceptions to patent rights. However, in a post-TRIPS world, although national discretion technically exists under TRIPS, the extent of that discretion is widely disputed.<sup>269</sup> The TRIPS provision permitting compulsory licensing is one such example of where TRIPS clearly permits national discretion, yet that discretion has been challenged.

The competing perspectives are also relevant to the currently unanswered question concerning the relevance of policy in the face of clear law. In particular, patent owners as well as all uber-right view holders repeatedly suggest that compulsory licenses present a huge threat to innovation that must be considered regardless of global rules. Those who view patents as privilege predictably state that the present rules reflect negotiated rules after a discussion of policy. Who is correct?

If global rules can be easily jettisoned based on one side's argument that the rule is not proper policy, what then is the point of the rule of law? In addition, considering policy after rules have already been enacted should be done in a uniform way. If patent owners want to consider policy issues in discussing

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*Fear of Gun Control, and the Fear of Cultural Politics: Constructing a Better Gun Debate*, 55 EMORY L.J. 569, 570–71 (2006) (“[T]he only meaningful gun control debate is one that explicitly addresses whether and how the underlying cultural visions at stake should be embodied in American law.”); John Gastil et al., *Deliberation Across the Cultural Divide: Assessing the Potential for Reconciling Conflicting Cultural Orientations to Reproductive Technology*, 76 GEO. WASH. L. REV. 1772, 1781 (2008).

269. See TRIPS, *supra* note 2, arts. 7–8, 30 (granting countries discretion to formulate, administer, and enforce intellectual property laws through the use of permissive language subject to varying interpretations, especially “may” and “should”).

whether compulsory licenses should be issued, nations should also be able to reevaluate the policy of having a patent system to begin with because there is no clear data that patents alone lead to more prosperity. Patent owning companies are unlikely to want to reevaluate whether nations should be permitted to deviate from the TRIPS requirement to have some level of minimum patent rights. So, why should they be permitted to deviate from the TRIPS rules regarding exceptions to patent rights? Moreover, if countries could at any time revisit previously negotiated rules, wouldn't that wreak havoc on the rule of law and make all negotiations moot?

On the other hand, if every international accord—whether an official treaty or new “solution”—simply papers over existing (albeit non-negotiated) perspectives, continued conflicts seem inevitable. If this is true, there is a broader lesson for all future attempts to legislate in the international arena. In particular, signing an international agreement does not necessarily indicate consensus—at least not on critical perspectives. While this may be an obvious point to some in the international arena, the tension surrounding issues of patents and public health perhaps depicts an important example for future attempts to modify national laws through international negotiation.

In addition, while this Article exposed the existence of perspectives, more work remains to be done to better understand and mediate these perspectives. Social science research informs us that even among academics, there may be implicit biases that work against seeing these perspectives. Accordingly, further examples, together with greater use of research from cognitive science, may be necessary. After all, that very research tells us that people may cling to beliefs in the face of contrary evidence. This Article takes a first step towards challenging beliefs, but further discussion and elaboration of some of the current controversies discussed here may help bolster the case for the existence of perspectives. However, additional research into the existence and interplay of divergent perspectives may be central to eventually addressing how to best mediate competing views of patents that have tremendous implications for any attempt to eventually provide a sustainable outcome that balances patents and public health.