

**PATENT BREAKING OR BALANCING?:  
SEPARATING STRANDS OF FACT FROM  
FICTION UNDER TRIPS**

*Cynthia M. Ho*<sup>†</sup>

ABSTRACT

This article provides the first comprehensive analysis of when compulsory licensing of patents is permissible as a matter of international law under the Agreement of Trade-Related Aspects of Intellectual Property (TRIPS).

Thailand's recent compulsory licenses of patents on a variety of medications provide a convenient vehicle to analyze the limits of compulsory licensing under TRIPS. Thailand's actions are unique; most countries hesitate to issue compulsory licenses in the wake of legal uncertainties regarding TRIPS requirements as well as political pressure. This article capitalizes on the many issues involved in Thailand's licenses to provide an authoritative interpretation of the scope of compulsory licensing under TRIPS.

This article has three goals. First, it diffuses current misconceptions by providing an accurate interpretation of TRIPS. Second, it explores key terms regarding compulsory licenses that require further analysis. Finally, it provides a new framework for understanding competing patent perspectives that presently infiltrate discussions and interpretations of the law. Understanding these competing perspectives is important not only to address current and future controversies concerning compulsory licenses, but also for confronting broader issues at the global and domestic intersection of patents and public health.

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<sup>†</sup> Clifford E. Vickrey Research Professor, Loyola University of Chicago School of Law. The author is grateful for the helpful comments and suggestions of Professors Margo Bagley, Margaret Chon, Tim Holbrook, Nancy Kim, Susan Kuo, Jacqui Lipton, Kevin Outterson, Sean Pager, Song Richardson, John Tehranian, and Angela Upchurch. The article also benefitted from the comments of participants of the Conference of Asian Pacific American Law Faculty and the Michigan State University Law Faculty Workshop. The author also thanks Anna Barreiro, Christina Laga, Patricia Scott, Kyle Shamberg, Megan Simpson, and LeighAnne Thompson for their research assistance.

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## I. Introduction

Accused of theft, stealing, and confiscation, Thailand captured the attention of the world when it issued a series of compulsory licenses on patented drugs.<sup>1</sup> Thailand issued the licenses with little prior warning and at a royalty rate of only one-half percent of the total sale price—far below the market price sold by the patent owners.<sup>2</sup> A compulsory license permits a nation to use (or authorizes a third party to use) a patented invention without the permission of the patent owner at a government-imposed royalty rate that is likely below what the patent owner would freely negotiate.<sup>3</sup> The Thai licenses met this traditional definition. However, the licenses were noteworthy because they involved drugs for non-infectious diseases, such as heart disease and cancer

<sup>1</sup> See, e.g., Ronald Cass, *Drug Patent Piracy*, WALL ST. J., May 7, 2007, at 15 [hereinafter *Drug Patent Piracy*]; Editorial, *Theft in Thailand*, WALL ST. J., Feb. 10, 2007, at A8; Christopher Homer, *Thailand Stealing Out of WTO?* WASH. TIMES, May 17, 2007, at 1; Amy Kazmin & Andrew Jack, *Thailand Breaks Patent for AIDS Drug to Cut Costs*, FIN. TIMES, Nov. 30, 2006, at 9 [hereinafter *Thailand Breaks*]; Nicholas Zamiska, *Thai Ministry to Recommend Ignoring Patents on Cancer Drugs*, WALL ST. J., Mar. 11, 2008, at A16; see also Nirmal Ghosh, *Thailand Breaks Patents For Heart and AIDS Drugs*, STRAITS 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 the editorial by stating that “Thailand has overruled the international patent system”); Jonathan Head, *Thailand Takes on Drugs Giants*, BBC NEWS, Apr. 26, 2007, available at <http://news.bbc.co.uk/2/hi/asia-pacific/6587379.stm> (referring to Thailand’s actions as “breaking” patents while simultaneously stating that Thailand’s action is “completely legal” under international law); Nicholas Zamiska, *Abbott Escalates Thai Patent Rift*, WALL ST. J., Mar. 14, 2007, at A9 [hereinafter *Abbott Escalates Thai Patent Rift*] (“[p]harmaceutical executives say the Thai government decision, . . . effectively steals the drugs from the companies that own them”). Thailand’s actions continue to attract controversy. See, e.g., *Compulsory Licensing Will Continue, Says Minister*, BANGKOK POST, Aug. 15, 2008, available at [http://www.bangkokpost.com/150808\\_News/15Aug2008\\_news96.php](http://www.bangkokpost.com/150808_News/15Aug2008_news96.php).

<sup>2</sup> See *infra* notes 203-211, 242-244 and accompanying text (providing details of compulsory license chronology and criticisms).

<sup>3</sup> See, e.g., JEROME H. REICHMANN WITH CATHERINE HASENZAHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS 10 (UNCTAD-ICTSD 2003) (providing definition of compulsory licensing).

that have not been traditionally subject to compulsory licenses.<sup>4</sup> Moreover, Thailand's status as a middle-income country also captured the attention of critics. For example, the Financial Times characterized Thailand's licenses as setting a "precedent that will alarm other western pharmaceutical companies."<sup>5</sup> Similarly, an editorial in the Wall Street Journal asserted that "there is growing appreciation that trampling patents to allow a middle-income nation to cut its spending on drugs seriously threatens the world's system of protection for innovation."<sup>6</sup>

An essential part of the story often given inadequate attention or erroneous treatment is whether the Thai licenses were permissible under international law. Global rules on intellectual property expressly permit all member countries to the World Trade Organization (WTO)—a group of nearly 200 countries at all levels of economic development—to issue such licenses, but there is presently widespread controversy on when compulsory licenses may be issued under the Trade-Related Aspects of Intellectual Property Rights (TRIPS), to which all WTO members are bound.<sup>7</sup> Humanitarian groups, including the Nobel Prize winning Doctors Without Borders<sup>8</sup> and the William J. Clinton Foundation,<sup>9</sup> praise

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<sup>4</sup> See, e.g., *infra* notes 249-254 (discussing controversy regarding license on Plavix heart medication).

<sup>5</sup> *Thailand Breaks*, *supra* note 1; see also Ronald Cass, *Patent Remedy*, WALL ST. J. ASIA, Aug. 28, 2007, available at [http://online.wsj.com/article/SB118824874547610202.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB118824874547610202.html?mod=googlenews_wsj) [hereinafter *Patent Remedy*] (noting that the U.S. protests "Thailand's effective theft of pharmaceutical companies' intellectual property"); *The Thai Flu*, WALL ST. J., Mar. 14, 2007, at A14 (describing Thailand's licenses as an "attempt to confiscate drug patents" as well as "seizing" patents).

<sup>6</sup> *Patent Remedy*, *supra* note 5; see also Darren Schuettler, *Angered U.S. Firm Excludes Thailand From New Drugs*, REUTERS, Mar. 14, 2007, <http://www.reuters.com/article/europeCrisis/idUSBKK277146> (noting that an Abbott spokesman stated that "Thailand has chosen to break patents on numerous medicines, ignoring the patent system").

<sup>7</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1143 (1994) [hereinafter TRIPS]; see also *infra* notes 241-264 and accompanying text (suggesting Thailand's actions were not compliant with TRIPS).

<sup>8</sup> This group is a humanitarian organization dedicated to helping people who are victims of natural or man-made disasters with access to medical care as just one of its goals. See Doctors Without Borders: About Us, <http://www.doctorswithoutborders.org/aboutus/> (last visited Feb. 8, 2009). The group is also known by its French name

Thailand for using “flexibilities” under TRIPS to ensure access to medicine.<sup>10</sup> Multinational drug companies, on the other hand, assert that the Thai licenses are impermissible under TRIPS on a number of grounds including the contention that there is no national emergency<sup>11</sup> and that conditions such as heart disease and cancer are “lifestyle” issues that should not be subject to compulsory licenses.<sup>12</sup>

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Médecins Sans Frontières (MSF). *See id.*

<sup>9</sup> The Clinton Foundation was established by President Clinton at the end of his second term to achieve a number of policy objectives, including increasing global access to HIV drugs. For further information about the Clinton Foundation see <http://www.clintonfoundation.org/about-the-clinton-foundation/> (last visited Feb. 8, 2009).

<sup>10</sup> *See, e.g.*, Press Release, Médecins Sans Frontières, MSF Welcomes Move to Overcome Patent on AIDS Drug in Thailand (Nov. 30, 2006), available at [http://www.msfaaccess.org/media-room/press-releases/press-release-detail/?tx\\_ttnews%5Btt\\_news%5D=20&cHash=f8040f62f5&no\\_cache=1&print=1](http://www.msfaaccess.org/media-room/press-releases/press-release-detail/?tx_ttnews%5Btt_news%5D=20&cHash=f8040f62f5&no_cache=1&print=1) (“[MSF] welcomes this important move and urges the government to issue such licenses for the production of other essential medicines”); Letter from Ira Magaziner, Chairman, Clinton Foundation, to Mongkol Na Gonkhla, Minister of Public Health (Feb. 16, 2007), reprinted in THAI MINISTRY OF PUBLIC HEALTH AND THAI NATIONAL HEALTH SECURITY OFFICE, FACTS AND EVIDENCES ON THE TEN BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND 96 (Dr. Vichai Chokevivat ed., Sangsue Co., Ltd., Thailand, 2007), available at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> [hereinafter TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS] (stating that Thailand’s actions are consistent with international law); *see also Clinton Backs Thailand, as AIDS Drug Deal is Signed*, NATION, May 10, 2007, available at [http://www.nationmultimedia.com/2007/05/10/headlines/headlines\\_30033839.php](http://www.nationmultimedia.com/2007/05/10/headlines/headlines_30033839.php) (noting support of former president Bill Clinton for Thailand’s compulsory licenses of HIV drugs).

<sup>11</sup> *See, e.g.*, *Bangkok’s Drug War Goes Global*, WALL ST. J. ASIA, Mar. 7, 2007, at 13 (“Thailand clearly doesn’t have an HIV/AIDS epidemic and heart disease isn’t a ‘national emergency’”); Ronald Cass, *Thai Patent Turmoil*, WALL ST. J. ASIA, Mar. 13, 2007, at 13 [hereinafter *Thai Patent Turmoil*] (suggesting that Thailand does not have an HIV crisis relative to infection rates in other developing countries); *Patent Remedy*, *supra* note 5 (noting that Thailand is a “relatively developed nation facing no epidemic”); *see also* Juliano Froehner, *Compulsory Licensing: Inevitable Failures of the Thailand Strategy in the Global Fight Against HIV/AIDS*, Jul. 20, 2007 (unpublished exploratory paper, available at [http://www.essentialinnovation.org/wordpress/wpcontent/uploads/2007/09/cl\\_paper\\_finalized.pdf](http://www.essentialinnovation.org/wordpress/wpcontent/uploads/2007/09/cl_paper_finalized.pdf)) (asserting that neither Thailand nor Brazil has an actual emergency that justifies a compulsory license for AIDS treatment).

<sup>12</sup> *See, e.g.*, Piya Wong, *Thailand Backs off Threat to Break Drug Patents*, SCIDEV.NET, Feb. 8, 2007, <http://www.scidev.net/en/news/thailand-backs-off-threat-to-break-drug-patents.html> (referring to Plavix as medication for a ‘life-style disease’ because it is “not for AIDS or an epidemic”).

Determining the appropriate scope of compulsory licenses under TRIPS is essential to the future of the TRIPS/WTO system.<sup>13</sup> As the number of countries that must comply with TRIPS continues to increase,<sup>14</sup> the permissible exceptions to patent rights are increasingly important not only to individual countries desiring to provide low cost drugs to its citizens but also for the global supply of medicines. Prior to TRIPS, countries could deny patent protection for drug compositions<sup>15</sup> and thus legally make unpatented generic versions for a mere fraction of their cost in countries where they were patented.<sup>16</sup> These low-cost drugs could

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<sup>13</sup> This article acknowledges that there is a broader normative question concerning whether compulsory licenses in general are good or bad policy, which are touched upon in Part VI. However, a full discussion of such policy is not only beyond the scope of this article, but also tangential to the existing international reality that permits such licenses under TRIPS—an agreement to which most countries have agreed to be bound. Since TRIPS is here to stay, a careful analysis of the scope of TRIPS provisions such as compulsory licenses is appropriate and consistent with respect for the rule of law.

<sup>14</sup> Recognizing that member countries have different levels of development and that some WTO members never previously provided these patents, only some signatories were required to bring their laws into immediate compliance with TRIPS; whereas developing countries were provided additional time to come into full compliance. See TRIPS, *supra* note 7, arts. 65-66. Currently, only “least-developed countries” do not have to be in full compliance with TRIPS. See *id.* art. 66; Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (July 1, 2002), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/art66\\_1\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm) [hereinafter *Extension of the Transition Period*] (extending deadline for least developing countries until January 2016).

<sup>15</sup> Prior to TRIPS, about fifty countries did not grant patents on drugs and some also excluded patents for methods of making drugs. See, e.g., United Nations Conference on Trade and Development, *The TRIPS Agreement and Developing Countries*, Geneva, Switz., 30, UNCTAD/ITE/1 (1996).

<sup>16</sup> Although a patent does not mandate a high price, a patent legally entitles its owner to exclude all others from making or selling the patented product, such that the patent owner can and typically does charge a premium price. See, e.g., 35 U.S.C. § 271(a) (2000) (providing that a patent grants its owner the right to exclude all others from making, using, selling, offering to sell, or importing the patented invention for the term of the patent). Although the costs of patented drugs are not the only factor impacting access to medicine, such costs can often be a major barrier to developing countries with minimal funds. See, e.g., World Health Organization, *Intellectual Property Rights, Innovation, and Public Health*, Report by the Secretariat, at 4, A56/17 (May 12, 2003), available at <http://www.who.int/phi/A5617.pdf> (noting that drug prices are a highly significant factor determining lack of access to essential medicines in developing countries); see also Jakkrit Kuanpoth, *TRIPS-Plus Intellectual Property*

be distributed not only within the manufacturing country but also shipped to other countries without patent rights.<sup>17</sup> Prior to TRIPS, a market for generic HIV drugs flourished and became an essential part of the arsenal against global HIV epidemics.<sup>18</sup>

However, the ability to contain HIV epidemics with low cost drugs may be in jeopardy. As more countries must comply with TRIPS, they must provide patents on new drugs such as new HIV treatments. While countries can continue to provide generic versions of older HIV drugs, they may be increasingly less effective because HIV patients typically become resistant to drugs over time.<sup>19</sup> Accordingly, compulsory licenses are important as a possible avenue to achieve lower-cost, but necessary HIV drugs in a post-TRIPS world.<sup>20</sup>

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*Rules: Impact on Thailand's Public Health*, 9 J. W. INTELL. PROP. 573, 580-81 (2006) (noting the price of antiretrovirals (ARV) as a factor in the accessibility of HIV treatment in Thailand).

<sup>17</sup> For example, until recently India did not provide patents on medical products, enabling it to legally make generic versions of drugs and sell them to other countries that did not provide for patent protection. See also Janice Mueller, *The Tiger Awakens, The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 PITT. L. REV. 491, 495 (2007). Compare The Patents (Amendment) Act, No. 15 of 2005 (India), ch. II, § 3, available at <http://www.patentoffice.nic.in/ipr/patent/patents.htm> (not excluding all medical inventions from the scope of patentable invention) with The Patent Act, No. 39 of 1970 (India), ch. II, § 5, available at <http://indiacode.nic.in/> (excluding patents "claiming substances intended for use, or capable of being used, as food or as medicine or a drug").

<sup>18</sup> See, e.g., Médecins Sans Frontières, *Will the Lifeline of Affordable Medicines for Poor Countries be Cut?: Consequences of Medicines Patenting in India*, Feb. 2005, <http://msf.fr/drive/2005-02-01-msf.pdf>.

<sup>19</sup> See, e.g., U.S. GENERAL ACCOUNTABILITY OFFICE, GLOBAL HIV/AIDS EPIDEMIC, SELECTION OF ANTIRETROVIRAL MEDICATIONS PROVIDED UNDER U.S. EMERGENCY PLAN IS LIMITED 6 (2005), available at <http://www.gao.gov/new.items/d05133.pdf>; Marta Darder & Andrew Boule, *Second-line ARV Treatment: Unaffordable Luxury?*, MÉDECINS SANS FRONTIÈRES, July 11, 2004, at 3, available at [http://www.msf.org/msfinternational/invoke.cfm?objectid=F510B9F6-920E-42A3-BF9C6FDC72A65DA8&component=toolkit.article&method=full\\_html&CFID=8240915&CFTOKEN=80683592](http://www.msf.org/msfinternational/invoke.cfm?objectid=F510B9F6-920E-42A3-BF9C6FDC72A65DA8&component=toolkit.article&method=full_html&CFID=8240915&CFTOKEN=80683592). In addition, in resource-limited countries, patients may be more likely to become resistant to ARV drugs because of an inadequately potent initial drug or interruption of treatment, although the WHO is working to achieve a unified global strategy to prevent unnecessary resistance. See Diane E. Bennett et al., *The World Health Organization's Global Strategy for Prevention and Assessment of HIV Drug Resistance*, 13 Supp. 2 ANTIRETROVIRAL THERAPY 1, at 2 (2008), available at [https://www.who.int/hiv/drugresistance/WHO\\_HIVDR\\_strategy.pdf](https://www.who.int/hiv/drugresistance/WHO_HIVDR_strategy.pdf).

<sup>20</sup> Even if compulsory licensing is permissible, there are additional complications.

Thailand's licenses provide a useful lens for considering whether TRIPS permits middle-income countries not only to utilize compulsory licenses as a general matter, but also to use such licenses to treat non-communicable yet life-threatening diseases. While there is currently substantial opposition by drug companies to the idea of middle-income countries using compulsory licenses in general and especially for conditions beyond HIV,<sup>21</sup> the World Health Organization (WHO) has noted that non-communicable diseases, such as heart disease and cancer, are a leading cause of death in low- and middle-income countries.<sup>22</sup> Although there is a common perception that middle-income countries that wish to use compulsory licenses are getting a free ride when they could afford the full fare,<sup>23</sup> this perception does not match reality. In most such countries, there is a wide disparity in income, with a small percentage of the population able to afford premium costs for drugs while the rest of the population remains uninsured and therefore paying more per capita than most citizens in wealthy countries.<sup>24</sup> For example, in Thailand, where

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For example, not every country has the resources to manufacture generic versions of drugs.

<sup>21</sup> See *infra* notes 249-253 and accompanying text (discussing opposition to Thai license of heart drug Plavix).

<sup>22</sup> World Health Organization, *Prevention and Control of NonCommunicable Diseases: Implementation of the Global Strategy*, Report by the Secretariat, at 1, EB 120/22 (Jan. 8, 2007), available at [http://www.who.int/gb/ebwha/pdf\\_files/EB120/b120\\_22-en.pdf](http://www.who.int/gb/ebwha/pdf_files/EB120/b120_22-en.pdf) [hereinafter *Prevention and Control of NonCommunicable Diseases*] (noting that chronic non-communicable diseases constituted eighty percent of deaths in low- and middle-income countries in 2005 and are estimated to increase seventeen percent in the next decade); see also Kevin Outterson, *Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?*, 34 AM. J.L. & MED. 279, 283, 290-91 (2008) (noting that contrary to popular belief, non-communicable diseases, including cardiovascular disease and cancer represent a significant and ever-increasing role in developing countries).

<sup>23</sup> See, e.g., Roger Bate & Kathryn Boateng, *Drug Pricing and its Discontents*, HEALTH POL'Y OUTLOOK NO. 9, Aug. 2007, at 2 (suggesting that middle-income countries are generally unwilling to pay their share of the cost of research and development); *Drug Patent Piracy*, *supra* note 1 (suggesting that Thailand is financially well-off with a reasonably large economy, such that compulsory licenses are simply a free-ride); Sally Pipes, *Thailand's Misuse of Compulsory Licensing Allowed Corrupt Officials to Steal Millions*, CHARLOTTE OBSERVER, Mar. 31, 2008, at 13A (asserting that TRIPS was "never intended to be used by countries that could afford the medicines but are simply choosing to pay less").

<sup>24</sup> See, e.g., Peter Hammer, *Differential Pricing of Essential AIDS Drugs: Markets,*



the bottom twenty-five percent of citizens subsist on less than two dollars a day, Plavix, one of the drugs subject to a compulsory license, was initially priced at about two dollars per day.<sup>25</sup> Moreover, the assertion that compulsory licenses will negatively impact innovation—even if true—is a red herring because the pertinent question is what the parties agreed to in TRIPS, which is the current rule of law.

Thailand has thus far maintained six compulsory licenses despite retaliation from patent owners,<sup>26</sup> and political pressure from the European Union (E.U.) and the United States that includes the possibility of trade sanctions.<sup>27</sup> In addition, other

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*Politics and Public Health*, 5 J. INT'L ECON. L. 883, 888 (2002) (noting that only the wealthiest ten percent of citizens in developing countries typically purchase drugs and that these drugs are often sold at higher prices than in developed countries because of lack of economies of scale); see also Ashwan Vasani et al., *The Pricing and Procurement of Antiretroviral Drugs: An Observational Study of Data from the Global Fund*, 84 BULL. W. HEALTH ORG. 393, 396 (2006) (noting that lower middle income nations are often as financially constrained as low income countries because of high levels of inequality, such that access to antiretroviral therapy may be jeopardized).

<sup>25</sup> See UNITED NATIONS DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT 2007/2008—THAILAND, available at [http://hdrstats.undp.org/countries/data\\_sheets/cty\\_ds\\_THA.html](http://hdrstats.undp.org/countries/data_sheets/cty_ds_THA.html); Shiao Yuasan, *Thailand Threatens to Expand Generic Drugs for Cancer, AIDS*, AGENCE FRANCE-PRESSE, Mar. 18, 2007, available at <http://www.aegis.com/news/afp/2007/AF070337.html>.

<sup>26</sup> Patent owner Abbott responded to a compulsory license by withdrawing six drugs from the Thai market, including a heat-stable HIV medication that would be particularly suited to the Thai climate. See, e.g., Ambika Ahuja, *Thailand: Abbott Laboratories Won't Introduce New Drugs in Thailand Due to Breaking of Patent*, ASSOCIATED PRESS, Mar. 14, 2007, <http://www.aegis.com/news/ap/2007/AP070327.html>; *Putting Meaning Back into TRIPS*, BANGKOK POST, Mar. 22, 2007, available at <http://www.aegis.org/news/bp/2007/BP070308.html>; *Abbott Escalates Thai Patent Rift*, supra note 1, at A9. 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 OF 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, <http://www.livemint.com/2008/03/13164842/Sanofi-in-talks-with-Thai-govt.html>.

<sup>27</sup> The United States has placed Thailand on the “priority watch list” of countries, which may lead to unilaterally imposed economic sanctions. OFFICE OF THE U.S. TRADE REPRESENTATIVES, SPECIAL 301 REPORT 27 (2007) [hereinafter 2007 SPECIAL 301 REPORT]; OFFICE OF THE U.S. TRADE REPRESENTATIVES, SPECIAL 301 REPORT 36-37 (2008) [hereinafter 2008 SPECIAL 301 REPORT]; see also *infra* notes 386-390 and accompanying text (discussing Thailand’s placement on the priority watch list in the

countries, including Brazil, Indonesia and India, have issued or have taken steps to issue compulsory licenses of patented drugs to promote access to medicines.<sup>28</sup> Nonetheless, whether Thailand or other countries may utilize compulsory licenses in the future remains an important open question and one that is ripe for objective scholarly inquiry.

This article will use Thailand's licenses to help illustrate the appropriate scope of compulsory licensing under TRIPS.<sup>29</sup> A clear

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context of repercussion for compulsory licensing even when there is no actual violation of TRIPS). In addition, although no other country has taken action towards retaliation, Switzerland and the E.U. Trade Commissioner have publicly suggested that Thailand's licenses were inappropriate. AIDE MEMOIRE: COMPULSORY LICENSES IN THAILAND ON PHARMACEUTICALS UNDER PATENT PROTECTION (Feb. 25, 2008), *available at* [http://www.keionline.org/misc-docs/1/swiss2thailand\\_cl.pdf](http://www.keionline.org/misc-docs/1/swiss2thailand_cl.pdf) [hereinafter SWISS AIDE MEMOIRE]; Letter from Peter Mandelson, E.U. 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?rd=1](http://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf?rd=1) [hereinafter Peter Mandelson July 10 Letter].

<sup>28</sup> See Andrew Jack, *Brazil Overrides Merck Patent on HIV Drug*, FIN. TIMES, May 4, 2007, *available at* <http://www.ft.com/cms/s/2/c7d3f1f4-fa78-11db-8bd0-000b5df10621.html> (noting Brazil's compulsory license of Efavirenz); William New, *Indonesia Mulls Compulsory Licenses on Three More HIV/AIDS Drugs*, INTELL. PROP. WATCH, Nov. 26, 2007, <http://www.ip-watch.org/weblog/index.php?p=841> (reporting that Indonesia is contemplating issuing compulsory licenses of three second-line antiretrovirals); William New, *India Cancer Patients Seek To Use Courts For Access To Patented Drugs*, INTELL. PROP. WATCH, Apr. 3, 2008, <http://www.ip-watch.org/weblog/index.php?p=989> (noting that Cancer Patients Aid Association is seeking to declare cancer a national emergency, as a first step towards issuing a compulsory license of cancer drugs in India); see also Robert Weissman, *Columbia Health Organizations File For Compulsory License on Lopinavir/ritonavir*, ESSENTIAL ACTION, Jul. 17, 2008, <http://www.essentialaction.org/access/index.php?archives/166-Columbia-Health-Organization-file-for-compulsory-license-on-lopinavirritonavir.html> (noting that Colombian health organizations are asking the Colombian government to issue a compulsory license on Abbott's HIV drug Kaletra).

<sup>29</sup> This article analyzes Thailand's compliance with TRIPS based on the current TRIPS rules. Notably, actions cannot currently be brought against countries that do not violate the literal language of the agreement, otherwise known as non-violation complaints. TRIPS initially provided a moratorium on such disputes and the 2005 WTO Ministerial Convention (Hong Kong) extended the moratorium. TRIPS, *supra* note 7, art. 64(2) (noting a five year moratorium on non-violation complaints); World Trade Organization, Ministerial Declaration of 18 December 2005, ¶ 45, WT/MIN(05)/DEC (Dec. 22, 2005), *available at* [http://www.wto.org/english/thewto\\_e/minist\\_e/min05\\_e/final\\_text\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm) (noting continued moratorium on non-violation complaints while TRIPS Council continues to study issue); World Trade Organization, Ministerial Declaration of 14 November 2001, ¶ 11.1, WT/MIN(01)/17 (Nov. 20, 2001), *available at* [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/min01\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm) (stating that

understanding of TRIPS is particularly important because despite extensive criticism and political pressure, no country has formally challenged Thailand under the WTO system; in addition, a challenge seems unlikely because challenges are often the function of political considerations.<sup>30</sup> In the meantime, the lack of a definitive interpretation of the appropriate scope of compulsory licensing by a WTO panel leaves an interpretative vacuum that may allow incorrect perceptions to flourish.<sup>31</sup> Using the facts of

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members shall not initiate such complaints while the TRIPS Council continues to study the issue); *see also* DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 340-41 (2d ed., Sweet & Maxwell 2003) (explaining non-violation complaints). If the moratorium were lifted, there may be an argument that because some member countries were so desirous of getting patent protection of pharmaceuticals, they might find exceptions to granting patent protection, such as compulsory licenses, to nullify or impair the benefit of patent protection. However, this provision was contentious at the time TRIPS was signed and there seems to be continued resistance. *See, e.g.*, CARLOS M. CORREA, *TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS* 488-49 (2007) [hereinafter CORREA 2007]; *see also* Haochen Sun, *TRIPS and Non-Violation Complaints—From a Public Health Perspective*, available at <http://www.cid.harvard.edu/cidtrade/Papers/Sun-TRIPS.pdf> (noting particular concern for implications on public health of permitting non-violation complaints).

<sup>30</sup> Although the United States and the E.U. have pressured Thailand, they are not intent on following the political pressure with a formal WTO challenge. Sarah Rimmington, *Briefing Note: EU Confirms The Legality of Thai Generic Medicines Policy; Denies Threatening WTO Litigation*, ESSENTIAL ACTION, Mar. 12, 2008, <http://lists.essential.org/pipermail/ip-health/2008-March/012329.html>; Sarah Rimmington, *Inside U.S. Trade: USTR Not Preparing Case Against Thailand For Compulsory Licenses*, ESSENTIAL ACTION, Feb. 29, 2008, <http://lists.essential.org/pipermail/ip-health/2008-February/012260.html>.

<sup>31</sup> Although there is an existing body of literature discussing TRIPS Article 31, most of the scholarship focuses on an important but distinct issue from that posed by Thailand; namely how the TRIPS requirement that compulsory licenses be used for “predominantly domestic use” can be overcome so that least developed countries without resources to manufacture generic drugs can effectively use compulsory licenses. *See, e.g.*, World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 6, WT/MIN(01)/DEC/W/2, 41 I.L.M. 755 (2002) [hereinafter Doha Public Health Declaration]. There is an existing, albeit complicated, waiver of this provision of TRIPS, but there remains controversy. *See, e.g.*, General Council Decision of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003) [hereinafter 2003 General Council Decision]; Frederick M. Abbott & Jerome H. Reichmann, *The Doha Round’s Public Health Legacy*, 10 J. INT’L ECON. LAW 921, 956 (2007). Meanwhile the more general requirements of compulsory licenses that apply in all cases have been largely overlooked. There are a few notable exceptions that provide some analysis of aspects of Article 31, but none that provide a comprehensive interpretation of all the requirements. *See, e.g.*, Aditi Bagchi, *Compulsory Licensing and*

Thailand's licenses to help better define current controversial terms and conditions, this article conducts a careful evaluation of TRIPS requirements, especially with regard to when prior negotiations with the patent owner may be waived. In addition, this article highlights terms that need further clarification but have thus far escaped serious consideration. This article also notes some important considerations beyond the scope of TRIPS that should be considered before issuing a compulsory license, including retaliation by drug companies and nations where those companies reside. The article concludes by suggesting that there may be some fundamentally different perspectives of patents that help explain the current controversy, as well as lay the foundation for future solutions.

Part II begins by providing background to fundamental patent law concepts, as well as the patent requirements that nations must now provide under TRIPS. Part III introduces and interprets Article 31 of TRIPS, the currently contested provision regarding compulsory licensing. Part IV provides details on the contested Thai compulsory licenses against the broader framework of the Thai health care system, together with global criticism of Thailand's actions. Part V then analyzes whether Thailand's licenses are consistent with the TRIPS and also uses the licenses as an illustrative vehicle to shed interpretive light on provisions of TRIPS that are not directly pertinent to Thailand but nonetheless subject to current confusion. Part VI moves beyond the TRIPS analysis to consider additional issues involved with compulsory licensing and concludes with suggestions for how to bring greater clarity as well as global consensus to the issue of compulsory licensing.

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*the Duty of Good Faith in TRIPS*, 55 STAN. L. REV. 1529, 1553-54 (2003); Daniel Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 138-47 (focusing almost exclusively on remuneration issue); Outtersson, *supra* note 22, *passim* (providing detailed explanation for why Article 31 is not limited to some types of diseases); Daya Shanker, *Korea, The Pharmaceutical Industry and Non-commercial Use of Compulsory Licenses in TRIPS* (Univ. of Wollongong Econ. Working Paper Series, WP 03-15, December 2003), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=438880](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=438880) (focusing exclusively on public non-commercial use issue); Antony Taubman, *Rethinking TRIPS: "Adequate Remuneration" For Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927 *passim* (2008) (focusing on meaning of adequate remuneration).

## II. Background

### A. Patent Fundamentals

A patent is an official document granted by a nation that conveys certain legal rights. In particular, a patent owner typically can exclude others from using the patented invention for a limited time—usually less than twenty years.<sup>32</sup> A patent does not grant an absolute right to use an invention—other laws may restrict use or impose additional regulations before an invention may be sold.<sup>33</sup> For example, before a patented drug can be sold, a government agency must typically determine whether it is safe and effective.<sup>34</sup> Nonetheless, the ability to exclude others from an invention usually enables a patent owner to charge a premium price for the patented invention.<sup>35</sup>

Countries are more likely to grant patents when they achieve a certain level of economic development; however, even then, there is not uniformity.<sup>36</sup> A frequently stated policy justification for providing patents is that they provide a necessary incentive or reward for research that ultimately benefits society by promoting innovation that is shared with the public (because patents are public documents) rather than kept secret.<sup>37</sup> To help ensure that

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<sup>32</sup> See, e.g., TRIPS, *supra* note 7, art. 33 (noting that term of patent protection for all WTO countries); 35 U.S.C. § 154(a)(2) (2000) (providing term for US patents).

<sup>33</sup> See, e.g., 35 U.S.C. § 271(a) (2000) (providing patent owners with the right to exclude, but not an affirmative right to use the patented invention).

<sup>34</sup> See, e.g., 21 U.S.C. § 355 (2000) (approval of new drugs in the United States).

<sup>35</sup> See, e.g., 35 U.S.C. § 271(a) (2000) (providing patent owners with the right to exclude all others from patented invention). Although patented drugs are more expensive than generics, the cost of even patented drugs may be mediated by a variety of mechanisms, including price caps, reference pricing, as well as government-negotiated lower prices. See, e.g., GRETCHEN A. JACOBSON, PHARMACEUTICAL COSTS: AN INTERNATIONAL COMPARISON FOR GOVERNMENT POLICIES (Cong. Res. Service 2007) (providing overview of strategies used by different governments to contain drug costs).

<sup>36</sup> For example, some industrialized countries, including Japan, Switzerland and Italy, did not provide patents for drug products until the late 1970s. See, e.g., F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 VAND. L. REV. 2245, 2247-50 (2002).

<sup>37</sup> See, e.g., *Bonito Boats, Inc. v. ThunderCraft Boats, Inc.*, 489 U.S. 141, 149 (1989) (noting that patents are a “carefully crafted bargain” that encourages innovation); *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980) (noting that patent protection “may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives”).

patents promote social welfare, many nations utilize common exceptions to the default patent rights to promote other social goals. Compulsory licenses, for example, are commonly utilized to promote public health and welfare.<sup>38</sup>

Although few consider patents a perfect tool for innovation, even critics understand that they are legal and business realities<sup>39</sup> with criticisms focused on modifications of the existing system rather than whole-sale elimination of patents altogether.<sup>40</sup> Patents are a legal reality under TRIPS as discussed in the next section. In addition, patents are a business reality, as many businesses, especially pharmaceutical companies, rely on patents as part of their business plan.<sup>41</sup> Such companies typically state that the high costs of drug discovery make patent protection for the few successful drugs critical because higher prices for patented drugs

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<sup>38</sup> See, e.g., REICHMANN WITH HASENZAHN, *supra* note 3, at 11-12.

<sup>39</sup> See, e.g., KEVIN RIVETTE & DAVID KLINE, REMBRANDTS IN THE ATTIC 122-23 (2000); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 2 MGMT. SCI. 17, 176-77 (1986) (noting that patenting is common even for industries that do not consider patents as crucial to commercialization).

<sup>40</sup> A number of recent studies of the patent system have found flaws and suggested reforms, but none have suggested entirely eliminating patents. See, e.g., FED. TRADE COMM., TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (2003); NAT'L RES. COUNCIL OF THE NAT'L ACADS., A PATENT SYSTEM FOR THE 21<sup>ST</sup> CENTURY 18-39 (Merrill et al. eds. 2004); WORLD HEALTH ORGANIZATION, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 9 (2006) [hereinafter WHO COMMISSION STUDY]; see also S. COMM. ON THE JUDICIARY, 85TH CONG., AN ECONOMIC REVIEW OF THE PATENT SYSTEM, STUDY OF THE SUBCOMM. ON PATENTS, TRADEMARKS, AND COPYRIGHTS, STUDY NO. 15 80 (Comm. Print 1958) (reporting study by Fritz Malchup) ("If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it."). In addition, in response to public criticisms of the U.S. patent system, there have been bills to reform, but not eliminate the system. See, e.g., Patent Reform Act of 2008, S. 3600, 110th Cong. (2008); *Patent Reform Act of 2007: Hearing on H.R. 1908 Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Committee on the Judiciary*, 110th Cong. (2007).

<sup>41</sup> See Mansfield, *supra* note 39, at 174-75; Richard Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. DEV. 783, 796 (1987); Richard R. Nelson & John P. Walsh, *Protecting their Intellectual Assets: Appropriability Conditions and Why US Manufacturing Firms Patent (or not)* (Nat'l Bureau of Econ. Research, Working Paper No. 7552, Feb. 2000).

are needed to subsidize the expensive development process.<sup>42</sup> Accordingly, the question is not whether or not to grant patents in general, but rather how patents can be balanced against other socially desirable goals, such as access to medicine.<sup>43</sup> A further question addressed in the next section is how to achieve the balance under the international rules of TRIPS.

## B. Patents Under TRIPS

### 1. Overview of Requirements

Under TRIPS, all WTO members must provide minimum levels of patent protection,<sup>44</sup> enforceable through the highly

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<sup>42</sup> See, e.g., PHRMA, WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS 2-3 (2005), available at [http://www.phrma.org/files/Cost\\_of\\_Prescription\\_Drugs.pdf](http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf) (discussing cost of drug discovery); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 475 (2007) (reporting that the estimated cost of drug discovery is as high as \$1.3 billion); Bruce Jaspen, *Abbott Defends Price Boost on AIDS Drug at US Hearing*, CHIC. TRIB., May 26, 2004, at C1 (noting that Abbott defended 400% price hike on AIDS treatment Norvir by stating that it was undervalued in the market and that expected revenues would help foster research of other drugs); cf. Levin et al., *supra* note 41, at 783-90 (noting that patents are of particular importance to the pharmaceutical industry). But see MARCIA ANGELL, THE TRUTH ABOUT DRUG COMPANIES 37-46 (2004) (suggesting that the popularly recited numbers are over-inflated and only represent a small segment of the most expensive drugs, rather than an average of all drugs); Donald W. Light, Book Review, *Misleading Congress about Drug Development*, 32 HEALTH POL'Y & L. 895, 895 (2007) (criticizing Congressional Budget Office study for failing to critically review DiMasi Study's contentions).

<sup>43</sup> There are two principle points at which patents can be modified to promote short-term access to medicine—either by limiting the scope of patentable subject matter or by limiting patent rights. Countries have used both options in their patent laws. See, e.g., 35 U.S.C. 287(c) (providing immunity to medical practitioners for infringement of a patented medical activity); European Patent Convention, art. 53(c), October 5, 1973, 13 I.L.M. 268 (2000) (precluding methods of treatment of humans and animals from patentability); The Patent Act, No. 39 of 1970 (India), ch. II, § 5, available at <http://indiacode.nic.in/> (excluding patents “claiming substances intended for use, or capable of being used, as food or as medicine or a drug”). See also REICHMANN WITH HASENZAHN, *supra* note 3, at 33-34 (noting that in the past, Canadian laws only permitted patents on drug processes but not products, and broadly allowed compulsory licenses to manufacture drugs as a way to increase public access to low cost drugs).

<sup>44</sup> TRIPS, *supra* note 7, art. 27 (setting forth basic patent requirements); *id.* art. 1.1 (noting that members may provide more protection than required under TRIPS). Although least-developed countries must eventually comply with all TRIPS provisions, they do not have to fully comply until 2016. *Extension of the Transition Period*, *supra* note 14.

effective WTO dispute resolution procedure.<sup>45</sup> While individual nations still issue their own patents, they must generally provide patents for inventions that are new, inventive, and useful,<sup>46</sup> subject to a few exceptions not pertinent here.<sup>47</sup> In addition to specifying the general requirements for patentability, TRIPS prohibits countries from excluding entire classes of inventions from the scope of patentability—such as all drugs—because TRIPS requires patents be provided without discrimination based upon technology.<sup>48</sup> In addition, TRIPS also requires that nations provide patent owners with the right to exclude others from making, using, selling, offering to sell, or importing the patented invention into the country for the term of the patent.<sup>49</sup>

TRIPS provides a framework of patent standards, including exceptions to the usual requirements. For example, although the general rule is that patent owners have the right to exclude all others, TRIPS provides two exceptions: one for “limited

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<sup>45</sup> If members fail to amicably settle the disagreement on their own, there is a quasi-judicial process under the WTO for determining whether a violation has occurred. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125 (1994) [hereinafter DSU]. Even more importantly, decisions have “teeth” in that the breadth of WTO agreements enables the WTO to enforce decisions by withdrawing privileges under other WTO agreements. *United States—Measures Affecting The Cross-Border Supply Of Gambling And Betting Services*, WT/DS285/ARB (Dec. 21, 2007) (permitting Antigua to suspend copyright provisions of TRIPS as retaliation against the United States who was previously determined to violate a different WTO agreement—the General Agreement on Trade in Services—and had failed to comply with a prior WTO panel decision). Agreements under the WTO that are enforceable via the DSU are considered the most effective means of enforcing international law. See, e.g., Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 276–77 (1997); Laurence Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 22 (2004).

<sup>46</sup> See, e.g., TRIPS, *supra* note 7, art. 27(1).

<sup>47</sup> Patents on living matter, methods of treatment and immoral inventions, may be excluded. *Id.* art. 27(2)-(3).

<sup>48</sup> *Id.* art. 27(1).

<sup>49</sup> *Id.* art. 28. However, TRIPS is unclear about whether the right to exclude others from importation includes exports of products first sold under patent in another country; in other words, does a nation consider patent rights to be internationally exhausted by the first legitimate sale by the patentee anywhere in the world? *Id.* art. 6 (stating that the question of exhaustion of rights is not the subject of disputes).



exceptions” and another for compulsory licenses.<sup>50</sup> The compulsory license provision essentially provides a long list of procedural requirements that must be satisfied for a TRIPS-compliant license.<sup>51</sup>

## 2. Impact on Public Health

Whether TRIPS provisions improve or limit access to medicine is an important question. Proponents of TRIPS argue that increasing patent protection is necessary to promote innovation,<sup>52</sup> that it will also improve the industrial development of countries generally, and that it will increase foreign direct investment because companies desire strong legal protection for

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<sup>50</sup> *Id.* art. 30 (providing for limited exceptions to patent rights); *id.* art. 31 (providing for exceptions other than those provided under Article 30); *see also* CHRISTOPHER GARRISON, EXCEPTIONS TO PATENT RIGHTS IN DEVELOPING COUNTRIES, 19-41 (UNCTAD/ICSTD 2006), available at <http://www.iprsonline.org/resources/docs/Garrison%20-%20Patent%20Exceptions%20DC%20-%20Blue%2017.pdf> (providing analysis of TRIPS Article 30).

<sup>51</sup> *See* TRIPS, *supra* note 7, art. 31.

<sup>52</sup> *See, e.g.*, Negotiating Group of Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Meeting of 24 March 1987, ¶ 4, MTN.GNG/NG11/1 (noting that greater protection of intellectual property rights was necessary to provide incentives to innovate); CORREA 2007, *supra* note 29, at 91 (noting that proponents of TRIPS emphasized the importance of promoting intellectual property rights to incentivize innovation); EDWIN MANSFIELD, PROTECTION OF INTELLECTUAL PROPERTY RIGHTS IN DEVELOPING COUNTRIES 26 (World Bank 1989); Martin Adelman & Sonia Baldia, *Prospects and Limits Of The Patent Provision In The TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT'L L. 507, 517, 530 (1996) (suggesting that patent provisions of TRIPS will spur India to innovation). However, because discovery of new drugs is resource-intensive, simply increasing the strength of patent protection is unlikely to promote domestic innovation in developing companies. *See, e.g.*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 22 (2002), available at [http://www.iprcommission.org/papers/pdfs/final\\_report/CIPRfullfinal.pdf](http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf) (noting that until a country has relatively high levels of per capita income, strengthening of IP laws does not spur economic development). In addition, there is doubt as to whether increasing the strength of patent protection globally will lead to increased global innovation, or simply increase costs. *See, e.g.*, WORLD HEALTH ORGANIZATION AND WORLD TRADE ORGANIZATION, WTO AGREEMENTS AND PUBLIC HEALTH: A JOINT STUDY BY THE WHO AND THE WTO SECRETARIAT 91 (2002), available at [http://www.wto.org/english/res\\_e/booksp\\_e/who\\_wto\\_e.pdf](http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf); Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement*, 23 WORLD ECONOMY 733 *passim* (2000) (evaluating implication of changes to Indian patent laws as a result of TRIPS and concluding that prices will increase).

their inventions.<sup>53</sup> Opponents of TRIPS, on the other hand, suggest that requiring patents worldwide will unduly increase the costs of drugs in developing nations and inherently compromise current access to necessary medication because patented drugs are typically priced at a premium.<sup>54</sup>

Of relevance to the current controversy over compulsory licenses is that no consensus was ever achieved during the negotiation of TRIPS concerning the desirability of increased patent protection or the precise scope of protection—indeed TRIPS is formulated as a “minimum standards” agreement for which many required standards are not defined in the agreement.<sup>55</sup> In addition, the conclusion of TRIPS does not represent an agreement whose provisions were in the interest of all signing countries; rather, developing countries agreed to TRIPS in part to obtain greater access to markets for goods and services through the

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<sup>53</sup> 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 argument that increased intellectual property protection may increase economic development, while simultaneously critiquing its lack of empirical basis); Michelle McGrath, *The Patent Provisions in TRIPS: Protecting Reasonable Remuneration for Services Rendered—Or the Latest Development in Western Colonialism?*, 7 EUR. INTELL. PROP. REP. 398, 400 (1996).

<sup>54</sup> See Carlos A. Primo Braga, *Trade-Related Intellectual Property Issues, the Uruguay Round Agreement and its Economic Implications*, in URUGUAY ROUND AND THE DEVELOPING COUNTRIES 341, 364-65 (Martin & Winter eds. 1996); Jean O. Lanjou, *The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering?* 6-10 (Nat'l Bureau of Econ. Research Working Paper No. 775, 1997); see also Watal, *supra* note 52, at 747 (evaluating policy options for India to minimize welfare losses in light of heightened patent requirements under TRIPS). Developing countries also questioned whether intellectual property issues should even be discussed within the context of the GATT/WTO framework. See, e.g., J.H. Reichmann, *Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection*, 22 VAND. J. TRANSNAT'L L. 747, 765 (1989).

<sup>55</sup> See TRIPS, *supra* note 7, art. 1(1) (providing that members may provide more protection); *id.* art. 27 (providing that patents must be granted for “inventions,” without defining what constitutes invention). In fact, prior to the inclusion of intellectual property standards in TRIPS, developing countries had attempted to revise the Paris Convention to lower the standards of protection while developed countries attempted to increase standards. See, e.g., Abdulqawi Yusuf, *TRIPS: Background, Principles and General Provisions*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 5 (Correa & Yusuf 2nd ed., Kluwer Law Int'l 2008); see also Reichmann, *supra* note 54, at 817 (providing details of what developing countries hoped to modify in Paris Convention that helped to move intellectual property from the arena of WIPO to the WTO).

related WTO agreement.<sup>56</sup> Developing countries may have believed that TRIPS would permit adequate flexibility for domestic priorities based upon language within TRIPS addressing the importance of social policy goals beyond promoting patent rights as well as the inclusion of exceptions to both patentability and patent rights.<sup>57</sup> For example, as discussed in the next section, developing countries rejected language that would have constrained the use of compulsory licenses to a narrow set of situations. However, since TRIPS was concluded, WTO panels have interpreted exceptions narrowly in formal dispute resolutions.<sup>58</sup> In addition, countries such as Thailand face pressure in defending whether they are within existing exceptions to TRIPS outside of the formal WTO process.<sup>59</sup>

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<sup>56</sup> See, e.g., Monique Cordray, *Gatt vs WIPO?*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 121, 137-41 (1994) (describing effective strategy of moving intellectual property discussions to the WTO in comparison to the failed attempts to revise the Paris Convention because of disagreements over compulsory licenses of patents); 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 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) (arguing that TRIPS is analogous to a contract of adhesion of which developing countries had little choice to accept); Arie Reich, *The WTO As a Law-Harmonizing Institution*, 25 U. PA. J. INT'L ECON. L. 321, 362 (noting that the WTO negotiations succeeded where prior WIPO negotiations failed because TRIPS was presented as a package deal to which countries could not resist if they wanted access to global markets).

<sup>57</sup> See, e.g., CORREA 2007, *supra* note 29, at 102-03; Denis Borges Barbosa et al., *Slouching Towards Development in International Intellectual Property*, 2007 MICH. ST. L. REV. 71, 110 (2007). Another impetus for developing countries to agree to the TRIPS provisions was a belief that they would no longer be subject to unilateral pressure and economic sanctions by wealthier countries demanding increased protection of intellectual property. See, e.g., CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES 11 (2000); Barbosa et al., *supra* note 57, at 124; Reichmann, *supra* note 54, at 885.

<sup>58</sup> See, e.g. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada—Pharmaceutical Patents*]; Appellate Body Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/D550/AB/R (Dec. 19, 1997); Barbosa et al., *supra* note 57, at 112-13; Robert Howse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*, 3 J. W. INTELL. PROP. 493, 496-98 (2000).

<sup>59</sup> See *infra* note 363-390 and accompanying text (discussing retaliation by drug companies and countries against Thailand).

### III. Compulsory Licenses Under TRIPS

The pertinent inquiry for a TRIPS analysis should focus not on the question of whether compulsory licenses might impede innovation in the abstract, but on whether the licenses are permissible under TRIPS. In other words, the relevant inquiry is what TRIPS requires, as opposed to what patent owners desire. Accordingly, this Part focuses on analyzing the existing and appropriate legal framework of permissible compulsory licenses under TRIPS.

This Part explains the appropriate method for TRIPS interpretation and provides a detailed analysis of individual requirements of TRIPS Article 31—the pertinent provision governing compulsory licensing. Although there are a dozen individual requirements to this provision, this Part will focus on the most controversial points relevant to the Thai licensing controversy. In particular, this Part will begin with what subject matter may be subject to compulsory licensing under TRIPS, followed by what it means to grant a license on “individual merits,” as well as the scope of the prior negotiation requirement (including important exceptions to the requirement). In addition, this Part will discuss certain procedural requirements to compulsory licenses that are commonly misunderstood, such as what constitutes “adequate remuneration.”

#### A. *Interpretative Framework for TRIPS*

To assess whether Thailand is in compliance with the TRIPS rules for compulsory licensing, it is first important to consider the proper interpretative framework for TRIPS. If a formal dispute was brought against Thailand, the WTO's Dispute Settlement Rules would apply, which require that customary rules of interpretation of public international law be used to interpret all WTO agreements, including TRIPS.<sup>60</sup> The customary rules, in turn, apply the Vienna Conventions' rules of interpretation, which give primary weight to the text of a treaty, but also require that the “ordinary meaning” of the treaty text be interpreted in its

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<sup>60</sup> DSU, *supra* note 45, art. 3.2; *see also* Panel Report, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*, ¶ 7.23, WT/DS79/R (Aug. 24, 1998) (using customary rules of interpretation); Panel Report, *United States—Anti-Dumping Measures*, ¶ 7.27, WT/DS184/R (Feb. 28, 2001).

appropriate “context,” as well as in light of the treaty’s “object and purpose.”<sup>61</sup> The appropriate context includes the treaty preamble and annexes,<sup>62</sup> as well as subsequent agreements between all the parties of the treaty.<sup>63</sup> Unlike interpretation of U.S. statutes, drafting history is not normally part of the initial context to be consulted. Rather, such supplementary material may only be used to confirm a meaning derived from the standard procedure, or to provide meaning when the standard procedure results in an ambiguous meaning or an unreasonable result.<sup>64</sup>

Before addressing the specific elements of Article 31, clarification is needed about the appropriate “context” against which Article 31 should be interpreted. Since the Vienna Convention expressly considers the treaty preamble to be part of the context, this is a useful starting point. The preamble places the intellectual property requirements of TRIPS against the backdrop of reducing distortions to world trade.<sup>65</sup> In addition, the preamble

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<sup>61</sup> Vienna Convention on the Law of Treaties, art. 31(1), Mar. 21, 1986, 1155 U.N.T.S. 331, 8 I.L.M. 679 [hereinafter Vienna Convention] (stating that “[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose”). Although all seem to agree that this is the appropriate interpretive framework, a number of scholars have suggested that in practice, the WTO dispute settlement panels have often emphasized literal text and given inadequate weight to the broader context. *See, e.g.*, Barbosa et al., *supra* note 57, at 101-02; Susy Frankel, *WTO Application of the Customary Rules of Interpretation of Public International Law to Intellectual Property*, 46 VA. J. INT’L L. 365, 385 (2005-06); Howse, *supra* note 58, at 496-501.

<sup>62</sup> Vienna Convention, *supra* note 61, art. 31(2).

<sup>63</sup> *Id.* art. 31(3); *see also* Canada—Pharmaceutical Patents, *supra* note 58, ¶ 7.14 (noting that the appropriate interpretive framework for TRIPS includes not only the TRIPS agreement, but also any agreement between the parties according to the Vienna Convention art. 31.2).

<sup>64</sup> Vienna Convention, *supra* note 61, art. 32. However, some scholars have argued for broader interpretations of TRIPS that would require interpretation of a disputed provision in the context of the entire body of relevant international law. *See* Barbosa et al., *supra* note 57, at 102-03; *see also* Gabrielle Marceau, *A Call for Coherence in International Law: Praises for the Prohibition against Clinical Isolation in WTO Dispute Settlement*, 33 J. WORLD TRADE 87 *passim* (1999). Moreover, some scholars have specifically suggested that an “evolutive interpretive” approach that considers the changing context and a “vectorial” approach that acknowledges and balances competing issues be simultaneously applied. Barbosa et al., *supra* note 57, at 104-13.

<sup>65</sup> TRIPS, *supra* note 7, pmb. (“[r]ecognizing the underlying public policy objectives of national systems for the protection of intellectual property, including development and technological objectives”).

specifically notes the importance of recognizing domestic public policy objectives that include development.<sup>66</sup> The notion of a balance between producers and users of intellectual property rights is further discussed under Article 7, labeled “Objectives,” which states that intellectual property rights should be enforced “in a manner conducive to social and economic welfare, and to a balance of rights and obligations.”<sup>67</sup> The type of public policy objective that should be recognized is further clarified in Article 8, labeled “Principles,” which states that in formulating TRIPS-consistent provisions, members may adopt “measures necessary to protect public health and nutrition.”<sup>68</sup> While Articles 7 and 8 seem to clearly suggest some type of balance,<sup>69</sup> the manner in which that balance is to be achieved in any given case is less clear; thus far, WTO panels have not consistently considered Articles 7 and 8,<sup>70</sup> and the WTO Appellate Body has suggested that appropriate interpretation and application of these provisions has not yet occurred.<sup>71</sup> Some scholars suggest that because there are multiple objectives inherent in TRIPS, disputes over the appropriate interpretation of open-ended TRIPS provisions should give deference to national law when there is no clear international norm

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<sup>66</sup> *Id.*; see also Maggie Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2836-49 (2006).

<sup>67</sup> TRIPS, *supra* note 7, art. 7.

<sup>68</sup> *Id.* art. 8.

<sup>69</sup> See, e.g., CORREA 2007, *supra* note 29, at 102 (noting that although a WTO panel has stated that Articles 7 and 8 are important, it failed to elaborate on the specifics). On the other hand, some have tried to assert that these provisions are simply hortatory and of no value. See, e.g., *id.* at 93.

<sup>70</sup> See also Ruth L. Okediji, *Public Welfare and the Role of the WTO: Reconsidering the TRIPS Agreement*, 17 EMORY INT'L L. REV. 819, 914 (2003) (stating the WTO panels and Appellate Body have not yet properly applied the preambular statements, as well as Articles 7 and 8). Compare *Canada—Pharmaceutical Patents*, *supra* note 58, at 51-52 (suggesting that the preamble and Article 7 of TRIPS were not appropriate contextual guidance regarding the TRIPS article in dispute) with Panel Report, *United States—Section 110(5) of the U.S. Copyright Act*, ¶ 6.43, n. 49, WT/DS160/R (June 15, 2000) (suggesting that TRIPS must be read as a whole).

<sup>71</sup> At this point, there is no definitive interpretation from WTO case law. While a panel mentioned these provisions in *Canada—Patent Protection of Pharmaceutical Products*, the WTO Appellate Body has since suggested that “those articles still await appropriate interpretation.” Appellate Body Report, *Canada—Term of Patent Protection*, ¶ 101, WT/DS170/AB/R (Sept. 18, 2000).

since TRIPS only provides minimum standards.<sup>72</sup>

An important question is whether the 2001 Doha Public Health Declaration (Declaration),<sup>73</sup> which explicitly discusses compulsory licenses, constitutes a subsequent agreement between the parties that may be considered as part of the appropriate context in interpreting TRIPS Article 31.<sup>74</sup> If pertinent, the Declaration provides important clarification that individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency” with regard to compulsory licenses.<sup>75</sup> Some argue that the Declaration is a mere political statement of no interpretive weight.<sup>76</sup> On the

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<sup>72</sup> Barbosa et al., *supra* note 57, at 109-12 (arguing that because Articles 7 and 8 reflect opposing interests, a proper interpretation according to these articles should not exclude any single approach); Frankel, *supra* note 61, at 393-94 (noting that for open-ended terms regarding opposing interests, deference should be given to a disputed national law in the absence of an international norm, consistent with Article 31 of the Vienna Convention).

<sup>73</sup> Doha Public Health Declaration, *supra* note 31.

<sup>74</sup> The Declaration specifically addressed the tension between patents and public health, including the scope of compulsory licenses. For example, the Declaration stated that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” *Id.* ¶ 4.

<sup>75</sup> *Id.* ¶ 5(c); see also *infra* notes 126-132 and accompanying text (providing further analysis of this phrase).

<sup>76</sup> See U.S. GEN. ACCOUNTING OFFICE, INTELLECTUAL PROPERTY—U.S. TRADE POLICY GUIDANCE ON WTO DECLARATION ON ACCESS TO MEDICINES MAY NEED CLARIFICATION 3 (GAO 2007) (noting that the United States considers the Doha Declaration to be a political statement that does not modify TRIPS); Press Release, Pharmaceutical Research and Mfrs. of America, WTO Doha Declaration Reaffirms Value of Intellectual Property Protection (Nov. 14, 2001), available at <http://www.phrma.org/mediaroom/press/releases///14.11.2001.310.cfm> (stressing that the Declaration was a “political statement”); Press Release, U.S. Trade Representative, Zoellick Says World Has Chosen Path of Hope, Openness, Development and Growth (Nov. 14, 2001) available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2001/November/USTR\\_Zoellick\\_Says\\_World\\_Has\\_Chosen\\_Path\\_of\\_Hope\\_Openness\\_Development\\_Growth.html](http://www.ustr.gov/Document_Library/Press_Releases/2001/November/USTR_Zoellick_Says_World_Has_Chosen_Path_of_Hope_Openness_Development_Growth.html) (referring to USTR remarks on Doha Public Health Declaration as a “political signal”). Even some who are sympathetic to the need to accommodate public health and TRIPS have characterized the Doha Public Health Declaration as a political statement. See, e.g., Walden Bello, *Learning from Doha*, Dec. 7-9, 2001, <http://www.focusweb.org/publications/2001/learning-from-doha.html> (suggesting that the importance of the Declaration should not be exaggerated in light of the fact that some statements are merely political); James Love, Consumer Project on

other hand, scholars who have analyzed this issue generally conclude that the Declaration is, in fact, a subsequent agreement.<sup>77</sup>

There are a number of factors that support the Declaration's status as a subsequent agreement. First, the Declaration was issued after months of negotiations and several competing versions were proposed.<sup>78</sup> A number of scholars point to the fact that the Declaration was adopted in accordance with proper procedures as relevant to considering it a subsequent agreement of the parties.<sup>79</sup>

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Technology, *Views on the Draft Declaration on the TRIPS Agreement and Public Health*, Nov. 13, 2001, <http://www.focusweb.org/publications/2001/views-on-draft-declaration-on-trips-and-health.html> (referring to Declaration as a "political statement that did not modify in any way the TRIPS agreement").

<sup>77</sup> See, e.g., CARLOS CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON TRIPS AGREEMENT AND PUBLIC HEALTH 45 (WHO 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); Barbosa et al., *supra* note 57, at 131-32 (viewing the Doha Public Health Declaration as not only a subsequent agreement, but one that establishes the right to health as an important right not to be trumped by provisions of TRIPS in a call for a broader interpretation of evolving international norms); Steve Charnovitz, *The Legal Status of the Doha Declarations*, 5 J. INT'L ECON. L. 207, 211 (2002) (evaluating both the Public Health Declaration, as well as the Ministerial Declaration and concluding that while their legal category is ambiguous, they could be considered subsequent agreements by the parties); Frankel, *supra* note 61, at 400-01 (using the Doha Health Declaration as an example of a subsequent agreement between the parties, although also stating that the Declaration does not necessarily provide more clarity to rules that were already clear); Carmen Otero Garcia-Castrillon, *An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health*, 5 J. INT'L ECON. L., 212, 212 (2002) (noting that the Declaration constitutes a supplementary means of interpretation); James 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) (evaluating three possible legal categories of the Doha Public Health Declaration and concluding that at a minimum the Declaration should constitute persuasive soft law and at its maximum as a subsequent agreement of the parties that has the same status as TRIPS itself).

<sup>78</sup> See, e.g., Proposal from a Group of Developing Countries, *Draft Ministerial Declaration on the TRIPS Agreement and Public Health*, IP/C/W/312 (Oct. 4, 2001), [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/mindecdraft\\_w312\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/mindecdraft_w312_e.htm); Council for Trade-Related Aspects of Intellectual Property Rights, *Preambular Language for Ministerial Declaration*, IP/C/W/313 (Oct. 4, 2001); Press Release, World Trade Org., TRIPS Council Meeting on Access to Medicine (June 22, 2001), available at [http://www.wto.org/English/news\\_e/pres01\\_e/pr233\\_e.htm](http://www.wto.org/English/news_e/pres01_e/pr233_e.htm).

<sup>79</sup> See, e.g., CORREA, *supra* note 77, at 24-25 (suggesting that because member states adopted the Declaration based on their competence to interpret a WTO agreement, it is immune from challenge); Gathii, *supra* note 77, at 300-01 (noting that the Declaration emerged from appropriate and established practice of decision-making by



In addition, the TRIPS Council, an official organ of the WTO system, has taken action in accord with the Declaration. For example, the TRIPS Council has acted in accordance with paragraph seven of the Declaration that requests extending the compliance period for least-developed countries until January 1, 2016 for full protection of pharmaceutical products.<sup>80</sup> Similarly, the TRIPS Council has also answered the instruction in paragraph six of the Declaration to find an “expeditious solution” to the problem of WTO members with inadequate manufacturing capacities, such that they cannot adequately utilize compulsory licenses under TRIPS.<sup>81</sup> In fact, the directive in paragraph six of the Declaration has led to a formal amendment proposed by the TRIPS Council in 2005 that is currently pending approval by WTO member states.<sup>82</sup> For all these reasons, the Declaration seems to be a subsequent agreement that provides appropriate context for interpreting Article 31. The remainder of this article uses the Declaration as an appropriate subsequent agreement to confirm the meaning of Article 31.<sup>83</sup>

#### *B. Article 31 Overview*

This section provides an overview of the entirety of Article 31 to give appropriate analytic context for interpretation of specific provisions of Article 31.<sup>84</sup> As noted earlier, customary rules of interpretation of international law require examining the ordinary meaning of the treaty text in light of the appropriate context.<sup>85</sup> While context extends beyond Article 31 to include the entirety of TRIPS, it also includes the entirety of the Article 31 provision.<sup>86</sup>

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consensus).

<sup>80</sup> *Extension of the Transition Period*, *supra* note 14; *see also* Press Release, World Trade Org., Council Approved LCD Decision with an Additional Waiver (June 28, 2002), available at [http://www.wto.org/english/news\\_e/pres02\\_e/pr301\\_e.htm](http://www.wto.org/english/news_e/pres02_e/pr301_e.htm).

<sup>81</sup> *See* 2003 General Council Decision, *supra* note 31; Doha Public Health Declaration, *supra* note 31, ¶ 6.

<sup>82</sup> *See* 2003 General Council Decision, *supra* note 31.

<sup>83</sup> Even for those who dispute the legal status of the Declaration, it should be noted that the Declaration is used simply to support interpretation of the actual treaty language and not relied upon as the sole source.

<sup>84</sup> TRIPS, *supra* note 7, art. 31.

<sup>85</sup> Vienna Convention, *supra* note 61, art. 31(1).

<sup>86</sup> TRIPS, *supra* note 7.

Accordingly, before attempting to analyze individual aspects of Article 31, a review of the full text of Article 31 is pertinent. Article 31 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 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, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(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;

LeighAnne Thompson 2/10/09 11:02 PM

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LeighAnne Thompson 2/11/09 12:32 AM

**Comment:** Again, should there be a space?

(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 . . . ;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply . . . <sup>87</sup>

Before addressing individual aspects of Article 31, a few points may be helpful. First, the many provisions of Article 31 only apply where a member state permits a patent to be used without authorization from the patent owner; in other words,

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<sup>87</sup> *Id.* art. 31.

Article 31 does not require nations to impose compulsory licenses, but does impose a number of requirements—noted in provisions (a)-(l)—if a nation's laws permit such licenses. Second, the preamble explicitly indicates that this provision applies to use by either the government or a third party authorized by the government.<sup>88</sup> Therefore, TRIPS permits nations to issue compulsory licenses not only for governmental manufacture of patented inventions, but also for a government authorized third party.<sup>89</sup> None of the provisions (a)-(l) further discuss what type of third party the government may authorize, thus suggesting that the government is free to license to any party.

The bulk of Article 31 relates to procedural requirements nations must follow to grant TRIPS-compliant compulsory licenses.<sup>90</sup> Some provisions are likely to be non-issues in most cases, including the Thai situation. For example, one requirement is a compulsory license be non-exclusive, meaning the government-imposed license does not prevent the patent owner from licensing other entities; each of the compulsory licenses issued by Thailand, while controversial on other grounds, were provided on a non-exclusive basis.<sup>91</sup> Similarly, the requirement that the license be non-assignable is probably a non-issue in most cases<sup>92</sup> because the licensed entity was selected to manufacture a generic version of the patented drug.<sup>93</sup> In addition, the requirement that patent owners be able to challenge compulsory licenses is not an issue with the Thai licenses because national law explicitly provides for such challenge.<sup>94</sup> Moreover, the requirement that the compulsory license be authorized “predominantly for supply of the domestic market” is a non-issue in Thailand's case since the licenses are to supply the Thai domestic market,<sup>95</sup> although it is a key issue for least-developed

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<sup>88</sup> *Id.*

<sup>89</sup> *See id.*

<sup>90</sup> *See id.*

<sup>91</sup> *See* TRIPS, *supra* note 7, art. 31(d)-(e).

<sup>92</sup> *See id.* art. 31(e).

<sup>93</sup> For example, in the case of Thailand, each of the licenses is to the Government Pharmaceutical Organization. *See, e.g., infra* note 201.

<sup>94</sup> *See* TRIPS, *supra* note 7, art. 31(g), (i), (j); Thai Patent Act B.E. 2322 § 50.

<sup>95</sup> TRIPS, *supra* note 7, art. 31(f). If a substantial number of the drugs properly made under compulsory license in Thailand were exported to other countries, there could

countries without the capacity to manufacture their own generic versions of patented products.<sup>96</sup> Other Article 31 requirements are not relevant for every compulsory license. For example, some provisions relate to specific situations, such as semi-conductor technology, compulsory licenses as penalty for anti-competitive acts, and use of a second patent.<sup>97</sup> None of these specific situations are pertinent to the Thai licenses.

The following sections categorize the many requirements of Article 31 into a logical order for analyzing the Thai licenses. The next section addresses what subject matter may be appropriate for a compulsory license because this is a frequent point of confusion. Then, it explains Article 31 requirements for how licenses are issued, including whether prior negotiation with the patent owner is required. After clarifying the fundamentals of how a license may be initiated, additional requirements such as requisite remuneration and the duration of the license are discussed.

### *C. Permissible Subject Matter*

The ordinary meaning of Article 31, the provision on compulsory licensing, is the starting place for an analysis of what may be subject to such a license.<sup>98</sup> While this provision is quite lengthy, having over a dozen sub-parts, there is no specific provision that limits the scope of inventions that may be subject to licensing.<sup>99</sup> There is a single provision within this article that discusses the subject matter of licenses; however, subject matter is only mentioned with respect to an additional requirement that must be imposed only for licenses issued to remedy anti-competitive action, or licenses on semi-conductor technology and

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be a violation of this provision since the goods would no longer be predominantly for domestic use. However, to date, this is simply a hypothetical. Nonetheless, it is a significant concern for major drug companies since there is language concerning re-importation in the waiver of compulsory license rules for countries without adequate manufacturing capacities. See 2003 General Council Decision, *supra* note 31, ¶ 4 (noting that importing members must take “reasonable measures . . . to prevent re-exportation”).

<sup>96</sup> See 2003 General Council Decision, *supra* note 31; see also Abbott & Reichmann, *supra* note 31.

<sup>97</sup> TRIPS, *supra* note 7, art. 31(c), (k), (l).

<sup>98</sup> See *id.* art. 31.

<sup>99</sup> See *id.*

dependent patents.<sup>100</sup> Importantly, the segregation of these separate areas suggests that there is no general restriction on what subject matter may be licensed.<sup>101</sup>

The negotiating history of this provision similarly confirms an interpretation of Article 31 that does not impose any subject matter restriction.<sup>102</sup> In particular, an earlier version contained an enumerated list of permissible subject matter that could be subject to licensing.<sup>103</sup> These limitations disappeared in the next draft of the provision.<sup>104</sup> Accordingly, subject matter limitations were

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<sup>100</sup> See *id.* art 31(c).

<sup>101</sup> JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 321 (2001). In addition, the limitations on the licensing of semiconductor technology were previously proposed by the United States to apply to all compulsory licenses. *Id.*

<sup>102</sup> One question raised by a minority of scholars is whether there is anything in the requirements of the Paris Convention, a global treaty regarding some patent rules, that would restrict the scope of subject matter that may be subject to compulsory licensing. See Richard Rozek & Renee Rainey, *Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy*, 4 J. WORLD INTELL. PROP. 463, 468 (2001). Pursuant to TRIPS Article 2, TRIPS does incorporate certain requirements of the Paris Convention, but that agreement has only limited discussion of compulsory licenses. The Paris Convention provides that all members "shall have the right" to provide for compulsory licenses "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent." Paris Convention for the Protection of Industrial Property, art. 5A(2), July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305. However, the Paris Convention neither limits licenses to abuses, nor provides an exhaustive list of what constitutes abuse.

<sup>103</sup> In contrast to the current Article 31, the 1990 draft stated that "compulsory license may only be granted for the following purposes." GERVAIS, *supra* note 29, at 248. In particular, the six permissible subjects suggested as appropriate to compulsory licenses include a remedy of an adjudicated competition law, to address a national emergency, national security or critical peril of life, overriding public interest or the possibility of exploitation by the government or third parties, dependent patent, or failure to work an invention. *Id.* at 246-47.

<sup>104</sup> The final version of Article 31 is notably different from prior U.S. proposals that attempted to restrict compulsory licenses solely to adjudicated violation of competition laws or to address a declared national emergency. See Draft Agreement on the Trade Related Aspects of Intellectual Property Rights, Communication from the United States, GATT Doc. No. MTN.GNG/NG11/W/70, at 11, art. 27 (May 11, 1990) [hereinafter Communication from the United States] (proposing that members utilize compulsory licenses "only to remedy an adjudicated violation of competition laws, or to address, only during its existence, a declared emergency"). The United States attempted to limit compulsory licenses, which it disfavored, from government use for which it wanted wide discretion in subject matter. WATAL, *supra* note 101, at 320. The United States negotiating position was intended to ensure that TRIPS would not require any

previously considered and rejected in the final version of TRIPS Article 31. The Doha Public Health Declaration, made subsequent to the conclusion of TRIPS, confirms that Article 31 does not impose any subject matter restriction.<sup>105</sup> In particular, the Declaration clearly states that “[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted.”<sup>106</sup>

#### *D. Individual Merits*

A proper interpretation of this requirement begins with the words of Article 31 itself—that the authorization of a compulsory license be considered on its “individual merits.”<sup>107</sup> In particular, the question is the ordinary meaning of the term “individual merits” against the broader context of TRIPS. “Individual merits” suggest that a decision to grant a license should be decided based on the merits of an individual case, such as a specific patented drug, as opposed to an entire class of technologies.<sup>108</sup> The remainder of Article 31 supports the concept that each grant of a

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modification to existing United States law which enables the government—or those authorized by the government—to use any patent without authorization of the patent owner, subject only to subsequent suit for reasonable compensation. See 28 U.S.C. § 1498 (2000). During negotiations, the United States explicitly denied that its laws were limited to government defense; rather, it stated that its laws’ use was unlimited in subject matter. United States Review of Legislation in the Field of Patents, IP/Q3/USA/1, quest. 4 (May 1, 1998) (asserting that the U.S. provision was not limited to national security). After failing to persuade other members of any real distinction between government use and compulsory licenses, both were combined in one text that provides no subject matter restrictions. Committee on Trade and Environment, WT/CTE/W/8, ¶ 92 (June 8, 1995); WATAL, *supra* note 101, at 320-21.

<sup>105</sup> See Doha Public Health Declaration, *supra* note 28, ¶ 5(b).

<sup>106</sup> *Id.* Indeed, part of the impetus for negotiating the Declaration was that some developing countries were concerned that anticipated compulsory licenses would be considered in contravention of TRIPS. Council for Trade-Related Aspects of Intellectual Property Rights, Submission on TRIPS and Public Health by the African Group, IP/C/W/296 (June 29, 2001).

<sup>107</sup> TRIPS, *supra* note 7, art. 31(a).

<sup>108</sup> See, e.g., CORREA 2007, *supra* note 29, at 320 (noting that license cannot be granted by subject matter or title-holder because of the requirement for individual consideration); GERVAIS, *supra* note 29, at 165 (noting that a compulsory license cannot cover an entire category of inventions); UNCTAD/ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 468 (2005) [hereinafter RESOURCE BOOK ON TRIPS] (noting that governments should review each application and avoid “blanket authorizations” for entire technologies or enterprises).

compulsory license should be evaluated separately.<sup>109</sup> In particular, considering each license separately would make other procedural requirements of Article 31 make sense in terms of enabling legal challenges to a specific license, as well as challenging the amount of remuneration granted for a given license.

This interpretation is confirmed by examining the negotiating history. In particular, India proposed that certain types of subject matter viewed as especially important to developing countries, such as patents relating to food and drugs, be automatically granted a license without the need for individual review.<sup>110</sup> However, this proposal was not adopted.<sup>111</sup> Instead Article 31 requires that each patent be considered separately for compulsory licensing.<sup>112</sup>

#### *E. Prior Negotiation*

A nation usually must engage in prior negotiation with a patent owner prior to the issuance of a compulsory license.<sup>113</sup> There are in fact two distinct but related requirements because while TRIPS typically requires prior negotiation with the patent owner, it explicitly permits waiver of this requirement in some situations.<sup>114</sup> This section first explains the default rule of prior negotiation and then the situations that permit waiver of the general rule.

##### *1. General Rule*

Article 31 states that a compulsory license “may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable

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<sup>109</sup> TRIPS, *supra* note 7, art. 31(a).

<sup>110</sup> Standards and Principles Concerning the Availability Scope and Use of Trade-Related Intellectual Property Rights, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Communication from India, MTN.GNG/NG11/W/37, ¶ 15 (July 10, 1989) [hereinafter Communication from India] (proposing licenses of right for food, pharmaceuticals, and chemicals separate from individualized review of compulsory licenses, with no opportunity for administrative or judicial review).

<sup>111</sup> See TRIPS, *supra* note 7, art. 31.

<sup>112</sup> *Id.* art. 31(a).

<sup>113</sup> *Id.* art. 31(b).

<sup>114</sup> *Id.*



commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”<sup>115</sup> In other words, the general rule is that there must be prior negotiation with the patent owner in an attempt to secure a voluntary license before the government imposes a compulsory license.

There are some important interpretive questions concerning the scope of prior negotiations because key terms are undefined. In particular, while it is clear that prior negotiation requires an attempt to negotiate a voluntary license, TRIPS provides no guidance on what would constitute “reasonable commercial terms and conditions,” or a “reasonable period of time” to negotiate.<sup>116</sup> The ordinary meaning of the word “reasonable” suggests that it depends on the facts of each case and that in emergencies, less time is necessary to negotiate. However, the length of time that is reasonable is still undefined.<sup>117</sup> Furthermore, the requirements of this provision may be viewed differently by patent owners than by countries interested in compulsory licenses. For example, a patent owner may only consider terms similar to existing pricing agreements to be “reasonable.” However, even then, there are questions regarding whether what constitutes “reasonable” should be compared to all prices offered by a drug company, or the lowest possible global price, or some other criteria.

## 2. *Waiver of Prior Negotiation Requirement*

TRIPS, however, provides an important exception to the general rule. The subsequent sentence states that “[t]his requirement [of prior negotiation] 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.”<sup>118</sup> In other words, prior negotiation with the patent owner is not required by TRIPS in three situations—a national emergency, a “circumstance of extreme urgency,” or public non-commercial use.<sup>119</sup> Any of these three situations permits waiver of negotiations

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<sup>115</sup> *Id.*

<sup>116</sup> *Id.*

<sup>117</sup> See TRIPS, *supra* note 7, art. 31(b).

<sup>118</sup> *Id.* (emphasis added).

<sup>119</sup> *Id.* When prior negotiations are waived, however, the patent owner must be notified “as soon as reasonably practicable.” *Id.*

with the patent owner, contrary to often-cited statements in the media.<sup>120</sup>

*a. National Emergency or Extreme Urgency*

What constitutes a national emergency that would permit waiver of the prior negotiation requirement? TRIPS does not define national emergency or situation of extreme urgency.<sup>121</sup> However, in this context, the emergency could suggest the need for an abbreviated response where there is no time for negotiations with the patent holder.

Another important issue is who assesses whether a national emergency exists. There is nothing in TRIPS Article 31 to suggest that anyone other than the country considering a compulsory license should evaluate what constitutes a national emergency.<sup>122</sup> For example, nothing in the provision suggests that a member state must seek permission from the WTO or any other authority to determine whether a national emergency exists.<sup>123</sup> In the absence of an explicit requirement, it seems appropriate that a member state has authority to determine what constitutes a national emergency; after all, this has been the accepted practice for other TRIPS requirements that are undefined.<sup>124</sup> Of course, as with any requirement, a nation's initial decision can be challenged within the WTO dispute settlement proceedings.<sup>125</sup>

The Doha Public Health Declaration, as a subsequent agreement of the parties, confirms that assessing whether a national emergency exists is solely within the discretion of each

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<sup>120</sup> See *infra* notes 241-250 and accompanying text (reporting confusion regarding permissible waiver of prior negotiation).

<sup>121</sup> See TRIPS, *supra* note 7, art. 31.

<sup>122</sup> *Id.*

<sup>123</sup> See generally *id.* (providing no requirement that member states seek outside determination of what constitutes a national emergency).

<sup>124</sup> For example, it is uniformly accepted that because TRIPS does not define what constitutes an "invention," nations have flexibility to use their own interpretations. See, e.g., CORREA 2007, *supra* note 29, at 317; see also Jerome H. Reichmann, *Securing Compliance with the TRIPS Agreement after US v. India*, 1 J. INT'L ECON. L. 585, 597 (1998) (stating that the U.S. v. India panel decision "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").

<sup>125</sup> DSU, *supra* note 45, art. 3(2).

nation.<sup>126</sup> The Declaration states, “each member has the right to determine what constitutes a national emergency or other circumstances of extreme emergency.”<sup>127</sup> Moreover, it states that “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstance of extreme urgency.”<sup>128</sup> In other words, member states agreed that certain public health crises *per se* qualify as a national emergency or situation of extreme urgency.<sup>129</sup>

There is a question concerning whether national emergencies should be limited solely to those conditions specified in the Declaration. While some countries urge this narrow interpretation, it is inconsistent with the plain meaning of the Declaration.<sup>130</sup> First, the noted conditions are listed in the same sentence that declares that member states have the right to determine what constitutes a national emergency.<sup>131</sup> Moreover, the sentence that indicates certain diseases can represent a national emergency has no words that limit national emergencies to this list; by using the words “can represent,” the list is inclusive.<sup>132</sup>

*b. Public Non-commercial Use*

A currently ambiguous basis for waiving prior negotiations with the patent owner before authorizing a compulsory license is for “public non-commercial use.”<sup>133</sup> TRIPS does not define the

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<sup>126</sup> Doha Public Health Declaration, *supra* note 31, ¶ 5(c).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *See id.*

<sup>130</sup> 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>; Brook K. Baker, *Doha Redux—U.S. Enters New Phase of Bad Faith Bargaining*, CPTECH.ORG, July 2, 2003, <http://www.cptech.org/ip/wto/p6/hgap07022003.htm>; CPTech, Oxfam, & Third World Network, *Deadlock over Scope of Diseases Threatens to Kill Solution*, CPTECH.ORG, Nov. 27, 2002, <http://www.cptech.org/ip/wto/p6/ngos11272002.html>; Chakravarthi Raghavan, *TRIPS Consultations on Implementing Doha Recessed*, THIRD WORLD NETWORK, Nov. 29, 2002, <http://www.twinside.org.sg/title/5246a.htm>.

<sup>131</sup> Doha Public Health Declaration, *supra* note 31, ¶ 5(c).

<sup>132</sup> *Id.*

<sup>133</sup> TRIPS, *supra* note 7, art. 31(b).

phrase.<sup>134</sup> In addition, public non-commercial use is not given further clarification in the Doha Public Health Declaration.<sup>135</sup>

What is the plain meaning of “public non-commercial use?”<sup>136</sup> The phrase does not have a standard meaning within patent law.<sup>137</sup> Within the context of official disputes argued within the WTO dispute settlement system, WTO panels and the Appellate Body typically consult the Oxford English Dictionary for plain language meanings of words in interpreting undefined terms of the WTO and related agreements, such as TRIPS.<sup>138</sup> Accordingly, it is reasonable to consider how this dictionary defines both “public” and “noncommercial use.” The word “public” is defined as “[o]f or pertaining to the people as a whole; that belongs to, affects, or concerns the community or nation; common, national, popular.”<sup>139</sup> This definition is sufficiently broad to cover nearly any use relating to a nation’s citizens. Next, the definition of non-commercial must be defined by considering what would not be “commercial.” Since the word “commercial” means that something pertains to business or profit, non-commercial would likely require that the use not be for business or profit.<sup>140</sup> However, this does not necessarily end the inquiry. For example, can a for-profit business be granted a license to make a drug that is

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<sup>134</sup> *See id.*

<sup>135</sup> *See* Doha Public Health Declaration, *supra* note 31 (providing no mention of public non-commercial use).

<sup>136</sup> TRIPS, *supra* note 7, art 31(b).

<sup>137</sup> E. Richard Gold & Daniel K. Lam, *Balancing Trade In Patents—Public Non-Commercial Use and Compulsory Licensing*, 6 J. WORLD INTELL. PROP. 5, 19 (2003) (noting that the term is not defined under either patent or trade law and suggesting that because many terms are “fundamentally political compromises,” ascertaining a consistent definition may be difficult).

<sup>138</sup> *See, e.g., United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/R I, ¶ 8.49 (Aug. 6, 2001) [hereinafter *United States—Section 211*] (citing New Shorter Oxford English Dictionary for definition of “subject matter”); *United States—Section 211*, *supra*, ¶ 8.96 (citing same for definition of “substantiate”); *Canada—Pharmaceutical Patents*, *supra* note 58, ¶ 7.30 (citing Oxford English Dictionary to define meaning of “limited”); *Canada—Pharmaceutical Patents*, *supra* note 58, ¶ 7.54 (citing Oxford English Dictionary for definition of “normal”); *Canada—Term of Patent Protection*, WT/DS170/R, ¶ 6.34 (May 5, 2000) (citing Oxford English Dictionary for meaning of the word “subject matter”).

<sup>139</sup> THE OXFORD ENGLISH DICTIONARY 778 (2d ed. 1989).

<sup>140</sup> *Id.* at 552 (defining commercial as “engaged in commerce; trading”).

then distributed to the public without a profit?<sup>141</sup> In fact, such a scenario was explicitly contemplated and intended to be covered under Article 31 by the United States; in particular, the United States wanted to ensure that it could continue to provide a *de facto* license to any government contractor (which included for-profit companies) to use any patented invention subject only to subsequent payment.<sup>142</sup> Some scholars assert that a compulsory license may be granted to a commercial party to use patents on behalf of the government, citing U.S. practice as an example.<sup>143</sup> The rationale is that the use is exclusively for the public, even if production is by an entity that may be privately owned.<sup>144</sup>

Another consideration in the evaluation of “public non-commercial use” is in connection with other terms that are not defined under TRIPS. In particular, there is general consensus that although TRIPS requires each nation to provide patents on the basis of TRIPS requirements such as novelty, nations are granted freedom to define these terms in light of the lack of definition in TRIPS.<sup>145</sup> Using this logic, the lack of a definition of “public non-commercial use” would seem to suggest that each nation may define the term, unless and until such definition is clarified in a WTO dispute settlement proceeding. Indeed, some go so far as to say that the phrase is a “flexible concept, leaving governments with considerable flexibility in granting compulsory licenses without requiring commercial negotiations in advance.”<sup>146</sup>

If public non-commercial use may be subject to definition by

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<sup>141</sup> WATAL, *supra* note 101, at 328; RESOURCE BOOK ON TRIPS, *supra* note 108, at 471.

<sup>142</sup> See *supra* note 104 (noting United States attempt to distinguish government authorized use of patents from compulsory licenses). One commentator suggests that the phrase “public non-commercial use” was coined to encompass the type of use that is permitted by the United States under section 1498. JACQUES GORLIN, AN ANALYSIS OF THE PHARMACEUTICAL RELATED PROVISIONS OF THE WTO-TRIPS INTELLECTUAL PROPERTY AGREEMENT 34 (1999).

<sup>143</sup> CORREA 2007, *supra* note 29, at 317.

<sup>144</sup> *Id.*

<sup>145</sup> See, e.g., *id.* (describing flexibility of term “invention,” as well as TRIPS criteria of patentability); see also Reichmann, *supra* note 124, at 597 (stating that the U.S. v. India panel decision “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”).

<sup>146</sup> RESOURCE BOOK ON TRIPS, *supra* note 108, at 471.

individual nations, that may potentially encompass a broad range of activity. On the other hand, this simply means that nations can determine when to waive prior negotiations with a patent owner before issuing a compulsory license and does not necessarily mean that the license is TRIPS compliant. Even if the prior negotiation requirement is waived for public non-commercial uses, the compulsory license must still comply with a number of additional procedural requirements to be consistent with TRIPS, as discussed in the next section.

#### *F. Procedural Requirements*

##### *1. Limited to Authorized Purpose*

Another important requirement under Article 31 is that the scope and duration of a compulsory license be limited “to the purpose for which it was authorized.”<sup>147</sup> Importantly, this provision does not state that the license must be limited;<sup>148</sup> rather, the license is to be limited to the *purpose for which it was authorized*.<sup>149</sup> While this statement may seem obvious, it bears repetition in light of the fact that some have suggested that compulsory licenses should be generally limited—a proposition that is not supported by a careful analysis of the text.<sup>150</sup>

An examination of the negotiating history will confirm that compulsory licenses are not to be limited as a general matter. An earlier draft stated that “parties shall minimi[z]e the grant of compulsory licenses in order not to impede adequate protection of patent rights” as a general qualification on all compulsory licenses.<sup>151</sup> However, this language does not appear in the current version of Article 31,<sup>152</sup> suggesting that this language was

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<sup>147</sup> *Id.* art 31(c).

<sup>148</sup> Notably, Article 31 does not state that compulsory license is a limited exception to patent rights, in contrast to Article 30. Compare TRIPS, *supra* note 7, art. 31 with TRIPS, *supra* note 7, art. 30.

<sup>149</sup> TRIPS, *supra* note 7, art. 31 (emphasis added).

<sup>150</sup> See *infra* notes 259-267 and accompanying text (noting that some suggest that compulsory licensing should be generally limited, or only permitted as a matter of “last resort”).

<sup>151</sup> See Status of Work in the Negotiating Group: Chairman's Report to the GNG, GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990).

<sup>152</sup> See TRIPS, *supra* note 7, art. 31.

considered and rejected in negotiations of the final text; at a minimum, the disappearance of this language from the final text supports a conclusion that the final text should not mean something that was proposed but not included. Accordingly, it seems that there should be no general presumption against compulsory licensing.

The important question thus becomes, when are licenses limited—in scope and duration—with regard to their authorized purpose? TRIPS does not state how to evaluate this issue or who should decide.<sup>153</sup> Should any scope that is rationally related to the purpose suffice? In addition, is a determination of appropriate scope solely within national discretion—subject, of course, to a challenge by another WTO member under the formal dispute settlement rules?

One possible reading is that the scope and duration of a license is limited to the authorized purpose so long as there are no modifications to the scope or duration of the license after the license is granted. In other words, if a license is issued initially on an HIV drug to treat AIDS for two years, a country cannot thereafter modify the license by either using the drug to treat other diseases or automatically extending the license beyond the initial terms. Similarly, if the initial license specifies that 5000 tablets of a patented drug may be made, the scope would be violated if a nation made twice that amount. Such a reading should be fairly easily satisfied or at least easy to assess since one could readily compare the license terms with subsequent actions.

An alternative reading would give more substantive meaning to this clause. In particular, requiring that the scope and duration of the license be “limited to the purpose for which it was authorized”<sup>154</sup> could suggest that an initial grant of a license is only proper if the scope and duration of the terms are limited to the purpose stated in the license. This requirement would allow a nation’s license to be challenged, for example, if the length of the license seemed to be longer than the purpose for which the license was authorized. Similarly, if a compulsory license was issued for a limited viral epidemic, such as the periodically threatened avian flu, a compulsory license might need to be limited in duration to

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<sup>153</sup> *See id.*

<sup>154</sup> *See id.*

the period necessary to contain the disease.

While the second reading may at first blush suggest greater scrutiny, even that reading provides substantial leeway to member states. Importantly, there is nothing in the clause suggesting that the license must use least restrictive means, or that the patent owner's rights be balanced, unlike other provisions in the WTO.<sup>155</sup> Similarly, the language states that the scope and duration is limited to the purpose for which it was authorized, but does not suggest that anyone other than the member state authorizing the compulsory license be permitted to second guess that authorization.<sup>156</sup> A WTO panel could theoretically impose such an interpretation based on its reading of TRIPS.<sup>157</sup> However, a plain reading of the clause does not suggest that the limitation should be evaluated based upon an objective criterion.<sup>158</sup> For example, the clause does not require that the license be limited to a "legitimate" purpose—a term that does appear in the only other exception to patent rights—which might suggest an independent assessment.<sup>159</sup> Assuming that the lack of the use of "legitimate" in this clause was intentional, presumably no such independent evaluation of the "authorized purpose" is permissible. After all, the entirety of the clause focuses on whether the scope and duration is limited to the authorized purpose and not whether the scope and duration is limited to a legitimate purpose.<sup>160</sup> Permitting member states to make their own assessment on whether a license is "limited to the

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<sup>155</sup> Compare *id.* with TRIPS, *supra* note 7, art. 30 (requiring that patent owners rights be balanced against other interests); Agreement on Technical Barriers to Trade Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1A, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, art. 2, ¶ 2.2-2.3 (1994); Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act, Annex 1A, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, art. 5 ¶, 6 (1994) (requiring that members take least trade restrictive actions).

<sup>156</sup> See TRIPS, *supra* note 7, art. 30.

<sup>157</sup> Although WTO panels are technically not permitted to create new law, their interpretation of ambiguous terms can nonetheless permit the WTO some leeway in its interpretation of laws pursuant to the DSU. See also *supra* note 64 (suggesting that WTO panels take a broader interpretation of TRIPS). See generally, DSU, *supra* note 45, art. 3(2).

<sup>158</sup> See TRIPS, *supra* note 7, art. 31.

<sup>159</sup> Compare *id.* with *id.* art. 30.

<sup>160</sup> *Id.* art. 31.



purpose to which it was authorized” seems consistent with other TRIPS provisions, such as requirements for patentability, that do not provide explicit definitions for member states.<sup>161</sup> In addition, this interpretation would seem consistent with the balance of interests expressed in TRIPS Articles 7 and 8.<sup>162</sup>

## 2. *Adequate Remuneration*

Another important issue is what constitutes “adequate remuneration” for a compulsory license.<sup>163</sup> As with the other provisions of Article 31, the proper starting place is to consider the ordinary meaning of the TRIPS provisions. TRIPS provides that the patent owner shall be paid “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”<sup>164</sup> TRIPS does not provide any further explanation of how to evaluate this phrase.<sup>165</sup> Notably, the clause states the economic value should be taken into account, but does not state that the remuneration is based solely on the economic value.<sup>166</sup> The sparse language of this provision makes the definition of “adequate” important. The ordinary meaning of adequate means something that is acceptable or satisfactory; however, by definition, “adequate” is not ideal, or even the most preferred option.<sup>167</sup> In addition, what does it mean to take into account the “economic value of the authorization?”<sup>168</sup> Is the economic value the value to the country imposing the license, or the value to the patent owner?

Since the language here is ambiguous, consulting prior negotiating texts seems appropriate. Earlier drafts proposed a variety of different standards,<sup>169</sup> including the following:

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<sup>161</sup> See *id.*; see also *supra* note 147 and accompanying text (explaining that nations have flexibility to define terms left undefined in TRIPS).

<sup>162</sup> See *id.* art. 7-8.

<sup>163</sup> See TRIPS, *supra* note 7, art. 31(h).

<sup>164</sup> *Id.*

<sup>165</sup> See *id.* art. 31.

<sup>166</sup> See *id.* art. 31(h).

<sup>167</sup> THE OXFORD ENGLISH DICTIONARY, *supra* note 139, at 150 (defining adequate as “equal in magnitude or extent; commensurate; neither more nor less”).

<sup>168</sup> See TRIPS, *supra* note 7, art. 31(h).

<sup>169</sup> Some countries did not propose any language about what type of remuneration should be provided the patent owner; rather, they simply required that the patent owner

“remuneration to the right holder adequate to compensate the right holder fully for the license”<sup>170</sup>

“an equitable remuneration to the right holder corresponding to the economic value of the licen[s]e”<sup>171</sup>

“payment commensurate with the value of the invention”<sup>172</sup>

“appropriately compensated”<sup>173</sup>

“fair and equitable” or “adequate” remuneration.<sup>174</sup>

The choice of the term “adequate remuneration” in the final text of TRIPS over the other terms suggests that the other definitions were considered and rejected, or at a minimum that the final language is chosen instead of other alternatives such that it should not be interpreted as synonymous with language that was abandoned.<sup>175</sup> In particular, it is possible to consider the meaning of the other terms to help define how “adequate” is different than these provisions. However, this task is still somewhat challenging because these terms may have different interpretations depending on who is analyzing them. For example, a “fair and equitable” remuneration would likely be viewed differently by a patent owner than by a country issuing a compulsory license.<sup>176</sup> Nonetheless,

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be provided compensation that could be subject to legal review. *See, e.g.*, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *Proposal by the Nordic Countries for the Negotiations on Standards and Principles for the Trade-Related Aspects of Intellectual Property Rights*, MTN.GNG/NG11/W36, at 3 (Jul. 10, 1989).

<sup>170</sup> *See* Communication from the United States, *supra* note 104, at 11, art. 27.

<sup>171</sup> *See* Draft Agreement on Trade-Related Aspects of Intellectual Property, Communication from the European Communities, GATT Doc. MTN.GNG/NG11/W/68, art. 26 (Mar. 29, 1990).

<sup>172</sup> Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Standards and Principles Concerning the Availability, Scope and Use of Trade-Related Intellectual Property Rights, Communication from Switzerland*, MTN.GNG/NG11/W/38, at 4 (Jul. 11, 1989).

<sup>173</sup> Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Suggestion by Japan for Achieving the Negotiating Objective*, MTN.GNG/NG11/W/17, at 6 (Nov. 23, 1987).

<sup>174</sup> GERVAIS, *supra* note 29, at 246 (language from Brussels Draft).

<sup>175</sup> *See* TRIPS, *supra* note 7, art. 31(h).

<sup>176</sup> Thailand provides an excellent example of differing perspectives. Thailand has publicly announced its royalty scheme and seems to believe the amount provided is more than adequate. *See, e.g.*, TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 11 (noting that the presumptive royalty rate has been set at between one-half to two percent of sale consistent with the range in most developing countries for public

the rejection of one proposed standard in particular may be helpful—the suggestion that the remuneration compensate the right holder “fully” for the license. Rejection of this standard may suggest that the current provision is not intended to fully compensate the right holder—at least at prevailing market rates in the most profitable countries.

There seems to be a need to consider the value of the license to both the licensee as well as the patent owner since Article 31 requires that the license take into account the “economic value of the authorization.”<sup>177</sup> However, this does not necessarily settle the question since the economic value will be measured differently by the patent owner compared to the country imposing the license.

With no clear limits, the interpretation of what constitutes adequate remuneration seems left to the discretion of national authorities, subject only to potential review within the WTO system.<sup>178</sup> However, because there is no definition in TRIPS, nations arguably have discretion to choose from a wide variety of options as noted in a thorough report prepared by James Love for the WHO.<sup>179</sup> In addition, WTO panels cannot create new law.<sup>180</sup> As stated by one commentator, “no guidelines have been given under TRIPS and none can be imposed arbitrarily by commentators in interpretation.”<sup>181</sup> It seems that Article 31 may

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non-commercial use, and that the fees can be negotiated); *see also id.* at 6 (suggesting that if patent holders voluntarily produce prices within five percent of generic competitors, Thailand will not impose compulsory licenses to “reward the loyalty” of patent owners). Drug companies and their supporters, on the other hand, seem to find any compulsory license to be a problem. *See, e.g., Drug Patent Piracy, supra* note 1 (suggesting that no royalty would be adequate since “compulsory licenses . . . almost always leave the rights holder with far less than a reasonable economic return”).

<sup>177</sup> *See* TRIPS, *supra* note 7, art. 31(h). Although not directly relevant to interpretation of remuneration under Article 31 generally, the General Council decision regarding countries without adequate facilities to produce patented drugs under compulsory license states that adequate remuneration should “take into account the economic value to the importing member of the use.” 2003 General Council Decision, *supra* note 31, ¶ 3.

<sup>178</sup> TRIPS, *supra* note 7, art. 31(h).

<sup>179</sup> WHO, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES, HEALTH ECONOMICS AND DRUGS 5 (WHO 2005) [hereinafter WHO—REMUNERATION GUIDELINES].

<sup>180</sup> *See* DSU, *supra* note 45, art. 3(2) (noting that rulings can not “add to or diminish” rights and obligations under WTO agreements).

<sup>181</sup> WATAL, *supra* note 101, at 326.

enable countries to impose a price through compulsory licensing that the country could not obtain through voluntary negotiations.<sup>182</sup>

### *G. Recap of Article 31 Requirements*

Before moving on to the case study of Thailand's licenses, a brief recap of the relevant requirements of TRIPS provisions may be useful. TRIPS permits any member state to issue a compulsory license for any patented invention.<sup>183</sup> Article 31 provides no restrictions on the subject matter that may be licensed, as confirmed by the Doha Public Health Declaration.<sup>184</sup> Rather than dictate specific inventions that may be licensed, TRIPS imposes procedural requirements.<sup>185</sup> For example, a compulsory license can only be issued based on consideration of its "individual merits," such that broad licensing of classes of inventions would be impermissible.<sup>186</sup> In addition, prior to imposition of a compulsory license the patent owner must typically be consulted first in hopes of securing a voluntary license.<sup>187</sup> However, no such consultation is required if there is a national emergency, other situations of extreme urgency, or public non-commercial use.<sup>188</sup> The Doha Public Health Declaration verifies that member states are within their rights to determine what constitutes a national emergency or situation of extreme urgency.<sup>189</sup> What constitutes a

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<sup>182</sup> Professor Reichmann has argued that "any government that seeks to bring a patentee's practices into line with its own policies, especially with regard to disciplining the prices at which the patented articles are to be locally distributed, can achieve its aims within the confines of Article 31." REICHMANN WITH HASENZAHN, *supra* note 3, at 15. In addition, the UNCTAD Resource Book on TRIPS goes even further in suggesting that a developing country granting a license to address a public health crisis affecting a substantial portion of the population could justify payment of a "minimal royalty." RESOURCE BOOK ON TRIPS, *supra* note 108, at 476-77.

<sup>183</sup> See *supra* notes 99-106 and accompanying text (explaining that a proper interpretation of TRIPS provides no subject matter restrictions for compulsory licenses).

<sup>184</sup> See Doha Public Health Declaration, *supra* note 31; see also *supra* notes 105-106 and accompanying text.

<sup>185</sup> See TRIPS, *supra* note 7, art. 31.

<sup>186</sup> See *id.* art. 31(a); see also *supra* notes 107-112 and accompanying text (explaining requirement).

<sup>187</sup> See TRIPS, *supra* note 7, art. 31(b); see also *supra* notes 113-117 and accompanying text (describing general rule).

<sup>188</sup> See TRIPS, *supra* note 7, art. 31(b); see also *supra* notes 118-120 and accompanying text.

<sup>189</sup> See Doha Public Health Declaration, *supra* note 31; see also *supra* notes 122-

public non-commercial use is more ambiguous and subject to differing views; critics assume a license to a for-profit entity could fail to constitute public non-commercial use.<sup>190</sup>

Article 31 also requires that the scope and duration of the license be limited to its authorized purpose, which is different than requiring that licenses be limited.<sup>191</sup> This provision has caused some confusion, but if properly interpreted most licenses should easily satisfy this provision. The appropriate royalty, on the other hand, may be challenging to assess. TRIPS requires that the patent owner be paid “adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization,” but with no guidance for how to do so.<sup>192</sup>

#### IV. Thailand’s Compulsory Licenses

##### A. Chronology

Thailand has a national mandate to provide universal access to essential medicine to all its citizens pursuant to the National Health Security Act of 2002 and access to antiretrovirals for all AIDS patients since 2003.<sup>193</sup> While some suggest that universal access to necessary drugs was a mere populist measure,<sup>194</sup> others including the WHO praise Thailand as a leader in providing treatment for HIV patients.<sup>195</sup> However, the World Health

<sup>129</sup> and accompanying text.

<sup>190</sup> See *infra* notes 255-258 and accompanying text; see also *supra* notes 133-146 and accompanying text (discussing proper interpretation of requirement).

<sup>191</sup> See TRIPS, *supra* note 7, art. 31; see also *supra* notes 147-152 and accompanying text.

<sup>192</sup> See TRIPS, *supra* note 7, art. 31(h); see also *supra* notes 148-152 and accompanying text.

<sup>193</sup> Thai National Health Security Act B.E. 2245; see also Thai Constitution B.E. 2250, § 51 (noting that “a person shall enjoy an equal right to receive standard public health”).

<sup>194</sup> See, e.g., James Hookway & Nicholas Zamiska, *Harsh Medicine: Thai Showdown Spotlights Threat to Drug Patents*, WALL ST. J., Apr. 24, 2007, at 1 (suggesting that Thailand is using populist rhetoric and policies to curry favor with the Thai people).

<sup>195</sup> WORLD HEALTH ORGANIZATION, EXTERNAL REVIEW OF THE HEALTH SECTOR RESPONSE TO HIV/AIDS IN THAILAND 35-36 (WHO 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]. Doctors Without Borders described Thailand as having “one of the gold standard treatment programs for the developing world.” Kazmin

Organization and the World Bank predict that Thailand will face dramatic price increases in treating their HIV population because HIV patients normally become resistant to initial treatments and need to switch to newer, patented drugs.<sup>196</sup> In fact the World Bank specifically notes that compulsory licenses of second-line HIV treatment would be one way for Thailand to provide cost-effective treatment,<sup>197</sup> although it recognizes that it will require “high-level political commitment” to deal with the implications.<sup>198</sup>

Thailand issued compulsory licenses to achieve its mandate of providing access to essential drugs, including antiretroviral drugs that cannot otherwise be provided despite increases in the public health budget<sup>199</sup> after years of negotiation with patent owners that failed to yield price cuts beyond the level of currency appreciation.<sup>200</sup> Although Thailand asserts that it engaged in prior negotiations with the patent owners, each of its compulsory licenses stated that it could grant compulsory licenses without prior negotiations in the case of public use based on the “right to . . . protect . . . public health” as supported by the Doha Public Health Declaration.<sup>201</sup> The licenses were issued to cover only Thai

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& Jack, *supra* note 1; *see also* Press Release, MSF, *supra* note 10 (praising Thailand’s action and suggesting that other nations follow suit).

<sup>196</sup> *See* ANA REVENGA ET AL., THE WORLD BANK, THE ECONOMICS OF EFFECTIVE AIDS TREATMENT: EVALUATING POLICY OPTIONS FOR THAILAND 169 (2006), *available at* <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/EASTASIAPACIFIC/XT/EXTEAPREGTOPHEANUT/EXTEAPREGTOPHIVAIDS/0,,contentMDK:21024879~pagePK:34004173~piPK:34003707~theSitePK:503157,00.html>; EXTERNAL REVIEW, *supra* note 195, at 36.

<sup>197</sup> *See* REVENGA ET AL., *supra* note 196, at 36.

<sup>198</sup> *See id.* at 15.

<sup>199</sup> Thailand reports that it has increased the overall public health budget to more than ten percent and that although its spending on antiretrovirals is highest among the lower middle income developing countries, it still can not satisfy its mandate to provide universal access. TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 2. On the other hand, others noted that Thailand increased its military budget. *See infra* note 264 (suggesting that Thailand’s actions are suspect).

<sup>200</sup> A division of the Thai government sought lower prices for patented antiretrovirals, but with no significant price reduction. TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 5. Although some patent owners reduced prices in 2006, the reductions were less than twenty percent and reportedly approximated the level of currency appreciation. *Id.*

<sup>201</sup> Each license stated “member countries have a right to issue a safeguard measure to protect public health, especially universal access to essential medicines using

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>202</sup> Accordingly, the licenses should expand revenue for patent owners who can continue to sell their drugs at a premium to wealthy Thai citizens in addition to obtaining compulsory license royalties for the drugs provided to low-income citizens.

On November 29, 2006, Thailand issued a compulsory license to its Government Pharmaceutical Organization (GPO) on Merck's patented drug Efavirenz (sold by the patent owner under the brand name Stocrin), an effective first line treatment for AIDS that has fewer adverse side effects, including life-threatening side effects, than the generic antiretroviral Nevirapine.<sup>203</sup> Thailand's license stated that it was for non-commercial purposes and for the public interest to help achieve its policy of universal access to antiretrovirals for the 500,000 Thai citizens that need them for long-term use. The compulsory license also stated that the high cost of Efavirenz without a license resulted in many Thai patients having inadequate access.<sup>204</sup> The compulsory license was expected to halve the treatment cost so that more patients could be covered with the eventual goal of having all new patients treated with Efavirenz initially, just as patients are treated in developed

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compulsory licensing on the patent of pharmaceutical products." Notification of the Department of Disease Control, Ministry of Public Health, Re: Exercising of Right Under Drugs and Pharmaceuticals Products Patent (Nov. 29, 2006), *reprinted in* TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 39 [hereinafter Efavirenz License]; Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Combined Formulation of Lopinavir and Ritonavir (January 24, 2007), *reprinted in* TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 43 [hereinafter Kaletra License]; Notification of the Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Clopidogrel (Jan. 25, 2007), *reprinted in* TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 45 [hereinafter Plavix License].

<sup>202</sup> TEN BURNING QUESTIONS—GOVERNMENT USE OF PATENTS, *supra* note 10, at 1-2, 6.

<sup>203</sup> Efavirenz License, *supra* note 201.

<sup>204</sup> *Id.* In addition, some noted that the compulsory license also addressed the problem of inadequate supply from patent owner Merck. See Press Release, MSF, *supra* note 10 (noting that patent owner Merck's supply had been unreliable and resulted in treatment interruptions).

countries.<sup>205</sup>

A Thai compulsory license on the AIDS drug Kaletra was issued to the GPO on January 25, 2007.<sup>206</sup> Kaletra is a patented combination of two antiretrovirals that is often used for patients that become resistant to basic formulations of HIV medications, such as Efavirenz. The Thai government estimated that around ten percent of patients require second-line treatments such as Kaletra within the first few years, or else such patients will die.<sup>207</sup> The Kaletra license was designed to support an increasing number of patients and thus save more lives. Prior to the compulsory license, Kaletra was priced at \$2200 per patient per year by patent owner Abbott, a cost that is close to the yearly income of a Thai citizen.<sup>208</sup>

On the same day, January 25, 2007, Thailand issued a compulsory license to the GPO for Bristol Myers' anti-platelet drug Plavix, a drug useful for treating heart disease.<sup>209</sup> According to the license, heart disease is one of the top three causes of death in Thailand and although some non-drug preventative measures could be taken there is a need for drug treatment to prevent unnecessary mortality.<sup>210</sup> Without the license only twenty percent of government insured patients could access the medicine, which is inconsistent with the Thai policy of providing universal coverage of essential medicine.<sup>211</sup>

In February 2007, Thailand issued a ninety page white paper, entitled "Facts and Evidence on the Ten Burning Issues Relating to the Government Use of Patents in Thailand," including supporting documents to defend its three compulsory licenses.<sup>212</sup> In the white paper Thailand explained its health needs as well as

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<sup>205</sup> See TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 13-14.

<sup>206</sup> Kaletra License, *supra* note 201.

<sup>207</sup> TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 14.

<sup>208</sup> See, e.g., Robert Weissman, *Cakewalk Ken Adelman Returns to the Stage*, MULTIN'L MONITOR, Mar. 1, 2007, available at <http://www.multinationalmonitor.org/mm2007/032007/weissman.html>.

<sup>209</sup> Plavix License, *supra* note 201.

<sup>210</sup> *Id.* (stating that medicine is needed for "treatment and secondary prevention from thrombosis which leads to morbidity and mortality").

<sup>211</sup> *Id.*

<sup>212</sup> TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10.



why its actions were consistent under TRIPS.<sup>213</sup> However, some statements in this white paper likely induced additional concern. In the context of explaining that Thailand was authorized to issue licenses without first negotiating with patent owners in cases of public non-commercial use, the white paper asserted that issuing compulsory licenses without prior negotiation is generally more effective.<sup>214</sup> The document also went beyond supporting the existing compulsory licenses to telegraph Thailand's intent to consider issuing additional licenses on up to fifteen percent of patented drugs not only for epidemics but also when the market price was considered too high to achieve Thailand's universal access to essential drugs.<sup>215</sup> In addition to making such claims in its white paper, Thailand announced that it was considering imposing compulsory licenses on eleven patents in a February 2007 press conference.<sup>216</sup>

Even though controversy never subsided regarding the initial licenses,<sup>217</sup> Thailand continued to explore additional compulsory

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<sup>213</sup> *Id. passim* (providing ninety pages of comprehensive explanation and supporting documents).

<sup>214</sup> *Id.* at 6 ("prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations"). This statement is somewhat at odds with other assertions in the same document that Thailand previously negotiated with patent owners. *See id.* at 5 (stating that the Thai government sought lower prices in 2006, but the reductions only approximated the level of currency appreciation). It is possible that although Thailand negotiated prices generally with patent owners, it never explicitly mentioned the possibility of compulsory licenses. Furthermore, it is possible that the TRIPS requirement of prior negotiation with patent owners contemplates an express suggestion of a compulsory license if negotiations fail.

<sup>215</sup> *Id.* at 10. The criteria for consideration of a drug for compulsory license is listing on the National Essential Drug List; or a need to solve public health problems, an emergency, or an epidemic; or for life-saving 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 "life-style" drugs, such as those to treat baldness, acne, or erectile dysfunction would not be considered for compulsory licenses. *Id.*; *see also* Sinfah Tunsarawuth, *Thailand: 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).

<sup>216</sup> Hookway & Zamiska, *supra* note 194.

<sup>217</sup> Indeed, controversy arguably increased as 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. *See infra* notes 363-366 and accompanying text. During the same month, the

licenses. In June 2007, Thailand established two exploratory committees to consider possible compulsory licenses on cancer medications considered necessary for the universal healthcare scheme.<sup>218</sup> At the same time, Thailand was pressured against perceived broad use of compulsory licenses by E.U. Trade Commissioner Peter Mandelson, as well as by the U.S. Ambassador to Thailand, Ralph Boyce.<sup>219</sup> Thailand began negotiations for lower prices on patented cancer drugs in October 2007.<sup>220</sup> Although initial signs were promising the negotiations eventually broke down in December 2007.<sup>221</sup>

Thailand then issued licenses on four cancer drugs in January 2008 on the eve of a change in government administration.<sup>222</sup>

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USTR elevated Thailand to Priority Watch status on its Special 301 list. 2007 SPECIAL 301 REPORT, *supra* note 27, at 27.

<sup>218</sup> See, e.g., Beth Jinks & Haslinda Amin, *Thailand Buying Three Generic AIDS, Heart Drugs from India*, BLOOMBERG.COM, June 22, 2007, <http://www.bloomberg.com/apps/news?pid=20601203&sid=aRmSWtVJfJME&refer=insurance>.

<sup>219</sup> Peter Mandelson July 10 Letter, *supra* note 27 (noting concern about Thailand's use of compulsory licenses and asserting that "neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licenses wherever medicines exceed certain prices"); Letter from Ralph Boyce, U.S. Ambassador, to Surayud Chulont, Thai 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).

<sup>220</sup> THAI NATIONAL HEALTH SECURITY OFFICE, THE TEN BURNING QUESTIONS ON THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND 4 (Feb. 2008), *available at* [http://www.moph.go.th/hot/Second\\_white\\_paper\\_on\\_the\\_Thai\\_CL\\_%5BEN%5D.pdf](http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf) [hereinafter TEN BURNING QUESTIONS ON CANCER DRUGS].

<sup>221</sup> *Id.*; see also Sinfah Tunsarawuth, *New Thai Minister May Review Compulsory Licenses on Cancer Drugs*, INTELL. PROP. WATCH, Jan. 31, 2008, <http://www.ip-watch.org/weblog/index.php?p=914> (noting that despite several months of negotiations, Thailand was still contemplating licenses on several cancer drugs); Sinfah Tunsarawuth, *Thailand Avoids Compulsory License On Cancer Drug; 3 More Drugs Undecided*, INTELL. PROP. WATCH, Nov. 7, 2007, <http://www.ip-watch.org/weblog/index.php?p=906> (quoting Thai FDA secretary general as noting positive results with drug companies and suggesting that Thailand was near a deal with Sanofi-Aventis).

<sup>222</sup> On January 4, 2008, licenses were issued on Letrozole, a breast cancer medicine made by Novartis AG, Docetaxel, the breast and lung cancer drug by Sanofi-Aventis; Erlotinib, a drug for treating, lung, pancreatic, and ovarian cancer by Roche; and Imatinib, a cancer drug patented and sold by Novartis as Glivec. Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceuticals Products Patent for Docetaxel (Jan. 4, 2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 22-23 [hereinafter Docataxel License]; Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceutical Products Patent for Letrozole

Thailand asserted that they were necessary because cancer is currently the number one cause of death in Thailand, and most effective cancer treatments are patented, not covered on the Thai List of Essential Drugs due to their high cost, and thereby inaccessible to Thai citizens.<sup>223</sup> Thailand asserted that cancer is no less serious than HIV/AIDS, accounting for 30,000 deaths a year with 100,000 new cases diagnosed each year.<sup>224</sup> Moreover, Thailand noted that the licenses were critical to prevent either severe economic hardship, including bankruptcy or certain death, without treatment.<sup>225</sup>

However, unlike the initial compulsory licenses, Thailand delayed implementation of the signed licenses to enable continued negotiations. The continued negotiations yielded a successful outcome in one case; patent owner Novartis agreed to provide its drug Glivec at no cost to Thai citizens meeting certain income requirements, and Thailand revoked the license on Glivec.<sup>226</sup> On the other hand, Thailand was not satisfied with the prices of other patented drugs. Although the other patent owners offered discounts of up to one third the original price, Thailand stated that it would impose a compulsory license unless patent owners offered prices no more than five percent higher than those offered by generic competitors.<sup>227</sup>

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(Jan. 4, 2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 24-25 [hereinafter Letrozole License]; Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceutical Products Patent for Erlotinib (Jan. 4, 2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 26-27 [hereinafter Erlotinib License]; Notification of the Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Imatinib (Jan. 25, 2008), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 28-29 [hereinafter Imatinib License].

<sup>223</sup> TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 2-3.

<sup>224</sup> *Id.* at 2.

<sup>225</sup> *Id.*

<sup>226</sup> Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceuticals Products Patent for Imatinib, ), *reprinted in* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 222, at 34-35; *see also* *Novartis Wins Thai Battle, Setback For Indian Firms*, FIN. EXPRESS, Feb. 3, 2008, *available at* <http://www.financialexpress.com/news/novartis-wins-thai-battle-setback-for-indian-firms/268596/>; *Thailand Health Ministry Change Could Mean Fewer CLs*, PHARMA MARKETLETTER, Feb. 18, 2008.

<sup>227</sup> TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 4-6.

On February 7, 2008, the first day of taking office, the new Thai Public Health Minister announced that he would re-evaluate the decision to issue licenses on the cancer drugs.<sup>228</sup> Also of relevance was an attempt to clarify Thailand's position with the United States in hopes of avoiding negative economic repercussions, including loss of trade preferences under the Generalized System of Preferences<sup>229</sup> as well as potential trade sanctions if listed on the Special 301 Report.<sup>230</sup> Some American pharmaceutical companies had requested that Thailand be given Priority Foreign Country status, which is the most severe trade category and is most likely to result in trade sanctions.<sup>231</sup>

While medical experts and health advocates criticized this decision,<sup>232</sup> patent owners welcomed the new approach.<sup>233</sup> The president of the Pharmaceutical Research and Manufacturers

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<sup>228</sup> See, e.g., Ambika Ahuja, *Thailand to Review Decision to Break Patents on Cancer Drugs*, INT'L HERALD TRIB., Feb. 9, 2008, available at <http://www.iht.com/articles/ap/2008/02/09/asia/AS-GEN-Thailand-Cancer-Drugs.php>; *Bangkok's Drug War, Round Two*, WALL ST. J., Feb. 27, 2008, at 13.

<sup>229</sup> The Generalized System of Preferences [GSP] is a U.S. program that provides preferential treatment to imports from certain member countries and is consistent with the WTO rules. See also *infra* note 380 and accompanying text (noting that lack of effective intellectual property protection may impact GSP status). See generally United States Trade Representatives, GSP Program Summary, [http://www.ustr.gov/Trade\\_Development/Preference\\_Programs/GSP/GSP\\_Program\\_Summary\\_\(available\\_in\\_multiple\\_languages\)/Section\\_Index.html](http://www.ustr.gov/Trade_Development/Preference_Programs/GSP/GSP_Program_Summary_(available_in_multiple_languages)/Section_Index.html) (last visited Jan. 5, 2009); see also *infra* note 380 and accompanying text (noting that lack of effective intellectual property protection may impact GSP status).

<sup>230</sup> See *infra* notes 380-385 and accompanying text (explaining impact of being listed as a "Special 301" country).

<sup>231</sup> Letter from Lila Feisee, Managing Dir., Biotechnology Indus. Org., to Jennifer Choe Groves, Dir. for Intell. Prop. and Innovation and Chair of the Special 301 Comm., at 3-4 (Feb. 11, 2008), available at <http://www.pharmalot.com/wp-content/uploads/2008/02/bio-letter-to-ustr.pdf> [hereinafter BIO Feb 11 Letter]; PHARMA SPECIAL 301 SUBMISSION 2007 2 (2007); see also Phusadee Arunmas, *Thai Traders Urge 'Extreme Caution' on CL*, BANGKOK POST, Feb. 14, 2008, available at <http://www.biothai.org/cgi-bin/content/news/show.pl?0527> (suggesting that compulsory licenses should be viewed with caution in light of the fact that Thailand could be placed on the priority foreign country list, rather than the priority watch list).

<sup>232</sup> See, e.g., Pradi Ruangdit and Nareerat Wiryapong, *Minister Under Attack for Plan to Reverse CL*, BANGKOK POST, Feb. 19, 2008, available at <http://www.aegis.org/news/bp/2008/BP080213.html> (noting that that the new Thai Health Minister was criticized).

<sup>233</sup> See, e.g., *id.*; see also *Thailand Move to Reconsider Compulsory Licensing of Drugs Faces Opposition*, THAI PRESS REPORTS, Feb. 8 2008.

Association, representing many multinational pharmaceutical companies, called for Thailand to cease issuing compulsory licenses.<sup>234</sup> Some governments also made statements discouraging use of compulsory licenses.<sup>235</sup> On the other hand, a number of health advocates, including Oxfam, made public statements to encourage continuation of the compulsory licenses.<sup>236</sup> In addition, a WHO group confirmed that the use of TRIPS flexibilities, such as compulsory licenses, were a permissible means of cost containment in providing essential medicines that were not otherwise affordable.<sup>237</sup>

Ultimately, Thailand decided not to revoke any of the compulsory licenses issued on cancer drugs despite being told that the continued imposition of licenses threatened to impact Thailand's international trade.<sup>238</sup> Some suggested that cancelling the licenses would be inconsistent with the Thai Constitution and other laws requiring the government to provide low-cost drugs.<sup>239</sup> Thailand has also resisted the suggestion that it promised to forgo

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<sup>234</sup> Nareerat Wiriyapong, *Pharma: End Compulsory Licenses*, BANGKOK POST, Jan. 30, 2008.

<sup>235</sup> See SWISS AIDE MEMOIRE, *supra* note 27 (while stating general support for Thailand's HIV program, nonetheless expressing concern that without patent protection, the pharmaceutical industry will not have adequate incentive to develop new medicines such that compulsory license be used only in exceptional cases).

<sup>236</sup> See, e.g., *Oxfam Urges Thailand to Keep Generic Drugs Program*, INQUIRER.NET, Feb. 19, 2008, [http://newsinfo.inquirer.net/breakingnews/world/view\\_article.php?article\\_id=119868](http://newsinfo.inquirer.net/breakingnews/world/view_article.php?article_id=119868); Letter to Samak Sundarevej, Thai Prime Minister, and Chaiya Sasomsap, Minister of Pub. Health, from James Love, Knowledge Ecology International (Feb. 19, 2008) (explaining that the Thai licenses are consistent with TRIPS and that there should be no legitimate concern about placement on the U.S. Special 301 watch list); see also Letter to Ed. of the Wall St. J. from Virat Purahong, Chairperson of the Thai Network of People Living with HIV/AIDS, Concerning the article: *Bangkok's Drug War, Round Two* (Mar. 6, 2008) (rebutting criticism of prior editorial regarding Thailand's licenses).

<sup>237</sup> WORLD HEALTH ORGANIZATION, IMPROVING ACCESS TO MEDICINES IN THAILAND: THE USE OF TRIPS FLEXIBILITIES 5 (2008). Although the WHO report technically provides an overview of options for all developing countries, it explicitly states that it is not intended to assess Thailand's compliance with TRIPS. *Id.* at 2.

<sup>238</sup> See, e.g., Pongphon Sarnsamak, *No Cancellation of CL for Cancer Drugs*, NATION, Mar. 4, 2008, available at [http://www.nationmultimedia.com/2008/03/03/national/national\\_30067110.php](http://www.nationmultimedia.com/2008/03/03/national/national_30067110.php); Nicholas Zamiska, *Thai Ministry to Recommend Ignoring Patents on Cancer Drugs*, WALL ST. J. ONLINE, March 11, 2008, <http://online.wsj.com/article/SB120515886199824251.html>.

<sup>239</sup> Sarnsamak, *supra* note 238.

the option of compulsory licenses in the future; stating that to do so would be considered a “neglect of duty or failure to exercise the rights established by the law to safeguard public interest and public health and incur a criminal charge.”<sup>240</sup>

### B. Criticism of Thailand's Compulsory Licensing

This section provides an overview of common criticisms concerning whether Thai licenses violated TRIPS.<sup>241</sup> The licenses are suggested as improper because of a lack of prior negotiations with the patent owner, lack of a public emergency, and lack of public non-commercial use. In addition, Thailand was also criticized for using compulsory licenses in a manner more broadly than intended by TRIPS.

Lack of prior negotiation with patent owners was a frequent complaint regarding the initial three licenses.<sup>242</sup> A number of

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<sup>240</sup> TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 13.

<sup>241</sup> Other criticisms go far beyond the scope of either TRIPS or compulsory licensing policy. In particular, some critics have suggested that the Thai licenses are suspect because the licenses were issued to the GPO, which they allege to be historically corrupt with facilities not authorized by the WHO. Roger Bate, *Thai-ing Pharma Down*, WALL ST. J., Feb. 9, 2007, at 13 [hereinafter *Thai-ing Pharma Down*] (“The only winner will be Thailand’s historically corrupt Government Pharmaceutical Organization, or GPO, the state-owned pharmaceutical monopoly”). Others have suggested that licensed drugs imported from India, rather than made from the GPO, are also suspect because India is referred to as “the world’s most prolific source of counterfeit generics.” *Theft in Thailand*, *supra* note 1. However, the rhetoric against the GPO and India ignore the fact that an agency outside the patent system is designated to monitor safety of drugs. Moreover, not all drugs made and sold from India are counterfeit generics—due to compliance with TRIPS. The Patents (Amendment) Act, No. 15 of 2005, §10(c) (India), available at <http://indiacode.nic.in/> (permitting patent owners who filed applications before India provided product patents only to recover “reasonable royalties” against companies that were using the invention prior to January 1, 2005 and continue to do so).

<sup>241</sup> See, e.g., Nicholas Zamiska, *Thai Move to Trim Drug Costs Highlights Growing Patent Rift*, WALL ST. J., Jan. 30, 2007, at A8 (quoting Teera Chakajnarodom, president of the Pharmaceutical differing patent laws, India may legitimately make some generic drugs while remaining in compliance with TRIPS. The Patents (Amendment) Act, No. 15 of 2005, §10(c) (India), available at <http://indiacode.nic.in/> (permitting patent owners who filed applications before India provided product patents only to recover “reasonable royalties” against companies that were using the invention prior to January 1, 2005 and continue to do so).

<sup>242</sup> See, e.g., Nicholas Zamiska, *Thai Move to Trim Drug Costs Highlights Growing Patent Rift*, WALL ST. J., Jan. 30, 2007, at A8 (quoting Teera Chakajnarodom, president of the Pharmaceutical Research and Manufacturers Association (PhRMA), as stating that “everything is negotiable,” but Thailand’s approach of “taking away their property, their

patent owners noted that they were surprised to only learn about the compulsory licenses after the fact and drug makers reported that they were “stunned” to not receive prior warning.<sup>243</sup> Dr. Harvey Bale, the Director of the International Federation of Pharmaceutical Manufacturers, noted that Thailand had “no serious contacts” with patent owners regarding HIV drugs since two years before its “aggressive action to undermine the patents.”<sup>244</sup>

Contrary to the express language of TRIPS, patent owners frequently misrepresented that TRIPS requires an emergency as a pre-requisite to issuing a compulsory license.<sup>245</sup> Some noted that Thailand’s official licenses fail to state a public emergency as a basis for the license.<sup>246</sup> Others asserted that licenses should only be permissible if there is an emergency.<sup>247</sup> Some even suggested

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assets” without negotiation was inappropriate); *PhRMA Criticizes Thailand Compulsory License for HIV/AIDS Drug*, INSIDE U.S. TRADE, Dec. 8, 2006, available at <http://lists.essential.org/pipermail/ip-health/2006-December/010327.html> (quoting PhRMA president Billy Tauzin as suggesting that Thailand’s license without concomitant attempt to negotiate was of “grave concern”).

<sup>243</sup> See, e.g., Darren Scuetler, *Angered U.S. Firm Excludes Thailand from New Drugs*, REUTERS, Mar. 14, 2007, available at <http://www.reuters.com/article/healthNews/idUSBKK27714620070314> (noting in a single sentence both that the licenses are legal and also that the drug makers were stunned to receive no prior warning).

<sup>244</sup> Letter from Harvey Bale, Dir. of the Int’l Fed’n of Pharmaceutical Mfgs., to Wall. St. J., *Untangling Thailand’s Drug Policies* (Mar. 14, 2007) available at <http://lists.essential.org/pipermail/random-bits/2007-March/001411.html>.

<sup>245</sup> See *supra* note 11 and accompanying text (providing examples of misconceptions that the Thai licenses were improper as inadequate emergencies). In addition, confusion concerning whether a national emergency is “required” to issue a compulsory license continued to appear in the press. See, e.g., *Thailand to Review Decision to Break Patents on Cancer Drugs*, ASSOCIATED PRESS, Feb. 9, 2008, available at <http://www.tmcnet.com/news/2008/02/09/3259393/htm> (“according to international trade rules, a government may issue a compulsory license to manufacture a generic drug only in the case of a national public health emergency”).

<sup>246</sup> See, e.g., *PhRMA Criticizes Thailand Compulsory License for HIV/AIDS Drug*, *supra* note 242 (suggesting that without a public emergency, prior negotiation should have been required).

<sup>247</sup> See, e.g., Roger Bate, *Thailand’s Drug Wars*, AMERICAN, Mar. 12, 2008, available at <http://www.american.com/archive/2008/march-03-08/thailand2019s-drug-wars/> (neglecting to mention public noncommercial use as a possible grounds for issuing a license without prior negotiations); Bate & Boateng, *supra* note 23, at 4 (stating that the “only condition” authorizing a country to issue a compulsory license without prior negotiation is that there be a national emergency); Ashley Herher, *U.S. Drugmaker Abbott, Thailand Face Off in AIDS Drug Patent Stalemate*, INT’L HERALD TRIB., June 6,

that HIV is not an emergency in Thailand because it has done well in reducing deaths from AIDS as well as reducing the rate of new infections.<sup>248</sup>

Thailand's license on Plavix drew particular attention from patent owners as the first step on a slippery slope towards licensing any and all patents if heart disease were considered an emergency.<sup>249</sup> Although Thailand issued a license on Plavix based on the ground of public non-commercial use, the Plavix license was generally criticized for failing to constitute a public emergency—a different issue that is not always required for TRIPS-compliant compulsory licensing as further explained in the next section. For example Roger Bate, an economist associated with the conservative think tank, American Enterprise Institute,<sup>250</sup> noted that:

Plavix changes the debate entirely . . . it almost certainly breaks WTO rules. Combating HIV has always been seen by activists, if not others, as a health emergency, and under WTO rules, patents can be broken in emergencies. However, it's hard for anyone to argue that heart disease meets such

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2007, available at <http://www.iht.com/articles/ap/2007/06/07/business/NA-FIN-US-Thailand-Abbotts-AIDS-Fight.php> (noting that “compulsory licenses are not illegal, but their use in medicine typically involves treating public health emergencies”); Harish Mehta, *Cheap Life-saving Drugs: Thailand Shows the Way*, BUS. TIMES SINGAPORE, Oct. 18, 2007, available at [http://www.biotechsingapore.com/ttd\\_Bizenterprise/Singlenews.aspx?DirID=78&rec\\_code=107882](http://www.biotechsingapore.com/ttd_Bizenterprise/Singlenews.aspx?DirID=78&rec_code=107882) (asserting that a national emergency is the only grounds for issuing a compulsory license without prior consultation with the patent owner); see also PHARMACEUTICAL RESEARCH & MANUFACTURERS ASSOCIATION, PARTNERING FOR BETTER HEALTH: AN INDUSTRY PERSPECTIVE 26 (April 2007) [hereinafter PARTNERING FOR BETTER HEALTH] (suggesting by omission that the Doha Public Health Declaration only affirms the right to use flexibilities for health crises and emergencies); *Bangkok's Drug War, Round Two*, *supra* note 228 (mentioning only a national emergency as a possible exception to prior negotiation).

<sup>248</sup> Horner, *supra* note 1 (suggesting that Thailand can not qualify for the national emergency exception because they have a “comparatively low rate of AIDS infection” with less than one percent of the population infected, as opposed to other WTO members with rates as high as twenty percent); *Thai Patent Turmoil*, *supra* note 11 (suggesting that Thailand does not have an HIV crisis relative to other countries).

<sup>249</sup> *Thai Patent Turmoil*, *supra* note 11.

<sup>250</sup> See AEI's Organization and Enterprise, <http://www.aei.org/about/filter.all/default.asp> (last visited Feb. 8, 2009).



stringent tests.<sup>251</sup>

Some suggested that heart disease was a “life-style” condition that could not be considered an emergency.<sup>252</sup> Another editorial suggested that if cardiovascular disease were considered an emergency, what would constitute an emergency would be limitless—even though the same editorial earlier admitted the possibility of alternative grounds for issuing a compulsory license.<sup>253</sup> In addition, some went beyond the scope of TRIPS to suggest that the compulsory licenses were improper; one editorial critically asserted that “until now, governments have been careful to define disease outbreaks as ‘emergencies’ primarily because they don’t want to dissuade drug companies from investing in their government.”<sup>254</sup>

Even the few articles that recognize that compulsory licenses may be issued without a national emergency, such as for public non-commercial use, nonetheless suggested that Thailand’s action was inappropriate. Some suggested that because the license is issued to a government agency that is for-profit and possibly corrupt the licenses will presumably be sold for profit.<sup>255</sup> For

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<sup>251</sup> *Thai-ing Pharma Down*, *supra* note 241, at 13; *see also* Roger Bate, *Thailand and the Drug Patent Wars*, HEALTH POL’Y OUTLOOK, Apr. 2007, at 2 [hereinafter *Thailand and the Drug Patent Wars*] (arguing that Plavix is not an emergency and that compulsory licenses under TRIPS should be confined to national emergencies and epidemics).

<sup>252</sup> *See, e.g.*, Piya Wong, *Thailand Backs off Threat to Break Drug Patents*, SCIDEV.NET, Feb. 8, 2007, <http://www.scidev.net/en/news/thailand-backs-off-threat-to-break-drug-patents.html>; *see also* Roger Bate, *Thailand’s Patent Attack*, N.Y. SUN, Feb. 13, 2007, *available at* <http://www.nysun.com/opinion/thailands-patent-attack/48499/> (asserting that heart disease and leukemia are not epidemics); Ghosh, *supra* note 1 (asserting that heart disease afflicts the affluent, such that a compulsory license is not needed).

<sup>253</sup> *Thai Patent Turmoil*, *supra* note 11.

<sup>254</sup> *Theft in Thailand*, *supra* note 1.

<sup>255</sup> *See, e.g.*, *Abbott’s Bad Precedent*, WALL ST. J., Apr. 30, 2007, at A14 (noting that the GPO is for-profit); Horner, *supra* note 1 (noting that because the statute that created the Government Pharmaceutical Organization (GPO) states that it carries on “business” and the GPO has previously worked with private pharmaceutical companies, it will presumably use the licenses for commercial sale); *see also Good Medicine for Thailand*, WALL ST. J., May 29, 2008, *available at* [http://online.wsj.com/article/SB121199626353926559.html?mod=yahoo\\_buzz](http://online.wsj.com/article/SB121199626353926559.html?mod=yahoo_buzz) (suggesting that the GPO is considered to be in competition with the pharmaceutical industry, such that a license by the GPO can not be for non-commercial use).

example, one editorial by a sympathizer of patent-owning drug companies claimed that this phrase only refers to public research and not provision by a for-profit government agency, concluding that “only the most cynical distortion of the text could conceivably cover Thailand’s conduct here”<sup>256</sup>—in direct contradiction of the interpretations of legal scholars without financial ties to the industry.<sup>257</sup> Others assert that public non-commercial use is inappropriate when the licenses simply benefit the Thai budget, or that Thailand is exploiting a vague term such that it is at least violating the spirit of TRIPS.<sup>258</sup>

Some critics of the Thai licenses suggested that TRIPS requires licenses be limited in scope or issued under very limited circumstances. Switzerland’s public statement concerning the licenses noted that TRIPS Article 31(c) requires licenses be limited in scope and duration, thus suggesting that the Thai licenses were inadequately limited in these respects.<sup>259</sup> Others, such as the major pharmaceutical company GlaxoSmithKline, asserted that TRIPS only permits compulsory licensing in limited circumstances such as national health emergencies and only after lengthy efforts to first negotiate with patent owners.<sup>260</sup> Still others emphasize that compulsory licensing should only be permitted under “extraordinary conditions,” or as a “last resort,” although these terms are not used within Article 31 and are typically not defined.<sup>261</sup>

Other critics suggest that while Thailand may not violate any explicit provision of TRIPS, its actions were nonetheless

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<sup>256</sup> *Thai Patent Turmoil*, *supra* note 11.

<sup>257</sup> See *supra* notes 141-146 and accompanying text.

<sup>258</sup> Simon Montlake, *Thailand Takes On Drug Patents*, FAR E. ECON. REV., July/Aug. 2007, at 41 (noting that only Thailand’s public health care system benefits); *The Thai Flu*, *supra* note 5 (alleging that Thailand is “taking advantage of vague language” and that it is “turning its state-owned pharmaceutical monopoly into a regional drug store”).

<sup>259</sup> See, e.g., SWISS AIDE MEMOIRE, *supra* note 27.

<sup>260</sup> A *Gathering Storm*, THE ECONOMIST, June 9, 2007, at 71; see also *Patent Remedy*, *supra* note 5 (“[C]ompulsory licensing . . . is permitted under extraordinary circumstances, such as to produce essential goods,” which also suggests that the HIV drugs must not be essential).

<sup>261</sup> See, e.g., *Drugs in Thailand*, FIN. TIMES, Jan 31, 2007, available at [http://www.ft.com/cms/s/0/37500f5c-b0cf-11db-8a62-0000779e2340.html?nclick\\_check=1](http://www.ft.com/cms/s/0/37500f5c-b0cf-11db-8a62-0000779e2340.html?nclick_check=1); *Patent Remedy*, *supra* note 5.

impermissible, or at least suspect. For example, one editorial recognized that TRIPS “doesn’t list specific causes” for which governments can grant compulsory licenses—a condition which it considered “regrettably vague”—but was convinced that Thailand has clearly “breached the spirit, if not the letter” of the relevant provision.<sup>262</sup> Others suggested that Thailand’s action was inappropriate under TRIPS because TRIPS does not specifically permit use of licenses to address budgetary constraints,<sup>263</sup> with some further suggesting that any budgetary constraint were likely only a result of an increase in defense spending by a military-imposed Thai government.<sup>264</sup>

Some have also suggested that the clarifying statements in the Doha Public Health Declaration are of dubious value, or inapplicable to Thailand’s situation. Critics of the Thai licenses tend to characterize the Declaration as prompted by activists trying to alter TRIPS.<sup>265</sup> Moreover, these criticisms allege that Thai sympathizers unduly rely on the declaration to claim that TRIPS authorizes compulsory licenses on “any patent, especially any drug patent, for any reason.”<sup>266</sup> In addition, some suggest that the Doha Declaration was intended to be limited to health

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<sup>262</sup> *Theft in Thailand*, *supra* note 1; *see also* Commentary, *Lonely Thailand*, WALL ST. J., May 23, 2007, at 11 (suggesting that Thailand is “exploiting vague language” under TRIPS).

<sup>263</sup> *See, e.g.*, PARTNERING FOR BETTER HEALTH, *supra* note 247, at 26-27.

<sup>264</sup> *See, e.g.*, *The Impact of Coup-Related Sanctions on Thailand and Fiji: Helpful or Harmful to U.S. Relations?: Hearing Before the Subcomm. on Asia, the Pac., and the Global Env’t*, 110th Cong. 7-9 (2007) (testimony by Mark Stevin Kirk) (asserting that Thai military leaders have increased the military budget by over \$1 billion, given themselves a pay raise of \$9 million while cutting health care by at least \$12 million); Hookway & Zamiska, *supra* note 194 (suggesting that Thailand is using populist rhetoric and policies to curry favor with the Thai people); Pipes, *supra* note 23; *Thai Patent Turmoil*, *supra* note 11 (suggesting that any potential budget shortfall was self-imposed when the military leaders cut the public health budget by \$12 million while increasing the military budget by \$1.1 billion).

<sup>265</sup> Typically, such articles suggest that those sympathetic to the ability of countries to use compulsory licenses are activists that oppose all property rights in addition to trying to alter TRIPS. *See, e.g.*, Ghosh, *supra* note 1 (referring to “health activists” as supporting Thailand’s decision as legal); *Patent Remedy*, *supra* note 5 (“some groups have worked hard to alter the meaning of the TRIPS agreement and to encourage governments to use compulsory licensing to break IP protections”).

<sup>266</sup> *Patent Remedy*, *supra* note 5.

emergencies, but not budgetary shortfalls.<sup>267</sup>

## V. TRIPS Analysis of Thai Licenses

### A. Licenses Covered Permissible Subject Matter

Although the earlier analysis establishes that there is no limitation on what may be licensed consistent with Article 31, it is important to consider whether there is any merit to the contention that some subject matter such as cancer and heart drugs should not be subject to compulsory licenses. As noted earlier, the appropriate interpretation of TRIPS requires that the clear meaning of the text control. Here, the text does not provide any restriction on the type of subject matter that may be subject to compulsory licensing.<sup>268</sup> Indeed, other scholars support this view as well.<sup>269</sup> Similarly, while some suggest that permitting compulsory licenses on typically high-profit drugs such as cancer drugs will reduce incentives for future development, this argument is not relevant to what the parties agreed to in TRIPS Article 31. Although some WTO countries have suggested that any compulsory license reduces incentives for patent owners to develop drugs, that fails to change what all member states agreed to under TRIPS.<sup>270</sup> Additionally, the oft-stated fear that compulsory licenses will undermine innovation is likely an overstatement, as further discussed in Part VI.

### B. Individual Merits

The question in the case of the Thai licenses is whether the compulsory licenses were permissible under the criteria that the

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<sup>267</sup> See, e.g., BIO Feb. 11 Letter, *supra* note 231, at 3 (asserting that the Doha Declaration was intended for use with “acute crises,” but “not meant as an expedient to facilitate budgetary planning”).

<sup>268</sup> See *supra* Part III.C (discussing the text of TRIPS).

<sup>269</sup> See, e.g., Abbott & Reichmann, *supra* note 31, at 956 (“the suggestion that treatments for heart disease exceed a state’s right to grant a compulsory license conflicts directly with the TRIPS Agreement”); Outtersen, *supra* note 22, at 283 (“for all the bluster in the Wall Street Journal, it is clear that the controlling legal texts do not limit the use of TRIPS flexibilities to any particular set of diseases”).

<sup>270</sup> See SWISS AIDE MEMOIRE, *supra* note 22, ¶¶ 2-4 (suggesting that compulsory licenses should only be used in “exceptional cases”); Peter Mandelson July 10 Letter, *supra* note 22, ¶ 3 (stating that the Thai Licenses are “a matter of concern to the E.U. and would be detrimental to innovation and development of new drugs.”).

licenses be granted on their “individual merits.” In particular, some suggest that Thailand has engaged in an impermissible system of authorizing compulsory licensing for drugs viewed as too expensive for the national budget.<sup>271</sup> As noted above, individual merits simply require that the decision be made for individual drugs. If Thailand had a policy of granting compulsory licenses for all drugs once it exceeded a certain budgetary level that policy would likely be in violation of this provision. However, Thailand’s approach is more nuanced. Thailand has no law to license all pharmaceuticals.<sup>272</sup> According to Thailand, there is a committee that evaluates what patented drugs might possibly be considered for compulsory licensing and then negotiations are first attempted before any license is actually issued; however, it is unclear whether the negotiations were always made against an explicit threat of a compulsory license—especially with respect to the initial three licenses.<sup>273</sup> Each license was nonetheless based on individual merits as Thailand had a specific rationale for each.<sup>274</sup>

Determining whether the licenses were granted on their “individual merits” may also raise a related but distinct issue of whether the licenses are inconsistent with TRIPS Article 27, that bars discrimination of subject matter. TRIPS Article 27 states

<sup>271</sup> Peter Mandelson July 10 Letter, *supra* note 27 (suggesting that Thailand is engaging in a systemic imposition of licenses); *see also* PARTNERING FOR BETTER HEALTH, *supra* note 263, at 20 (asserting that Thailand will use compulsory licensing “as a routine way of accessing innovative medicines”). Others have raised a related argument against the use of compulsory licenses to address budgetary issues, but grounded the argument not in TRIPS, but in general policy as if TRIPS did not exist. *See, e.g.*, Global Insight, *Thai Government Expands Scope of Patent-Breaking Strategy Amid Unrest in Asia* (2007), <http://www.globalinsight.com/SDA/SDADetail8346.htm> (warning that the Thai licenses are dangerous because if “compulsory licensing in effect becomes a valid form of cost containment . . . that entirely sidelines the core meaning of intellectual property”).

<sup>272</sup> *Contra* Communication from India, *supra* note 110, ¶ 15 (suggesting compulsory licenses of right for all drugs).

<sup>273</sup> TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 9 (noting that a subcommittee evaluates each drug and considers both whether the drug is necessary on a health level, as well as if there are access problems, or a financial burden on the government health insurance scheme).

<sup>274</sup> Efavirenz License, *supra* note 201, at 38-39; Kaletra License, *supra* note 201, at 41-42; Plavix License, *supra* note 201, at 40; *see also* TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 11-12 (explaining process for deciding whether to issue a compulsory license).

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“patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology.”<sup>275</sup> While criticisms of Thailand have not directly raised this issue, there is nonetheless a question of whether this requirement of non-discrimination applies to compulsory licenses issued under Article 31.<sup>276</sup> The WTO panel in *Canada—Pharmaceutical Patents* previously noted that the non-discrimination requirement governs Article 30—a provision similar to Article 31 in that it also provides an exception from the usual requirements of Article 27—such that the provision would seem to equally apply to Article 31.<sup>277</sup> However, the question remains as to whether Thailand’s compulsory licenses discriminate as to the field of technology because all licenses thus far have been issued in the area of pharmaceuticals. The prior WTO panel noted that a law would not be *de jure* discriminatory unless its language limited its scope to only pharmaceuticals and that it would not be *de facto* discriminatory unless there was evidence of a discriminatory purpose. Even where the statute applied more to pharmaceuticals than other fields of technology, the panel found that it was not discriminatory unless the broader possible application was a sham.<sup>278</sup> Here, the compulsory license provision utilized is not limited to pharmaceuticals, so there is no *de jure* discrimination. In addition, there is no evidence of a discriminatory purpose against pharmaceuticals in general, such that there is no *de facto* discrimination. Notably, not all pharmaceuticals have been subject to compulsory licenses.

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<sup>275</sup> TRIPS, *supra* note 7, art. 27(1).

<sup>276</sup> Thailand and other developing countries are unlikely to raise this problem given that during the negotiation of TRIPS, developing countries insisted that compulsory licenses were not limited by the non-discrimination provision. See Council for Trade-Related Aspects of Intellectual Property Rights, Submission from the African Group et al., *TRIPS and Public Health*, ¶ 8, IP/C/W/296 (June 29, 2001) (stating that “in no way do articles 27.1 . . . limit the right of Members to issue compulsory licenses.”); see also Letter from Brook Baker et al. to Samak Sundaravej, Thai Prime Minister, and Chaiya Sasomsap, Minister of Public Health 4 (Feb. 19, 2008), available at <http://www.ci4life.net/th/media/legal.pdf> (suggesting that Article 27 of TRIPS is not a problem for the Thai compulsory licenses because each license has been considered on its own merits).

<sup>277</sup> *Canada—Pharmaceutical Patents*, *supra* note 58, ¶¶ 7.91-7.93.

<sup>278</sup> *Id.* ¶¶ 7.98-7.104.

### *C. Prior Negotiation*

This section analyzes whether Thailand complied with the requirement of prior negotiation—an issue of great importance to patent owners, yet also often misunderstood. More specifically, this section analyzes whether Thailand’s actions constitute prior negotiation or fall within a permissible exception to the prior negotiation.

#### *1. Prior Negotiation*

There are two groups of Thai licenses that can be analyzed with respect to the requirement of prior negotiation. The first group consists of the licenses for Efavirenz, Kaletra, and Plavix, which were admittedly issued with little prior warning to the patent owner. The second group of licenses was for cancer drugs.

Although Thailand’s first three licenses were explicitly premised on an exception to the requirement of prior negotiation, public non-commercial use, a brief analysis of whether they could comply with the prior negotiation requirement is nonetheless instructive for analyzing future cases. Thailand’s negotiations with patent owners highlight the questions of whether prior negotiation with patent owners must occur immediately before the license is issued and whether owners must be informed that a license is being contemplated if negotiations fail. In particular, the question is whether negotiations with patent owners for lower prices years before the licenses are issued should constitute prior negotiation. If the goal of the prior negotiation provision is to avoid compulsory licensing, this would not seem to suffice since patent owners would not be on notice that a license was being contemplated. Accordingly, Thailand was probably wise not to rely on past negotiations.

Perhaps reacting to criticism regarding its initial licenses, Thailand engaged in a more substantial period of negotiation with patent owners before imposing licenses on cancer drugs. Discussions began in mid-October, and there were reported to be more than twelve rounds of negotiations before the licenses were issued.<sup>279</sup> In addition, even after the licenses were signed, Thailand deferred implementation of the licenses to continue

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<sup>279</sup> TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 4, 20-21.

negotiations.<sup>280</sup>

Even though Thailand engaged in longer negotiations, there may nonetheless be an issue of whether Thailand was seeking reasonable commercial terms and conditions. Thailand stated that it would continue to negotiate with patent holders even after the licenses were signed and would be willing to buy direct from the patent holders if they offered to sell at a price within five percent of generic competitors. While Thailand has suggested that this five percent is “meant to reward the loyalty of the patent holders,” patent holders are more likely to see this as an unreasonable royalty rate in light of the fact that cancer drugs are typically high-profit drugs.<sup>281</sup>

## 2. *Exception to Prior Negotiation*

As noted earlier, a country can impose a compulsory license without prior negotiation with the patent owner if the patent owner is notified as quickly as possible and one of three conditions exists: national emergency, situation of extreme urgency, or public non-commercial use.<sup>282</sup> This section analyzes whether the Thai licenses qualified for an exception to prior negotiation.<sup>283</sup> Although Thailand's licenses all stated that they were for public non-commercial use,<sup>284</sup> they will be analyzed under this provision as well as the national emergency provision to help define these terms.

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<sup>280</sup> *Id.* at 5-6.

<sup>281</sup> *Id.* at 6; *see also infra* note 436 and accompanying text (noting that cancer drugs are one of the most profitable for drug companies). In addition, the prospect of compulsorily licensing cancer drugs could loom large considering that cancer drugs represent a disproportionate number of the current pipeline of drugs under development. *See* PhRMA, Profile 2008, at 8, <http://www.phrma.org/files/2008%20Profile.pdf> (last visited Feb. 8, 2009) (noting that there are nearly 600 drugs being developed for late stage cancer, versus only seventy-three for arthritis and fifty-seven for Alzheimer's Disease).

<sup>282</sup> TRIPS, *supra* note 7, art. 31(b).

<sup>283</sup> This section does not analyze whether the patent owner was notified as quickly as possible because of lack of available information. There might be an issue as to whether patent owners must be given direct notification, but in all cases the patent owners were immediately aware as soon as the licenses were authorized since the licenses were public.

<sup>284</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201; Plavix License, *supra* note 201.



### 3. *National Emergency or Situation of Extreme Urgency*

In Thailand's case, was there a national emergency regarding any condition that could have justified imposition of a license without prior negotiation with the patent owner? To answer this question, the licenses on HIV treatment should be considered separately from the licenses for heart disease and cancer medication. Thailand could have asserted a national emergency regarding the need to provide treatment for HIV using more effective second-line antiretrovirals. Treating HIV is generally considered an emergency.<sup>285</sup> However, some suggest that Thailand had no HIV emergency on several grounds: that Thailand's situation was less severe than South Africa, that Thailand had effectively limited a potential threat such that there was no emergency, or that any epidemic that exists is somehow inappropriate on the assumption that it is related to Thailand's sex industry.<sup>286</sup> Regardless of whether these accusations are true, Thailand's situation raises the question of whether a national emergency or situation of extreme urgency exists under Article 31 when non-action would result in an imminent emergency, even if one does not presently exist.

A tougher question is whether conditions such as heart disease and cancer can ever be considered a national emergency or situation of extreme urgency. Although Thailand did not rely on this basis, analyzing this exception is nonetheless important in evaluating the potential scope of a national emergency. The criticism from drug companies clearly indicates strong opposition to the concept that heart disease could be a national emergency.<sup>287</sup> However, if a substantial number of citizens are likely to die because of the inability to pay the patent owner's desired drug price, does that constitute a national emergency or situation of extreme urgency? The current criticisms underscore that there is

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<sup>285</sup> See, e.g., Doha Public Health Declaration, *supra* note 31, ¶ 5(c); see also United Nations, Office of the High Commissioner for Human Rights, Res. 2005/23, Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria, ¶ 1 (recognizing access to medication for HIV/AIDS as part of the right to health).

<sup>286</sup> See, e.g., Bate, *supra* note 251, at 2 (noting that Thailand's AIDS epidemic is "fueled by its notorious sex industry"); *Theft in Thailand*, *supra* note 1 ("it's hard to argue that Thailand has an AIDS epidemic, when its incidence is a little over one percent and countries such as South Africa are well over twenty percent").

<sup>287</sup> See *supra* notes 249-254 and accompanying text.

presently a lack of consensus on whether these conditions should be considered national emergencies. However, as previously noted, deciding what constitutes a national emergency is within the discretion of an individual nation.<sup>288</sup> In addition, the Doha Public Health Declaration explicitly notes that AIDS is only one example of when compulsory licenses can be issued—the document refers to “other epidemics,” thus opening the door for a country to declare other conditions to be national epidemics.<sup>289</sup> Some may suggest that an epidemic must be highly infectious and similar in nature to the listed diseases such as HIV and malaria.<sup>290</sup> On the other hand, if the number of citizens afflicted by heart disease or cancer is equivalent to HIV, why should a country be precluded from considering that a national epidemic? While drug companies and even the general public may see distinctions between communicable and non-communicable diseases, there should be no difference from a public health perspective if each impacts a large population similarly. Beyond what an individual country considers an epidemic, it is important to note that the global consensus may also change: at one time HIV epidemics in Africa and other countries were not considered situations to which compulsory licenses should be applied whereas now there is generally no question that HIV is a legitimate emergency.<sup>291</sup> The

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<sup>288</sup> See *supra* notes 123-124 and accompanying text.

<sup>289</sup> Doha Public Health Declaration, *supra* note 31, ¶ 5(c).

<sup>290</sup> See generally *supra* note 130 (discussing dispute concerning whether the Doha Public Health Declaration is limited to the explicitly listed diseases, all of which are highly infectious).

<sup>291</sup> When South Africa first amended its laws to enable broad-scale compulsory licenses, the pharmaceutical industry urged the USTR to take action. South African Medicines & Related Substances Control Act Amendments 90 of 1995 s. 15(c); PHARMA, SUBMISSION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA FOR THE ‘SPECIAL 301’ REPORT ON INTELLECTUAL PROPERTY BARRIERS (1998) (requesting that South Africa be named a priority foreign country). In 1998, the USTR placed South Africa on its “priority watch list,” urged the country to repeal its laws and suspended its GSP benefits. See, e.g., L.J. Davis, *A Deadly Dearth of Drugs*, MOTHER JONES, Jan. 1, 2000; South African Press Release, Office of the U.S. Trade Representative, U.S. Announces Reports of Special 301 Annual Review (Apr. 30, 1999), available at <http://www.techlawjournal.com/intelpro/19990430s301.htm>. The pharmaceutical industry also brought suit in South Africa to halt implementation of the law. Notice of Motion, *PhARMA v. Republic of South Africa*, No. 4183/98 (High Court, Transvaal Provincial Division, (1998), available at <http://www.eptech.org/ip/health/sa/pharmasuit.html>. However, after substantial public pressure, the United

infectious nature of HIV may have helped in promoting the perception of HIV as a national emergency, but the ability of global perception to change is nonetheless notable. However, Thailand was probably wise not to rely on the national emergency exception.

#### 4. *Public Non-commercial Use*

Based upon the above discussion, another examination of some of the criticisms of the Thai license on Plavix suggests that the criticisms are not well founded under TRIPS. For example, some suggest that the Plavix license was suspect because it was issued by a military-based government to a for-profit entity.<sup>292</sup> However, the appropriate question is not whether a licensed third party is generally a profit-making company, but whether the licensed party is making the patented drug for public non-commercial use. The fact that the authorized party is a for-profit entity would not necessarily preclude its license use from qualifying as public non-commercial use if done for the benefit of the public, as previously discussed.<sup>293</sup> In addition, TRIPS expressly permits the government to authorize a third party to use a compulsory license and makes no distinctions based upon the type of government.<sup>294</sup> 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>295</sup> In fact, other provisions of Article 31 suggest that discretion is given to the national authority without regard to how

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States enacted an executive order stating that South Africa would no longer be pressured. Exec. Order No. 13,155, 65 C.F.R. 30,521 (2000) *reprinted in* 17 U.S.C. §105 (2000); *see also* SUSAN SELL, *PRIVATE POWER, PUBLIC LAW* 152-53 (Cambridge University Press 2003) (describing public protests that targeted not only pharmaceutical companies, but also Al Gore's presidential campaign).

<sup>292</sup> *See, e.g.,* Commentary, *Lonely Thailand*, *supra* note 262 (suggesting that Thailand was "exploiting vague language" in the context of suggesting that use by a military-based government can not constitute public non-commercial use); *see also* notes 255-258 and accompanying text (describing objections to Thailand's licenses as constituting public noncommercial use).

<sup>293</sup> TRIPS, *supra* note 7, art. 31; *see also supra* notes 136- 146 (analyzing meaning of the term public non-commercial use).

<sup>294</sup> TRIPS, *supra* note 7, art. 31.

<sup>295</sup> *See id.*

it is organized.<sup>296</sup> For example, the decision of what constitutes permissible subject matter is one that is within the province of the national government.<sup>297</sup>

#### *D. Procedural Requirements*

##### *1. Scope and Duration Limited to Authorized Purpose*

The next question is whether the Thai licenses were appropriately limited in scope and duration to the authorized purpose.<sup>298</sup> While critics tend to assert that licenses must be generally limited,<sup>299</sup> the actual TRIPS requirement is that “the scope and duration of such use shall be limited to the purpose for which it was authorized.”<sup>300</sup> The qualifying language about what must be limited indicates that there is no general limit on compulsory licenses.<sup>301</sup> As noted earlier, this clause could be interpreted in two ways. First, it could mean that the licenses only permit use of a patent for the stated purpose such that a licensed entity cannot make the patented invention for an unstated purpose. The alternative view is that the clause requires the scope and duration of the initial license be limited by the authorized purpose; in other words, how long the license lasts and the breadth of its coverage could be limited by the authorized purpose.

This section analyzes the Thai licenses based on both of the above interpretations. The analysis will focus first on licenses of patented drugs for the antiretrovirals Efavirenz and Kaletra, the heart medication Plavix, and finally, cancer drugs. Under the first interpretation, all of the licenses would seem fine thus far since there have been no reports that Thailand has made or imported

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<sup>296</sup> See also notes 122-124 and accompanying text (explaining that member countries have discretion to assess what constitutes an emergency); note 156 and accompanying text (explaining that no one is permitted to second guess whether a license is appropriately limited under art. 31(c)). See generally *id.* (providing no mention or distinction of rules for compulsory licensing based on the type of government).

<sup>297</sup> TRIPS, *supra* note 7, art. 31; see also notes 98-106 and accompanying text (explaining that national authorities have discretion to decide what subject matter should be subject to compulsory license).

<sup>298</sup> *Id.* art. 31(c).

<sup>299</sup> See *supra* notes 259-261 and accompanying text.

<sup>300</sup> TRIPS, *supra* note 7, art. 31(c) (emphasis added).

<sup>301</sup> *Id.*

more of the licensed quantities than permitted; in addition, issues with duration remains to be seen since the duration of the licenses has not yet expired.<sup>302</sup> The second interpretation requires a bit more analysis but will ultimately indicate that the Thai licenses still meet this slightly more stringent requirement.

Thailand stated that the antiretroviral licenses were important to satisfy its mandate of universal access to HIV drugs within existing budget constraints. The Efavirenz license notes that it is necessary because it is not only effective but has fewer toxic side effects than some unpatented treatments.<sup>303</sup> The Kaletra license states that it is necessary for the 500,000 Thai patients that are or who will become resistant to more basic formulations of antiretrovirals.<sup>304</sup> The licenses also note that the budget available for treating HIV infected patients was limited and that the price for the drugs from the patent owners was substantially higher than the prices of generic equivalents available from some countries; for example the price of Efavirenz in Thailand was twice as high as the generic drug in India.<sup>305</sup> The licenses were intended to increase accessibility by enabling the government to finance drugs for a greater number of people.<sup>306</sup> The Efavirenz license was for a maximum of 200,000 citizens, whereas the Kaletra license was for no more than 250,000 afflicted citizens; in both cases the licensed drug was only available to the poorest citizens covered by one of several national health insurance plans.<sup>307</sup> The licenses are intended to last until 2011 for Efavirenz and until 2012 for Kaletra, the end of the patent term for each drug.<sup>308</sup>

The antiretroviral licenses are the least controversial with respect to the requirement that scope and duration be limited to the authorized purpose. The number of patients covered is relatively limited—given that there are 500,000 HIV affected Thai citizens, only half would be granted access under the compulsory

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<sup>302</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201; Plavix License, *supra* note 201.

<sup>303</sup> Efavirenz License, *supra* note 201.

<sup>304</sup> Kaletra License, *supra* note 201.

<sup>305</sup> Efavirenz License, *supra* note 201.

<sup>306</sup> *See id.*; Kaletra License, *supra* note 201.

<sup>307</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

<sup>308</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

licenses.<sup>309</sup> In addition, duration for the remainder of the patent term seems reasonable since HIV is a long-term condition and without such treatment patients will succumb to opportunistic infections and also infect additional citizens.<sup>310</sup> The need to contain HIV infections is generally understood as critical to avoid an epidemic that once established is much more difficult to control.

One important question is the extent to which the existence of a national mandate to provide access to antiretrovirals should be relevant to determining whether use is limited to the authorized purpose. On one hand, if a nation has a national policy, or even legal mandate to provide access to medicine, a compulsory license designed to help achieve that purpose would seem to provide a legitimate reason to help justify a license. However, some might suggest that any nation could claim a policy to promote health and proceed to then license any and all drugs. While this approach would clearly not be endorsed by major pharmaceutical patent owners, developing countries that never had patents prior to TRIPS might consider this approach a reasonable accommodation of agreeing to provide patents. TRIPS Articles 7 and 8 do suggest that policies other than the economic interests of the patent owner must be considered.<sup>311</sup> Moreover, the Doha Public Health Declaration clarifies that TRIPS Articles 7 and 8 must be considered in interpreting *all* provisions of TRIPS.<sup>312</sup> While an argument can be made that this provision of TRIPS permits a country to license a number of drugs that are deemed necessary for the “purpose” of providing universal access to drugs, it is likely that a country that aggressively pursued this option would face a WTO panel dispute. Unless and until that happens, there may be other issues that mitigate against aggressive use of compulsory licenses beyond the TRIPS arena, as further discussed in Part VI.

The next question is whether the license for Plavix, which was strongly criticized by patent owners, is limited to its authorized

<sup>309</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

<sup>310</sup> See, e.g., Bertozzi et al., *HIV/AIDS Prevention and Treatment, in DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES* 351, 353-55 (Dean T. Jamison et al. eds., Oxford University Press 2d ed. 2006).

<sup>311</sup> TRIPS, *supra* note 7, art. 7-8.

<sup>312</sup> Doha Public Health Declaration, *supra* note 31, ¶ 5(a).

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purpose. The license states it is necessary to address the cost involved in treating Thai patients who would otherwise be subject to high mortality and disability because heart disease is one of the top three causes of death.<sup>313</sup> Despite acknowledging that some non-drug preventative measures can be helpful, the license notes that Plavix is nonetheless necessary and an effective treatment to prevent undue morbidity and mortality.<sup>314</sup> In addition, the license suggests that whereas only twenty percent of currently covered patients can access the drug, a compulsory license should dramatically increase accessibility to six or twelve times the current coverage.<sup>315</sup> Unlike the initial antiretroviral licenses, the Plavix license states that it is to be provided to an “unlimited number of patients” who are covered by government health insurance, which are typically the lowest income citizens, for the duration of the patent or until “no essential need” exists.<sup>316</sup> Although there is no specific number of patients noted in the license, the fact that only patients who are covered by the governmental plan intended for lower income citizens does provide a limit.<sup>317</sup> Moreover, on the important question of whether the license is limited with regard to its *purpose*, the license does seem to be limited to the purpose of ensuring greater access to Plavix.<sup>318</sup>

Whether Plavix is the most effective treatment or even necessary in light of other available treatments raises the question of whether TRIPS permits nations to decide whether patented drugs may be compulsory licensed when alternatives exist. Arguably, any compulsory license would seem to achieve the purpose of lowering costs. While most of the criticism concerning Plavix focused on the fact that heart disease is not an “emergency,”<sup>319</sup> a better question is likely whether a patented drug is necessary to treat heart disease when unpatented alternatives,

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<sup>313</sup> Plavix License, *supra* note 201 (“myocardial ischemia and cerebro-vascular accident are the most serious public health burden because of high mortality and disability,” with mortality rate among the top three).

<sup>314</sup> *Id.* (noting that Plavix is necessary for secondary prevention of thrombosis).

<sup>315</sup> *Id.*

<sup>316</sup> *Id.*

<sup>317</sup> *See id.*

<sup>318</sup> *See id.*

<sup>319</sup> *See supra* notes 249-254 and accompanying text.

including aspirin, exist.<sup>320</sup> The Thai White Paper did not attempt to suggest that Plavix was superior to other alternatives; rather, it stated that it was “at least as effective as or more effective than Aspirin.”<sup>321</sup> There is notably nothing in TRIPS that requires that less restrictive options be pursued, but it is likely to nonetheless be expected by patent owners.<sup>322</sup>

The final question is whether the Thai licenses for cancer were adequately limited to their authorized purpose. Each license declares it is necessary because cancer is a leading cause of death that results in a serious economic burden and even financial catastrophe for patients and their families who have low- or middle-income status.<sup>323</sup> Three of the four licenses were for drugs noted as effective treatments for lung and breast cancer, which are stated to be of highest incidence among Thai men and women respectively.<sup>324</sup> The licenses each state they will last either until the patent expires or until there is “no essential need.”<sup>325</sup> As with the Plavix license, there is no absolute number given on the number of Thai citizens to be covered but the licenses state that they will only be for lower income citizens covered by government insurance.<sup>326</sup>

This analysis suggests that almost any license can meet the requirement that it be limited in scope and duration to its purpose. In each of the above cases, the licenses met their stated purpose: of providing universal access to antiretrovirals in light of a limited budget, of providing cheaper heart medication that is at least as

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<sup>320</sup> TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 14.

<sup>321</sup> *Id.*

<sup>322</sup> See TRIPS, *supra* note 7, art. 31.

<sup>323</sup> Docetaxel License, *supra* note 222; Erlotinib License, *supra* note 222; Imatinib License, *supra* note 222; Letrozole License, *supra* note 222. In addition, the Thai White Paper notes cancer has been a leading cause of death for more than a decade and is no less serious than HIV/AIDS. TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 2.

<sup>324</sup> Docetaxel License, *supra* note 222; Erlotinib License, *supra* note 222 (noting that lung cancer is highest among Thai men); Imatinib License, *supra* note 222; Letrozole License, *supra* note 222 (noting that breast cancer is highest among Thai women).

<sup>325</sup> Docetaxel License, *supra* note 222; Erlotinib License, *supra* note 222; Imatinib License, *supra* note 222; Letrozole License, *supra* note 222.

<sup>326</sup> Docetaxel License, *supra* note 222; Erlotinib License, *supra* note 222; Imatinib License, *supra* note 222; Letrozole License, *supra* note 222.



effective as unpatented aspirin, and of providing cheaper cancer treatment to limit a leading cause of death. However, each group of licenses pushes the boundaries of what limit, if any, exists in the TRIPS requirement that the license be limited in scope to its purpose. The literal language does not require that the purpose be one that is globally accepted; rather the key TRIPS language is that it be “authorized,” thus suggesting a bona fide government action but not an action subject to second-guessing by other countries.<sup>327</sup> Accordingly, the fact that only Efavirenz is listed on the WHO list of essential drugs and no cancer drugs are listed on the WHO list is technically irrelevant, at least to a TRIPS analysis.<sup>328</sup> Indeed, prior scholars suggest that this particular TRIPS requirement could be easily satisfied by developing countries wanting to use TRIPS flexibilities,<sup>329</sup> with some even suggesting that compulsory licensing could be a tool to enable governments to exercise price control.<sup>330</sup> While some might suggest that this flexibility indicates that TRIPS is overly permissive with regard to compulsory licensing, it could also be interpreted as an appropriate deference to national decisions regarding health priorities, an area that has traditionally been within the scope of national discretion.<sup>331</sup> Moreover, it should be

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<sup>327</sup> See TRIPS, *supra* note 7, art. 31.

<sup>328</sup> World Health Organization, WHO Model List of Essential Medicines (2007), <http://www.who.int/medicines/publications/essentialmedicines/en/>.

<sup>329</sup> See, e.g., CORREA 2007, *supra* note 29, at 320 (noting that a compulsory license may be limited, but also suggesting that it may nonetheless cover all claims of the patent for the duration of the term); NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS 327 (Kluwer Law International 2d ed. 2005) (stating that the duration must be tailored to the needs); WATAL, *supra* note 101, at 321-24. Others, however, have not as fully analyzed the possibilities of this provision. See, e.g., RESOURCE BOOK ON TRIPS, *supra* note 108, at 472-73 (noting briefly that the duration may be limited and that there may be restrictions on the use).

<sup>330</sup> REICHMANN WITH HASENZAHN, *supra* note 3, at 15. Professors Abbott and Reichmann have further asserted that there is no real difference between price controls of drugs—something that industrialized countries often use—and compulsory licenses of drugs when the price is too high. Abbott & Reichmann, *supra* note 31, at 955.

<sup>331</sup> One scholar has suggested that in interpreting other WTO agreements, WTO panels have indicated some deference to national health policies. M. Gregg Bloche, *WTO Deference to National Health Policy: Toward an Interpretive Principle*, 5 J. INT'L. ECON. L. 825, 835-37 (2002). In addition, other scholars have suggested interpreting TRIPS in the context of broader international norms, such as the norm of the right to health, together with the subsidiary right to health. See Barbosa et al., *supra* note 57, at

noted that this is only *one* of the many requirements of TRIPS Article 31.<sup>332</sup>

## 2. Adequate Remuneration

There has been extensive discussion that the licenses are financially detrimental to pharmaceutical companies as well as their general incentive to innovate,<sup>333</sup> but little discussion of whether the royalties provided in each of these cases are adequate. Some comments suggest that reasonable royalties would be inherently inadequate because they would “almost always leave the rights holder with far less than a reasonable economic return.”<sup>334</sup> While it may be true that a compulsory license provides below market rates and even inadequate economic returns, there is no requirement that compulsory licenses provide market rates.<sup>335</sup> Rather, this objection seems to be to any compulsory license—in direct contravention of what TRIPS permits.<sup>336</sup>

The question is whether the royalty rate provided in each of the licenses satisfies the TRIPS requirement that the amount be “adequate . . . taking into account the economic value of the authorization.”<sup>337</sup> As noted earlier, adequate in this case means satisfactory but not ideal, such that it must be lower than the patent owner’s generally preferred price.<sup>338</sup> The initial Thai licenses for the antiretrovirals and Plavix provide a royalty of one-half percent.<sup>339</sup> Thailand’s White Paper on the compulsory licenses

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118-20. However, thus far, WTO panels have actually been criticized for interpreting TRIPS too literally to the detriment of public health. *See, e.g.*, Howse, *supra* note 58, at 496-501; *see also* Okediji, *supra* note 70, at 84 (criticizing panels for giving inadequate weight to social considerations).

<sup>332</sup> *Id.*

<sup>333</sup> *See infra* notes 391-397 and accompanying text (noting concerns of pharmaceutical companies, as well as some nations that Thailand’s licenses are inconsistent with innovation policy).

<sup>334</sup> *Drug Patent Piracy, supra* note 1.

<sup>335</sup> *See generally* TRIPS, *supra* note 7, art. 31 (providing for reasonable compensation, but not mentioning market rates).

<sup>336</sup> *Id.*

<sup>337</sup> *Id.* art. 31(h).

<sup>338</sup> *See supra* note 167 and accompanying text.

<sup>339</sup> Efavirenz License *supra* note 201; Kaletra License, *supra* note 201; Plavix License, *supra* note 201.

explained that it was establishing a royalty rate of between one-half to two percent of sale value based upon the range used in most developing countries for public non-commercial use with the lower and upper limits being used for high and low retail value drugs respectively.<sup>340</sup> Despite setting two percent as the maximum, Thailand's licenses on the cancer drugs each provided three percent of the sale value of the drug.<sup>341</sup>

Whether the amounts are adequate may be one of the least clear issues with respect to a TRIPS analysis. There are no prior WTO panel decisions. In addition, it is unclear whether a member country would bring a dispute before the WTO, given that disputes thus far have been based upon clear violations rather than ambiguous terms. Moreover, unlike most other TRIPS disputes there is an ability to challenge the remuneration amount in domestic courts since TRIPS already requires that member states provide a means to challenge both a compulsory license as well as any remuneration decision.<sup>342</sup> There has been little discussion of this issue with regard to Thailand's actions. Even criticisms of Thailand's licenses rarely discuss the amount of remuneration, and there are not any alternative royalty rates proposed; rather, the alternative discussed is always simply not imposing a license.<sup>343</sup>

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<sup>340</sup> TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 11.

<sup>341</sup> Compare *id.* with TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220.

<sup>342</sup> TRIPS, *supra* note 7, art. 31.

<sup>343</sup> See, e.g., Bate & Boateng, *supra* note 23, at 7 (arguing that prices set by drug companies are required for continued research and development without any consideration of an appropriate royalty under a compulsory license and in fact characterizing compulsory licenses as “theft”); *Patent Remedy*, *supra* note 5, *passim* (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); *Thailand and the Drug Patent Wars*, *supra* note 251, *passim* (suggesting Thailand's licenses were not compliant with TRIPS because they were granted in an inadequate emergency situation, but never addressing appropriate level of remuneration); Benjamin Krohmal, Knowledge Ecology International, Notes from March 16<sup>th</sup> 2007 U.S. Capitol Briefing on Thailand's Compulsory Licenses, Statement of Richard Kjeldgaard, of PhRMA (Mar. 16, 2007) [http://www.keionline.org/index.php?option=com\\_content&task=view&id=37](http://www.keionline.org/index.php?option=com_content&task=view&id=37) (avoiding discussion of whether Thailand's licenses were consistent with TRIPS by characterizing such issues as “legal technicalities” and instead generally arguing that compulsory licenses are destructive to drug development). The lack of discussion of appropriate remuneration is widespread. See, e.g., Robert Steinbrook, *Thailand and the Compulsory Licensing of Efavirenz*, Perspective, 356 NEW ENG. J. MED. 544, 544 (Feb. 8, 2007) (mentioning the amount of remuneration provided

Even amidst the lack of clarity, there is a question about whether the amounts of remuneration are proper in light of the fact that TRIPS requires that the level of remuneration take into account the economic value of the authorization. Is it possible that the economic value of the authorization for two HIV drugs is equivalent to the value of the heart treatment drug Plavix? In addition, what is the economic value of the cancer drugs? On the one hand, an argument could be made that the economic value was taken into account since the royalty rate provided for the cancer drugs (three percent) was substantially higher than the HIV drugs (one-half percent). On the other hand, even amongst the HIV drugs some may suggest that the economic value was not taken into account since the royalty is identical, yet Kaletra is a second-line HIV treatment whereas Efavirenz is a first-line HIV treatment.<sup>344</sup>

While the earlier discussion suggests that national assessments of adequate remuneration should be given deference, additional discussion and clarification on this issue would be valuable. Perhaps additional detail on royalty rates for compulsory licenses that have previously been issued in both developed and developing countries would be pertinent for both general discussions. Canada's recent amendment to its patent act to allow compulsory licenses for exports to developing countries provides one model where the royalty is set as a function of the country's standing on the United Nations Human Development Index, with rates ranging from two-hundredths of a percent to a maximum of four percent.<sup>345</sup> In addition, the WHO has already compiled detailed information regarding remuneration amounts in a variety of different countries and contexts; however, this additional information has thus far not

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in the licenses, but not discussing the actual TRIPS requirement or whether the Thai licenses would comply with TRIPS); *A Gathering Storm*, *supra* note 260, *passim* (providing an overview of concerns about compulsory licensing, but no mention of remuneration requirement, or what it means).

<sup>344</sup> Kaletra License, *supra* note 201; Efavirenz License, *supra* note 201.

<sup>345</sup> Canadian Intellectual Property Office, Use of Patents for Humanitarian Purposes, <http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr00119e.html> (last visited Feb 8, 2009) (noting that royalties are calculated by multiplying the monetary value of the supply agreement between the holder of the authorization and the importing country by an amount that fluctuates on the basis of that country's standing on the United Nations Human Development Index, with a maximum royalty rate of four percent).

yielded a productive discussion.<sup>346</sup> Rather, drug companies dispute what constitutes a compulsory license, do not provide alternative rates, and instead seem to focus on trying to eliminate compulsory licenses.<sup>347</sup> Accordingly, while disputes over the definition of “reasonable remuneration” may not seem the most likely candidate for WTO panel resolution, some action at the WTO level may eventually be necessary whether through an official dispute settlement panel report or a declaration along the lines of the Doha Public Health Declaration.

#### *E. Conclusion*

While there are interpretative issues regarding whether the Thai licenses are appropriate, they are not the same issues raised by critics. All of the licensed drugs—for HIV, heart disease, and cancer—were appropriate subject matter under TRIPS because TRIPS does not limit the use of compulsory licenses to any specific list of diseases and that approach was rejected during negotiations.<sup>348</sup> Moreover, contrary to public opinion, there is no requirement that licenses be limited to emergencies.<sup>349</sup> Accordingly, criticisms that heart disease is not an emergency are simply irrelevant to compliance with current TRIPS requirements; how these issues should be considered as a matter of policy is addressed in Part VI.

The real issue is what constitutes public non-commercial use, such that prior negotiation with the patent owner before issuance of a compulsory license can be waived. The default rule is that parties should first engage in an attempt to reach a voluntary license before a compulsory license is issued.<sup>350</sup> However, TRIPS clearly states that this requirement can be waived for an emergency, a situation of extreme urgency, or a public non-

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<sup>346</sup> WHO—REMUNERATION GUIDELINES, *supra* note 179 (providing a variety of approaches to remuneration based upon guidelines by the Japanese Patent Office, Canadian Export Guidelines, and the UNDP Human Development Report).

<sup>347</sup> The lack of productive discussion may be based on drug company concerns that extend the remuneration rate of a single compulsory license to related issues, such as if a low rate in one country were to be used by a wealthier country that engages in reference pricing.

<sup>348</sup> See *supra* notes 102-106 and accompanying text.

<sup>349</sup> See *supra* notes 119-120 and accompanying text.

<sup>350</sup> TRIPS, *supra* note 7, art. 31(b).

commercial use.<sup>351</sup> Thailand's initial three licenses were imposed without prior negotiation—at least not with specific notification of the possibility of a compulsory license—and the licenses each stated that they were for public non-commercial use.<sup>352</sup> There are two issues here. First, does prior negotiation under TRIPS require that the patent owner be informed that a license is imminent? Or does any negotiation with a patent owner, even years before a license is issued, qualify as prior negotiation? Arguably prior negotiation under Article 31 requires the patent owner be informed that a license is a possibility.<sup>353</sup> However, even with that issue resolved, other aspects of the prior negotiation requirement remain unclear. For example, what constitutes negotiation for a reasonable time and under reasonable terms? The patent owner is likely to have a very different view than the country desirous of a compulsory license.

There is a reasonable argument that Thailand's first three licenses to provide drugs without profit to its citizens were for a public non-commercial use—especially since the negotiating history indicates that some member states, namely the United States, wanted a broad interpretation of this provision and that interpretation was not opposed by others.<sup>354</sup> Because what constitutes public non-commercial use is currently unclear, this rationale might be the weakest aspect of Thailand's license justification, but yet not a situation where Thailand clearly violated TRIPS.

Thailand also satisfied the procedural requirements under TRIPS with regard to issuing compulsory licenses. Importantly, because TRIPS only requires licenses to be limited in scope with regard to the authorized purpose and not limited in the abstract, each of the licenses seems appropriate.<sup>355</sup> Whether this requirement is interpreted as simply using the license for the

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<sup>351</sup> *Id.*

<sup>352</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201; Plavix License, *supra* note 201.

<sup>353</sup> See TRIPS, *supra* note 7, art. 31(b).

<sup>354</sup> See *supra* note 104 (noting that the United States wanted to ensure that TRIPS permitted the United States continued use of a law allowing use of any patent without authorization of the patent owner when the use was by the U.S. government or those authorized by the U.S. government).

<sup>355</sup> See TRIPS, *supra* note 7, art. 31.

initially designated purpose, or whether the scope and duration are substantively limited to the stated purpose, the licenses should satisfy the requirement. The amount of HIV drugs was limited with respect to only treating a fraction of HIV patients.<sup>356</sup> In addition, the scope of the license in terms of its duration was arguably limited with regard to the purpose—all the licensed drugs were to treat long-term conditions, such that the license was necessary for the duration of the patent term.<sup>357</sup> Similarly, the number of patients covered was also limited in all cases because only Thailand's poorest citizens were covered and not the ones who could afford the market-price of drugs offered by the patent owner.<sup>358</sup>

A possible unresolved issue generally ignored by patent owners is whether Thailand's remuneration was adequate under TRIPS as opposed to adequate based on desired profitability. The initial licenses only offered one-half percent of the net sales, with the cancer licenses offering two percent of the net sales.<sup>359</sup> The patent owners never challenged these numbers directly, but instead made statements suggesting that any compulsory license would be inadequate. The patent owners could have challenged both the license, as well as the royalty rates under the Thai law—legal options required by TRIPS Article 31—but declined to do so.<sup>360</sup> The question of what rate is appropriate for compulsory licenses in general is likely to be an issue even if it has thus far not been an issue with the Thai licenses. There are already ample resources that provide various mechanisms.<sup>361</sup> However, whether patent owners are willing to discuss actual royalty rates rather than challenge compulsory licenses in their entirety is yet to be determined.

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<sup>356</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

<sup>357</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

<sup>358</sup> Efavirenz License, *supra* note 201; Kaletra License, *supra* note 201.

<sup>359</sup> Docataxel License, *supra* note 222; Efavirenz License, *supra* note 201; Erlotinib License, *supra* note 222; Imatinib License, *supra* note 222; Kaletra License, *supra* note 201; Letrozole License, *supra* note *supra* note 222; Plavix License, *supra* note 201.

<sup>360</sup> TRIPS, *supra* note 7, art. 31(i)-(j); Thai Patent Act B.E. 2322 §§ 50-51.

<sup>361</sup> See discussion *supra* notes 179-182 and accompanying text.

## VI. Concerns Beyond TRIPS

Although Part V concluded that Thailand's licenses could be reasonably considered within the scope of TRIPS Article 31, there are important related issues that must be considered by Thailand, as well as any other country interested in considering compulsory licenses. In particular, retaliatory acts against Thailand cast a troubling shadow over TRIPS' legitimacy that needs to be addressed. This Part provides an overview of retaliatory actions and also explores underlying issues that may fuel not only the present controversy regarding TRIPS, but also the retaliation.

### A. Retaliation and Repercussions Beyond TRIPS

#### 1. Drug Company Retaliation

One important problem with issuing compulsory licenses is that patent owners may retaliate by withdrawing other drugs from the marketplace. Thailand, like most countries, requires drug manufacturers to establish that new drugs are safe and effective before they can be sold.<sup>362</sup> After Thailand issued a compulsory license on Abbott's HIV drug Kaletra, Abbott announced that it was withdrawing its application to sell seven new drugs in Thailand including its new HIV drug, Aluvia, that was well-suited to Thailand's climate.<sup>363</sup> Abbott's action is believed to be the first such retaliation by a drug company to a compulsory license,<sup>364</sup> prompting substantial criticism, calls for boycotts, and protests at

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<sup>362</sup> Thailand Drug Act B.E. 2510 (1967); *see also* Thailand Food and Drug Administration, Pre-marking Control-licensing, <http://www.fda.moph.go.th/eng/drug/pre.stm> (last visited Feb. 8, 2009) (discussing pre-marketing registration requirements).

<sup>363</sup> *See* discussion *supra* note 26 and accompanying text. Besides the new heat-stable version of Kaletra, sold under the market name Aluvia, Abbott withdrew painkiller Brufen, antibiotic Abbotec, blood clot drug Clivarine, arthritis drug Humira, blood pressure drug Tarka and kidney disease drug Zemplar. *See, e.g.*, Abbott Pharmaceuticals in Thailand: Fact Sheet (OxFam America), Apr. 13, 2007, [http://www.oxfamamerica.org/whatwedo/campaigns/access\\_to\\_medicines/news\\_publications/Abbott%20in%20Thailand](http://www.oxfamamerica.org/whatwedo/campaigns/access_to_medicines/news_publications/Abbott%20in%20Thailand) [hereinafter OxFam America Fact Sheet].

<sup>364</sup> *See, e.g.*, Marwaan Macan-Markar, *Thailand: U.S. Pharma Giant Faces Public Boycott*, IPS, Mar. 21, 2007, <http://www.aegis.com/news/ips/2007/IP070310.html>; Schuettler, *supra* note 243; *U.S. Drugmaker Abbott, Thailand Face Off in AIDS Drug Patent Stalemate*, INT'L HERALD TRIB., June 6, 2007, at 2; *see also* Hookway & Zamiska, *supra* note 194 (noting that some referred to Abbot's action as the "nuclear option").



Abbott's shareholder meeting.<sup>365</sup> Although Abbott eventually decided to register Aluvia and offer it at a discounted rate to Thailand, it has not changed its position on the other drugs.<sup>366</sup>

Abbott's decision not to introduce certain drugs in Thailand is beyond the reach of TRIPS. TRIPS requires nations to patent certain drugs but does not require patented drugs to be sold.<sup>367</sup> Accordingly, despite the fact that TRIPS provides the flexibility of using a compulsory license, that flexibility may be illusory if patent owners can respond by withdrawing other drugs from the market. After all, what good is a compulsory license of one drug for a relatively small population of 50,000 (the number for which Kaletra was licensed),<sup>368</sup> if it results in half a dozen other drugs being unavailable to all citizens of a country? The scope of the risk may be a function of what drugs are at issue—although Abbott remains steadfast in declining to sell certain drugs in

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<sup>365</sup> See, e.g., Nirmal Ghosh, *Battle Rages Over Thai Actions on Aids Drugs*, STRAITS TIMES, May, 28, 2007, available at [http://www.tillekeandgibbins.com/Publications/pdf/interview\\_thai\\_actions\\_on\\_aids\\_drugs.pdf](http://www.tillekeandgibbins.com/Publications/pdf/interview_thai_actions_on_aids_drugs.pdf); Macan-Markar, *supra* note 364; Bruce Jaspén, *AIDS Controversy Dominates Abbott Labs' Annual Meeting*, CHIC. TRIB, Apr. 27, 2007, available at [http://www.abbottsgreed.com/index.php?title=AIDS\\_controversy\\_dominates\\_Abbott\\_Labs%27\\_annual\\_meeting](http://www.abbottsgreed.com/index.php?title=AIDS_controversy_dominates_Abbott_Labs%27_annual_meeting); Tan Ee Lyn, *AIDS Activists Call for Boycott of Abbott Products*, Apr. 25, 2007, [www.abbottsgreed.com/index.php?title=AIDS\\_activists\\_call\\_for\\_boycott\\_of\\_Abbott\\_products](http://www.abbottsgreed.com/index.php?title=AIDS_activists_call_for_boycott_of_Abbott_products) (noting calls for boycotts of Abbott products); OxFam America Fact Sheet, *supra* note **Error! Bookmark not defined.**

<sup>366</sup> See, e.g., *Doubts Over Abbott's Latest AIDS Drug Claim*, NATION, Apr. 24, 2007, <http://www.actupny.org/reports/abbottgreed.html> (reporting Abbott's decision to introduce Aluvia in the Thai market at a lower price in reaction to public controversy); Hookway & Zamiska, *supra* note 194 (noting that in response to criticism, Abbott is offering to sell the new version of Kaletra if its patent is respected, but that Abbott remains unwilling to reinstate the other six applications); Nicholas Zamiska, *Abbott's Thai Pact May Augur Pricing Shift*, WALL ST. J., Apr. 23, 2007, at A3 (quoting Abbott Chief Executive Miles White as stating that "in the name of access for patients," Abbott had decided to sell Aluvia at a new price that Abbott asserts is lower than any generic if it is not subject to compulsory licensing, but that it will continue to withhold the other six drugs from the Thai market); see also Press Release, Abbott Laboratories, *Abbott Agrees with WHO Director-General to Expand Access to Kaletra/Aluvia* (April 10, 2007) (noting that Abbott will offer Kaletra/Aluvia to more than forty low- and middle-income countries at a new price of \$1000 per patient per year, which is allegedly lower than any generic price available and a reduction of fifty-five percent from the prior price, but without stating which specific countries are included).

<sup>367</sup> TRIPS, *supra* note 7.

<sup>368</sup> Kaletra License, *supra* note 201.

Thailand, most of the drugs were not unique.<sup>369</sup>

Abbott's action underscores that whether patients have access to medicine does not solely depend on patent issues, but also on whether a patent owner elects to seek permission to sell the patented drug. Technically, any entity that has a compulsory license could seek permission to sell a patented drug. However, the relevant laws to approve the sale of a new drug entail a substantial investment of time and resources; multiple stages of clinical testing of the drug in the laboratory, in animals, as well as in humans must be completed—a process that generally takes years and millions of dollars.<sup>370</sup> A company launching a newly patented drug can recover these expenses by charging more for the new drug.<sup>371</sup> However, if a second company seeks to sell a drug already on the market, the second company can often rely on the safety and efficacy studies of the first company's drug and then simply establish bioequivalence to the first drug, entailing minimal cost and time.<sup>372</sup> This bioequivalence is important with respect to

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<sup>369</sup> Most of the drugs that Abbott withdrew from the Thai marketplace have analogs offered by competitors. Two exceptions are the arthritis drug Humira, and the HIV drug Aluvia. However, Abbott notably bowed to public pressure in reversing its decision on Aluvia. See *supra* note 366 and accompanying text.

<sup>370</sup> See, e.g., U.S. CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 19-20 (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf>; DiMasi & Grabowski, *supra* note 42 (estimating cost of developing one drug to be as high as \$1.3 billion); PhRMA, Innovation, [www.phrma.org/innovation](http://www.phrma.org/innovation) (suggesting that the average period of drug development is fifteen years) (last visited Feb. 8, 2009).

<sup>371</sup> Patricia Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patients*, 3 INT'L J. HEALTH CARE FIN. & ECON. 183, 185 (2003) (noting that drug companies sell drugs at more than marginal cost to subsidize research costs). But see ANGELL, *supra* note 42, at 51 (quoting president and CEO of Merck as stating that "the price of medicines isn't determined by their research costs"); Donald W. Light & Joel Lexchin, *Foreign Free Riders and the High Price of U.S. Medicines*, 331 BRIT. MED. J. 958, 959 (2005) (stating that the claim of drug companies that prices must be set fifty to a hundred times production costs to recover research and development costs is unsubstantiated since such companies have not made underlying data available for public inspection). Nonetheless, drug companies continue to price patented drugs at a premium and to even steeply increase drug prices. See, e.g., Julie Appleby, *Prices for Some Drugs Skyrocket*, USA TODAY, Aug. 7, 2008, available at [http://www.usatoday.com/money/industries/health/drugs/2008-08-07-costlydrugs\\_N.htm](http://www.usatoday.com/money/industries/health/drugs/2008-08-07-costlydrugs_N.htm) (noting that some companies have increased prices by a hundred percent and more in a single year).

<sup>372</sup> See, e.g., U.S. CONG. BUDGET OFF., HOW INCREASED COMPETITION FROM

compulsory licenses because licenses are generally issued for drugs already sold, such that the approval costs are low.<sup>373</sup> On the other hand, if a compulsory license is issued for a drug that has never been previously sold, the license may be ineffective in reducing final costs to consumers because the necessary market approval tests may be expensive enough that the licensed company cannot sell drugs at a price that is both accessible to consumers and yields a profit.<sup>374</sup>

The costs involved in research and development of a drug, including the clinical tests necessary to obtain approval to sell a drug, are often a backdrop to discussions of compulsory licensing policy. Patent owners typically suggest that compulsory licenses threaten the patent system by removing research incentives with the implicit assumption that patents are necessary to recoup the costs of not only marketed drugs, but also the many drugs that are investigated but ultimately deemed unmarketable.<sup>375</sup> While this may seem at first blush a convincing argument, it neglects the fact that drug manufacturers obtain substantial profits in a relatively small number of markets, such that additional sales in middle-income and developing countries are *de minimus*.<sup>376</sup> In addition,

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GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xii, 44 (1998), available at <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (noting that the process to establish bioequivalence only takes a few years and a cost of \$1-2 million); *Canada—Pharmaceutical Patents*, *supra* note 58, ¶ 2.5 (noting that the approval time for a new drug is eight to twelve years, whereas the approval for a generic drug that is based on the original drug is three to six and half years).

<sup>373</sup> U.S. CONG. BUDGET OFF., *supra* note 372, at 44.

<sup>374</sup> Brook Baker noted that Abbott's withdrawal of Aluvia from the Thai registration process would make the approval of generic versions of Aluvia more difficult. Posting of Brook Baker to IP Disputes in Medicines blog, *Standing Up to Abbott's Decision to Withhold Registration and Marketing of Life-Saving Medicines—A New Variant of Pharmaceutical Apartheid*, <http://www.cptech.org/blogs/ipdisputesinmedicine/2007/03/standing-up-to-abbotts-decision-to.html> (March 13, 2007, 11:48 EST).

<sup>375</sup> See, e.g., Abbott Press Release, *supra* note 366 (noting that patents must exist so that there are incentives for research into new drugs); Press Release, Merck, Statement on Brazilian Government's Decision to Issue Compulsory License for Stocrin (May 4, 2007) (asserting that compulsory licenses ultimately hurt patients by eroding the incentive for research into new therapies) [hereinafter Merck Press Release]; see also Bate & Boateng, *supra* note 23, at 6-7 (suggesting that compulsory licenses or discounted prices for middle income countries will erode incentive for research).

<sup>376</sup> See, e.g., Richard M. Scheffler & Vikram Pathania, *Medicines and Vaccines for the World's Poorest: Is There Any Prospect For Public-Private Cooperation?*, 1 GLOBALIZATION AND HEALTH 10 (2005), available at <http://www.globalizationandhealth.org>.

although drug companies do finance clinical testing, they are among the most profitable businesses.<sup>377</sup> The financial well-being of drug companies is fostered not only by the high prices of patented drugs, but also by government subsidies through tax incentives, as well as by patent rights for federally funded inventions.<sup>378</sup>

## 2. *Unilateral Trade Sanction—Retaliation by Individual Countries*

Another very real implication of compulsory licenses is that countries may be subject to unilateral economic sanctions, or at least political pressure, imposed by individual countries even if a license is TRIPS-compliant.<sup>379</sup> Economic implications are a major

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com/content/1/1/10 (noting that the United States, Europe and Japan accounted for nearly eighty percent of the market in 2002); WORLD HEALTH ORGANIZATION, THE WORLD MEDICINES SITUATION 32 (2004) [hereinafter WHO, WORLD MEDICINES SITUATION] (noting that high income countries consume over ninety percent of world medicine, despite only comprising fifteen percent of the global population); Outterson, *supra* note 22, at 285 n.34 (noting that SEC filings confirm that between seven and a half and ten percent of global revenues are from developing countries).

<sup>377</sup> See, e.g., Fortune 500—2008 Report, <http://money.cnn.com/magazines/fortune/fortune500/2008/performers/industries/profits> (noting that the pharmaceutical industry is the third most profitable industry). In addition, although the current business model has drug companies providing for clinical testing, that business model is not necessarily immutable. Indeed, one scholar has suggested that because of the importance of clinical testing to society, as well as the potential for bias, such studies should be publicly funded. See, e.g., Tracy R. Lewis et al., *The Case for Public Funding and Public Oversight of Clinical Trials*, 4(1) ECONOMISTS' VOICE 1, 1-2 (2007), available at <http://www.bepress.com/ev/vol4/iss1/art3/>.

<sup>378</sup> See, e.g., David Henry & Joel Lexchin, *The Pharmaceutical Industry as a Medicines Provider*, 360 LANCET 1590, 1593 (2002); Outterson, *supra* note 22, at 287-88.

<sup>379</sup> Some have also suggested that compulsory licenses will also cause economic hardship if businesses are reluctant to invest in a country where they fear their rights will not be protected. PHARMA SPECIAL 301 SUBMISSION 2008 35 (2008), available at [http://www.ustr.gov/assets/Trade\\_Sectors/Intellectual\\_Property/Special\\_301\\_Public\\_Submissions\\_2008/asset\\_upload\\_file109\\_14495.pdf](http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/Special_301_Public_Submissions_2008/asset_upload_file109_14495.pdf) (asserting that Thailand's licenses are of concern to the entire business community because the environment is perceived as "harmful to international investors and which will ultimately work to disadvantage Thai citizens"); Anuchit Ngyuyen, *Thailand Risks Losing Investments from U.S. on Patents Dispute*, Mar. 20, 2007, BLOOMBERG.COM (quoting Daniel Christman, of the U.S. Chamber of Commerce as stating that "the vast majority of companies that have been surveyed by us have expressed serious concern about future investment climate in Thailand"); Peter Mandelson July 10 Letter, *supra* note 27 (suggesting that Thailand's

problem since any cost-saving from issuing a compulsory license may be dwarfed by more substantial economic sanctions.

The United States, for example, has enacted a number of trade laws that permit it to investigate other countries and potentially impose economic sanctions for a variety of perceived infractions, including intellectual property laws that are viewed as inadequate. In particular, the United States can withdraw trade benefits or impose duties on goods for a country that fails to provide “adequate and effective” protection for U.S. intellectual property rights.<sup>380</sup> By statute, the U.S. Office of Trade Representatives (USTR) must issue an annual report, called the “Special 301” report that lists countries with inadequate levels of intellectual property protection.<sup>381</sup> The worst offenders are labeled priority

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use of compulsory licenses “could lead to the isolation of Thailand from the global biotechnology investment community); Merck Press Release, *supra* note 375 (asserting that Brazil’s compulsory licenses “will have a negative impact on Brazil’s reputation as an industrialized country seeking to attract inward investment”). *But see* Letter from Dr. Mongkol Na Songkhla, Minister of Pub. Health to the Hon. Peter Mandelson, Member of the European Commission (Aug. 21, 2007), *available at* <http://www.keionline.org/misc-docs/thai/070821-MoPH-PM.pdf> (stating that Thailand “would like to learn, as implied in your letter, examples of . . . the isolation of any European Country that have implemented the CL on some medicines, from the global biotechnology investment community”).

<sup>380</sup> Trade Act of 1974, 19 U.S.C. §§ 2101-2497, § 2411 (2000). Imposition of trade sanctions is technically discretionary. 19 U.S.C. § 2411(d). In addition, the United States can remove trade preferences that are usually provided under the GSP based upon similar perceptions of inadequate intellectual property rights. 19 U.S.C. § 2462(c)(5) (permitting consideration of “the extent to which [a] country . . . provide[s] adequate and effective protection of intellectual property rights”). Although being listed on the Special 301 report is considered the worst penalty, withdrawal of preferences under GSP is also an issue. *See, e.g.*, Phusadee Arunmas, *Thailand Could Face Sanctions after lobbying by drug firms*, BANGKOK POST, Jan 31, 2008, *available at* <http://www.thailandwto.org/Doc/News/5817.pdf>; Robert Weissman, *Compulsory Licenses Are the Right Medicine*, NATION, Feb. 23, 2008, *available at* [http://www.nationmultimedia.com/2008/02/23/opinion/opinion\\_30066217.php](http://www.nationmultimedia.com/2008/02/23/opinion/opinion_30066217.php) (noting that that PhRMA has suggested that Thailand’s GSP status could be threatened). On the other hand, Thailand may be liable to lose some of its GSP status regardless of its compulsory licenses because it has become a more prosperous nation. *See, e.g.*, Weissman, *supra*; Letter from Professor Brook Baker et al. to Samak Sundaravej, Thai Prime Minister (Feb. 19, 2008), *available at* <http://www.cl4life.net/th/media/legal.pdf>. Indeed, Thailand’s White Paper concerning its cancer compulsory licenses suggests that reductions in GSP thus far have not been a problem. *See* TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 219, at 11.

<sup>381</sup> 19 U.S.C. § 2242(a). In addition, the report is not an independent assessment by a government agency; the statute explicitly permits the USTR to consider information

countries and are automatically subject to investigations that may result in the withdrawal of trade benefits.<sup>382</sup> Countries can and have been listed on the Special 301 report even if they are in full compliance with TRIPS and other international commitments.<sup>383</sup>

Typically, once a country is listed as a priority watch country, it is forced to enter into a trade agreement with the United States that imposes heightened standards of intellectual property.<sup>384</sup> Such an agreement may ensure that a country does not issue any further compulsory licenses by placing additional restrictions on compulsory licenses in the agreement.<sup>385</sup>

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submitted by interested persons. 19 U.S.C. § 2242(b)(2)(B) (permitting input from interested parties in determining priority foreign countries); *see also* PETER DRAHOS WITH JOHN BRAITHWAITE., *INFORMATION FEUDALISM* 94-99 (New Press 2002) (discussing close cooperation between USTR and companies in determining countries to include on Special 301 list). Accordingly, a major drug company and patent owner can not only directly retaliate against a country such as Thailand, but also suggest that the U.S. impose additional economic sanctions.

<sup>382</sup> 19 U.S.C. § 2242(b)(1) (2000) (providing that priority foreign countries have the “most onerous or egregious acts, policies, or practices” that either deny “adequate and effective intellectual property rights” or deny fair and equitable market access to US persons that rely on intellectual property rights); 19 U.S.C. §2242(e).

<sup>383</sup> 19 U.S.C. § 2242(d)(4) (2000) (noting that a foreign country may be determined to deny adequate and effective protection of intellectual property rights “notwithstanding the fact that the foreign country may be in compliance” with TRIPS).

<sup>384</sup> For example, the United States has offered to remove Thailand from the Special 301 Priority Watch List if Thailand promises to increase protection of intellectual property rights along the lines of a prior proposed Free Trade Agreement. *See* Pennapa Hongthong, *U.S. Action Plan Must be Opposed, Groups Tell Government*, *NATION*, May 9, 2007, available at [http://www.bilaterals.org/article.php3?id\\_article=8268](http://www.bilaterals.org/article.php3?id_article=8268); Posting of Brook Baker to [Healthcaregap.org](http://www.healthcaregap.org), *U.S. Action Plan for Thailand Comes Straight from Pharma*, <http://lists.essential.org/pipermail/ip-health/2007-May/011145.html> (May 9, 2007, 12:49 EST). Thailand had previously rejected a Free Trade Agreement with the United States on ground that it would be inconsistent with national sovereignty and human rights. *See, e.g.*, Third World Network, *Thai Human Rights Commission Criticises FTA with U.S.*, Jan. 26, 2007, [BILATERALS.ORG](http://www.bilaterals.org/article.php3?id_article=7012), [http://www.bilaterals.org/article.php3?id\\_article=7012](http://www.bilaterals.org/article.php3?id_article=7012).

<sup>385</sup> The United States has entered into a number of bilateral and regional trade agreements that are more restrictive than TRIPS. *See, e.g.*, Free Trade Agreement, U.S.-Singapore, art. 16.7(6)(a)-(b), May 6, 2003, 42 I.L.M. 1026 (requiring “reasonable and entire” compensation, rather than the adequate compensation required under TRIPS); Free Trade Agreement, U.S.-Korea, June 30, 2007, 46 I.L.M. 642 (providing no provision analogous to TRIPS Article 31 for compulsory licensing); *see also* Cynthia M. Ho, *A New World Order for Addressing Patent Rights and Public Health*, 82 *CHICAGO-KENT L. REV.* 1469, 1499-1500 (2007) (providing additional examples of free trade that limit compulsory licenses).

Thailand provides a useful illustration—Thailand’s compulsory licenses were noted as an issue in the 2007 and 2008 Special 301 reports, but Thailand was not alleged to have violated any specific provision of TRIPS.<sup>386</sup> Indeed, the United States may have no interest in asserting that Thailand violates TRIPS because the WTO rules concerning disputes for all WTO agreements require that individual nations not impose unilateral economic sanctions for violations of TRIPS; rather, nations are to use the WTO dispute settlement proceedings to settle any alleged violations of TRIPS.<sup>387</sup> However, as the Thailand case illustrates, a nation may be in compliance with TRIPS yet nonetheless vulnerable to unilateral trade sanctions—or, at least the threat of such sanctions, which includes pressure to enter into bilateral trade agreements that are likely unfavorable to Thailand. This situation may seem particularly unfair to developing countries because many of them entered into TRIPS with the assumption that the agreement would end unilateral trade sanctions.<sup>388</sup> Prior drafts of the WTO dispute settlement rules had broader language prohibiting any use of unilateral trade sanctions.<sup>389</sup> However, the final wording is much more limited, thus subjecting a country such as Thailand to the potential whim of other countries’ rules.<sup>390</sup>

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<sup>386</sup> See 2008 SPECIAL 301 REPORT, *supra* note 27, at 36-37; 2007 SPECIAL 301 REPORT *supra* note 27, at 27. Some members of Congress have suggested that Thailand’s priority status is unwarranted. See Letter from Henry A. Waxman et al., Members of Congress to Ambassador Susan Schwab, United States Trade Representative (June 20, 2007) available at <http://www.house.gov/waxman/pdfs/thailand%20letter%20to%20ustr%2006-20-07.pdf> (providing perspective of thirty-five Congressmen opposed to Thailand’s priority watch status).

<sup>387</sup> DSU, *supra* note 45, art. 23.2(a).

<sup>388</sup> See, e.g., Frederick M. Abbott, Commentary, *The International Intellectual Property Order Enters the 21<sup>st</sup> Century*, 29 VAND. J. TRANSNAT’L L. 471, 472-73 (1996); Barbosa et al., *supra* note 57, at 124; James Thuo Gathii, *Rights, Patents, Markets and the Global AIDS Pandemic*, 14 FLA. J. INT’L L. 261, 316-17 (2001-02).

<sup>389</sup> Draft Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Dec. 3, 1990, MTN.TNC/W/35/Rev. 1, at 226 (“Parties shall not have recourse in relation to other parties to unilaterally decided economic measures of any kind.”); RESOURCE BOOK ON TRIPS, *supra* note 108, at 661-63 (noting that the express reference against unilateral measures in the Brussels draft was absent from the next draft, the Dunkel draft).

<sup>390</sup> There has actually been a prior proceeding against the United States for its use of Section 301 actions, which are related to, but separate from the Special 301 annual report. Panel Report, *United States—Sections 301-310 of the Trade Act of 1974*,

## B. Underlying Issues

### 1. Are Compulsory Licenses Bad Policy?

One theme underlying the criticisms of the Thai licenses and even characterizations of the TRIPS issue is whether compulsory licenses are bad policy such that they should not be used even when permissible under TRIPS. This article began with the premise that TRIPS represents the current rule of law and is therefore the appropriate starting point for analysis. This article has established the appropriate legal interpretation of TRIPS, but because differing perceptions of compulsory license policy may subject countries, such as Thailand, to threat of retaliation, a brief review of policy issues is appropriate.

The majority of criticism invoked against Thailand focuses on compulsory licenses as inappropriate policy with respect to their impact on long-term innovation, rather than on whether they are permissible under TRIPS.<sup>391</sup> Patent owner Merck, for example,

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WT/DS152/R (Dec. 22, 1999). Since then, the United States has not imposed trade sanctions under Section 301 for any situation covered by the WTO, although it has continued to publish Special 301 Watch Lists. In addition, while there have been Congressional resolutions proposed to advocate that countries should not be placed on the Priority Watch List for exercising flexibilities under TRIPS, this apparently has not prevented Thailand from being placed on the list. See H.R. 525, 110th Cong. (2007); S.R. 241, 110th Cong. (2007).

<sup>391</sup> See, e.g., *U.S. Drugmaker Abbott, Thailand Face off in AIDS Drug Patent Stalemate*, INT'L HERALD TRIB., June 6, 2007 (quoting PhRMA President Billy Tauzin as stating that Thailand's "misguided focus on short-term 'budget fixes' could come at a far greater long term cost, potentially limiting importance incentives for research and development"); Suttinee Yuvejwattana & Beth Jinks, *Thailand Would Buy Abbott Drugs if Prices were Reduced*, CHIC. TRIB., June 6, 2007 (noting that PhRMA suggests compulsory licenses remove the incentive to invest in research); accord Benjamin Krohmal, Knowledge Ecology Studies, Notes from March 16<sup>th</sup> 2007 U.S. Capitol Briefing on Thailand's Compulsory Licensing, [http://www.keionline.org/index.php?option=com\\_content&task=view&id=37](http://www.keionline.org/index.php?option=com_content&task=view&id=37) (noting that a representative of PhRMA "began by stating that he would not focus on the legal technicalities" and argued instead that compulsory licenses destroyed incentives for innovation). Although the primary policy issue is innovation, some also comment that compulsory licensing is a dangerous policy because patent-owning drug companies are better suited to provide not only safe drugs, but also appropriate medical care and training. See, e.g., Bate, *supra* note 252 (asserting that drugs from patent owners are higher quality than those of Thailand's GPO); *Thai-ing Pharma Down*, *supra* note 241 (commenting that Western pharmaceutical companies provide training which ensures proper patient compliance and suggests that the costs are far greater than the costs of the drugs themselves). This objection seems to suggest that patented drugs are necessarily safer and ignores the fact



warned that the “expropriation of intellectual property sends a chilling signal to research-based companies.”<sup>392</sup> In addition, countries where multi-national drug companies reside have also criticized the compulsory licenses. The United States, home to Abbott, has referred to the compulsory licenses as “indications of a weakening respect of patents.”<sup>393</sup> Similarly, Switzerland, home to patent owner Novartis, issued a public “Aide Memoire” warning that research will be undermined if licenses are not used solely for “emergencies and other exceptional cases.”<sup>394</sup> In addition, E.U. Commissioner Peter Mandelson has written to the Thai Health Minister to state his view that Thailand’s licenses were “detrimental to the patent system, and so too innovation and the development of new medicines”<sup>395</sup> despite dissension among other E.U. officials.<sup>396</sup> In addition, Professor Richard Epstein has suggested not only that compulsory licenses will “cripple incentive[s]” necessary to invest in new drugs, but that there is a serious risk that drug companies will abandon the field of HIV

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that there is a separate agency in Thailand, as in the U.S., to investigate the safety and efficacy of any drugs sold to the public. Moreover the objection would extend beyond compulsory licenses to even generic drugs legally made after a patent expires.

<sup>392</sup> *Brazil, Thailand Override Big Pharma Patents*, 316 SCIENCE 1, May 11, 2007 (emphasis added).

<sup>393</sup> 2007 SPECIAL 301 REPORT, *supra* note 27, at 27; *see also* 2008 SPECIAL 301 REPORT, *supra* note 27, at 37 (“Thailand’s recent policies and actions concerning the compulsory licensing of patented medicines have contributed to continuing concerns regarding the adequate and effective protection of IPR in Thailand”).

<sup>394</sup> SWISS AIDE MEMOIRE, *supra* note 27, ¶ 4. The document further suggests that “broad use of compulsory licenses” might negatively impact foreign direct investment in Thailand. *Id.*

<sup>395</sup> Peter Mandelson July 10 Letter, *supra* note 27, ¶ 4. He also noted that the licenses “risk forcing more drug companies to abandon their patents and could lead to the isolation of Thailand from the global biotechnology investment community.” *Id.* at ¶ 3. In addition, Mandelson wrote another letter to the new Ministry of Commerce. *See* Letter from Peter Mandelson, Member, European Commission to Mingkwan Saengsuwan, Minister of Commerce, Thailand, ¶ 6 (Feb. 21, 2008), *available at* <http://www.keionline.org/misc-docs/thai/080221-PM-MoC.pdf> (suggesting that Thailand review the recent compulsory licenses on cancer, as well as concern that compulsory licenses only be used as an “exceptional measure”).

<sup>396</sup> David Cronin, *European Parliament Set to Reprimand Mandelson for Pressuring Thailand*, INTELL. PROP. WATCH, May 9, 2008, <http://www.ip-watch.org/weblog/index.php?p=1032>; David Cronin, *EU Split Over Thai Effort to Obtain Cheaper Patented Drugs*, INTELL. PROP. WATCH, Sept. 5, 2007, <http://www.ip-watch.org/weblog/index.php?p=732>.

research if other nations “follow Thailand’s lead” in exercising compulsory licenses.<sup>397</sup>

There are two assumptions lurking underneath these statements. First, compulsory licenses are assumed to be inappropriate and inconsistent with innovation, even though most nations historically permitted them—and many nations, including the United States, continue to grant them. Second, these statements suggest that maximum patent rights (without any compulsory licenses) in all countries are required for innovation.<sup>398</sup> Both of these propositions deserve further scrutiny.

The actual empirical data is equivocal on whether compulsory licenses dampen innovation. As noted recently by Professor Reichmann, a leading expert in the global debate about access to medicine, the “customary assertion of some economists that the use of compulsory licensing will depress investment in research and development requires careful and skeptical evaluation.”<sup>399</sup> There are few studies concerning the impact of compulsory licenses on innovation, but in the studies that exist, innovation was not shown to be negatively impacted.<sup>400</sup> In particular there are

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<sup>397</sup> Richard Epstein, *AIDS Drugs: Are Property Rights and Human Rights in Conflict?*, FT.COM, May 7, 2007, [http://us.ft.com/ftgateway/superpage.ft?news\\_id=fto051520070841096219&page=1](http://us.ft.com/ftgateway/superpage.ft?news_id=fto051520070841096219&page=1); Richard Epstein, *Thailand’s Actions have Long-Term Consequences*, FT.COM, May 7, 2007, <http://www.ft.com/cms/s/2/540bec3c-fcbb-11db-9971-000b5df10621.html>.

<sup>398</sup> See Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 288-89 (2008) (explaining that patent holders are able to “extract monopoly rents” which promote investment).

<sup>399</sup> REICHMANN WITH HASENZAH, *supra* note 3, at 6.

<sup>400</sup> See Donald McFetridge, *Intellectual Property, Technology Diffusion, and Growth in the Canadian Economy*, in COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE BASED ECONOMY 65 (Anderson & Gallini eds., 1998); Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. 853 *passim* (2003); F.M. Scherer, *The Economic Effects of Compulsory Patent Licensing*, in FINANCE AND ECONOMICS 1997, 84-88 (N.Y. Univ. Sch. Bus., Monograph Series No.1977-2, 1977). The studies, however, do not replicate the identical conditions. In particular, the studies involve licenses imposed as penalties for antitrust violations, as opposed to licenses imposed on the grounds of public health. Thus, there is a question as to whether companies will be less inclined to conduct research and development on drugs if they are more routinely subject to licensing on the grounds of public health, as opposed to penalties for antitrust violations which may seem more within the control of the company.

suggestions that compulsory licensing in a smaller market, such as Thailand, is less critical to influencing innovation.<sup>401</sup>

More specifically, there is the question of whether a compulsory license in one country will negatively impact global innovation, especially if the compulsory license is issued in a country that has a limited market.<sup>402</sup> Historically, many countries did not provide patents on drugs, such that any innovation prompted by patents was generated by a smaller group of countries.<sup>403</sup> Although TRIPS requires all member states to provide patents, drug companies continue to obtain most of their sales from financially wealthy countries, such as the United States.<sup>404</sup> Indeed, some have suggested that sales to developing countries are more akin to “windfall rents.”<sup>405</sup> Professors Abbott and Reichmann have suggested that so long as companies continue to recoup research costs in OECD markets, developing countries should simply pay marginal costs of production plus a five percent royalty and that this would already constitute “generous compensation.”<sup>406</sup> Based on their reasoning, patent-owning companies would still stand to reap substantial revenue even if multiple developing countries issued compulsory licenses.

There are no definitive studies that patents or increased patent rights promote innovation—contrary to often-stated assertions of the importance of strong patent rights.<sup>407</sup> Some assert that there is a correlation between strong intellectual property rights and expenditures on research, or that countries with strong patent

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<sup>401</sup> See, e.g., Chien, *supra* note 400, at 893-94; WORLD HEALTH ORGANIZATION & WORLD TRADE ORGANIZATION, *supra* note 52, at 91.

<sup>402</sup> Chien, *supra* note 400, at 883-95.

<sup>403</sup> See *supra* note 15 and accompanying text (noting that prior to TRIPS, fifty countries did not permit drug compounds to be patented).

<sup>404</sup> See, e.g., Abbott & Reichmann, *supra* note 31, at 971 (noting that companies typically recoup their costs plus profits in OECD markets); see also *supra* note 376 and accompanying text (noting that wealthy countries provide for eighty to ninety percent of global sales).

<sup>405</sup> REICHMANN WITH HAZENSHAL, *supra* note 3, at 6.

<sup>406</sup> Abbott & Reichmann, *supra* note 31, at 971 (quoting letter from Al Engelberg); see also Peter M. Gerhart, *The Tragedy of TRIPS*, 2007 MICH. ST. L. REV. 143, 163-67 (2007) (arguing that TRIPS extracts wealth for innovation that has already been incentivized under national frameworks).

<sup>407</sup> See Chien, *supra* note 400, at 883-92.

rights are more globally competitive.<sup>408</sup> However, correlation is not causation. In addition, history informs us that when nations have increased patent rights more innovation does not necessarily follow; on the other hand, the data is ambiguous because there could be many intervening factors, including the fact that in a global economy, stronger patent rights in one country may offset weaker rights in another country.<sup>409</sup> A number of policy studies suggest that increased patent rights do not necessarily improve domestic innovation if a nation is not at a level of economic development to benefit from patent rights.<sup>410</sup> Stronger patent rights may simply provide an opportunity for the same repeat patent players to reap additional revenue without increasing innovation.<sup>411</sup> Even for countries at a sufficient economic level of

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<sup>408</sup> See, e.g., Robert Evenson & Sunil Kanwar, *Does Intellectual Property Protection Spur Technological Change?* 6-8 (Yale Economic Growth Center Discussion Paper, No. 831, June 2001); Froehner, *supra* note 11, at 7.

<sup>409</sup> There is conflicting information about whether innovation increased in Canada once it ceased a policy of issuing compulsory licensing on drugs. See, e.g., HARVEY BALE, *TRIPS, PHARMACEUTICALS AND DEVELOPING COUNTRIES: IMPLICATIONS FOR HEALTH CARE ACCESS, DRUG QUALITY AND DRUG DEVELOPMENT* 13 (2000) (providing a graph that shows significant increase in Canadian pharmaceutical research and development spending after compulsory licensing policy eliminated in 1992); GORECKI, *REGULATING THE PRICE OF PRESCRIPTION DRUGS IN CANADA: COMPULSORY LICENSING*, OTTAWA ECONOMIC COUNCIL OF CANADA 159-62 (1981) (concluding that there is a decline in the absolute level of research and development, but that the decline is relatively slight when considered in the context of overall GNP and that it is unclear the extent to which compulsory licensing contributed to decline, given other existing variables). Similarly, the introduction of stronger patent protection in Italy did not increase pharmaceutical innovation. F.M. Scherer & Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 INT'L REV. INDUS. PROP. & COPYRIGHT L. 1009, 1017-23 (1995). However, some have noted that there may be other intervening factors, such as the fact that Italy imposed stringent price controls. Scherer & Weisburst, *supra*, at 2014.

<sup>410</sup> COMM'N ON INTELL. PROP. RIGHTS, *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY* 79-89 (2002), available at [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm) (noting that increased patent rights may or may not be the best means for protecting traditional knowledge in developing countries because of economic consideration); Carlos M. Correa & Sisule F. Musungu, *WIPO Patent Agenda: The Risks for Developing Countries* 23 (South Centre, Trade-Related Agenda, Development and Equity, Working Papers No.12, 2002) (noting that industrialized countries had varying evolutions of their patent systems that enabled them to take into account the competitive strength of their industries).

<sup>411</sup> For example, in the ten years since Mexico enacted stronger patent protection,

development to benefit from patents, increased protection may yield more modest gains than popularly asserted.<sup>412</sup> In fact, concurrent with a trend towards increasing global patent rights is a growing skepticism of the extent to which patents promote domestic innovation.<sup>413</sup>

In addition, even if patents promote some innovation, the innovation promoted by patents may be socially sub-optimal. Many suggest that the current patent system fails to promote innovation because despite a substantial increase in research expenses, the number of new drugs has decreased.<sup>414</sup> In addition, patent protection may encourage more development of similar drugs that are patentable, yet of little benefit to patients because most patent laws do not require that a drug be a substantial improvement over existing therapies.<sup>415</sup> Indeed, recent reports suggest a decline in the number of clinically significant new drugs.<sup>416</sup> Furthermore, patent protection only helps to promote innovation in areas that are profitable; it does not help promote innovation to treat conditions that primarily afflict individuals and countries with poor financial resources.<sup>417</sup>

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the number of patent applications from domestic applicants actually dropped by half. See CORREA 2007, *supra* note 29, at 96-97.

<sup>412</sup> See *id.* at 96 (citing Richard Levin et al., *Appropriating Returns from Industrial Research & Development*, 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY (1987)).

<sup>413</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, *ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW* 327 (2003) (noting that “incremental increases in patent protection are unlikely to influence inventive activity significantly”); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 125-27 (2006) (Breyer, J., dissenting) (noting that patents can impede research); see also *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-97 (2006) (Kennedy, J., concurring) (recognizing that patents may serve as a tool not for innovation, but to generate licensing fees).

<sup>414</sup> See, e.g., U.S. GOV’T ACCOUNTABILITY OFFICE, *NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS* 34 (2006).

<sup>415</sup> See, e.g., TRIPS, *supra* note 7, art. 27 (noting requirements that a patentable invention be new, useful, and nonobvious).

<sup>416</sup> See, e.g., WHO COMMISSION STUDY, *supra* note 40, at 66; see also Light & Lexchin, *supra* note 371, at 959 (“[o]nly ten to fifteen percent of new drugs provide important benefits over existing drugs”).

<sup>417</sup> This is often referred to as the drug gap, or ten-ninety problem, which stands for the fact that only ten percent of global spending on health research is for conditions that impact ninety percent of global disease burdens. See, e.g., SECRETARIAT OF THE GLOBAL FORUM FOR HEALTH RESEARCH, *THE 10/90 REPORT ON HEALTH RESEARCH 2003-2004*,

While no single system, including patents, is likely to be an ideal mechanism for all types of innovation, the shortcomings of the patent system should nonetheless be kept in mind against the prevalent rhetoric that any limitation to patent rights, such as compulsory licensing, would spell disaster. For example, although pharmaceutical companies assert that Thailand's licenses will thwart research and development of neglected diseases that predominantly effect countries with poor financial resources, this claim seems empty given that patents traditionally do not provide incentives for unprofitable diseases. Indeed, companies are currently investing little funding in such diseases, such that the impact of a compulsory license on these areas is likely to be minimal.<sup>418</sup> A compulsory license on a drug to treat a neglected disease might threaten incentives for further research in neglected diseases because the license would deprive a substantial market for revenue.<sup>419</sup> However, all the compulsory licenses issued by Thailand are for global drugs that generate most of their profits in wealthy countries, such that Thailand's licenses should have minimal impact on innovation.<sup>420</sup>

In addition, even if compulsory licenses were to negatively impact innovation the impact is likely more nuanced than current criticisms. While pharmaceutical companies seem uniformly opposed to compulsory licenses, the crux of their complaint actually focuses on revenue loss, which could be addressed by focusing on the TRIPS-required element of "adequate

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ch. 2, §1, at 35 (2004); Michael R. Reich, *The Global Drug Gap*, 287 *SCIENCE* 1979 (2000) (highlighting the discrepancy between the availability of new drugs on the market for the world's affluent and the unavailability of drugs that are needed by a majority of world's population in developing countries).

<sup>418</sup> See, e.g., Chien, *supra* note 400, at 892 ("[A] 2001 Harvard School of Public Health survey of twenty large pharmaceutical firms found that '[o]f 11 responders, eight had done no research over the past year in tuberculosis, malaria, African sleeping sickness, leishmaniasis, or Chagas disease; seven spent less than 1% of their research and development budget on any of these disorders.'").

<sup>419</sup> *Id.* at 894.

<sup>420</sup> See generally *supra* note 376 and accompanying text (noting that developing and middle income countries comprise only ten to twenty percent of global sales). *But see Thai Patent Turmoil*, *supra* note 11 (noting that Thailand's use of compulsory licensing may "threaten the precarious balance that promotes investment and trade in IP-intensive goods").

remuneration,” rather than eliminating all compulsory licenses.<sup>421</sup> Other scholars note that the remuneration provided by a compulsory license is important for evaluating the potential impact on innovation, with one scholar even suggesting that rates be set to provide full market compensation.<sup>422</sup>

## 2. *Should TRIPS Be Interpreted In Light of Policy Considerations?*

A related question to policy concerns about compulsory licenses is a consideration of how such concerns impact prevailing beliefs about TRIPS, as well as whether such concerns should be relevant to TRIPS interpretations. Although this article provides an interpretation of TRIPS based upon customary rules of interpreting international law, considering whether any of the policy considerations are legitimate may help to explain resistance to the proper interpretations of TRIPS.

An important initial issue is the premise for why middle-income countries should not be permitted to use compulsory licenses, separate from the fact that TRIPS permits this as a matter of international law. Some of the controversy may stem from the fact that middle-income countries are perceived as having adequate funds to pay the prices set by patent owners.<sup>423</sup> However, there is a wide range of income levels among middle-income countries and also wide disparities of income within countries.<sup>424</sup> For example, Thailand is a lower-middle-income country, whereas

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<sup>421</sup> See Chien, *supra* note 400, at 859-62. PhRMA's current criticism of the Thai licenses also likely represents the fear of an extrapolated effect from the current situation. In other words, PhRMA is likely concerned that if other countries followed Thailand's lead there would be a substantial aggregate impact. While this may seem compelling, it should also be considered that revenue from all low and middle income countries constitute a mere fraction of worldwide sales. See *supra* note 376 and accompanying text.

<sup>422</sup> See Cahoy, *supra* note 31, at 177-79; Chien, *supra* note 400, at 873 (suggesting that the royalty rate will likely determine innovation).

<sup>423</sup> See, e.g., *A Gathering Storm*, *supra* note 260, at 71 (noting that middle income countries use the threat of compulsory licensing to gain drug discounts and therefore get cheaper drugs than low income countries).

<sup>424</sup> See generally World Bank, Country Classifications, [http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20421402~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html#Low\\_income](http://web.worldbank.org/WBSITE/EXTERNAL/DATASTATISTICS/0,,contentMDK:20421402~pagePK:64133150~piPK:64133175~theSitePK:239419,00.html#Low_income) (last visited Feb. 8, 2009) (providing statistical data on income levels for several countries).

Brazil is a higher middle-income country,<sup>425</sup> but critics of compulsory licenses refer to middle-income countries generically as if they are identical.<sup>426</sup> Moreover, while the wealthiest Thai population can pay for drugs at the rate set by patent owners, the population to which the compulsory licenses apply cannot afford such rates because the poorest twenty-five percent of Thai citizens subsist on less than two dollars a day.<sup>427</sup> South Africa, which often is viewed as more deserving of reduced rate drugs and compulsory licenses, has thirty-four percent of its citizens at the same income level.<sup>428</sup>

Another issue is whether compulsory licenses should be permitted for chronic diseases. While there were many aspects of the Thai licenses that provoked criticism, the use of the compulsory licenses for non-infectious diseases seemed to prompt the strongest reactions—the license on Plavix repeatedly prompted criticism that heart disease was not an emergency.<sup>429</sup> The “requirement” of an emergency to issue a compulsory license is only a requirement desired by patent owners, rather than one actually imposed by TRIPS.<sup>430</sup> As a policy matter, there is nonetheless a question of whether drugs to treat chronic diseases,

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<sup>425</sup> See, e.g., *id.*

<sup>426</sup> See, e.g., *A Gathering Storm*, *supra* note 260, at 71 (referring to middle income countries versus the poorest countries, without recognition that Brazil and Thailand have different economic situations); *Drug Patent Piracy*, *supra* note 1 (referring to Thailand and Brazil as “relatively well off nations” and considering them similar based upon gross domestic production).

<sup>427</sup> U.N. DEV. PROGRAMME [UNDP], HUMAN AND INCOME POVERTY: DEVELOPING COUNTRIES 238 tbl.3, No.78 (2007/2008). Of course, income inequalities within countries may also suggest that comparing entire countries is inappropriate and that focusing on low income populations is more accurate. See *id.*

<sup>428</sup> *Id.* On the other hand, some countries on the African continent are plagued by much higher rates of poverty. For example, in Haiti and Rwanda, around eighty percent of the population is at this level of poverty. *Id.*

<sup>429</sup> See *supra* notes 249-253 and accompanying text (describing criticism of Plavix license). Although criticism of the licenses on cancer drugs was relatively muted, that may be more a function of the lack of surprise, as well as a belief that a leadership change would revoke the licenses, such that criticism was not necessary.

<sup>430</sup> Compare *supra* notes 11, 245-246 and accompanying text (providing perspective of drug companies) with *supra* notes 115-119 and accompanying text (explaining that although an emergency situation may waive the usual requirement of negotiating with a patent owner, TRIPS does not require an emergency as a pre-requisite to issuance of all compulsory licenses).



such as heart disease and cancer, are medications that are necessary for developing countries because there is an assumption that such diseases affect the rich at a higher level.<sup>431</sup> Recent data from the WHO indicates that these are popular misconceptions unsupported by the facts; the majority of deaths from heart disease actually take place in developing countries.<sup>432</sup> While it is true that developing countries' citizens suffer from HIV, they also suffer from some of the same chronic diseases that plague wealthier countries.<sup>433</sup> Moreover, the WHO estimates that deaths from non-communicable diseases are likely to account for more than twice the number of deaths from communicable diseases by 2015.<sup>434</sup> The question then becomes whether such countries and their citizens are entitled to the same medical treatment. The question is not simply an issue of what is a chronic disease that may have no finite end for a compulsory license. After all, HIV treatment is similarly chronic in that treatment of every infected person must continue for his or her lifetime.<sup>435</sup> Rather, an underlying issue may be that drugs to treat chronic diseases have traditionally reaped enormous profits for drug companies.<sup>436</sup> While they are also sold in developing countries, public pressure has thus far not required drug companies to sell these drugs at a discount to developing

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<sup>431</sup> See, e.g., Ghosh, *supra* note 1 (suggesting that heart disease afflicts the affluent disproportionately to lower income individuals).

<sup>432</sup> See *Prevention and Control of NonCommunicable Diseases*, *supra* note 22, at 1.

<sup>433</sup> See *id.*; see also MARC SUHRCKE ET AL., THE OXFORD HEALTH ALLIANCE, CHRONIC DISEASE: AN ECONOMIC PERSPECTIVE 12 (2006), available at <http://www.oxha.org/knowledge/publications/oxha-chronic-disease-an-economic-perspective.pdf> (noting that chronic diseases account for the majority of deaths in all countries outside of sub-Saharan Africa); WORLD HEALTH ORGANIZATION, PREVENTING CHRONIC DISEASES: A VITAL INVESTMENT 43 (2005), available at [http://www.who.int/chp/chronic\\_disease\\_report/contents/part1.pdf](http://www.who.int/chp/chronic_disease_report/contents/part1.pdf) [hereinafter PREVENTING CHRONIC DISEASES] (noting that eighty percent of deaths from chronic disease occur in low and middle income countries).

<sup>434</sup> See PREVENTING CHRONIC DISEASES, *supra* note 433, at 57.

<sup>435</sup> See, e.g., MÉDICINS SANS FRONTIÈRES, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 8 (2008), available at [http://www.msfaaccess.org/fileadmin/user\\_upload/diseases/hiv-aids/Untangling\\_the\\_Web/Untanglingtheweb\\_July\\_2008\\_English.pdf](http://www.msfaaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/Untanglingtheweb_July_2008_English.pdf) (noting that HIV is a life long condition requiring continuous access to drugs).

<sup>436</sup> See generally WHO, WORLD MEDICINES SITUATION, *supra* note 376, at 18 (noting that in 1999, over sixty percent of research was directed at drugs for cancer, metabolic, and cardiovascular disease).

countries. The marketing model for most drugs sold by major pharmaceutical companies has been to sell them at a high price in most countries even if that means fewer sales in countries such as Thailand where there are fewer people who can afford the high prices.<sup>437</sup> If companies are required to provide the drugs at lower costs, or forced to do so through compulsory licenses, that poses a fundamental challenge to an existing profit-maximizing strategy.<sup>438</sup> On the other hand, the same was once true for HIV medication and companies today often provide substantial discounts to developing countries—at least for first generation HIV treatments that are off patent.<sup>439</sup>

Another thorny question relates to the potentially limitless boundaries of compulsory licensing under TRIPS. After all, if TRIPS permits nations to issue a license for any drug, limited only with respect to the stated purpose of the license, a license could issue for any condition.<sup>440</sup> There is nothing in TRIPS that limits licenses to conditions that are life-threatening.<sup>441</sup> Furthermore, while Thailand did not issue licenses for what it considers to be unnecessary conditions, such as acne or baldness treatment, TRIPS would arguably not preclude such licenses, although even if

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<sup>437</sup> See, e.g., TEN BURNING QUESTIONS—GOVERNMENT USE OF PATENTS, *supra* note 10, at 1, 6 (noting that patented drugs were only purchased by two percent of the population prior to issuance of the compulsory licenses because they were not affordable to most citizens); Hammer, *supra* note 24, at 888 (noting that the small percentage of citizens in developing countries that are able to purchase drugs do not pay a discount and may in fact pay even higher prices than in developed countries); Carsten Fink, *Intellectual Property and Public Health: An Overview of the Debate with a Focus on U.S. Policy* 20 (Ctr. For Global Dev., Working Paper No. 146, 2008) (noting that companies often target wealthier citizens of lower income countries).

<sup>438</sup> See Fink, *supra* note 437, at 20.

<sup>439</sup> See, e.g., Bertozzi, *supra* note 316, at 357 (noting that the price of antiretrovirals have dropped by two orders of magnitude for some countries, although the pricing is not consistent). However, the discounted prices on HIV drugs were also prompted by competition from generic manufacturers—a fact not applicable to newer HIV drugs for which no generics currently exist. See, e.g., Fink, *supra* note 437, at 20.

<sup>440</sup> See *supra* notes 327-332 and accompanying text (explaining that the TRIPS requirement that licenses be limited in scope and duration to the authorized purpose provides substantial discretion to countries).

<sup>441</sup> See also Outtersson *supra* note 22, *passim* (explaining that TRIPS does not limit the types of drugs that may be subject to compulsory licensing). See generally TRIPS, *supra* note 7, art. 31 (outlining the conditions that must be met before a country can obtain a compulsory license without authorization from the patent holder).

permissible under TRIPS, countries might be vulnerable to political pressure and retaliation.<sup>442</sup> Even if cosmetic conditions are excluded, drug companies nonetheless have a justifiable fear that TRIPS could permit any country to claim health care is a priority sufficient to justify imposing a compulsory license whenever a country wishes to provide more medical treatment than it can afford at regular prices.<sup>443</sup>

An important question is whether the policies for using compulsory licenses pursuant to TRIPS should be considered anew. While it is tempting to focus on the concerns of major drug companies, TRIPS Article 31 should be considered as part and parcel of an overall package of patent rights agreed upon by all WTO members. Policy issues concerning compulsory licenses were considered during the negotiation of TRIPS. For example, whereas some countries wanted broad authority to issue compulsory licenses, the United States was strongly opposed to compulsory licenses.<sup>444</sup> An early proposal limited the types of subject matter that could be subject to compulsory licenses.<sup>445</sup> However, the member states ultimately agreed not only to compulsory licensing as a permissible exception but also to omit

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<sup>442</sup> See *supra* Part VI.A (discussing retaliation against Thailand after licenses issued). Granting a compulsory license for what is considered cosmetic could be seen as extreme. On the other hand, requiring nations to grant patents in the first instance is seen by some as extreme. See, e.g., *supra* note 15 (noting that a number of countries did not provide patent protection on drug compositions prior to TRIPS).

<sup>443</sup> Indeed, in Thailand's case, cancer drugs were not on the essential drug list and thus not part of the universal access plan. See generally TEN BURNING QUESTIONS ON CANCER DRUGS, *supra* note 220, at 2 (noting that the cancer drugs which were not listed as essential drugs because of their high cost and thus inaccessible to most Thai citizens without the compulsory licenses).

<sup>444</sup> See Communication from the United States, *supra* note 104, at 11, art. 27 (setting out several provisions which limits the issuance of compulsory licenses and outlining situations in which compulsory licenses may be revoked); Communication from India, *supra* note 110, ¶ 15 (proposing that all pharmaceutical patents be subject to automatic compulsory licenses). Although the United States generally asserts that it is opposed to compulsory licensing and does not provide for compulsory licensing, the United States in fact insisted on language in what has become TRIPS Article 31 that essentially enables the United States to continue to use a law that provides a de facto compulsory license of patents for any government use by the government, or by government contractors. See 28 U.S.C. § 1498; see also *supra* note 104 and accompanying text (discussing Article 31 negotiations).

<sup>445</sup> See *supra* note 103 and accompanying text.

any restrictions on the type of invention that could qualify.<sup>446</sup> In other words, some of the positions being strongly advocated by patent owners and governments today were previously considered but rejected in the overall negotiation of TRIPS. Not only were they rejected, but TRIPS as a whole likely would not have been concluded without the broad flexibilities encompassed by Article 31. After all, countries wanting to maintain broad flexibility for compulsory licenses previously granted only limited patents or no patents at all such that they were unlikely to agree to a scheme where licenses were severely restricted.<sup>447</sup>

The prior consideration and rejection of issues, such as whether compulsory licenses should be limited to certain conditions or diseases, raises the question of whether there is a proper basis for revisiting TRIPS Article 31. While patent owners and powerful governments may be effectively doing so through retaliatory acts, there is no legitimate basis for ignoring the clear language of TRIPS to resurrect previously rejected positions. First, it is unfair to consider compulsory licenses under Article 31 separate from the entirety of the TRIPS agreement because countries negotiated for the entire package of TRIPS rules; developing countries would not have agreed to the default requirement under TRIPS of providing patents without exceptions to patent rights, such as compulsory licenses.<sup>448</sup> Second, any attempt to resurrect rejected approaches to compulsory licenses reflects a lack of respect for international law.

### *3. Do Competing Policy Perspectives of Patents Account for Disagreements Over Compulsory Licenses?*

Another important issue is why Thailand's actions, as well as Article 31, are frequently misunderstood and mischaracterized. For example, why do some insist that compulsory licenses are

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<sup>446</sup> See *supra* text accompanying notes 102-106 (discussing negotiating history).

<sup>447</sup> See, e.g., Thiru Balasubramaniam, Knowledge Ecology International, March 8, 2007 Geneva Q&A Session on Thai White Paper (Mar. 8, 2007), [http://www.keionline.org/index.php?option=com\\_content&task=view&id=31](http://www.keionline.org/index.php?option=com_content&task=view&id=31) (noting that Brazil's representative to the U.N. has suggested that developing countries would not have accepted the TRIPS patent terms without compulsory licenses because of the need for balance).

<sup>448</sup> In addition, this view is further supported by TRIPS Articles 7-8, which also references the importance of balance. See TRIPS, *supra* note 7, arts. 7-8.

only permissible in the case of an emergency when the plain language of TRIPS lists an emergency as simply one of several criteria for waiving a procedural requirement of first negotiating with the patent owner? Similarly, why do some insist that middle-income countries cannot use compulsory licenses when there is nothing about developmental status mentioned under TRIPS? Also, why do some believe that compulsory licenses are only appropriate for some types of drugs when TRIPS does not include any criteria and the Doha Public Health Declaration explicitly states “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted?”<sup>449</sup>

There are a few possible explanations. First, Article 31 is notably a lengthy provision that may be difficult to understand, although this does not explain interpretations that defy the clear language of the Doha Health Declaration.<sup>450</sup> Alternatively, objections to compulsory licensing can mask fears that any drugs produced under such a license might be exported to high-income countries and under-cut profits in economically significant markets.<sup>451</sup> Some suggest that pharmaceutical companies misrepresent facts in their quest to secure maximum patent rights and accompanying revenues,<sup>452</sup> although a less cynical view may

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<sup>449</sup> Doha Public Health Declaration, *supra* note 31, ¶ 5(b).

<sup>450</sup> The complexity of Article 31 also may be compounded by the waiver of one provision that was crafted primarily to benefit countries without adequate manufacturing capacity to make generic versions of patented products under compulsory licenses—a situation that does not apply to Thailand despite some confusion in the press. *See A Gathering Storm*, *supra* note 260, at 72 (suggesting that there will be a “gold rush for generics firms” based on the waiver for countries without domestic manufacturing in the same discussion as Thailand’s licenses without indicating that the waiver is not relevant to Thailand).

<sup>451</sup> However, fears of diversion of products to high-income countries appear to be more fiction than fact. *See, e.g.*, Kevin Outtersson & Aaron S. Kesselheim, *Market-Based Licensing for HPV Vaccines*, 27 HEALTH AFF. 130, 136-37 (Jan/Feb 2008) (noting that amounts of illegal diversion have been overstated and that there is no empirical evidence to suggest that antiretroviral drugs supplied to developing countries have become a widespread problem).

<sup>452</sup> *See, e.g.*, Abbott & Reichmann, *supra* note 31, at 937 n. 69 (suggesting that comments in the Financial Times and Wall Street Journal that suggest that TRIPS is not intended to cover heart disease is “continuing evidence that PhRMA’s advertising and lobbying influence will seek to distort the plain language of the TRIPS Agreement and Doha Declaration when it suits their purpose”).

be that PhRMA simply believes TRIPS reflects its initial negotiating positions—especially given that TRIPS was the brainchild of companies including PhRMA.<sup>453</sup> While pharmaceutical companies are an easy target for criticism, the positions of governments or individual government officials that mirror the position of pharmaceutical companies are less clearly explained. A cynical response would be that governments are subject to industry capture and especially influenced by industry positions on issues outside of their traditional expertise, such as intellectual property.<sup>454</sup> This view may in fact be the case but even if that is true it is not helpful to diffusing current and continuing conflict.

Another possible explanation is that the debate over compulsory licensing simply reveals a fundamental fault line in the TRIPS agreement that must be addressed. All parties acknowledge that TRIPS was an agreement of compromise; this recognition inherently means that despite agreement on the final language of TRIPS, parties did not have uniform views on TRIPS.<sup>455</sup> In other words, even though compulsory licensing is permitted under TRIPS, that requirement has not changed strongly held beliefs that compulsory licensing is either a fundamental right or fundamentally wrong.<sup>456</sup>

The current problems related to the Thai compulsory licenses may in fact reveal a problem with the negotiation of TRIPS. Most agree that the patent and other intellectual property standards under TRIPS could never have been reached in a stand-alone

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<sup>453</sup> See DRAHOS WITH BRAITHWAITE, *supra* note 381, at 68-73 (discussing role of pharmaceutical giant Pfizer in setting the stage for the creation of TRIPS); SELL, *supra* note 291, at 1-2, 37-55 (discussing the role that twelve corporate executives representing pharmaceutical, entertainment, and software industries had in crafting TRIPS).

<sup>454</sup> See generally SELL, *supra* note 291, at 43-55 (describing entire negotiations of TRIPS as the result of successful lobbying by a handful of powerful companies and that intellectual property experts from the private sector were pivotal in influencing the government because the government was not generally familiar with this area).

<sup>455</sup> Some have previously noted that diverse views during TRIPS negotiations were resolved by intentional ambiguity, such that each side could claim a win. See, e.g., WATAL, *supra* note 101, at 7 (noting that conflicts were resolved by “constructive ambiguity”).

<sup>456</sup> Along similar lines, TRIPS likely has not modified beliefs about international exhaustion of patent rights. See, e.g., SELL, *supra* note 291, at 139-50 (discussing fervent opposition to TRIPS after its implementation).

international agreement because developing countries had nothing to gain from such an agreement; in fact, including such issues in the WTO framework was considered a savvy strategy to secure agreement because developing countries wanted greater access to wealthy markets provided through the WTO regime.<sup>457</sup> While this negotiating strategy was successful in concluding TRIPS, it has not changed fundamental attitudes on patents.<sup>458</sup>

The current controversy over compulsory licensing may also indicate the difficulties of imposing global norms for issues typically within national discretion. Prior to TRIPS, nations had the option of providing no patent protection and could do so to improve access to low-cost drugs.<sup>459</sup> While nations can no longer deny patents under TRIPS, their perspective on the importance of patents as opposed to healthcare is likely no different. Arguably, a WTO panel could settle a dispute regarding the extent to which national health care priorities, such as a national plan to provide access to essential medicines, should be considered in authorizing compulsory licenses.<sup>460</sup> However, a panel ruling is not likely to alter fundamental perspectives on the role of patents, as well as the government's role in promoting public health, just as the conclusion of TRIPS has not necessarily altered fundamental beliefs concerning patent rights or the right to public health.<sup>461</sup> In particular, it is possible that the competing interpretations of TRIPS reflect divergent perspectives on the role of patents that were negotiated around without reaching consensus under TRIPS, such that continued conflicts are inevitable. If so, understanding competing perspectives is just as important as attempting to

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<sup>457</sup> See *supra* note 56 and accompanying text (noting that conclusion of TRIPS did not necessarily reflect consensus on its substantive points). See also ROGER NORMAND, BACKGROUND, SEPARATE AND UNEQUAL: TRADE AND HUMAN RIGHTS REGIMES 34 (2000) (noting that "many developing countries objected to TRIPS entering the WTO system yet lacked the resources, expertise, and political will to withstand the pressure from developed countries").

<sup>458</sup> See *id.*

<sup>459</sup> See *supra* note 15 and accompanying text.

<sup>460</sup> See, e.g., Barbosa et al., *supra* note 57, at 104-03 (suggesting that WTO panels could consider and balance a variety of interests).

<sup>461</sup> See generally Tom R. Tyler, *Compliance with Intellectual Property Laws, A Psychological Perspective*, 29 N.Y.U. J. INT'L L. & POL. 219, 226-29 (1997) (noting research that suggests laws alone do not change behavior if laws are not in accordance with personal beliefs).

provide proper legal interpretations of TRIPS provisions.

The controversy concerning the Thai licenses may reflect two fundamentally competing visions of patents on a spectrum of perspectives. The perspectives range from a conception of patents as a near absolute property right to a view of patents as a mere privilege granted by the state that is inherently subject to limitations.<sup>462</sup> These two extremes are bookends to a vast spectrum of more nuanced positions.<sup>463</sup> However, examining the most radical positions may be informative in identifying a fundamental tension underlying current positions concerning TRIPS that do not seem to mesh with proper legal interpretations.

The dichotomy of perspectives can easily be seen from the controversy concerning Thailand's compulsory licenses. On one side of the spectrum are statements regarding the potential evils of compulsory licensing to long-term innovation, as well as accusations that a compulsory license is akin to stealing.<sup>464</sup> On the other side of the spectrum are statements that suggest compulsory licensing, as well as other exceptions to patent rights, are inherently appropriate because unlike human rights, including the right to health, patent rights are a mere economic tool.

Reconciling the existence of these perspectives under TRIPS may be difficult. On one level, the current language in TRIPS may be flexible enough to simultaneously support competing interpretations. For example, Article 7 may be relied upon by both

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<sup>462</sup> This novel framework of competing patent visions is proposed without prejudice to more traditional discussions of patents based primarily on property versus liability rules. Both frameworks may co-exist and complement each other. For more information on the property versus liability rule distinction, see for example, Mark Lemley, *Should Property or Liability Rules Govern Information?*, 85 TEX. L. REV. 783 (2007). Under this framework, a compulsory license would be appropriate as a liability rule. *See id.* at 834-35. However, the property versus liability rule distinction nonetheless fails to address the fundamental issue of how to achieve consensus surrounding which type of rule to adopt. *See id.* at 841. On the other hand, the framework of competing patent visions better explains the problem.

<sup>463</sup> For example, even though public statements may fall at one or the other extreme, the positions of individual actors may change depending on the situation; for example, a patent owner enforcing its own patent may espouse a view of patents as akin to an absolute property right yet argue that someone else's patent should be invalid when defending against patent infringement.

<sup>464</sup> *See supra* note 1 and accompanying text (providing a number of references that characterize Thailand's actions as theft or stealing).



patent proponents as well as public access advocates. Article 7 can be read to suggest that TRIPS should be interpreted in “a manner conducive to social and economic welfare, and to a balance of rights and obligations.”<sup>465</sup> At the same time, Article 7 can also support the point of view that “protection and enforcement of intellectual property rights,” including patents, will necessarily “contribute to promotion of technical innovation . . . to the mutual advantage of producers and users” without any need to provide for balancing of rights other than what already exists in the agreement.<sup>466</sup> Similarly, Article 8 can seem to support an argument to permit member states to take measures necessary to “protect public health and nutrition,”<sup>467</sup> but the commentary regarding public health could also be considered superfluous because Article 8 also states that any measures must be “consistent with the provisions of this Agreement.”<sup>468</sup> However, the differing perspectives may inevitably lead to differing interpretations on the scope of exceptions: To those that see patents as a privilege that must give way to more important human rights, the TRIPS language in Article 31 should be read broadly.<sup>469</sup> On the other hand, to those that believe patents are an absolute property right, any exceptions to patent rights, even if legal, may be viewed as inappropriate.<sup>470</sup> For example, to absolute property right advocates, the literal words of Article 31 may be de-emphasized in favor of the belief that compulsory licenses should only be imposed in exceptional circumstances.<sup>471</sup>

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<sup>465</sup> See TRIPS, *supra* note 7, art. 7.

<sup>466</sup> *Id.*

<sup>467</sup> See *id.* art. 8.

<sup>468</sup> *Id.*

<sup>469</sup> See, e.g., TEN BURNING ISSUES—GOVERNMENT USE OF PATENTS, *supra* note 10, at 4 (noting that the compulsory licenses reflect a government commitment to place the “right to life” above commercial interests); see also Report of the High Commissioner, Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 52d Sess., Item 4 of the Provisional Agenda, Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, U.N. Doc. E/Cn.4/Sub.2/2001/13, ¶ 66 (June 27, 2001) (encouraging states to read TRIPS Article 31 to enhance the promotion of the right to health).

<sup>470</sup> See *supra* note 1 (describing Thailand’s actions as inappropriate and akin to stealing).

<sup>471</sup> This was illustrated by the misinterpretation of whether an emergency is required in the case of the Thai licenses. See *supra* notes 245-247 and accompanying text; see

While some might advocate simply relying on a proper interpretation of TRIPS, the reality of retaliatory actions suggest that a legalistic interpretation alone is an inadequate solution, not only for Thailand, but also for continuing questions about the proper balance between patents and public health. In addition, even if a country were to directly challenge Thailand, a WTO panel decision is unlikely to quell long-held perspectives on patents. It may instead simply direct attention and activity towards other forums where those perspectives can be imposed on other parties, such as free trade agreements.

A full exploration of competing patent perspectives is beyond the scope of this article but seems vital ground for further analysis. Accordingly, considering the role of competing perspectives under TRIPS, as well as how such perspectives can be changed, if at all, will be the subject of a separate article. For example, the existing TRIPS provisions may arguably support two competing perspectives of TRIPS such that tension is inevitable. Moreover, some perspectives may be difficult to change; literature from the field of cognitive psychology suggests individuals may continue to cling to beliefs that defy new evidence.<sup>472</sup> On the other hand, a historical view of patents indicates that perspectives can change.<sup>473</sup>

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also *Patent Remedy*, *supra* note 5 (suggesting that compulsory licenses should be limited, but ignoring the text of TRIPS).

<sup>472</sup> See, e.g., Craig A. Anderson et al., *Perseverance of Social Theories: The Role of Explanation in the Persistence of Discredited Information*, 39 J. PERSONALITY & SOC. PSYCHOL. 1037, 1037-48 (1980); Kari Edwards & Edward E. Smith, *A Disconfirmation Bias in the Evaluation of Arguments*, 71 J. PERSONALITY & SOC. PSYCHOL. 5, 5-24 (1996); Helen Harton & Bibb Latane, *Information-and Thought-Induced Polarization: The Mediating Role of Involvement in Making Attitudes Extreme*, 12 J. SOC. BEHAV. & PERSONALITY 271, 272-94 (1997); Lord et al., *Biased Assimilation and Attitude Polarization: The Effects of Prior Theories on Subsequently Considered Evidence*, 37 J. PERSONALITY & SOC. PSYCHOL. 2098, 2098-108 (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, 561-73 (1993).

<sup>473</sup> For example, the United States has arguably moved more strongly to patents as privileged property. See generally Adam Mossoff, *Patents as a Constitutional Private Property: The Historical Protection of Patents under the Takings Clause*, 87 B.U. L. REV. 689, 715-20 (discussing the history of patents protection as a privilege under the takings clause of the constitution). In addition, on the international scale, perspective to compulsory licenses for least developed countries softened after substantial focus on this issue by NGOs and popular press in connection with South Africa's AIDS epidemic. See, e.g., Emily S. Saslow, Guest Editorial, *Compulsory Licensing and the AIDS*

A tougher question, however, may be whether they should change and whether TRIPS should require such a change.

Once competing patent perspectives are further delineated and explored, a return to considering not only the policy implications of compulsory licenses but also how to accommodate differences under TRIPS may be appropriate. For example, if TRIPS fundamentally reflects two competing perspectives of patents but panel decisions generally only embrace one perspective, future panelists could take corrective action. In addition, perhaps an understanding of competing perspectives will help currently warring parties better understand their divergent views, such that they can work towards a solution that better accommodates both sides.

### **VII. Conclusion**

Thailand's aggressive use of compulsory licenses has provided an excellent opportunity to evaluate the scope of compulsory licensing under TRIPS Article 31, as well as problems outside the WTO/TRIPS system. While this article is unlikely to reduce criticism of Thailand's compulsory licensing, it hopefully helps to clarify the appropriate interpretation of TRIPS, as well as identify future issues in need of true clarification. For example, contrary to what is reported in the popular press and by patent owners, no national emergency is required to issue a compulsory license—a country can issue one on grounds of public non-commercial use. However, an important open question is what constitutes public non-commercial use since if construed broadly a license could almost always be granted without initially consulting with the patent owner. Similarly, although there is a popular perception that only drugs to treat epidemics such as AIDS are subject to compulsory licensing, an appropriate interpretation of TRIPS readily reveals that there are no restrictions on the type of drug that may be licensed. In addition, despite the desire of patent owners to limit compulsory licenses to very limited circumstances, the actual TRIPS provision only requires that licenses be limited in scope and duration to the stated purpose. Granted, this may seem

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*Epidemic in South Africa*, 13 AIDS PATIENT CARE AND STDs 577, 578-80 (1999); see also *supra* note 291 and accompanying text (providing additional explanation for this change in perspective).

very broad and perhaps needs further inquiry, but, at a minimum, recognizing the current exaggerations of patent owners is a useful first step.

This article aims to provide a better understanding of TRIPS, as well as underlying issues which will help position global discussions to focus more fruitfully on remaining points of ambiguity. There are some notable issues for interpretation of TRIPS, such as what constitutes adequate remuneration, and public non-commercial use. Continued exploration of the underlying reasons for competing interpretations of TRIPS requirements is important to any long-term resolution of competing claims by patent owners and public health advocates in the global arena.