

# PROTECTING INTELLECTUAL PROPERTY IN THE DEVELOPING WORLD: NEXT STOP—THAILAND

CORTNEY M. ARNOLD<sup>1</sup>

## ABSTRACT

*This iBrief examines the U.S. strategy for strengthening the protection of intellectual property rights (IPRs) in Southeast Asia through the use of free trade agreements (FTAs). After briefly examining the U.S. methodology for strengthening IPRs outside the U.S., this iBrief predicts that the intellectual property provisions in the final text of the U.S.-Thailand FTA, which is currently being negotiated, will be very similar to the provisions in previous FTAs that the United States has negotiated with other developing countries.*

## INTRODUCTION

¶1 The violation of intellectual property rights (IPRs) is a huge global problem. The World Customs Organization estimates that counterfeiting accounts for six percent of global merchandise trade.<sup>2</sup> The World Health Organization reports that approximately ten percent of medicines worldwide are counterfeited, costing the pharmaceutical industry over forty-five billion dollars a year.<sup>3</sup> What is more, thirty-nine percent of the software used by companies worldwide qualifies as being pirated.<sup>4</sup>

¶2 Like many developing nations, Thailand is a source of pirated goods.<sup>5</sup> According to the International Anti-Counterfeiting Coalition, in recent years nearly sixty percent of counterfeit apparel seized by customs

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<sup>1</sup> J.D. Candidate, 2007, Duke University School of Law; B.S. in Marketing and Operations Management, 2003, University of Dayton. The author would like to thank Edward Kelly and Edward Madden of Tilleke & Gibbins International Ltd. (Bangkok, Thailand), Duke Law Professor Jerome Reichman, and DLTR Executive Editor Zia Cromer for their advice in the preparation of this iBrief. All errors and misstatements are the author's alone.

<sup>2</sup> Frederik Balfour, *Fakes! The Global Counterfeit Business is Out of Control, Targeting Everything from Computer Chips to Life-Saving Medicines*, BUS. WK. (Asian Edition), Feb. 7, 2005, at 54.

<sup>3</sup> *Id.*

<sup>4</sup> Alan M. Field, *Pirate's Bounty*, J. COMMERCE, May 10, 2004, at 28.

<sup>5</sup> See Larry Jagan, *Thailand's Struggle With Goods Piracy*, B.B.C. NEWS, Dec. 13, 2001, <http://news.bbc.co.uk/1/hi/world/asia-pacific/1709267.stm>.

authorities in the European Community originated in Thailand.<sup>6</sup> Furthermore, Thailand has been designated by the United States Trade Representative (USTR) as a country that needs to improve its intellectual property (IP) protection regime.<sup>7</sup>

¶3 For over twenty years, the U.S. has been increasing its emphasis on the protection of IPRs outside its borders, and Thailand is the next stop on this campaign. This iBrief examines the U.S. strategy for strengthening IPRs in developing nations and predicts some of the provisions to be included in the intellectual property chapter of the U.S.-Thailand Free Trade Agreement (FTA).

## I. THE EVOLUTION OF INTELLECTUAL PROPERTY RIGHTS PROTECTION OUTSIDE THE U.S.

¶4 Since the 1960s, IP protection around the globe has been critical to the developed world, the U.S. included. Developed countries were losing their traditional advantage in the production of manufactured goods, and the only remaining comparative advantage rested in high-tech goods. Because high-tech goods are generally expensive to create but cheap to copy, and because international trade meant that these high-tech goods were sold around the world, countries like the U.S. needed IPRs to be enforced globally.<sup>8</sup>

¶5 The U.S. first sought to protect IPRs through an international agreement on the trade of counterfeit goods, introduced at the Tokyo Round of negotiations of what later became the World Trade Organization (WTO). However, the agreement was thwarted by a united front of developing countries, and the U.S. was forced to change strategies to accomplish its goals.<sup>9</sup> First, the U.S. turned to unilateral pressure to increase IPRs in the

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<sup>6</sup> Cortney Arnold and Edward Kelly, *Developments in IP: Enforcement in Thailand*, THAILAND: IP DEVELOPMENTS (a publication of Tilleke & Gibbins' Intellectual Property Division), July 2005, at 2 (citing STACY BAKER, THE GLOBAL REPORT ON COUNTERFEITING Ch. 5 (About Publishing Group 2005)), [http://www.tillekeandgibbins.com/Publications/pdf/IP\\_bulletin\\_july05.pdf](http://www.tillekeandgibbins.com/Publications/pdf/IP_bulletin_july05.pdf).

<sup>7</sup> OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2005 SPECIAL 301 REPORT, EXECUTIVE SUMMARY, at 1 [hereinafter 2005 SPECIAL 301 REPORT], available at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2005/2005\\_Special\\_301/asset\\_upload\\_file948\\_7645.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file948_7645.pdf).

<sup>8</sup> Lecture given by Professor Jerome Reichman at Duke Law School in September 2005. Notes on file with DUKE LAW AND TECHNOLOGY REVIEW.

<sup>9</sup> Forum shifting entails one party shifting negotiations from a forum in which it encounters resistance to a forum where it is likely to achieve its objectives. See Peter Drahos, *BITs and BIPs—Bilateralism in Intellectual Property*, 4 J. WORLD INTELL. PROP. 791, 792 (2001).

developing world through legislation called “Special 301.”<sup>10</sup> The U.S. later turned its attention to bilateral negotiations resulting in dozens of bilateral investment treaties and FTAs.<sup>11</sup>

#### A. *Special 301*

¶6 In order to achieve the desired levels of IP protection in developing nations, the U.S. amended the Trade Act of 1974 to link trade and IP via an instrument known as “Special 301.”<sup>12</sup> The “Special 301” provisions of the amended Trade Act require the USTR “to identify foreign countries that deny adequate and effective protection of intellectual property rights or fair and equitable market access” for U.S. citizens or entities that rely on IP protection.<sup>13</sup> Depending on the extent of deficiency of IP protection, these foreign countries are placed onto either the “Priority Foreign Countries” list, the “Priority Watch List,” the “Watch List,” or the “Section 306 Monitoring” list.<sup>14</sup>

¶7 In its 2005 Special 301 Report, the USTR placed fifty-two countries on one of these lists.<sup>15</sup> “A 301 investigation may culminate in a bilateral agreement between the [U.S.] and the target state, or failing that, the imposition of trade sanctions by the [U.S.] . . . .”<sup>16</sup> As a result, bilateral agreements between the U.S. and its trading partners have been increasing since the 1980s.<sup>17</sup>

¶8 Eventually, the Uruguay Round of WTO negotiations produced an agreement known as the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires all WTO members to adhere to minimum standards of IP protection.<sup>18</sup> Despite having the TRIPS agreement, the U.S. continues to use bilateral agreements to extend the level

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<sup>10</sup> See discussion *infra* para. 6–7.

<sup>11</sup> Further information on these agreements can be found at the USTR Website, <http://www.ustr.gov/>.

<sup>12</sup> Office of the United States Trade Representative, Background on Special 301, [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2005/2005\\_Special\\_301/asset\\_upload\\_file223\\_7646.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2005/2005_Special_301/asset_upload_file223_7646.pdf) (last visited Mar. 11, 2006).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> 2005 SPECIAL 301 REPORT, *supra* note 7, at 1.

<sup>16</sup> Drahos, *supra* note 9, at 792.

<sup>17</sup> *Id.* at 792-93.

<sup>18</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS], available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm).

of IP protection in developing nations beyond the minimal standards laid out in TRIPS.<sup>19</sup>

### *B. Bilateral Policy: BITs and FTAs*

¶9 As one of the world's most ardent advocates of stronger protections for IP, "the U.S. has consistently followed a policy of elevating IPRs standards abroad through the use of unilateral, bilateral, and multilateral action."<sup>20</sup> Bilateral investment treaties (BITs) and FTAs are part of "a ratcheting process that is seeing IP norms globalize at a remarkable rate."<sup>21</sup>

¶10 The U.S. is a party to nearly forty BITs.<sup>22</sup> A BIT is an agreement between two sovereign nations to establish a stable investment climate within their borders for the investors of the parties to the agreement. While the purpose of a BIT is to protect investment, IP also receives protection as a byproduct. For example, the Mozambique Bilateral Investment Treaty,<sup>23</sup> which entered into force in 2005, protects intellectual property as a type of investment.<sup>24</sup>

¶11 BITs are not the best method for improving IP protection in developing nations for a number of reasons, all relating to their brevity in comparison to FTAs. An FTA is an agreement between two or more sovereign nations to remove all substantial barriers to trade (e.g. tariffs, regulatory requirements) between the nations. First, BITs, while including IP as a type of investment, do not devote an entire article or chapter to IP as FTAs do. Therefore, the protection afforded IP by the treaty is less detailed and also less predictable. Second, the main purpose of BITs is the assurance that foreign investors will be given the same treatment afforded to

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<sup>19</sup> In the Bipartisan Trade Promotion Authority Act of 2002, Congress stated that "[t]he principal negotiating objectives of the United States regarding trade-related intellectual property are . . . to further . . . protection of intellectual property rights . . . ensuring that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights . . . reflect a standard of protection similar to that found in United States law." 19 U.S.C. § 3802(b)(4)(A) (2000).

<sup>20</sup> Pedro Roffe, *Bilateral Agreements and a TRIPS-plus World: The Chile-USA Free Trade Agreement* TRIPS Issues Papers (Quaker International Affairs Programme, Ottawa) 2004, at 3, available at [http://geneva.quino.info/pdf/Chile\(US\)final.pdf](http://geneva.quino.info/pdf/Chile(US)final.pdf).

<sup>21</sup> Drahos, *supra* note 9, at 798.

<sup>22</sup> The Trade Compliance Center lists these agreements, <http://www.tcc.mac.doc.gov/>.

<sup>23</sup> Mozambique Bilateral Investment Treaty, U.S.-Mozam., Dec. 1, 1998, S. TREATY DOC. NO. 106-31 (1998).

<sup>24</sup> *Id.*, art. I.

domestic investors.<sup>25</sup> On the other hand, the IP chapters in FTAs seek to completely change the IP regime in the developing signatory State, thus giving foreign IP owners in developing nations more protection than existed in developing countries before the FTA was signed.

¶12 Consequently, the U.S. has become increasingly involved in FTA negotiations. The remainder of this iBrief will focus on the FTA negotiations between Thailand and the U.S. More specifically, this iBrief will use the precedent set by previous U.S. FTAs to demonstrate that the IP provisions that will be included in the U.S.-Thai agreement will likely be very similar to those previously negotiated agreements.

¶13 FTA negotiations between the U.S. and Thailand began in July 2004 and are expected to conclude sometime this year.<sup>26</sup> Thus far, six rounds of negotiations have occurred,<sup>27</sup> and IPRs, especially relating to the pharmaceutical industry, have already been dubbed “a sensitive issue” by negotiators on both sides.<sup>28</sup>

## II. A SNAPSHOT OF THAI IP LAW

¶14 Thailand has numerous laws in place to protect IP.<sup>29</sup> However, enforcement of those laws remains an issue. Enforcement of IPRs in Thailand is slowly meeting foreign investors’ objectives in policing the marketplace to suppress fakes and pirated goods.<sup>30</sup> “A key factor to improvement of enforcement efforts is having IP owners work in close cooperation with Thai law enforcement and government agencies.”<sup>31</sup> Such

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<sup>25</sup> See the first page of the latest model U.S. Bilateral Investment Treaty (completed in 2004), *available at* <http://www.state.gov/documents/organization/38710.pdf>.

<sup>26</sup> *Thailand, US Agree to Wrap Up FTA Talks in 2006*, THAI PRESS REP., Sept. 23, 2005.

<sup>27</sup> As of January 13, 2006. See USTR—Statement of Barbara Weisel (Jan. 13, 2006), [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2006/January/Statement\\_of\\_Barbara>Weisel\\_Assistant\\_US\\_Trade\\_Representative\\_Regarding\\_the\\_6th\\_Round\\_of\\_the\\_US-Thailand\\_FTA\\_Negotiations.html](http://www.ustr.gov/Document_Library/Press_Releases/2006/January/Statement_of_Barbara>Weisel_Assistant_US_Trade_Representative_Regarding_the_6th_Round_of_the_US-Thailand_FTA_Negotiations.html).

<sup>28</sup> See, e.g., *Thailand, US Agree to Wrap Up FTA Talks in 2006*, *supra* note 26.

<sup>29</sup> Legal protection of intellectual property is based on the provisions of the Trademark Act B.E. 2534 (A.D. 1991), the Trademark Act (No. 2) B.E. 2543 (A.D. 2000), the Patent Act B.E. 2522 (A.D. 1979), the Patent Act (No. 2) B.E. 2535 (A.D. 1992), the Patent Act (No. 3) B.E. 2542 22 (A.D. 1999), the Copyright Act B.E. 2521 (A.D. 1978), the Copyright Act B.E. 2537 (A.D. 1994), as well as other laws such as the Civil and Commercial Code, Penal Code, and Consumer Protection Act.

<sup>30</sup> Arnold and Kelly, *supra* note 6, at 2.

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

cooperation is slowly happening throughout the country, but Thailand still has a significant way to go before IP infringement will be under control.

¶15 While enforcement is of utmost priority in improving the IP regime in Thailand, the new IP provisions of the Thai FTA provisions are also extremely important. These new provisions will have a significant impact on the IP marketplace as Thai IP law is brought more in line with U.S. law.

### III. PREDICTIONS FOR THE U.S.-THAI AGREEMENT

¶16 Due to the strength of the U.S. as compared to the majority of its trading partners, the bilateral agreements to which it is a party are typically very similar. Drahos notes that:

In bilateral trade negotiations between states involving a strong and weak state, generally speaking the strong state comes along with a prepared draft text which acts as a starting point for the negotiations... In order to lower the transaction costs of bilateralism the [U.S.] has developed models or prototypes of the kind of bilateral treaties it wishes to have with other countries... So, for example, ... the Free Trade Agreement that the [U.S.] has negotiated with Jordan will serve as a model for other FTAs being negotiated with Chile and Singapore.<sup>32</sup>

¶17 A central aspect of the most recent series of FTAs entered into by the U.S. is the establishment of IP protections that exceed the TRIPS minimum standards. This section of the iBrief predicts the IP provisions of the Thai-US FTA based on an examination of the IP chapters in the following U.S. FTAs:<sup>33</sup>

1. The Singaporean FTA, signed in January 2003, is the first FTA between the U.S. and a Southeast Asian State;<sup>34</sup>
2. The Chilean FTA, signed in June 2003, is the first FTA between the U.S. and a South American country;<sup>35</sup> and

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<sup>32</sup> Drahos, *supra* note 9, at 794.

<sup>33</sup> These particular agreements were chosen because their intellectual property provisions are representative of the intellectual property chapters in *all* the most recent U.S. FTAs. For a more in-depth discussion involving all of the most recent FTAs, see Home Page of Consumer Project on Technology, <http://www.cptech.org/> (last visited Jan. 4, 2006).

<sup>34</sup> United States—Singapore Free Trade Agreement, U.S.-Sing., May 6, 2003 [hereinafter Singapore FTA], *available at* [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Singapore\\_FTA/Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html).

3. The Australian FTA, signed in May 2004, is the first FTA signed in the 21<sup>st</sup> century between the U.S. and a developed country.<sup>36</sup>

#### *A. Patent Law: Pharmaceuticals*

##### *1. Patent Term Extension*

¶18 Much of the controversy surrounding IP protection involves issues affecting the pharmaceutical industry.<sup>37</sup> One such protection, which is strongly advocated by the pharmaceutical industry, is patent term extension. Extension for a patent term is sought when an abnormal delay in the regulatory approval process reduces the effective life of a patent. The Singaporean, Chilean, and Australian FTAs all contain provisions granting patent term extensions when a delay in the granting of a patent exceeds a certain amount of time (four to five years).<sup>38</sup> In addition, each of the agreements grants extensions to compensate for “unreasonable delay” in the granting of regulatory marketing approval.<sup>39</sup>

¶19 Because patent term extension provisions have been included in the most recent U.S. FTAs, it is highly likely that similar provisions will also be included in the final text of the Thai agreement. As the Thai drug regulatory office frequently delays approval of drugs,<sup>40</sup> it is expected that

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<sup>35</sup> Chile—United States Free Trade Agreement, U.S.-Chile, June 6, 2003 [hereinafter Chile FTA], available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Chile\\_FTA/Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Texts/Section_Index.html).

<sup>36</sup> Australia—United States Free Trade Agreement, U.S.-Austl., May 18, 2004 [hereinafter Australia FTA], available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Australia\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html).

<sup>37</sup> See, e.g., Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, 15 ALB. L.J. SCI. & TECH. 433, 433 (2005); Hamed El-Said and Mohammed El-Said, *TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector*, 2 Manchester J. Int'l Econ. L. 59, 59 (2005); Adam Graham-Silverman, *Big Pharma's Free Ride*, Salon.com, Aug. 12, 2005, [http://www.salon.com/news/feature/2005/08/12/cafta\\_drugs/index\\_np.html](http://www.salon.com/news/feature/2005/08/12/cafta_drugs/index_np.html).

<sup>38</sup> Singapore FTA, *supra* note 34, art. 16.7.7; Chile FTA, *supra* note 35, art. 17.9.6; Australia FTA, *supra* note 36, art. 17.9.8.a.

<sup>39</sup> Singapore FTA, *supra* note 34, art. 18.8.4; Chile FTA, *supra* note 35, art. 17.10.2.a; Australia FTA, *supra* note 36, art. 17.9.8.b.

<sup>40</sup> “The major obstacles to foreign companies lie in skirting the regulatory system's widespread corruption, which can manifest itself in everything from intentional delays in the approval process to weak IPR protection.” Ames Gross, *New Regulatory Trends In Thailand's Pharmaceutical Market*, Pacific Bridge

patent term extension provisions will be heavily relied on by the foreign pharmaceutical industry in Thailand to lengthen the effective life<sup>41</sup> of its drug patents.

## 2. Compulsory Licensing

¶20 A second issue is the compulsory licensing of patents, which is currently allowed (though never exercised) by the government under Thai law.<sup>42</sup> This issue has been addressed by the U.S. FTAs in two different manners.<sup>43</sup> The first approach, used in the Chilean agreement, applies the TRIPS standards.<sup>44</sup> TRIPS states that governments may issue compulsory licenses for any reason so long as a certain number of conditions are met (e.g. prior negotiations for a voluntary license, and royalty payments).<sup>45</sup> Additionally, TRIPS allows for the waiver of the conditions in certain situations.<sup>46</sup> A second approach, used in the Singaporean and Australian agreements, limits the use of compulsory licenses to antitrust remedies, public non-commercial use, or national emergencies.<sup>47</sup>

¶21 In the Thai agreement, the provision for compulsory licenses could follow either of the manners described above—TRIPS standard or limitation to certain situations. Because the majority of pharmaceutical innovators in Thailand are foreign-owned, the TRIPS standard will be sought by the Thai negotiators, because it arguably allows greater opportunity for generic companies to make patented drugs via compulsory licenses granted by the Thai government.<sup>48</sup> However, even if the more stringent standard for issuing compulsory licenses found in the Singapore and Australian FTAs was used, the Thai government would still be able to

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Medical—Thailand Medical Publications (1999),

<http://www.pacificbridgemedical.com/publications/html/ThailandMar1999.htm>.

<sup>41</sup> The effective life of a patent is the patent term remaining once full regulatory approval has been granted. While the patent term in the U.S. is twenty years, the average effective patent life of a drug is ten to twelve years.

<sup>42</sup> *Thailand Legal Basics: Intellectual Property Rights Laws*, a publication by Tilleke & Gibbins Int'l Ltd., at 18,

[http://www.tillekeandgibbins.com/Publications/thailand\\_legal\\_basics/index.html](http://www.tillekeandgibbins.com/Publications/thailand_legal_basics/index.html).

<sup>43</sup> A compulsory license gives permission to another producer to make the patented product without the patent holder's consent.

<sup>44</sup> Chile FTA, *supra* note 35, art. 17.1.5.

<sup>45</sup> TRIPS, *supra* note 18, art. 31.

<sup>46</sup> *Id.*

<sup>47</sup> Singapore FTA, *supra* note 34, art. 16.7.6; Australia FTA, *supra* note 36, art. 17.9.7.

<sup>48</sup> See Carsten Fink and Patrick Reichenmiller, *Tightening Trips: The Intellectual Property Provisions of Recent US Free Trade Agreements*, (Int'l Trade Dep't of the World Bank Group) Feb. 7, 2005, at 2, <http://www.cptech.org/ip/health/trade/worldbank02072005.pdf>.

issue compulsory licenses under the conditions of a national emergency or for public, non-commercial use.<sup>49</sup>

### 3. *Linkage Between Patent Status and Generic Drug Approval*

¶22 A third issue involves the linkage between a patent's status and generic drug marketing approval. In other words, the issue is whether a generic drug can be given marketing approval during the life of the patent from which the generic drug is derived. For this particular issue, the Singaporean agreement has been the gold-standard, its wording adopted almost verbatim by all subsequent U.S. FTAs.<sup>50</sup> The Singaporean agreement states that the regulatory authority may not grant marketing approval to a generic drug while the brand name drug is under patent (unless authorized by the patent owner), and, in addition, the patent owner must be notified of the name of the generic company requesting marketing approval.<sup>51</sup>

¶23 It is highly probable that the Thai agreement will also proscribe Thailand from granting marketing approval for generic drugs while the brand name drug is under patent (unless authorized by the patent holder). This provision effectively renders compulsory licenses ineffectual since it is unlikely that a pharmaceutical patent owner will grant permission for a generic company to market its patented drug, effectively undercutting the patent holder in the marketplace.<sup>52</sup> Additionally, even once the drug goes off patent, this provision will still delay the availability of generic drugs since they may no longer be approved and prepared for market distribution while the brand name drug is under patent.

### 4. *Data Exclusivity*

¶24 A fourth issue is data exclusivity. To obtain marketing approval, pharmaceutical manufacturers must submit a significant amount of clinical data to regulatory bodies—data that typically costs hundreds of millions of dollars to produce.<sup>53</sup> Generic drug manufacturers can later use that data to develop and approve their own generic versions of the drugs, thus bypassing a significant cost of pharmaceutical manufacturing. Data exclusivity

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<sup>49</sup> The generic manufacturers, however, would need to become state-owned, or in some other manner, non-commercial.

<sup>50</sup> See, e.g., Chile FTA, *supra* note 35, art. 17.10.2.b-c.; Australia FTA, *supra* note 36, art. 17.10.4.b-c.

<sup>51</sup> Singapore FTA, *supra* note 34, art. 16.8.4.b-c.

<sup>52</sup> Fink and Reichenmiller, *supra* note 48, at 2.

<sup>53</sup> See Pharmaceutical Research and Manufacturers of America Website, *What Goes Into the Cost of Prescription Drugs*, June 2005, [http://www.phrma.org/files/Cost\\_of\\_Perscription\\_Drugs.pdf](http://www.phrma.org/files/Cost_of_Perscription_Drugs.pdf).

provisions essentially grant patent-like protection of the clinical data to their creator for a certain amount of time and for many of the same reasons that an actual patent is given to the pharmaceutical innovators. Again, the Singapore FTA has set the standard for all subsequent agreements, providing five years of data exclusivity for the creators of clinical data.<sup>54</sup> Additionally, under the Australian agreement's provisions, once marketing approval has been granted in another territory based on clinical data, that clinical data gains exclusivity in the territories of the Parties to the agreement.<sup>55</sup>

¶25 Like its predecessor, the Thai FTA will likely have a provision which grants data exclusivity for five years. Due to the huge expense in gathering clinical data, this provision will hamper the efforts of generic drug companies seeking to approve drugs based on data previously submitted by pharmaceutical innovators, and will also present another obstacle for the Thai government when seeking to make use of compulsory licenses.<sup>56</sup>

¶26 It is likely that the U.S. negotiators will also push for a provision like that in the Australian agreement (described above), which grants data exclusivity in all FTA jurisdictions once the data has been approved by a regulatory authority in another country—even if that country is not a signatory of the FTA. Thus in Thailand, generic manufacturers will not be allowed for a certain amount of time to rely on the clinical data submitted to a *foreign* regulator when seeking regulatory or marketing approval for its generic drug in Thailand.<sup>57</sup>

### 5. Implications

¶27 Because many of the issues above are not addressed in detail, if at all, under current Thai law, the above predicted provisions will have a number of effects in Thailand with regards to pharmaceutical drugs. First, the above provisions will likely hamper the availability of generic drugs. The agreement will likely reduce the amount of generic drugs that come to market and will also likely lengthen the amount of time it takes for generics to get to market. Additionally, the added protections given to pharmaceutical patents and clinical data will increase costs to local generic manufacturers due to the added burden of obtaining regulatory and marketing approval. This in turn will raise costs of generic medicines. These higher costs will likely lead to the prescribing of older, off-patent

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<sup>54</sup> Singapore FTA, *supra* note 34, art. 16.8.1-3; *See, e.g.*, Chile FTA, *supra* note 35, art. 17.10.1.

<sup>55</sup> Australia FTA, *supra* note 36, art. 17.10.

<sup>56</sup> Fink and Reichenmiller, *supra* note 48 at 2.

<sup>57</sup> “In other words, test data exclusivity applies automatically in all FTA jurisdictions, once a company submits test data to a drug regulator in one territory—even outside the FTA area.” *See id.* at 3.

drugs, by government physicians because the older, off-patent drugs are less expensive, and thus are more likely to be approved for use under the national health plan.

### *B. Patent Law: Plants*

¶28 A fifth issue, also related to patent law, is the patenting of life forms and, specifically, plants. Those that support life form patenting maintain that granting patents motivates researchers to develop more healthy and productive forms of plants and animals. Patented life forms include pesticide-resistant crops, larger, meatier livestock, etc. Those that oppose the patenting of life forms fear that “big business” will oust local farmers and lay claim to the natural resources of developing countries. Both the Singaporean and the Chilean agreements include no general exclusions of plants and animals from patentability.<sup>58</sup> The Australian agreement allows exclusions of life form patents only for “moral, health, or safety reasons.”<sup>59</sup>

¶29 All recent U.S. FTAs have included provisions allowing for patenting of life forms, especially plants, and it is more than likely that a similar provision will be included in the Thai agreement. This is one of the most highly debated areas within the Thai agreement negotiations due to the fact that plants are not protected under the current regime<sup>60</sup> and due to the argument that such a provision would have a detrimental impact on Thailand’s jasmine rice industry. The National Human Rights Commission of Thailand contends that such a provision “would allow the American plant genetic researchers and companies to patent over any new variety of rice developed from Thai jasmine rice.”<sup>61</sup> The Commission believes that this provision will greatly damage the agricultural industry in Thailand.<sup>62</sup> However, others maintain that such a provision will not greatly alter the jasmine rice industry in Thailand nor be overtaken by foreign competitors.<sup>63</sup> Proponents of life form patents maintain that patenting new types of rice will not prevent local farmers from growing the original strain of rice.

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<sup>58</sup> Singapore FTA, *supra* note 34, art. 16.7.1; Chile FTA, *supra* note 35, art. 17.9.2.

<sup>59</sup> Australia FTA, *supra* note 36, art. 17.9.2.a.

<sup>60</sup> *See supra* note 29.

<sup>61</sup> National Human Rights Commission of Thailand, Official Statement of Concern over Ongoing Negotiations on the Thai-US Free Trade Agreement (Aug. 14, 2005), *unofficial translation available at* [http://www.bilaterals.org/article.php?id\\_article=2485](http://www.bilaterals.org/article.php?id_article=2485).

<sup>62</sup> *Id.*

<sup>63</sup> Pichit Likitkijsonboon, *Of Rice and Men*, TECH CENT. STATION, July 8, 2005, <http://www.techcentralstation.com/070805PL.html>.

### C. Copyright Law

¶30 Patent law is not the only sector of IP to be affected by FTAs. The copyright provisions of the U.S.-Thai agreement will likely also reflect the trend of increasing IPR protection. Many of the provisions relating to copyright have been standard since the Singapore FTA, and it is unlikely that the U.S. negotiators will vary from those provisions. For example, beginning with the Singaporean agreement and onward, FTA provisions on the term of copyright protection have been virtually identical—life of the author plus seventy years, or if the term is decided on the basis on something other than the author’s life, seventy years from the publication or creation of the work.<sup>64</sup> Consequently, the Thai agreement will likely mimic the provisions in the Singapore FTA, bringing Thai copyright terms into conformity with the majority of the developed world. Currently, Thailand’s term for copyright protection is fifty years.<sup>65</sup> Thus, this new provision will substantially alter the copyright regime in Thailand and will also have a substantial impact on the issue of works falling into the public domain.

¶31 Another example of copyright protection standardization in U.S. FTAs is illustrated by the technological protection measures given to copyrighted works.<sup>66</sup> Again, beginning with the Singaporean agreement and moving forward, the provisions on this matter are virtually identical, stating that countries must provide “adequate legal protection and effective remedies” against acts or devices that circumvent technological protection measures, with exemptions given to certain institutions (e.g., libraries and educational institutions).<sup>67</sup> As in previous FTAs, the Thai FTA will likely state that Thailand must provide adequate protections and remedies against actions or devices that circumvent technological protection measures.

¶32 Thai law has not kept up with evolving technology and the FTA provisions will add much in this area. For example, currently computer programs are not given defined protection under copyright law in Thailand. Needless to say, the issue of technological protection measures also has not been addressed. Thus, the FTA provisions, while modernizing Thailand’s copyright protection regime, will at the same time be taking away many of the “rights” Thai IP users are accustomed to having under the current regime.

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<sup>64</sup> See, e.g., Singapore FTA, *supra* note 34, art. 16.4.4; Chile FTA, *supra* note 35, art. 17.5.4; Australia FTA, *supra* note 36, art. 17.4.4.

<sup>65</sup> See Thailand Copyright Act B.E. 2521 (A.D. 1978) and Thailand Copyright Act B.E. 2537 (A.D. 1994).

<sup>66</sup> Technological protection measures are devices and software developed to prevent unauthorized copying of digital works. Fink and Reichenmiller, *supra* note 48, at 4.

<sup>67</sup> Singapore FTA, *supra* note 34, art. 16.4.7. See, e.g., Chile FTA, *supra* note 35, art. 17.7.5; Australia FTA, *supra* note 36, art. 17.4.7.

## CONCLUSION

¶33 Thailand has much to gain from a FTA with the U.S. The U.S. is Thailand's largest export market with sales of a variety of goods and commodities climbing sixteen percent last year to almost eighteen-billion dollars.<sup>68</sup> Additionally, according to a study conducted by the Thailand Development Research Institute in Bangkok, the U.S.-Thailand FTA is projected to boost trade between the two countries by a full five percent.<sup>69</sup>

¶34 It is likely that the U.S.-Thailand FTA will contain IP provisions similar to those found in previous U.S. FTAs, which will require a number of broad changes to occur in Thailand. First, many of Thailand's IP laws will need to be re-written, or entirely new laws will need to be passed, in order to comply with the FTA. Additionally, as enforcement of IPRs in Thailand remains a consistent problem, the U.S. will undoubtedly place a heavier emphasis on this issue in the months and years following the signing of the agreement.

¶35 While the FTA provisions will perhaps harm certain sectors of the Thai economy like generic drug manufacturing in the short term, the FTA will prove to be a driving force in the development and growth of the Thai economy as a whole. Trade will increase with the U.S. as a result of the FTA, and foreign investors will be less apprehensive about making IP investments into the country if Thailand increases IP protection.

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<sup>68</sup> *Benefits of US, Thai Free Trade Agreement Examined*, CalTrade Rep., July 18, 2005, [http://www.bilaterals.org/article.php3?id\\_article=2315](http://www.bilaterals.org/article.php3?id_article=2315).

<sup>69</sup> *Id.*