

## CHAPTER 30

### CURRENT CONTROVERSIES CONCERNING PATENT RIGHTS AND PUBLIC HEALTH IN A WORLD OF INTERNATIONAL NORMS

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*This chapter will examine current issues concerning the appropriate balance between patent rights and public health under TRIPS. After reviewing the background to TRIPS, it will analyze TRIPS members' efforts to address these issues and discuss their reactions to the recent trend towards increasing patent rights. Recent action taken by India (2005 amendment to patent laws) and Thailand (compulsory licenses) will be given particular emphasis.*

#### INTRODUCTION

Patents are often touted as important and even essential to promoting innovation in the area of drug discovery, but the potential benefits may be illusory or even non-existent. In particular, to the extent that patent rights entitle their owner to exclude others from the making of the invention, the patent owner may price a patented drug at levels that are beyond what some countries can afford. Pharmaceutical companies that obtain patents emphasize that the patents promote research that helps all of society and that higher costs for patented drugs are an unfortunate, but necessary reality to funding expensive research and development of drugs. Such companies point to sunk costs such as extensive clinical testing of drugs, including those that never reach the marketplace. Human rights advocates and developing countries, on the other hand, emphasize that giving corporations rights to control access to medicine is inhumane where due to patent protection, treatment is available, but not affordable.

Can patent rights be reconciled with public health? Technically, every nation has the ability to decide whether or not to grant patents, including patents on pharmaceutical compounds. Historically, many nations elected not to provide any patents, or only limited patent rights as one method to promote greater access to medicine. However, while this option technically still exists, it is increasingly an illusory option in light of other realities. In particular, many countries of the world, including less developed countries, are members of the World Trade Organization (WTO).<sup>1</sup> One of the benefits of membership is access to global markets. However, the privilege of membership also carries certain obligations, including a commitment to comply with all related agreements to the WTO. One such agreement is the Trade-Related Intellectual Property Agreement ("TRIPS"), which established the first-ever minimum levels of patent rights on a global scale.<sup>2</sup> Essentially, TRIPS requires every WTO member to provide minimum levels of

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1. WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO: THE ORGANIZATION: MEMBERS AND OBSERVERS (last visited Feb. 2007), at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) (listing 150 member states).

2. TRIPS (1994).

patent rights, including restrictions on what must be patentable subject matter, as well as permissible exceptions. Accordingly, under TRIPS, nations no longer have the flexibility to decide how to best balance patent rights against other goals, such as providing nutrition, or accessible health care.

This chapter aims to highlight some current global controversies concerning the appropriate balance between patent rights and public health. This chapter is divided into three parts. First, a brief background to TRIPS is provided, including its genesis, an overview of the patent provisions, and its place in the international world order. Second, current controversies concerning national attempts to address domestic interests while adhering to TRIPS are analyzed. Third, this chapter discusses heightened standards of patent rights that are imposed by international agreements since the conclusion of TRIPS. The fourth and final issue of this chapter discusses counter-movements to the general global trend towards ever-increasing patent rights.

## I. TRIPS

### A. Background

#### 1. Genesis

Although TRIPS is now considered a cornerstone of international law, as well as a principal influence on national patent laws, its existence importantly does not reflect a uniform consensus amongst nations concerning the appropriate scope of patents. The negotiation of TRIPS was highly contentious; whereas wealthy countries with substantial intellectual property interests pressed for TRIPS, it was opposed by countries that previously had provided no patent protection, or only limited patent protection. The conclusion of TRIPS was substantially aided by the fact that it was part of a larger “package deal” with the negotiation of the WTO. In particular, any country desiring greater access to markets through the WTO was required to accept related WTO agreements, such as TRIPS. The linkage of TRIPS to the WTO enabled wealthier countries to succeed in raising levels of global intellectual property protection because they were able to use market access as a bargaining chip; prior attempts to negotiate international agreements that simply raised intellectual property standards failed since developing countries had nothing to gain by acceding to such requirements.<sup>3</sup> 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.<sup>4</sup>

Although the minimum standards under TRIPS clearly benefited the wealthy countries, they suggested that the new requirements would benefit all countries by setting the stage for increased foreign direct investment, as well as an environment that fostered

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<sup>3</sup> See, e.g., Gana (1996: 334) (noting that “the TRIPS Agreement accomplishes, through the potential threat of economic ostracism, what could not be accomplished through negotiations independent of the international economic framework”); Helfer (2004:2–3) (noting that TRIPS is defended as a package deal); Reich (2004: 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>4</sup> See, e.g., Correa (2000: 11).

innovation. This suggestion was not backed by empirical data and indeed, many policy institutes suggested that countries at different levels of developments should have different types of intellectual property laws.<sup>5</sup>

The conclusion of TRIPS may also have been aided by the fact that developing countries initially believed that TRIPS would not be unduly invasive on sovereign interests because of language concerning social policy goals beyond patent rights within TRIPS. For example, article 7, entitled “Objectives,” explicitly states that intellectual property rights should contribute “to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare.”<sup>6</sup> Article 8, entitled “Principles,” similarly refers to values beyond promoting innovation and explicitly states that members may adopt measures to protect public health and nutrition; however, the scope of such measures has always been controversial since only measures that are “consistent” with TRIPS are permissible.<sup>7</sup> Exceptions from the default standards for patentability as well as patent rights also have language concerning social norms. For example, one permissible exception from the default standard of patentability is for diagnostic and therapeutic treatments.<sup>8</sup> Another exception to patent rights notes not only the interests of the patent owner, but also the “legitimate interests of third parties,” which have been speculated to include an interest in a quicker supply of low-cost generic drugs.<sup>9</sup>

Despite such language concerning social norms, the ability of member states to balance patent rights against other social interests has been an ongoing issue since the conclusion of TRIPS. Countries have raised a number of disputes under TRIPS concerning the scope of patent rights, including issues concerning public health. Indeed, concern over the impact of TRIPS on public health gathered increasing momentum and led to the conclusion of the Doha Public Health Declaration in 2001, which provided some clarification on the interpretation of TRIPS, including some social policies.<sup>10</sup> Although the Declaration was unanimously agreed to at the time, it was signed in the wake of a globally recognized AIDS epidemic. In addition, the unanimous declaration did not quell all disputes since some statements could be ambiguously interpreted – just as with TRIPS itself. For example, although the declaration proclaimed that “TRIPS does not and should not prevent Members from taking measures to protect public health,” it did not provide much detail on how TRIPS should – or should not – be implemented to achieve this goal.<sup>11</sup> The Declaration did clarify a few discrete issues, including the fact that the grounds upon which compulsory licenses are issued are within the discretion of national governments. However, even this clear statement has not prevented continuing disagreements as later discussed within the section on compulsory licenses.

## 2. Overview

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<sup>5</sup> See, e.g., U.N. Doc. E/C.12/2001/15 (2001: 15), (noting that uniform rules may be inappropriate for nations at different levels of development); Commission on Intellectual Property Rights (2002:8) (noting that “[d]eveloping countries should not be deprived of the flexibility to design their IP systems that industrialized countries enjoyed in earlier stages of their own development.”); Correa & Musungu (2002: 23) (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>6</sup> TRIPS, art. 7.

<sup>7</sup> TRIPS, art. 8(1).

<sup>8</sup> TRIPS, art. 27(3). In addition, “ordre public or morality” is referenced in a different exception from patentability. *Id.* art 27(2).

<sup>9</sup> TRIPS, art. 30.

<sup>10</sup> Doha Public Health Declaration, paras. 5(a), (c).

<sup>11</sup> Doha Public Health Declaration, para 4.

TRIPS not only mandates that patents exist for all WTO member countries, but also sets forth certain minimum requirements for the patent systems of each country. In particular, TRIPS provides a general standard for patentable subject matter that effectively prohibits nations from limiting patents based upon social goals – other than those permitted under TRIPS. For example, countries can no longer unilaterally decide to bar patents on drug compositions because of their domestic preference for widespread access to drugs; so long as the new drug satisfies the patentability standards, there is no wholesale exception for banning patents on inventions that impact health. TRIPS also provides general standards for the scope of patent rights, including both the activities that constitute infringement, as well as what exceptions from patent rights are permissible. TRIPS also establishes the patent term, as well as additional rights that may effectively extend exclusivity for owners of drug patents through a new international norm regarding secrecy of information provided for regulatory approval.

### *Patentable Subject Matter*

TRIPS requires that patents be generally available for all “inventions” in all fields of technology if they comply with the technical patentability requirements of being new, useful and nonobvious.<sup>12</sup> In particular, TRIPS specifies that patents must be available for products and processes.<sup>13</sup> This is a major change for dozens of countries that had previously provided no patents, or excluded drugs from the scope of product patents to improve the accessibility of drugs. TRIPS provides some exceptions to patentability; for example, members retain the right to exclude methods of medical treatment, as well as inventions that would violate morality if commercial exploitation were permitted.<sup>14</sup>

Countries maintain some flexibility regarding what must be patented based on the lack of definition of key terms. For example, while TRIPS requires patents to be granted for all inventions, the term “invention” is not defined under TRIPS; similarly, what constitutes a “field of technology” is not defined. Accordingly, TRIPS does not demand that member states provide patents on isolated or purified compounds, or provide patents on methods of doing business – national discretion on such subjects may continue. In addition, countries also retain some flexibility in denying patents for inventions that they deem to lack novelty, industrial application, or inventive step. In particular, although these must be criteria under national patent acts, TRIPS similarly provides no definitions of these key terms.

### *Patent Rights*

In addition to requiring that patents be granted, TRIPS also dictates the scope of patent rights. Under TRIPS, a patent owner is entitled 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>15</sup> The term of patent rights “shall not end before the expiration of

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<sup>12</sup> TRIPS, art. 27(1).

<sup>13</sup> Ibid.

<sup>14</sup> TRIPS, art. 27(2)-(3).

<sup>15</sup> TRIPS, art. 29.

twenty years counted from the filing date.”<sup>16</sup> Unlike some prior patent regimes that provided a fixed patent term calculated from the date of issuance, TRIPS does not specify when the patent term should begin and only states the earliest time that patent protection may expire. Although the only benchmark given is the filing date, TRIPS does not require that protection begin with the filing date of the patent application; accordingly, nations may continue to provide protection only from grant of an issued patent, or publication of an application. What is important, however, is that the term may not end before twenty years from filing. In particular, the WTO dispute process found Canada’s patent act in violation of this provision because its term of 17 years from date of grant (for applications filed before 1989 - prior to TRIPS) did not always provide a term that would last 20 years from filing.<sup>17</sup> Canada argued that given the fact that examination of patent applications typically took five years, its absolute grant of 17 years from patent issuance was effectively the same and in some cases provided longer term than a grant of twenty years from issuance minus the period of examination. The WTO panel and the Appellate Body concurred that TRIPS requires that the term be provided as a matter of legal certainty.<sup>18</sup>

### *Exceptions from Patent Rights*

As with granting of patents, there are permissible exceptions to patent rights under TRIPS —with respect to either the exclusive rights over the patented invention or the patent term.<sup>19</sup> The first exception, under article 30, explicitly states that it is a “limited exception” and has been narrowly interpreted by a WTO panel to have three separate and cumulative conditions that substantially restrict the ability of member states to deviate from the standard patent rights.<sup>20</sup> The second exception, under article 31, essentially permits compulsory licenses, but only if a dozen procedural criteria are satisfied.<sup>21</sup> The exception for compulsory licenses has been highly contentious, and will be discussed in greater detail in the next section.

### *Data Protection*

In addition to demanding that patents be provided, TRIPS also mandates the first-ever international norm for trade secrecy. The trade secret right required under TRIPS is only for information that is provided to governmental agencies, but otherwise “undisclosed” to third parties.<sup>22</sup> In other words, TRIPS provides protection from “unfair competition” for information that must be submitted to obtain approval of the marketing of a pharmaceutical or agricultural compound. Although the type of information covered is clear, the scope of the provision is less clear since TRIPS does not define what

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<sup>16</sup> TRIPS, art. 33

<sup>17</sup> See WTO, *Canada—Term of Patent Protection*, WT/DS170/R (May 5, 2000), *aff’d*, WT/DS170/AB/R (Sept. 18, 2000).

<sup>18</sup> WTO, *Canada—Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000), para. 90. The ruling resulted in an extension of the patent term of some blockbuster drugs and concomitant delay of related generics onto the market.

<sup>19</sup> TRIPS, art. 30-31.

<sup>20</sup> WTO, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000). The panel noted that the three separate elements must be “presumed to mean something different” from each other or else there would be redundancy. *Id.* ¶¶ 7.20–7.21.

<sup>21</sup> TRIPS, art. 31

<sup>22</sup> TRIPS, art. 39.

constitutes the impermissible “unfair competition.” In addition, TRIPS also does not state how long the protection from unfair competition should last. The interpretation of these terms would be important in assessing whether and when a generic manufacturer could rely on the submission of a pioneering drug company to obtain approval for its own product. Although there have been disputes, there has thus far not yet been an official determination by a WTO panel concerning the scope of this provision.<sup>23</sup> On the other hand, this right may be irrelevant for the many countries subject to heightened requirements under TRIPS-plus agreements discussed in a later section.

### 3. Enforcement

One important aspect of TRIPS lies in the enforceability of its provisions. Although some countries were given a transition period to fully comply with TRIPS in light of their developmental stage, all requirements, including transitional provisions, are ultimately enforceable under the WTO framework. TRIPS is enforceable pursuant to the Dispute Settlement Understanding (DSU) that governs all WTO agreements.<sup>24</sup> The DSU is considered the most powerful enforcement mechanism of any international agreement because decisions pursuant to the DSU are backed by the WTO. Nations who do not comply may lose WTO benefits.<sup>25</sup>

One result of the DSU is that TRIPS provisions tend to dominate over not only domestic interests, but also competing international agreements and norms. Because other international instruments and organizations do not have the same enforcement ability, their interests are effectively not promoted. For example, the universally recognized rights to health, and right to life, as recognized by UN agreements, are not easily definable, let alone enforceable. In contrast, patent criteria under TRIPS are clearly defined and have strong enforceability under the DSU. WTO panels that consider TRIPS violations pursuant to the DSU must take into account international norms when interpreting WTO rules, such as TRIPS.<sup>26</sup> However, international norms also dictate that where a treaty’s terms are clear, there is no need to look beyond the text.<sup>27</sup> Moreover, even if a WTO panel were to consider human rights norms in interpreting TRIPS, that would be a far cry from enforcing international norms *beyond* TRIPS. For example, UN resolutions suggesting that fundamental human rights, such as a right to health, be given “primacy” over TRIPS, are not enforceable under the WTO framework and also lack independent enforceability.

Since each international regime provides its own rights and enforcement provisions, the regime with the strongest enforcement ability – WTO/TRIPS – effectively

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<sup>23</sup>The United States brought a formal case against Argentina for alleged failure to comply with this provision, but the case failed to produce clear rules since it was ultimately settled after two years of discussion. See World Trade Organization, Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, WT/DS171/3, WT/DS196/4, IP/D/18/Add.1, IP/D/22/Add.1 (June 20, 2002). For an interesting review of the background leading to the TRIPS provision, including limitations to its interpretation, Reichman (2004).

<sup>24</sup> DSU, art. 23

<sup>25</sup> Dreyfuss & Lowenfeld (1997: 276-77); Helfer (2004: 22).

<sup>26</sup> DSU, art. 3(2). Customary rules include at least the interpretative rules under the Vienna Convention, which requires that a treaty be interpreted in “good faith” in accordance with the “ordinary meaning” of the treaty terms in their context and in light of the object and purpose of the treaty. Vienna Convention on the Law of Treaties, art. 31(1).

<sup>27</sup> Vienna Convention on the Law of Treaties, May 23, 1969, 8 I.L.M. 679 art. 31.

dominates over other international norms. Outside of specific cases of TRIPS violations, there is no separate mechanism to consider the extent to which TRIPS conflicts with or even nullifies other international norms. There is no official requirement that TRIPS not impinge on other international treaties and even in the event of such an arguable conflict, it would not constitute a justiciable action under the WTO.

## B. Current Issues

### 1. Patentability

As noted earlier, TRIPS mandates patent protection for all “inventions” that satisfy the criteria of patentability, but does not define what constitutes an invention, thereby allowing some domestic differences and flexibility. However, the limits of that flexibility may be challenged by India’s current patent act because it provides a new gloss to the limits of patentable subject matter. Although India’s 2005 amendments to its patent act did extend patent protection to products in all fields of technology, notably including drug patents for the first time, it did so with a major caveat. In particular, the current law excludes certain products from the scope of patent protection where they are considered to be variations of existing compounds. Section 3(d) of the present Indian patent law provides that:

Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [can not be patented].<sup>28</sup>

In addition, an explanation to this provision clarifies that chemical derivatives, such as salts, esters, isomers, and other combinations, shall be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.<sup>29</sup>

India’s provision is unique in excluding subject matter from the scope of patentability that would generally be considered – if at all – under other patentability criteria. Other countries do not exclude compounds from consideration as patentable subject matter based on the similarity to prior compounds. Rather, most other countries consider similarity to prior compounds only under the other requirements of whether a compound is new and has an inventive step. In addition, although a related compound might seem likely to be considered to lack an inventive step, many patent laws construed this requirement in a manner that in fact considered chemically similar products to often satisfy the test. Whether or not something is more efficacious is more akin to a question typically considered by an agency concerned with sale of drugs. However, even then, the question typically only focuses on whether the new drug is safe and effective, but not necessarily *more* effective than other products, let alone one that is chemically similar.

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<sup>28</sup> India Patents (Amendment) Act, 2005 ¶ 3(d).

<sup>29</sup> *Ibid.*

The Indian law limiting patentability of modified compounds was done with the specific intention of avoiding a practice common within the pharmaceutical industry of obtaining a portfolio of patent protection based upon a single drug that essentially enables a company to obtain exclusivity far beyond the term of a single patent. Often referred to as “life cycle management” or “evergreening,” this occurs when multiple patents are obtained related to a single commercial product based upon slight variations after an initial patent on the underlying chemical compound. For example, subsequent patents issued to the same patent holder may be for new uses of the same compound or new dosing mechanisms. Although criticized by generic drug companies and patients’ rights groups, evergreening is an established practice in many industrialized countries. India, however, apparently was not interested in simply following suit.

The scope of India’s exception to patentability has already been the subject of one globally watched dispute surrounding the denial of a patent on a cancer drug to Novartis for its drug Glivec, alternatively marketed as Gleevec. In particular, the above exception was the focus in two related petitions brought by Novartis after denial of its patent application.<sup>30</sup> Novartis not only sought judicial relief from the denial of its patent application, but also a declaration that the Indian law was invalid.<sup>31</sup> Novartis asserted that section 3d of the Indian patent law was invalid as inconsistent with TRIPS; it suggested that the exclusions established “new hurdles for pharmaceutical innovation, unjustifiably and illegally narrowing what is patentable.”<sup>32</sup> In addition, Novartis asserted that the provision was also invalid as arbitrary, illogical and vague, such that it was unconstitutional under Article 14 of India’s constitution.<sup>33</sup>

The Novartis case was closely watched by both patent holders and public health advocates worldwide. For multinational pharmaceutical companies such as Novartis, the case was essential to determining its patent rights not only in Glivec, but in other compounds as well.<sup>34</sup> Such companies also believed that challenging India’s patent law was essential to ensuring strong global patent rights. On the other hand, public health advocates were concerned that if the Indian law was found invalid, access not only to Novartis’ Glivac drug, but other medicines would be affected. In particular, such advocates saw the case as a small window of opportunity to prevent patents on variations that were not sufficiently inventive to justify extended monopoly terms.

Novartis disputed that its possible success might negatively impact access to medicine. Novartis asserted that protecting patent rights is essential because patents “save lives by stimulating innovation.”<sup>35</sup> Novartis also asserted that its litigation was only about the fundamental legal principles and would not have an impact on access to

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<sup>30</sup> The denial of its patent application also terminated its exclusive marketing right, a right that WTO member states were required to provide if they did not immediately provide patent protection. *See* TRIPS, art. 70(9).

<sup>31</sup> *See, e.g.* Gentleman (2007).

<sup>32</sup> Novartis (2007).

<sup>33</sup> *See, e.g.,* Novartis v. Union of India, para. 1 (Madras H.C. June 8, 2007)

<sup>34</sup> Although the Novartis case was of primary interest to multinational pharmaceutical companies, the challenged Indian provision was also questioned by some Indian pharmaceutical companies. In particular, some believed that most innovations of current Indian companies are primarily incremental and might thereby be denied patent protection whereas multinational companies would be the only companies with adequate resources to develop patentable products.

<sup>35</sup> Novartis (2007).



Glivec since 99% of patients in India currently receive it without cost from Novartis.<sup>36</sup> Novartis also suggests that generic versions of Glivec would not improve access to medicine because factors other than drug cost impede access.

Novartis was pressured repeatedly to withdraw its case. The U.S. Chair of the Congressional Committee on Oversight and Government Reform wrote to Novartis to suggest that it reconsider its position for fear that its suit would have a severe impact on worldwide access to medicine.<sup>37</sup> Similarly, five members of the European parliament issued a declaration asking Novartis to drop the case.<sup>38</sup> The German minister of economic Cooperation and Development also asked Novartis to drop the case.<sup>39</sup> However, Novartis resisted all these pressures and persisted in its legal challenge.

Whether Novartis deserved an Indian patent on Glivec is an interesting question since the drug is recognized as an important cancer drug. Novartis highlights the fact that the drug is a medical breakthrough that is recognized world-wide and patented. However, Novartis does not emphasize that its contested application is not for the fundamental breakthrough drug – which has already been patented – but, rather, for a variation on that drug that would essentially enable Novartis to continue to have a monopoly in the marketplace for the drug beyond the original patent term, thereby preventing lower-cost generics from entering the marketplace. The application at issue here is for a new beta crystal version of Glivec. Although one opinion of the patent office suggested that the beta crystal version was previously known, the controversy focused on whether the crystal version, if not known, would be barred under section 3(d). According to some, even the new beta crystal version should have met India's standard because the new version is more stable at room temperature and has a 30% improvement in bioavailability.<sup>40</sup> Arguably, an increase in bioavailability could constitute an improvement of efficacy, however, what constitutes efficacy is not explicitly defined, let alone how the efficacy should be proven.

Although the Indian high court ultimately rejected Novartis' challenge, the narrow scope of the opinion suggests that is not the final chapter to this controversy. The court held that Novartis had no standing to challenge whether India's patent act complied with TRIPS and suggested that any such issue should be subject to resolution within the WTO system.<sup>41</sup> In addition, the court rejected the constitutionality challenge since it found that the term "efficacy" is well known to those in the pharmaceutical field and that a law is not necessarily arbitrary and vague simply because it sets out a general framework.<sup>42</sup> Even though it agreed that the current language could result in arbitrary application by the patent office, the court contended that the appropriate remedy was not invalidation of the statute, but appeal of individual cases denied by the patent office.<sup>43</sup>

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<sup>36</sup> Ibid.

<sup>37</sup> Statement by Henry Waxman (2007).

<sup>38</sup> Statement by Anne Ferreira et al (2007).

<sup>39</sup> Gerhardsen, 15 Feb. 2007.

<sup>40</sup> Bate (2007).

<sup>41</sup> *Novartis v. India*, para. 8.

<sup>42</sup> *Novartis v. India*, paras 13-14.

<sup>43</sup> *Novartis v. India*, paras 11, 16-18.

Although Novartis cannot bring a case before the WTO, it may petition a WTO member country to do so. In addition, if India rejects additional patent applications of interest to multinational corporations and/or WTO members, a challenge before the WTO may be likely. However, unless and until a WTO panel rules on the Indian patent law, the Indian law remains on the books and the TRIPS question remains outstanding.

In the meantime, as this book goes to press, there is a new legal controversy that may implicate section 3d of the Indian Patent Act once again. This time the provision is being raised as a defense to a patent infringement action brought by Roche against India generic maker Cipla; moreover, Cipla is seeking to have the patent be revoked on this ground.<sup>44</sup> The Delhi High court has heard arguments by the parties concerning whether to impose an injunction against Cipla for marketing the patented drug Tarceva, which is used to treat cancer.<sup>45</sup> Cipla apparently asserts that the active ingredient in Tarceva is a derivative of an earlier substance called gefatinib, such that a patent is impermissible unless increased efficacy is established.<sup>46</sup>

## 2. Patent Rights – “Limited Exception”

The scope of the “limited exception” to patent rights may also be reconsidered in the near future. One possible dispute concerning what constitutes a “limited” exception to patent rights may focus on a provision of India’s patent laws that limits patent rights for some owners. Although India is the only country that currently has this law, it may be important since India is the source of many generic drugs and supplies the majority of generic AIDS medications.

India took a novel approach to limiting patent rights for patents filed under the “mailbox” provision of TRIPS. For countries that did not allow product patents at the time TRIPS was concluded, they were required to immediately adopt a procedure whereby owners of patents in other countries could file applications in India to be reviewed once product patent protection was authorized in the order in which they were received.<sup>47</sup> In other words, although the patent applications would not be immediately examined, once product patent protection existed, they would be reviewed in the order in which they were received and the Indian filing date, or any applicable earlier priority date would be utilized with respect to prior art. The questionable aspect of India’s patent law is that it does not provide the same rights to mailbox applications that ultimately are granted patents as other applications. In particular, the owner of a patent based on a mailbox application may only recover “reasonable royalties” against companies that were using the invention prior to January 1, 2005. Moreover, the patent owner is powerless to enjoin such companies from continuing to make and sell the invention.<sup>48</sup> The law technically only limits the patent owner from obtaining full remedies against those who “have made a significant investment”, were producing the product prior to January 1, 2005, and continue to manufacture the product.<sup>49</sup>

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<sup>44</sup> Shrivastava (Feb. 9, 2008).

<sup>45</sup> Ollier (Jan. 28, 2008).

<sup>46</sup> Ollier (Jan. 28, 2008); Shrivastava (Feb. 9, 2008).

<sup>47</sup> TRIPS art. 70(8).

<sup>48</sup> India Patents Act 2005, § 11A(7).

<sup>49</sup> *Ibid.*

The effect of this provision is to enable generic manufacturers of inventions subject to mailbox applications to continue to do so with a de facto compulsory license, so long as they had the foresight to begin their production before January 1, 2005 and subject only to the caveat a “significant investment” (undefined in the law). Practically, this means that although product patents are permissible under Indian law, the generic drug industry may continue to exist at least for drugs that were produced prior to January 1, 2005. This generic production would be *in addition* to production of any drugs denied patentability under India’s novel section 3d of its patent laws barring patents on variations of existing compounds that are more efficacious.

The issue is whether India’s de facto compulsory license could be considered a “limited exception” under TRIPS. After all, TRIPS states that all patents must be entitled to the same scope of rights without discrimination based on technology. In addition, Article 28 clearly states that the patent owner is entitled to bar third parties from making, using, offering for sale, selling or importing the patented invention. Such a right is facially compromised by a provision allowing unauthorized use of the patented invention, subject only to payment of a reasonable royalty. Also, the “limited exception” under Article 30 has been interpreted very narrowly in the single WTO case considering the exception. The first requirement is that the exception be a “limited” one in scope and the unlimited making and sale of a patented product seems far from limited.<sup>50</sup> Indeed, in the Canada Generic Medicines case, the WTO panel rejected a far more limited use; in particular, it rejected Canada’s claim that so long as the patentee had the exclusive right to sell, the other rights could be restricted.<sup>51</sup> Here, even that right is not exclusive to the patentee.

### 3. Compulsory Licensing

The scope of compulsory licenses under article 31 has recently been at issue in the wake of licenses issued by Thailand and Brazil. Although Brazil quickly withdrew its single compulsory license after obtaining a favorable reduction in price, Thailand has thus far resisted generally resisted pressure to withdraw its licenses.<sup>52</sup> Over the course of a few months, Thailand issued three licenses on both HIV treatment, as well as on the heart drug Plavix. More recently, on the eve of a change in administration, Thailand approved compulsory licenses on four cancer drugs.<sup>53</sup> The new administration has stated that it will review all the licenses in light of pressure from patent owners, as well as other nations.<sup>54</sup> However, regardless of whether Thailand bows to political pressure, its licenses, as well as the controversy concerning them serve as a useful example to clarify what actually is required under TRIPS. In particular, this section will address the contention that the licenses were inappropriate in view of the patented subject matter, as well as whether prior negotiation with the patent holder was required before issuing the

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<sup>50</sup> WTO, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000).

<sup>51</sup> *Ibid* para 7.33.

<sup>52</sup> In one case, a compulsory license was deemed not necessary when patent holder Novartis agreed to give its cancer drug Glivec for free to Thai patients below a certain income level. *Thailand Giant Drugmaker Novartis (Thailand) To Give Free Cancer Drug to Thai Patients*, (Feb. 4, 2008).

<sup>53</sup> Ministry of Public Health and National Health Security Office of Thailand (2008).

<sup>54</sup> *Thailand Public Health Minister to Review Thai Compulsory Licensing*, (Feb. 11, 2008); *Thailand Health Ministry Change Could Mean Fewer CLs* (Feb. 8, 2008).

licenses. This section also uses the Thailand situation to illustrate that there are additional issues beyond TRIPS that implicate the feasibility of actually using such licenses to improve access to medicine.

Article 31 applies to national legislation that permits unauthorized use by the government, or third parties authorized by the government, in situations that do not fall under article 30 *and* satisfy a long list of procedural requirements. Generally, a state must attempt to negotiate for a license directly from the patent holder before imposing a compulsory license.<sup>55</sup> However, this negotiation may be waived in cases of “national emergency,” or other circumstances of “extreme urgency,” or “public non-commercial use.”<sup>56</sup> Regardless of whether a country is entitled to avoid an initial consultation with a patent owner prior to compulsory licensing, that country must always satisfy a number of other conditions according to TRIPS.<sup>57</sup> For example, conditions governing the grant of a license include that use shall be “considered on its individual merits,”<sup>58</sup> and that the scope and duration of the use must be “limited” to the authorized purpose.<sup>59</sup> Additional mandatory procedural safeguards also exist in the form of judicial or other independent review of the use authorization.<sup>60</sup> Even if the use is authorized, it is contingent on “adequate remuneration” being paid to the patent holder. Such remuneration must take into account the “economic value of the authorization.”<sup>61</sup> As with the review of the use authorization, remuneration decisions are subject to judicial or other independent review.<sup>62</sup>

### *Permissible Subject Matter*

What constitutes appropriate subject matter for compulsory licensing has been a key point of contention in the Thai licenses. In addition, since it has been an issue since the conclusion of TRIPS, exploring this issue is important. As with all analyses of TRIPS, the proper place to begin is with the text of TRIPS itself. The negotiation history should be consulted only when the text is ambiguous, or to confirm a meaning. As will be shown, all analyses point to a conclusion that there is no limit on the type of subject matter that may be subject to compulsory licensing under TRIPS.

Article 31 is a lengthy provision that has many procedural requirements, but no explicit provision limiting the type of subject matter for which it applies. To the contrary, the only provision mentioning subject matter relates to additional requirements for the scope and duration of licenses only in the case of semi-conductor technology.<sup>63</sup> The mention of only one type of technology and only for one sub-section of Article 31

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<sup>55</sup>TRIPS, art. 31(b) (noting that compulsory use should not be permitted unless the proposed user has first “made efforts to obtain authorization” for use from the patent owner on “reasonable commercial terms” and those efforts have “not been successful within a reasonable period of time”).

<sup>56</sup>Ibid. Even in cases where waiver of negotiations with the patent owner is applicable, the patent owner must be notified of the use “as soon as reasonably practicable.” Ibid.

<sup>57</sup>In addition, other grounds include non-commercial use, dependent patents, and anti-competitive practices. *See* TRIPS, art. 31(a)–(l).

<sup>58</sup>TRIPS, art. 31(a).

<sup>59</sup>TRIPS, art. 31(c).

<sup>60</sup>TRIPS, art. 31(i).

<sup>61</sup>*Ibid.* For example, Thailand considers a royalty rate of 0.5% of the total sale value to be compliant. *See, e.g.,* Khwankhom (2006).

<sup>62</sup>TRIPS, art. 31(j).

<sup>63</sup> Whereas the general requirement for scope and duration of compulsory licenses is that use be limited to the purpose for which it was authorized,” for semi-conductor technology, use “shall only be for public non-commercial use or to remedy a practice determined ... to be anti-competitive.” TRIPS, art. 31(c).

requirements suggests that there is no general restriction on what subject matter may be licensed.<sup>64</sup>

In addition, although some member states continue to contest whether there should be limits to what subject matter may be licensed, the Doha Public Health Declaration is very clear on this point. In particular, it states that “each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses were granted.”<sup>65</sup> Indeed, part of the impetus for negotiating this declaration was that some developing countries were concerned that anticipated compulsory licenses would be considered in contravention of TRIPS.<sup>66</sup>

In addition, the negotiating history confirms that there should be no restrictions on the type of subject matter considered permissible since such restrictions were actually contemplated and specifically rejected. For example, the additional limitations on the licensing of semiconductor technology were previously proposed by the U.S. to apply to all compulsory licenses.<sup>67</sup> In addition, while most of the procedural requirements in the final version of article 31 are similar to the initial draft in 1990,<sup>68</sup> one major distinction is that the initial draft contained a specific list of permissible subject matter that could be subject to licensing.<sup>69</sup> In addition, even these limitations disappeared in the next draft of the provision. Accordingly, subject matter limitations were previously considered and *rejected* before the final text of TRIPS article 31 was concluded.

In addition, to differences in the draft text based upon the input of all parties, 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. The U.S. attempted to distinguish limit compulsory licenses, which it disfavored, from government use, for which it wanted wide discretion in subject matter. The U.S. negotiating position was intended to ensure that TRIPS would not require any modification to existing U.S. 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.<sup>70</sup> During negotiations, the U.S. explicitly denied that its laws were limited to government defense; rather, it stated that its use was unlimited in subject matter.<sup>71</sup>

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<sup>64</sup> Watal (2001: 321).

<sup>65</sup> Doha Public Health Declaration, para. 5(b).

<sup>66</sup> See, e.g., Draft Ministerial Declaration (2001: pmbl) (noting “the ‘vulnerability of developing and least developed country members to the imposition or the threat of imposition of sanctions . . .”).

<sup>67</sup> Watal (2001: 244).

<sup>68</sup> Both require a presumption of negotiation with the patent owner prior to compulsory license, yet both waive this requirement in the case of a national emergency. Compare TRIPS, art. 31 with WTO (1990:para 5A.2.1-5A.2.4)(qualifying language with “except in the case of a manifest national emergency.” Both require consideration of the individual merits, limitation in scope to the initial purpose, non-exclusive use, supply predominantly for the domestic market, judicial review, as well as some type of remuneration.

<sup>69</sup> In contrast to the current article 31, the 1990 draft stated that “compulsory license may only be granted for the following purposes.” Gervais (2003: 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. Gervais (2003: 246-47).

<sup>70</sup> See 28 USC 1498.

<sup>71</sup> See, e.g., United States Review of Legislation in the Fields of Patents, IP/Q3/USA/1, at 12 (May 1, 1998)(denying that 1498 was limited to activities within the national security sector and claiming that any ‘noncommercial use by or for the government’ would qualify’).

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.<sup>72</sup> Although the negotiating strategies of individual countries are not technically part of the supplemental record that is pertinent to interpretation of treaties, it does suggest that at least the U.S. believed that article 31 covered a broad range of subject matter. This is consistent with the prior interpretation and useful background with regard to subsequent controversy between the U.S. and Thailand regarding whether the Thai licenses were improper.

### *Is a “National Emergency” Required?*

Considering the explicit declaration of the Doha Public Health Declaration in 2001, the continuing misperception that a national emergency is required deserves further discussion. Part of the problem may be that the Doha Public Health Declaration addressed a number of different topics, such that differing provisions may be improperly conflated. For example, while it clearly states that members have the freedom to determine the grounds upon which licenses were granted, a more frequently remembered provision is for a different topic relating to when initial negotiation with the patent owner may be waived. In particular, as will be discussed in more detail in the next section, although there are no limits to the types of subjects that may be licensed under article 31, certain subjects may permit a government to avoid an initial consultation with the patent owner. One of these situations, a national emergency, was expressly discussed in the Doha Public Health Declaration. In particular, it clarified that “[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS . . . and other epidemics can represent a national emergency or other circumstances of extreme urgency.”<sup>73</sup>

Past situations involving use of compulsory licenses may have reinforced a perception that compulsory licenses are limited to national emergencies simply because of the attention devoted to use of licenses in such circumstances. For example, Brazil has repeatedly threatened to issue compulsory licenses for HIV drugs to address AIDS. Indeed, the Doha Public Health Declaration was prompted by the concern of developing countries that their ability to issue compulsory licenses to address AIDS epidemics might be unduly challenged; they sought an express clarification from all WTO countries.<sup>74</sup>

### *Prior Negotiation*

The next disputed issue is when – if ever -- a country is permitted to waive the usual requirement of prior negotiation with the patent owner prior to issuance of a compulsory license. Criticism of the Thai licenses suggests that some believe prior negotiation is always required. For example, patent owner Merck suggested that it was always entitled to negotiation prior to the issuance of a compulsory license under

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<sup>72</sup> Watal (2001: 320-21).

<sup>73</sup> Doha Public Health Declaration, para. 5(c).

<sup>74</sup> See, e.g., Draft ministerial Declaration (2001).

TRIPS.<sup>75</sup> This section will show that this is incorrect based upon a proper analysis of TRIPS that begins with the text of TRIPS itself.

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 commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”<sup>76</sup> Importantly, however, this is not the end of the provision. Rather, the very next sentence states that “[t]his 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.”<sup>77</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. Although discussion often emphasizes that prior negotiation may be waived for a national emergency, this is only one of three possible situations where prior negotiation is not required.

Turning to the controversy concerning Thailand, there are actually two conflated issues. First, there was the erroneous perception by some that a national emergency is always required. However, as just noted, although a national emergency may be relevant to compulsory licenses, it is never a requirement for issuance of such a license. Rather, it is only of possible relevance if a country wishes to *waive* the prior negotiation requirement. As noted in the last section, compulsory licenses are not limited to situations of national emergency since there is no subject matter requirement. The second, and more pertinent issue is whether Thailand’s issuance of the licenses was consistent with the prior negotiation requirement. There is actually a factual dispute concerning whether Thailand did in fact conduct prior negotiations. If Thailand did so, then there is no need to consider whether its actions fell within one of the three permissible waivers of the negotiation requirement. However, given that this requirement has engendered so much confusion, further analysis is needed to better understand the requirement.

Assuming that there were no prior negotiations between Thailand and the patent owners, could Thailand qualify for a waiver of negotiation for its compulsory licenses? The actual licenses each stated that they were issued based upon public non-commercial use, which is one of the three situations that permits waiver of prior negotiations. However, to distinguish the differences amongst the waiver situations, this section will analyze not only whether public non-commercial use was proper (as well as what it means), but also whether Thailand could have avoided negotiation based upon the national emergency condition. The licenses can be analyzed as two separate groups –the licenses for antiretrovirals versus licenses on Plavix, a heart drug medication. The national emergency exception to prior negotiation is discussed first, followed by public non-commercial use.

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<sup>75</sup> Kazmin (2006: 9).

<sup>76</sup> TRIPS, art. 31(b).

<sup>77</sup> *Ibid.*

### *National Emergency*

The first question is whether any of the licenses could have been issued based upon a national emergency. There should be no serious question regarding the two patented antiretrovirals since there is global recognition that AIDS can be a national emergency. WTO member countries specifically included AIDS as an example of what would constitute a permissible national emergency or situation of extreme urgency under the unanimously agreed Doha Public Health Declaration in 2001.<sup>78</sup> However, some controversy erupted over whether the Plavix license reflected Thailand's belief that there was a national emergency concerning heart disease.<sup>79</sup> Thailand never asserted such a belief and the controversy seemed to surround a misunderstanding concerning another basis upon which prior negotiation may be waived; namely, whether there was a public non-commercial use. Indeed, the next section explicitly considers whether Thailand's license of Plavix constitutes a public non-commercial use, such that prior negotiation with the patent owner was unnecessary under TRIPS. Although there has thus far been less news concerning reports of licenses of anti-cancer drugs, perhaps in light of current Thai reconsideration of such licenses, the analysis for such licenses would be the same.

### *Public Non-Commercial Use*

According to customary principles of international law for interpreting treaties, such as TRIPS, the ordinary and customary meaning of terms should be used. Only if the terms are ambiguous should supplementary text, such as prior drafts, be used. In addition, although supplementary texts may be used to confirm a meaning, prior history is fairly minimal in this case such that this is not much of an issue.

What is the plain meaning of "public non-commercial use?" The term is not defined in TRIPS or the Doha Public Health Declaration. The lack of direct guidance in the Declaration concerning the scope of public noncommercial use simply means that the text of TRIPS – albeit limited – is the primary focus for analysis, together with any ordinary and customary meaning.

So, the question remains, what is the ordinary and customary meaning of "public noncommercial use?" Many sources concerning TRIPS give scant attention to the scope of this definition.<sup>80</sup> However, the ones that do suggest that the term could be broadly interpreted. One resource book on TRIPS suggests that "public" may broadly refer to either use by the government, or use that is for the public benefit.<sup>81</sup> However, what constitutes "noncommercial use?" Can use by a private company ever constitute noncommercial use, even if it is for public benefit? Some have suggested that a

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<sup>78</sup> Doha Public Health Declaration, para 5 (c).

<sup>79</sup> See, e.g., Gerhardsen (Feb. 16, 2007), (noting that Sanofi-Aventis was surprised by the Plavix compulsory license since lack of access would not constitute an "extreme emergency."); *Bangkok's Drug War goes Global*, (Mar. 7, 2007) (noting that "heart disease isn't a 'national emergency'"); Cass (Mar. 13, 2007) (suggesting that if treatment for heart disease is considered a national emergency, Thailand not only starts down a "slippery slope," but also sets "dangerous precedent" for TRIPS that threatens "all intellectual property").

<sup>80</sup> For example, the Gervais book on TRIPS generally provides detailed analyses of provisions, but does not attempt to define public noncommercial use. Rather, it's "comment" concerning this term only addresses the fact that the right holder just be notified if it has reason to know that the technology is patented. Gervais (2d ed. 2003: 251).

<sup>81</sup> UNCTAD-ICTSD (2005: 471).



commercial enterprise could qualify if the licensed product is sold without a profit, such that it is not functioning as a typical commercial enterprise.<sup>82</sup> This interpretation is also reinforced by the fact that the term was intended – at least by U.S. negotiators – to allow the U.S. to continue to grant government contractors the ability to use patented technology.<sup>83</sup> During the negotiation of TRIPS, the U.S. stated that this ability was not limited to inventions relating to national security, but could include any patented invention, even though it has most often been used for things such as creating planes and missiles.<sup>84</sup> In addition, during the brief anthrax scare, the U.S. contemplated a compulsory license under the same provision to enable a company to produce greater quantities of the antibiotic ciprofloxacin to ensure an adequate supply. Moreover, permitting a broader interpretation of public noncommercial use could be consistent with reading article 31 in light with the objectives and principles of TRIPS, as required pursuant to the Doha Public Health Declaration. In particular, article 7 provides that “intellectual property rights should contribute to ... dissemination of technology, to the mutual advantage of producers and users ... in a manner conducive to social and economic welfare.”<sup>85</sup> In the case of Thailand, the third party would be making low-cost quantities of HIV drugs to ensure that Thai citizens have access to essential medicines as required by law.

Based upon the above discussion, another examination of some of the criticisms of the Thai license on Plavix suggest that the criticisms are not well-founded under TRIPS. For example, some have suggested that the Plavix license was suspect because it was issued by a military-based government to a for-profit entity.<sup>86</sup> TRIPS expressly permits the government to authorize a third party to use a compulsory license. Moreover, the fact that the authorized party is a for-profit entity would not necessarily preclude its licensed use from qualifying as public non-commercial use if done for the benefit of the public. So, what about the fact that the license is from a military-based government? Is the political leaning of a government an issue under TRIPS? There is nothing under the terms of TRIPS article 31 about 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. In fact, other provisions of article 31 suggest that discretion is given to the national authority – without regard to how it is organized. For example, the decision of what constitutes permissible subject matter is one that is within the province of the national government.

### *Compulsory Licenses Under TRIPS as a Non-Existent Option*

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<sup>82</sup> Watal (2001: 328); UCTAD-ICTSD (2005:471). Moreover, one resource book goes 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 . UNCTAD-ICTSD (2005: 471).

<sup>83</sup> One commentator suggests that the phrase “public non-commercial use” was coined to encompass the type of use that is permitted by the U.S. under section 1498. Gorlin (1999:34).

<sup>84</sup> United States Review of Legislation in the Fields of Patents, WTO, IP/Q3/USA/1 (May 1, 1998), at 12 (denying that 1498 was limited to activities within the national security sector and claiming that any “noncommercial use by or for the government” would qualify).

<sup>85</sup> TRIPS, art. 7.

<sup>86</sup> See, e.g., Lonely Thailand, May 23, 2007 (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).

Although the above discussion shows that Thailand's licenses should be permissible under TRIPS, there are other important factors that may impact whether Thailand continues its licenses, as well as whether other countries will follow suit. In particular, despite the fact that Thailand took the unprecedented step of issuing a ninety page document to explain the TRIPS-consistency of its licenses for antiretrovirals, as well as Plavix, controversy has not abated.<sup>87</sup>

### *No New Drugs*

Patent owner Abbott announced that it was withdrawing registration of half a dozen new drugs in Thailand even after Thailand issued its explanatory report.<sup>88</sup> Despite widespread condemnation and protests of Abbott's actions by patient rights groups and doctors, Abbott thus far has not backed down from its decision to blacklist Thailand.<sup>89</sup>

Abbott's actions underscore that issuing a TRIPS-complaint compulsory license may have the unintended effect of *worsening* overall access to medicine. Abbott's decision not to register certain drugs is not governed by TRIPS because TRIPS only governs whether a certain country provides patent rights. It does not govern whether drug manufacturers must seek patent rights or registration of patented drugs.<sup>90</sup> Nonetheless, if countries are practically precluded from using the "flexibility" under TRIPS for fear of retaliation beyond the scope of TRIPS, such flexibility is essentially non-existent. After all, what good is a compulsory license of one drug for a relatively small population of 50,000, if it results in seven other drugs not being available for any citizens?

Although Abbott is the only patent owner to have taken retaliatory action of the three owners of licensed patents, the unexpected and drastic measure of removing additional drugs from the Thai market may make Thailand as well as other countries wary of exercising their right to authorize compulsory licenses in the future. The fact that retaliation through removal of drugs from the registration process is not governed by TRIPS or any other international agreement means that a country such as Thailand is without any international legal recourse to challenge Abbott's actions.

### *US Retaliation*

In addition to suffering retaliation from Abbott, Thailand may also suffer broader economic losses as a result of its compulsory licenses. In particular, the most recent Special 301 Report issued by the U.S. Trade Representatives Office lists Thailand as a

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<sup>87</sup> Ten Burning Issues (Feb. 2007).

<sup>88</sup> See, e.g., Gerhardsen (March 3, 2007); Hookway & Zamiska (2007).

<sup>89</sup> Abbott's decision was not a positive one for public relations as it resulted in worldwide protests, as well as protests at the annual shareholder meeting. See, e.g., Jaspén (2007).

<sup>90</sup> If a company does seek to sell a drug, TRIPS does require that the information submitted to the regulatory agency be protected from unfair competition under article 39. However, there is nothing under TRIPS that mandates a company to submit such information in the first instance.

priority watch country.<sup>91</sup> The listing is the first step towards possible economic sanctions unilaterally determined and imposed by the United States.

In addition, the listing of Thailand as a priority watch country emphasizes that TRIPS compliance does not provide a country with immunity from sanction under the U.S. trade act. Technically, the U.S. could list any country that it believes is in violation of an international trade agreement, such as TRIPS. However, the fact that the recent report failed to note any specific provision of TRIPS that Thailand has violated, suggests that there is no provision at issue. Rather, the report noted that the licenses as cause for “serious concern” and as “indications of a weakening respect of patents.”<sup>92</sup> While this may seem odd, the U.S. trade laws behind the Special 301 priority list do not require any actual violation of international laws.<sup>93</sup> Rather, the U.S. may initiate proceedings against any “unjustifiable” act of a foreign government that “burdens or restricts” U.S. commerce.<sup>94</sup> Failure of other countries to provide desired IP laws has been deemed to suffice. The U.S. has previously used this procedure to force other countries to agree to standards beyond those required by TRIPS. Although Special 301 may not be compliant with the WTO and has in fact been previously subject to a review under the WTO, the U.S. has not shied away from using this trade act.<sup>95</sup>

#### 4. Issues on the Horizon

The current challenges to balancing public health interests against patent rights required under TRIPS are likely only to become more severe. In particular, as the scope of WTO member countries continues to increase, there are fewer places for nations to find low-cost generic drugs. The changing landscape of full patent protection of TRIPS will be a particular concern to the global AIDS crisis in developing countries. While some countries such as Brazil have been able to make substantial inroads in treating HIV through low cost generic medicines, many HIV patients are now becoming resistant to ‘first-line’ HIV treatments and need access to newer, and likely patented drugs. The “second-line” treatments used to treat drug-resistant AIDS patients can cost from seven to twenty-eight times the price of the unpatented generics on an annual basis.<sup>96</sup> To the extent that such drugs are patented and countries prohibited from using compulsory licenses – either because of narrow interpretations of TRIPS, or because of challenges beyond TRIPS, there could be a serious public health crisis.

The ability of India to continue to make generic drugs is of particular concern. Presently, India provides the majority of generic HIV medications, but its ability to

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<sup>91</sup> Office of the USTR (2007). This report is an annual report by the United States Trade Representatives office concerning global intellectual property issues that is conducted pursuant to section 301 of the U.S. Trade Act of 1974. The report not only describes perceived deficiencies in the protection or enforcement of intellectual property, but also designates different priority status to countries. A country designated as a priority watch is given heightened attention over one that is merely listed as a watch country.

<sup>92</sup> Office of the USTR (2007). The same document claims that the United States “is firmly of the view that international obligations such as those in the TRIPS Agreement have sufficient flexibility to allow countries . . . to address the serious public health problems that they face.” Office of the USTR (2007: 12).

<sup>93</sup> Although violation of U.S. rights under trade agreements may be grounds for retaliation under special 301, those are not the only grounds. 19 U.S.C. §2411(a)(1).

<sup>94</sup> 19 U.S.C. §2411(a)(1)(B)(ii).

<sup>95</sup> Appellate Body Report, *United States Sections 301-310 of the Trade Act of 1974*, WT/DS152/R art. 23 (Dec 22, 1999).

<sup>96</sup> Medicines Sans Frances (2005).

continue to do so is unclear. India actually has several provisions under its current patent law that soften its transition to providing patents on products, as opposed to solely processes of making drugs. First, as previously discussed, some generic manufacturers can continue to make generic versions of drugs that they were making prior to 2005 subject to a compulsory license if they have made a “substantial investment” *and* if the Indian law permitting them to do so remains unchallenged by a WTO panel. Perhaps of greater importance for new drugs subject to patent applications after 2005 is the long-term status of section 3(d) of India’s patent law that currently prohibits patents on slight variations of prior patented compounds unless they show improved efficacy. The Novartis decision allows this provision to remain in effect, but given the significance of this law to patent owners, it will likely be subject to future challenges. While the law remains effective, the Indian patent office has a powerful weapon to deny patents on variations of old HIV compounds that do not show increased efficacy, which can then enable the Indian generics drug industry to continue to be a major supply for developing countries worldwide.<sup>97</sup>

Moreover, for developing countries that do not have the ability to manufacture lower-cost drugs, even if they could issue a compulsory license, the issue is of particular concern. While there is technically a “solution” under TRIPS to enable such countries to import patented drugs from a different country, the solution involves complex procedures that make the normal requirements for compulsory licenses pale by comparison.<sup>98</sup> In the four years since this option has been available, only two developing countries, Rwanda and Nepal have attempted to use this option, with the results still unclear.<sup>99</sup>

### *Parallel Imports*

Controversy may also move away from compulsory licensing and more towards discussion of whether to permit parallel imports. This is sometimes also referred to as a question of whether to recognize international exhaustion of patent rights. TRIPS does not explicitly state whether a nation must also exclude others from importing the patented invention *if it has been previously sold under patent in a different country*. Rather, TRIPS simply states that parallel imports shall not be the subject of dispute settlement proceedings under TRIPS.<sup>100</sup> In addition, the Doha Public Health Declaration technically affirms the right of each country to use this principle; in particular, it states that TRIPS is intended to “leave each Member free to establish its own regime for such exhaustion without challenge.”<sup>101</sup> However, since other affirmed “rights” under the Doha Public Health declaration have been challenged, such as the right of each nation to determine what subject matter is appropriate for compulsory licensing, this right may be as well.

The controversy focuses on whether a country may preclude importation of patented products that were previously sold in a different country subject to patent rights.

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<sup>97</sup> For example, prior to the Novartis court ruling, MSF suggested that if Novartis succeeded, Abbot’s request to patent new forms of lopinavir and ritonavir would similarly be entitled to patents and thereby negatively impact access to medicine. Medecins Sans Frontieres (2006).

<sup>98</sup> WTO General Council Decision of 30 August 2003.

<sup>99</sup> Gerhardson, July 20, 2007; MacInnis (2007); Anderson, Feb. 20, 2008; Allen, Feb. 27, 2008.

<sup>100</sup> TRIPS art. 6.

<sup>101</sup> Doha Public Health Declaration, ¶ 5(d).

If a country recognizes international exhaustion of patent rights that means that it considers a patent owners rights in a patented product to be “exhausted” by the first sale of the product anywhere in the world. For example, if a patented product was first sold in Canada, the patent owner could not then try to claim that its importation right in India was infringed if India recognized international exhaustion. On the other hand, for a country that does not recognize international exhaustion, such as the United States, the fact that a patented product was subject to an authorized sale in Canada would not bar the patent owner from also exercising its rights at the border of the United States to prevent importation.

Permitting parallel imports is touted as consumer-friendly since it enables drugs to be sold at a lower price in the second country. Pharmaceutical companies, on the other hand, assert that parallel imports are dangerous since counterfeiting might be involved. Moreover, even if the parallel imports are from a legitimate source, they also object to exhaustion of patent rights since their current business model relies on price discrimination amongst different markets. If consumers are free to buy the cheapest product that is globally available, the differing national prices set by drug companies become irrelevant.

The utility of parallel imports may be diminished in a world where most countries provide patent protection, but it would not be entirely eliminated. In particular, even if patent protection existed in all countries, that does not mean that drug costs would be uniform. Indeed, even among developed countries that currently provide patent protection, there is a great differential in prices. This is largely a function of whether national governments demand lower prices for drugs. But, regardless of the reason, to the extent that there is any differential, there still remains some utility to parallel imports. However, given the controversy of this topic at TRIPS, continued controversy is likely if countries attempt to more aggressively use this option.

## **II. Beyond TRIPS**

### **A. TRIPS-Plus Agreements**

The most significant development in the decade since TRIPS was signed is the proliferation of “TRIPS-plus” agreements that require member countries to embrace standards of intellectual property that go beyond TRIPS. In general, these are bilateral or regional free trade agreements (FTAs) negotiated between a major industrialized country (such as the U.S. or Canada) and a developing country.<sup>102</sup> As with the WTO Agreement, these subsequent agreements involve countries agreeing to higher intellectual property standards as part of a bargain for increased market access. This part highlights some

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<sup>102</sup>To a lesser extent, there are also bilateral investment agreements that require intellectual property standards or condition trade benefits on the level of intellectual property rights in force. *E.g.*, Andean Trade Preference Act, 19 U.S.C. § 3202(d)(9) (2000); Caribbean Basin Economic Recovery Act, 19 U.S.C. § 2702(c)(9). In addition, a committee under the auspices of WIPO is negotiating draft treaty on standards of patentability, the Substantive Patent Law Treaty (“SPLT”). WIPO (2003); GRAIN (2002: 3) (noting that if successful, the SPLT “could make . . . TRIPS . . . obsolete” to the extent that TRIPS only provides the minimum, whereas the SPLT “will spell out the top and the bottom line”). However, discussions have largely stalled on that agreement. *E.g.*, WIPO (2004: ¶ 7).

typical requirements of FTAs regarding patentability, patent rights, and data protection.<sup>103</sup>

### *Patentability*

Whereas TRIPS allowed countries some flexibility in defining the terms of patentability to meet their individual needs, subsequent FTAs further infringe on that limited flexibility. For example, whereas TRIPS allows countries to define what constitutes “new” and “patentable,” some TRIPS-plus agreements explicitly limit national discretion to define these terms. Some agreements specify that a new use of a previously known compound is *per se* patentable subject matter, thereby nullifying prior flexibility under TRIPS.<sup>104</sup> In addition, some agreements provide that an invention may be considered novel even if it was publicly disclosed prior to the patent application by the inventor.<sup>105</sup> While this is consistent with United States law, it is a more permissive standard, resulting in more patents – which could negatively impact public health – than what TRIPS requires.<sup>106</sup>

National ability to assess patentability is also limited in some FTAs through provisions that limit the ability for thorough review of patent applications. In particular, some FTAs specifically restrict countries from permitting third parties to oppose the issuance of patents until after the patent is granted.<sup>107</sup> In contrast, TRIPS only dictates that enforcement provisions exist for granted patents. Accordingly, since India is not a signatory to any FTA, India is able to permit third parties to bolster the patent review process by filing oppositions both prior to patent issuance as well as after patent issuance. The pre-grant oppositions seem to be particularly important; indeed, the denial of an India Glivec patent seems to have been prompted by a pre-grant opposition filed by the Cancer Patient Aid Association of India.<sup>108</sup>

### *Patent Term*

The patent term in many TRIPS-plus agreements goes beyond the TRIPS requirement that the term not end before twenty years from the date of application. In particular, many agreements allow for extension of the patent term if there are “unreasonable delays” in the patent examination.<sup>109</sup> “Unreasonable delays” may be as

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<sup>103</sup> See, e.g., Free Trade Agreement, art. 17.9; Chile FTA, art. 15.9; U.S.-Morocco. In addition, some agreements do not set specific requirements, but rather mandate adoption of the “highest international standards” of intellectual property rights. See, e.g., Euro-Mediterranean Agreement, art. 39; Eur. Cmty.-S. Afr., art. 46, Oct.

<sup>104</sup> See, e.g., U.S.-Oman (2006), art. 15.8(1)(b) (stating that the agreement “confirms that . . . patents [are] available for . . . known product[s] . . . for the treatment of particular medical conditions”); U.S. – Korea FTA, art. 18.8,], (stating that the “Parties confirm that patents shall be available for any new uses or methods of using a known product.”)

<sup>105</sup> See, e.g., United States - Panama Trade Promotion Agreement, art. 15.9(7) (noting that public disclosures by the inventor within one year of application shall not be considered in assessing whether the invention is novel or has inventive step); U.S.- Korea FTA, art. 18.8(7) (noting that public disclosures “made or authorized by, or derived from, the patent applicant” within one year of the patent application shall be disregarded in assessing novelty and inventive step).

<sup>106</sup> See 35 USC 102(b)(providing a grace period for disclosures that exist one year prior to the patent application);

<sup>107</sup> See, e.g., US-Korea FTA, art. 18.8(4) (noting that if opposition proceedings are provided to third parties, “a party shall not make such proceedings available fore the grant of the patent.”)

<sup>108</sup> See, e.g. MSF (2006).

<sup>109</sup> See, e.g., US-Oman FTA, art. 15.8(6)(a); Trade Promotion Agreement, U.S.-Peru (2006), art. 16.9(6)(a); US-Australia FTA, art. 17.9(8)(a); US-Korea FTA, art. 18.8(6)(a) (defining “unreasonable delay” as including a period of more than four years from the date of filing of an application).

few as four years from the date of filing or two years from the request for examination.<sup>110</sup> Some agreements also allow for a further extension of a patent term for activity that occurs outside the patent office. For example, some require an extension of the patent term if marketing approval for sale of a patented drug results in “unreasonable curtailment” of the effective patent term.<sup>111</sup> The rationale for extending the patent term of such patented drugs is that marketing approval is based upon clinical data that often does not exist at the time of the patent application, such that marketing approval is often not granted until after patent issuance; because the patented drug can not be sold without marketing approval, the *effective* patent term may be shortened.<sup>112</sup> The required patent term extensions under TRIPS-plus agreements for marketing approval delays essentially provide protection to pharmaceutical patent owners that the WTO panel considered beyond the scope of patent rights in the *Canada—Patent Protection of Pharmaceutical Products* decision. Although that decision focused on whether generic manufacturers were liable for making the patented invention during the patent term for regulatory approval, in the course of addressing this ultimate issue, the panel found that there was no “legitimate interest” for pharmaceutical patent owners to maintain an effective patent term equivalent to that of patent owners who did not need regulatory approval to make use of their inventions.<sup>113</sup> However, for countries that are members to TRIPS-plus agreements, this panel finding is *de facto* inapplicable.

### *Limited Compulsory Licensing*

FTAs also limit compulsory licensing beyond TRIPS. Whereas TRIPS does not specify the grounds under which compulsory licensing may be permitted, and the Doha Public Health Declaration purports to leave this matter within the discretion of national authorities, currently negotiated TRIPS-plus agreements limit circumstances under which developing nations may issue compulsory licenses authorizing generic manufacturers to produce lower cost versions of patented drugs.<sup>114</sup> The Singapore agreement, for example, limits compulsory licensing to remedying anti-competitive behavior, public non-commercial use, and national emergencies.<sup>115</sup> Moreover, some FTAs entirely omit any provision that is analogous to the compulsory licensing provision of TRIPS article 31; rather, the only exception to patent rights is a provision similar to TRIPS article 30, which only provides “limited exception” from patent rights.<sup>116</sup>

Even for FTAs that do not have provisions explicitly governing compulsory licensing, other provisions may impede use of patented inventions. In particular,

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<sup>110</sup>See, e.g., Peru TPA, art. 16.9(6)(a). Alternatively, others define unreasonable delay as four years from filing or two years from a request for examination, whichever is later. See, e.g., Australia FTA, art. 17.9(8)(a); Oman FTA, art. 15.8(6)(a).

<sup>111</sup>See, e.g., Free Trade Agreement, U.S.-Sing (2003), art. 16.8(4)(a); US-Chile FTA, art. 17.10(2)(a); CAFTA, art. 15.9(6)(b); Korea FTA, art. 18.8(6)(b). Similarly, where countries allow marketing approval based upon approval in another country, a patent term extension may be required in some cases based upon a delay in that other country’s approval process. See, e.g., US-Singapore (2003) FTA, art. 16.7(8).

<sup>112</sup>See, e.g., Cong. Budget Office (1998: ch. 4) (noting that the average “effective” patent term is about eleven to twelve years).

<sup>113</sup>The panel noted that “[o]n balance . . . the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized *that it could be regarded as a ‘legitimate interest’ within the meaning of Article 30.*” WTO Report, *Canada Generics*, para. 7.82 (emphasis added).

<sup>114</sup>In particular, the agreement stated that “[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Doha Public Health Declaration, para. 5(b).

<sup>115</sup>Singapore FTA, art. 16.7(6)(a) (anti-competitive practices); Singapore FTA, 16.7(6)(b) (public non-commercial use or national emergencies).

<sup>116</sup>See, e.g., Korea FTA art. 18.8(3), Panama TPA art. 15.9(3) and Columbia FTA art. 16.9(3)(providing for “limited exceptions” to the patent rights in a manner similar to TRIPS article 30, but without any mention of other uses similar to TRIPS article 31).

compulsory licensing may be a non-issue if a generic drug company cannot obtain the regulatory approval necessary to sell a drug because of rules that prevent the generic company from relying on the data of the patent owner. Although TRIPS does provide protection for information submitted by a patent owner to government agencies for regulatory approval, it is only against “unfair commercial use.”<sup>117</sup>

In subsequent agreements, the scope of protection is more explicit and expansive. Whereas TRIPS does not provide any timing requirements, most subsequent agreements mandate that no one other than the originator of the information can use it for five to ten years.<sup>118</sup> During this time, the patent owner *de facto* becomes the only possible manufacturer and seller of patented drugs, with the concomitant result of higher priced drugs to consumers. In addition, the period of *de facto* monopoly to the patent owner may be increasing. For example, in one of the most recent agreements, Russia appears to have agreed to protect undisclosed test data for at least six years. This agreement also suggests that the data is barred from public non-commercial use, although TRIPS explicitly requires only that such information be protected against unfair *commercial* use.<sup>119</sup>

While large pharmaceutical companies allege that data protection is necessary to recoup the investment in creating the clinical data they submit, the data protection necessarily delays the availability of generic drugs if manufacturers of generic drugs are not permitted to rely on similar data.<sup>120</sup> The patent owner and originator of the data may suggest that generic manufacturers are not impeded since they could create their own clinical data. However, generic manufacturers typically operate on slim profit margins since they do not own patents, but rather, they manufacture and sell off-patent drugs in open competition with other generic companies, as well as the patent owner. From a public health perspective, permitting a second company to rely on existing clinical data on efficacy, rather than forcing the second company to generate its own expensive data would enable a generic manufacturer to enter a market and provide lower cost drugs to consumers.<sup>121</sup>

Some FTAs entitle the patent owner to a commercial monopoly if the patent term expires before the period of data protection.<sup>122</sup> In addition, other FTA provisions delay the approval of generic drugs by precluding reliance on information submitted for marketing approval during the term of the patent.<sup>123</sup>

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<sup>117</sup>TRIPS, art. 39(3).

<sup>118</sup>See, e.g., North American Free Trade Agreement (1992), art. 1711(6) (requiring member states to provide protection to test data for a “reasonable” time, which is explicitly defined as lasting at least five years); Chile FTA, art. 17.10(1) (requiring five years of data protection of pharmaceutical products that use a “new chemical entity”); Singapore FTA, art. 16.8(2) (requiring five years of protection for test data of pharmaceutical products—a category perceived as broader than new chemical entities); CAFTA, art. 15(10) (providing five years of protection for pharmaceutical products); FTAA, ch. XX, subsec. B.2.j, art. 1.2 (providing for at least five years of non-reliance on test data for marketing approval); Oman FTA, art. 15.9(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Peru TPA, art. 16.10(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Australia FTA, art. 17.10 (providing at least five years for new pharmaceutical products and ten years for agricultural chemical products).

<sup>119</sup>See, e.g., Office of the U.S. Trade Representative (Nov. 19, 2006); *Russian Accession: New Potential Hurdle with EU* (2006).

<sup>120</sup>This is particularly significant given that developing and marketing a new drug costs an average of 800 million dollars and takes ten to fifteen years to complete. See INT’L FED’N PHARM. MFRS. & ASS’NS,(2005).

<sup>121</sup>In addition, it may be arguably unethical to even require patients to undergo duplicative tests where scientific protocol would require some patients be precluded from obtaining known therapeutic treatment if they were in a “control” group.

<sup>122</sup>See, e.g., Korea FTA, art. 18.9(3); Columbia FTA, art. 16.10(2).

<sup>123</sup>See, e.g., Peru FTA, art. 16.10.3(a); Columbia FTA, art. 16.9.6; Panama FTA, art. 15.9.6.



## *No Parallel Imports*

In addition to limiting compulsory licensing, some countries have utilized TRIPS-plus agreements to obtain a clear bar against use of parallel imports. Some of these agreements prohibit developing countries from importing patented drugs from countries that sell them at the lowest price; that is, they prohibit parallel importation and reject the principle of international exhaustion. For example, the U.S.-Singapore and U.S.-Morocco Free Trade Agreements limit parallel importation by requiring member countries to provide patent holders with the means to block importation of patented drugs if it violates a distribution agreement.<sup>124</sup>

### B. Counter-Movements

Although FTAs continue to be negotiated, there are some signs that the tide is turning, or that there are at least alternative approaches being discussed and proposed. This section highlights some of these alternative approaches. In particular, shifting public support and scrutiny of FTAs are discussed. In addition, contrary paradigm proposals to TRIPS-plus agreements are also highlighted. Although the competing paradigms are a long-shot for adoption in their current form, discussion and consideration of these approaches may help to shift the focus away from ever-increasing rights for owners of intellectual property.

#### *FTA – Shifting Tide*

One remarkable shift is that the breadth of some previously negotiated FTAs may actually be limited. For example, the United States Trade Representatives announced new trade rules for FTAs with developing countries that aim to strike a better balance between promoting innovation and public health rights.<sup>125</sup> Although the actual language of the FTAs remains to be both crafted and approved by Congress (as well as the other countries), Congress did provide a bilateral agreement of principles, including the fact that the “side letter” currently included as part of the noted FTAs should be made a part of the text of the FTA.<sup>126</sup> In addition, the EU Parliament separately adopted a resolution that called on the EU Council to prevent negotiations of drug-related TRIPS-plus provisions that impact public health and access to medicines, with specific reference to data exclusivity, patent extensions and limits on grounds of compulsory licenses.<sup>127</sup>

#### *Access to Knowledge – Proposed Treaty*

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<sup>124</sup>Singapore FTA, art. 16.7(2)–(3); Morocco FTA, art. 15.9(4); *see also* FTAA, ch. XX, subsec. B.2.e, art. 7.1 (technically permitting parallel imports, but requiring members to review their domestic laws “with a view to adopting at least the principle of regional exhaustion” within five years).

<sup>125</sup> Letter to Susan Schwab from Charles Rangel and Sander Levin, May 10, 2007. The new rules are to apply to pending agreements with Peru and Panama; but not to Korea and Russia. Office of the United States Trade Representative (May 2007) (noting that modified provisions relating to medicines and health only apply to “developing country partners.”). In addition, the pending agreement with Columbia may ultimately join Peru and Panama, but is currently stalled because of violence against trade unionists. *See* Letter to Susan Schwab from Charles Rangel and Sander Levin, May 10, 2007.

<sup>126</sup> The document states that parties “(1) would affirm their commitment to the Doha Declaration, (2) clarify that the Chapter does not and should not prevent the Parties from taking measures to protect public health or from utilizing the TRIPS/health solution, and (3) include an exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and subsequent protocols for its implementation.” Peru & Panama FTA Changes, at 8 (May 10, 2007: 8).

<sup>127</sup> European Parliament Resolution of 12 July 2007 on the TRIPs Agreement and Access to Medicine, para 11.

There is a separate movement to promote a treaty that embodies a norm contrary to the one in TRIPS. In particular, there is a proposed Treaty on Access to Knowledge (“A2K”) that aims to ensure a true balance between intellectual property owners and users; A2K was initially proposed in A2k and has been subject to continued discussion since then.<sup>128</sup> While TRIPS has language concerning balance, the interpretation of TRIPS thus far tilts predominantly in favor of rights holders. The A2k framework, on the other hand, utilizes a minimum standards framework, but for a contrary purpose to TRIPS. Whereas TRIPS requires all members to adopt certain minimum levels of protection, A2K suggests all members adopt certain minimum standards of *access*.<sup>129</sup>

A2K directly challenges the scope of patentable subject matter as well as patent rights under TRIPS. For example, A2K suggests excluding higher life forms from patentability.<sup>130</sup> This is in direct contravention to TRIPS article 27(3)(b) as well as the law of many industrialized countries that require higher life forms to be patented. With respect to patent rights, A2K suggests a safe harbor from infringement for improvement inventions, as well as “compassionate use” of medicine and medical technology.<sup>131</sup> Although the phrase “compassionate use” may lead to a quagmire of interpretive problems, the suggestion that patents be used for promoting public health is important and a novel suggestion in the international framework. Indeed, domestic laws may allow far less than compassionate use. For example, in the United States there is no statutory safe harbor, and common law exclusions for experimental use have been narrowly interpreted.<sup>132</sup>

Specific suggestions on how to balance health issues with patent rights were also embraced in a draft text for a “Paris Accord,” discussed at a meeting of the Transatlantic Consumer Dialogue (“TACD”) in June 2006.<sup>133</sup> The goal of the Accord echoes that of A2K in aiming to provide a balanced approach. In particular, it declares that “science depends upon access to knowledge” and that intellectual property rules “should not prevent experimental use.”<sup>134</sup> In addition, it sets forth specific proposals that stand in contravention of most TRIPS-plus rules regarding data exclusivity. The proposal suggests that “methods of protecting investments in clinical trials for new medicines should not prevent governments from making medicines available at affordable prices or require unethical or unnecessary replication of human experiments.”<sup>135</sup> In other words, rules providing data exclusivity that are premised on the necessity to protect financial

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<sup>128</sup>For example, Yale Law School has hosted two major conferences on A2K that brought together academics as well as activists. See Yale Access to Knowledge Conference, <http://research.yale.edu/isp/eventsa2k.html> (last visited Feb. 16, 2007). Additional information about the substance of the conference and subsequent discussions is available on a wiki at [http://research.yale.edu/isp/a2k/wiki/index.php/Yale\\_A2K\\_Conference](http://research.yale.edu/isp/a2k/wiki/index.php/Yale_A2K_Conference) (last visited Feb. 16, 2007).

<sup>129</sup>Draft Treaty on Access to Knowledge (2005), art 1-2 On the patent dimension, A2K echoes the Doha Public Health Declaration by reinforcing that TRIPS does not and should not prevent member states from adopting measures to protect public health. Draft Treaty on Access to Knowledge, art. 1-3(c).

<sup>130</sup> Draft Treaty on Access to Knowledge, art. 4-1(a)(viii).

<sup>131</sup> Draft Treaty on Access to Knowledge, art. 4-1(b)(ii), (iv).

<sup>132</sup>*E.g. Madey v. Duke Univ.*, 307 F.3d 1351, 1360–62 (Fed. Cir. 2002). *But see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (providing a slightly expanded interpretation of a limited statutory provision exempting certain activity from the scope of infringement). The lack of exceptions to patent infringement has been repeatedly noted as a problem, but despite repeated discussion of the issue, there has been no change thus far to the patent laws. See *generally*, Eisenberg (1989:1017); O’Rourke (2000:1177).

<sup>133</sup>Draft Paris Accord, June 17, 2006. The TACD is comprised of over sixty U.S. and EU consumer organizations that aim to propose joint recommendations to their respective governments. See TACD, About TACD, <http://www.tacd.org/about/about.htm> (last visited Feb. 16, 2007).

<sup>134</sup>Draft Paris Accord, 2.

<sup>135</sup> *Ibid*.

investment in clinical trials should not function in a way that would interfere with public access to medicine. The more difficult question is how to *achieve* this goal—especially in light of TRIPS-plus agreements that may already interfere with public health. In addition to supporting A2K goals, the draft text also supports a global agreement to better support financing of drug research<sup>136</sup> and specifically rejects the traditional business model of multinational pharmaceutical companies that uses high drug prices to finance research.<sup>137</sup>

Most recently, some A2K goals entered mainstream political discussions within the World Intellectual Property Organization (WIPO). In particular, WIPO members agreed to “initiate discussions on how, within WIPO’s mandate, to further facilitate access to knowledge and technology for developing countries and LDCs.”<sup>138</sup> In addition, the member states agreed that WIPO should “promote norm-setting activities related to IP that support a robust public domain.”<sup>139</sup> While the WIPO discussions lack the detail of prior proposals of A2K, the inclusion of A2k principles is nonetheless noteworthy and seen as a major step forward.<sup>140</sup> Although the WIPO general assembly must still approve the report, the consensus is considered a major achievement; one report suggested that the discussion “potentially rewrote the UN Body’s mandate.”<sup>141</sup>

### *Research & Development – Proposed Treaty*

Beyond the aspirational goals embodied in A2K-type proposals, there are additional proposals to radically modify current systems in order to achieve a better balance between patents and public health. These proposals involve both systems for promoting health research and systems to address intellectual property barriers. For example, some have suggested global research and development treaties that would ask countries to adopt a variety of different mechanisms to support all diseases, rather than those deemed most profitable by pharmaceutical companies.<sup>142</sup> Some proposals suggest that countries should provide differing amounts of support for research based upon their national income levels. Others suggest giving trade credits to countries that foster projects promoting social or public interest objectives. One of the boldest suggestions for addressing the TRIPS-plus movement lies in the Medical Research and Development Treaty Proposal of 2005, which suggests that countries not only develop alternative means for supporting research, but also forego dispute resolution and trade sanctions under various trade agreements. Rather, countries would utilize the treaty framework to support innovation.<sup>143</sup>

An interesting recent development is the resolution by the World Health Organization to take a greater role in promoting development of research and access to drugs. At the annual WHO summit, member states adopted a resolution that not only encouraged the organization to provide support to countries that “intend to make use of the flexibilities” in TRIPS, but also to “encourage the development of proposals for

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<sup>136</sup> Ibid (noting that “[g]overnments must support global agreements to share in the costs of evaluating new medicines”).

<sup>137</sup> Ibid (suggesting that “when possible and appropriate” the current system of stimulating research and development through high prices “should be replaced with new systems that reward developers . . . for improved health care outcomes”).

<sup>138</sup> See, e.g., Gerhardsen, June 14, 2007.

<sup>139</sup> Ibid.

<sup>140</sup> See *WIPO Members Agree on Development Agenda*, June 20, 2007.

<sup>141</sup> New, June 18, 2007.

<sup>142</sup> See, e.g., Hubbard & Love (2004).

<sup>143</sup> Medical Research and Development Draft Treaty (2005: art. 2.3)

health-needs driven research and development” that would include a range of incentive mechanisms.<sup>144</sup> The resolution is particularly noteworthy since just one month previously, members were divided with respect to WHO’s appropriate role both with respect to TRIPS, as well as with respect to proposals to foster research and development.<sup>145</sup>

## CONCLUSION

The final chapter of how patents and public health are balanced is still not written. However, this chapter hopefully at least provides an outline of current issues that are important to understanding the current framework, as well as possible competing frameworks. While the trend towards TRIPS-plus agreements and aggressive enforcement of patent rights may be troubling, the bold and creative actions of countries such as India and Thailand in the face of this environment suggest that the battle is far from over. In fact, the idea that a balance is necessary seems to have captured the attention of stakeholders beyond patent owners such that the future may hold a more balanced calibration.

## References

WORLD TRADE ORGANIZATION, UNDERSTANDING THE WTO: THE ORGANIZATION: MEMBERS AND OBSERVERS (last visited Feb. 15, 2007), at [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

*Russian Accession: New Potential Hurdle with EU; TRIPS-Plus IP Commitments with U.S.*, 10 BRIDGES WEEKLY TRADE NEWS DIGEST at 40 (2006), at <http://www.ictsd.org/weekly/06-11-29/index.htm>.

*Bangkok’s War Goes Global*, WALL ST. J. ASIA, March 7, 2007.

*Lonely Thailand*, WALL ST. J., May 23, 2007, commentary.

*Thailand Giant Drugmaker Novartis (Thailand) To Give Free Cancer Drug to Thai Patients*, THAI PRESS REPORTS, Feb. 4, 2008.

*Thailand Health Ministry Change Could Mean Fewer CLs*, PHARMA MARKETLETTER, Feb. 8, 2008.

*Thailand Public Health Minister to Review Thai Compulsory Licensing*, THAI PRESS REPORTS, Feb. 11, 2008.

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<sup>144</sup> World Health assembly (2007). Despite the resolution, the U.S. has disassociated itself from the decision. See *WHO Members Adopt Resolution on Pharmaceutical Innovation*, May 23, 2007.

<sup>145</sup> See, e.g., *WHO Members Divided over Plan for Promoting Pharmaceutical Innovation*, Apr. 25, 2007 (noting controversy over whether WHO should deal with TRIPS and bilateral trade agreements, as well as controversial funding mechanisms for pharmaceutical innovation).

CENTER FOR POLICY ANALYSIS ON TRADE AND HEALTH, PERU & PANAMA FTA CHANGES (May 10, 2007), at [http://www.cpath.org/sitebuildercontent/sitebuilderfiles/2007\\_new\\_trade\\_policy\\_details5-10-07.pdf](http://www.cpath.org/sitebuildercontent/sitebuilderfiles/2007_new_trade_policy_details5-10-07.pdf).

*WHO Members Divided over Plan for Promoting Pharmaceutical Innovation*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST 14 (2007), at <http://www.ictsd.org/weekly/07-04-25/story3.htm>.

*WHO Members Adopt Resolution on Pharmaceutical Innovation*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST 18 (2007), at <http://www.ictsd.org/weekly/07-05-23/story2.htm>.

*WIPO Members Agree on Development Agenda*, BRIDGES WEEKLY TRADE NEWS DIGEST, 11 (2007), at <http://www.ictsd.org/weekly/07-06-20/story1.htm>.

Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [TRIPS].

Agreement on Trade, Development and Cooperation between the European Community and its Member States, of the One Part, and the Republic of South Africa, of the Other Part, Dec. 4, 1999, 1999 O.J. (L 311) 3.

Jonathan Allen, *India Mulls Overriding Patents in Test Case*, REUTERS, Feb. 27, 2008, at <http://www.reuters.com/article/latestCrisis/idUSDEL86732>.

Tatum Anderson, *India Considers Compulsory Licenses for Exportation of Drugs*, INTELL. PROP. WATCH (Feb. 20, 2008), at <http://www.ip-watch.org/weblog/index.php?p=933>.

Andean Trade Preference Act, 19 U.S.C. § 3202(d)(9) (2000).

Roger Bate, *India and the Drug Patent Wars*, Health Policy Outlook, AEI ONLINE, Feb. 7, 2007.

Caribbean Basin Economic Recovery Act, 19 U.S.C. 2702 (1996).

Ronald A. Cass, *Thai Patent Turmoil*, WALL ST. J., March 13, 2007.

COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 73-95, (Commission on Intellectual Property Rights 2002).

- CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY, ch. 4 (1998), at <http://www.cbo.gov/ftpdoc.cfm?index=655&type=0&sequence=0>
- CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES (Zed Books Ltd. 2000).
- CARLOS M. CORREA & SISULE F. MUSUNGU, CENTRE FOR MANAGEMENT OF INTELLECTUAL PROPERTY IN HEALTH RESEARCH AND DEVELOPMENT, WIPO PATENT AGENDA: THE RISKS FOR DEVELOPING COUNTRIES, TRADE-RELATED AGENDA, DEVELOPMENT AND EQUITY (T.R.A.D.E.)WORKING PAPER 12, SOUTH CENTRE (2002), at <http://www.mihl.org/?q=node/view/125>, (last accessed 27 September 2007).
- Paris Accord (draft, June 17, 2006), available at <http://www.cptech.org/a2k/pa/ParisAccord-june17draft.pdf>.
- Treaty on Access to Knowledge, arts. 1-2 (draft, May 9, 2005), available at [http://www.cptech.org/a2k/a2k\\_treaty\\_may9.pdf](http://www.cptech.org/a2k/a2k_treaty_may9.pdf).
- Rochelle C. Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275-277 (1997).
- Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017-1086 (1989).
- Euro-Mediterranean Agreement, Feb. 26, 1996, Eur. Cmty.-Morocco, 2000 O.J. (L 70) 2.
- EUROPEAN PARLIAMENT RESOLUTION ON THE TRIPS AGREEMENT AND ACCESS TO MEDICINE (July 12, 2007), available at <http://www.europarl.europa.eu/oeil/FindByProcnum.do?lang=en&procnum=RSP/2007/2595>.
- Ruth L. Gana, *The Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL'Y 315-343 (1996).
- Amelia Gentleman, *Novartis Files Suit Against India Ruling on Drug Patents*, INT'L HERALD TRIBUNE, January 29, 2007, <http://www.iht.com/articles/2007/01/29/business/novartis.php>.
- Tove Gerhardesen, *Opposition Gains Support Against Novartis Patent Lawsuit in India*, INTELL. PROP. WATCH (Feb. 15 2007), at <http://www.ip-watch.org/weblog/index.php?p=535&res=1024>.

- Tove Gerhardsen, *Drug Company Reacts to Thai License; Government Ready to Talk*, INTELL. PROP. WATCH (Feb. 16 2007), at <http://www.ip-watch.org/weblog/index.php?p=563&res=1280&print=0>.
- Tove Gerhardsen, *Thailand Presents Report on Compulsory Licensing Experience*, INTELL. PROP. WATCH (Mar. 3 2007), at <http://www.ip-watch.org/weblog/index.php?p=563&res=1280&print=0>.
- Tove Gerhardsen, *Negotiators Agree to Add Access to Knowledge to WIPO Mandate*, INTELL. PROP. WATCH (June 14, 2007), at <http://www.ip-watch.org/weblog/index.php?p=654&res=1280&print=0>.
- Tove Gerhardsen, *RWANDA PIONEERS USE OF WTO PATENT FLEXIBILITY FOR HIV/AIDS MEDICINE*, INTELL. PROP. WATCH (July 20, 2007), at <http://www.ip-watch.org/weblog/index.php?p=696&res=1280&print=0>.
- DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, (Sweet & Maxwell 2003).
- JACQUES GORLIN, *THE INTELLECTUAL PROPERTY INSTITUTE, AN ANALYSIS OF THE PHARMACEUTICAL RELATED PROVISIONS OF THE WTO-TRIPS (INTELLECTUAL PROPERTY) AGREEMENT* (1999).
- GRAIN, *WIPO MOVES TOWARD "WORLD" PATENT SYSTEM* (2002), at [http://www.grain.org/briefings\\_files/wipo-patent-2002-en.pdf](http://www.grain.org/briefings_files/wipo-patent-2002-en.pdf)
- Laurence Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1-1086 (2004)
- James Hookway & Nicholas Zamiska, *Harsh Medicine: Thai Showdown Spotlights Threat to Drug Patents*, WALL ST. J., (Apr. 4, 2007)
- Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLOS BIOLOGY 147-150 (2004).
- The Indian Patents (Amendment) Act 2005. *English text at* [http://patentoffice.nic.in/ipr/patent/patent\\_2005.pdf#search=%22India%C20patents%](http://patentoffice.nic.in/ipr/patent/patent_2005.pdf#search=%22India%C20patents%22)
- INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASSOCIATIONS, *A REVIEW OF EXISTING DATA EXCLUSIVITY LEGISLATION IN SELECTED COUNTRIES* (2005), at [http://www.ifpma.org/documents/NR2306/DataExclusivity\\_JAN05\\_revised.doc](http://www.ifpma.org/documents/NR2306/DataExclusivity_JAN05_revised.doc).

Bruce Jaspen, *AIDS Controversy Dominates Abbot Labs' Annual Meeting*, CHI. TRIB., (April 27, 2007).

Amy Kazmin & Andrew Jack, *Thailand Breaks Patent for AIDS Drug to Cut Costs*, FIN. TIMES, (Nov. 30, 2006).

Arthit Khwankhom, *Thailand to Break HIV Drug Patent*, NATION (Nov. 30, 2006), available at <http://www.nationmultimedia.com/search/page.arcview.php?clid=2&id=30020346&date=2006-11-30>.

BENJAMIN KROHMAL, KEI, NOTES FROM MARCH 16TH 2007 U.S. CAPITOL BRIEFING ON THAILAND'S COMPULSORY LICENSES (2007), at [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) (1st visited Sept. 27 2007).

Laura MacInnis, *Rwanda Launches Key Test of WTO Drug Patent Waiver*, REUTERS (July 20, 2007), available at <http://www.reuters.com/article/healthNews/idUSL2088068720070720>.

Madey v. Duke Univ., 307 F.3d 1351, 1360–62 (Fed. Cir. 2003), cert denied 539 U.S. 958 (2003).

Medical Research and Development Treaty (draft, Feb. 7, 2005), available at <http://www.cptech.org/workingdrafts/rndtreaty.html>.

MEDECINES SANS FRONTIERES, THE SECOND WAVE OF THE ACCESS CRISIS: UNAFFORDABLE AIDS DRUG PRICES... AGAIN (Dec. 10 2005), at [http://www.doctorswithoutborders.org/news/hiv-aids/briefing\\_doc\\_12-10-2005.cfm](http://www.doctorswithoutborders.org/news/hiv-aids/briefing_doc_12-10-2005.cfm).

MEDECINES SANS FRONTIERES, A KEY SOURCE OF AFFORDABLE MEDICINES IS AT RISK OF DRYING UP (Dec. 20, 2006), at <http://www.accessmed-msf.org/documents/Novartis%20Briefing.doc> .

Merck v. Integra Lifesciences, Ltd., 545 U.S. 193 (2005).

MINISTRY OF PUBLIC HEALTH AND NATIONAL HEALTH SECURITY OFFICE OF THAILAND, THE 10 BURNING QUESTIONS ON THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND (Feb. 2008), 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).

MINISTRY OF PUBLIC HEALTH AND NATIONAL HEALTH SECURITY OFFICE OF THAILAND, FACTS AND EVIDENCE ON THE TEN BURNING ISSUES RELATING TO THE GOVERNMENT USE OF PATENTS IN THAILAND (FEB. 2007), <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> (“Ten Burning Issues”).



William New, *In a 'Major Achievement', WIPO Negotiators Create New Development Mandate*, INTELL. PROP. WATCH (June 18, 2007), at <http://www.ip-watch.org/weblog/index.php?p=656&res=1280&print=0>.

North American Free Trade Agreement, U.S. Dec. 17, 1992, U.S.-Can.-Mex., art. 1711(6), 32 I.L.M. 289.

NOVARTIS, NOVARTIS PERSPECTIVE: IMPROVING INDIAN PATENT LAW HELPS PATIENTS AND SOCIETIES (2007), at [http://www.novartis.com/downloads/Novartis\\_position-livec\\_patent\\_case\\_india.pdf](http://www.novartis.com/downloads/Novartis_position-livec_patent_case_india.pdf).

*Novartis AG v. Union of India* (Madras H.C. June 8, 2007).

Peter Ollier, *India's Patent Law Faces New Scrutiny*, MANAGING INTELLEC. PROP., Jan 28, 2008, available at <http://www.managingip.com/Article/1858239/Indias-patent-law-faces-new-scrutiny.html>

OFFICE OF THE U.S. TRADE REPRESENTATIVE, RESULTS OF BILATERAL NEGOTIATIONS ON RUSSIA'S ACCESSION TO THE WTO: ACTION ON CRITICAL IPR ISSUES (Nov. 19, 2006).

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, TRADE FACTS – INTELLECTUAL PROPERTY (May 2007).

Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177-1250 (2000).

Arie Reich, *The WTO As a Law-Harmonizing Institution*, 25 U. PA. J. INT'L & ECON. L. 321,362 (2004).

Jerome H. Reichman, *Undisclosed Clinical Data Trial Under the TRIPS Agreement and Its Progeny: A Broader Perspective* (2004), at [http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004-2/bell4\\_documentation.htm](http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004-2/bell4_documentation.htm).

Bhuma Shrivastava, *Roche-Cipla Row Test Case for Balancing Health Issues, Patents*, Live Mint, (Feb. 9, 2008), available at <http://www.livemint.com/2008/02/08230319/RocheCipla-row-test-case-for.html>.

SIXTIETH WORLD HEALTH ASSEMBLY, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (May 24, 2007), at [http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R30-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf).

Anne Ferreira et al, Letter from Five Members of the European Parliament to Novartis (Feb. 9, 2007), at <http://www.cptech.org/ip/health/c/india/meps02092007.html>, (last visited September 27, 2007).

Letter from Charles Rangel & Sander Levin to Susan Schwab (May 10, 2007).

Letter by Henry Waxman to Novartis (Feb. 13, 2007), at <http://www.keionline.org/misc-docs/liebermanplus4.pdf> (last visited Sept. 27, 2007).

Trans Atlantic Consumer Dialogue Website, at <http://www.tacd.org/about/about.htm> (last visited Feb. 16 2007).

Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22, Apr. 15 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments--Results of the Uruguay Round, [33 I.L.M. 1126 \(1994\)](#) (“DSU”).

UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT, (Cambridge University Press 2005).

Vienna Convention on the Law of Treaties, May 23, 1969, art. 31(1), 331, 8 I.L.M. 679 (“Vienna Convention”).

UNITED NATIONS, ECOSOC, SUBSTANTIVE ISSUES ARISING IN THE IMPLEMENTATION OF THE INTERNATIONAL COVENANT OF ECONOMIC, SOCIAL AND CULTURAL RIGHTS, HUMAN RIGHTS AND INTELLECTUAL PROPERTY, UC Doc E/C. (Dec. 14 2001).

United States Tariff Act of 1930, 19 U.S.C §1337 (2000).

United States Patent Act, 35 U.S.C. §271 (2000).

United States Judiciary Act, 28 U.S.C. § 1350 (2005).

U.S. Trade Representative, 2006 Special 301 Report, at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2006/2006\\_Special\\_301\\_Review/asset\\_upload\\_file473\\_9336.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2006/2006_Special_301_Review/asset_upload_file473_9336.pdf)

United States-Caribbean Basin Trade Partnership Act of 2000 (CBTPA), 19 U.S.C. § 2703 (2000).

United States-Central America Free Trade Agreement (CAFTA) (2004), *see* <http://www.ustr.gov/new/fta/Cafta/final/index.htm>.

United States – Korea Free Trade Agreement, U.S.-S.Korea, June 30, 2007, *available at* [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Republic\\_of\\_Korea\\_FTA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Section_Index.html)

- United States – Morocco Free Trade Agreement, 19 U.S.C. 3805 (2004).
- United States-Chile Free Trade Agreement Implementation Act, 19 U.S.C. 3805 (2004).
- United States-Oman Free Trade Act, 19 U.S.C. 3805 (2004).
- United States-Peru Free Trade Agreement, U.S.-Peru, Dec. 7, 2005, *available at*  
[http://www.ustr.gov/Trade\\_Agreements/Bilateral/Peru\\_TPA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Section_Index.html).
- United States-Panama Trade Promotion Agreement, U.S.-Pan. art. 15.9(7), *available at*  
[http://www.ustr.gov/Trade\\_Agreements/Bilateral/Panama\\_TPA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Panama_TPA/Section_Index.html)
- United States-Singapore Free Trade Agreement, May 6, 2003, US-Singapore, *available at*  
[http://www.ustr.gov/Trade\\_Agreements/Bilateral/Singapore\\_FTA/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Section_Index.html).
- JAYASHREE WATAL, *INTELLECTUAL RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* 244, 320-321 (Oxford University Press 2001).
- World Health Organization, 60<sup>th</sup> World Health Assembly, *Public Health, Innovation and Intellectual Property*, WHA60.30 (May 24, 2007), *available at*  
[http://www.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R30-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA60/A60_R30-en.pdf) .
- World Intellectual Property Organization, Substantive Patent Law Treaty, Standing Committee on the Law of Patents, Tenth Session, SCP/10/2 (draft, Sept. 30, 2003).
- World Intellectual Property Organization. Standing Committee on the Law of Patents, Tenth Session, SCP/10/10 (May 14, 2004).
- World Trade Organization. Chairman's Report to the Group of Negotiation on Goods, MTN.GNG/NG11/W/76 (July 23, 1990).
- World Trade Organization, *Review of Legislation in the Fields of Patents, Layout-designs (Topographies) of Integrated Circuits, Protection of Undisclosed Information and Control of Anti-competitive Practices in Contractual Licenses: United States*, IP/Q/USA/1 (May 1, 1998).
- World Trade Organization (17 March 2000), *Canada – Patent Protection of Pharmaceutical Products*, WT DS114/R (March 17, 2000).
- World Trade Organization (5 May 2000), *Canada—Term of Patent Protection*, WT/DS170/R (May 5, 2000).

World Trade Organization, *Canada—Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000).

World Trade Organization, *Declaration of the TRIPS Agreement and Public Health*, WT/MIN(01)/Dec/2 (Nov. 20, 2001) (“Doha Public Health Declaration”).

World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, *Ministerial Declaration: Proposal from a Group of Developing Countries*,. IP/C/W/312, WT/GC/W/450 (draft, Oct. 4 2001).

World Trade Organization, *Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement*, WT/DS171/3, WT/DS196/4, IP/D/18/Add. 1, IP/D/22/Add. 1 (June 20, 2002).

World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003).

Yale University, *Access to Knowledge (A2K) Conference 2006*, see <http://research.yale.edu/isp/eventsa2k.html>, last accessed 16 February 2007.