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A NEW WORLD ORDER FOR ADDRESSING PATENT RIGHTS AND PUBLIC HEALTH

CYNTHIA M. HO*

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INTRODUCTION

Can patent rights and public health coexist? This is a pressing global question in an era where the AIDS pandemic rages in countries that cannot afford to pay for the most effective—and patent-protected—AIDS treatment. Even in countries with higher levels of income, patent problems may nonetheless loom large in unanticipated situations that could turn deadly without access to patented drugs, such as the 2001 anthrax “crisis” or the potential avian flu epidemic.

Each of these examples is further complicated by the existence of international agreements that mandate certain levels of patent protection. Historically, nations could decline to provide patent protection for drug compositions to promote innovation and competition, resulting in low-cost and widespread access to drugs. However, such flexibility is now a non-existent luxury for most nations after the conclusion of the landmark international agreement, the Trade-Related Intellectual Property Agreement (“TRIPS”), which established the first-ever minimum levels of patent rights on a global scale.¹ Although there is language in TRIPS that suggests nations have some flexibility to balance public health against patent rights, that flexibility has been repeatedly challenged.² In addition, while United Nations declarations provide a competing framework to support a right to health, the relative lack of enforceability of such a right compared to the exceptionally strong enforcement of patent rights under TRIPS, pursuant to the highly effective Dispute Settlement Understanding (“DSU”) that governs TRIPS and all other agreements to the World Trade Organization (“WTO”),³ shifts the balance in favor of patent rights.⁴

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1143 (1994) [hereinafter TRIPS]. The new patent requirements are binding on all member states of the comprehensive World Trade Organization (“WTO”). Because of the breadth of the WTO membership, TRIPS effectively established near universal requirements of patent rights. See Understanding the WTO: The Organization: Members and Observers, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Feb. 15, 2007) (listing 150 member states).

2. See, e.g., TRIPS, *supra* note 1, arts. 7–8; see also *infra* Part I.

3. Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Legal Instruments—Results of the Uruguay Round, art. 23, app. 1, 33 I.L.M. 1125 (1994) [hereinafter DSU].

4. Agreements under the WTO that are enforceable via the DSU are universally considered the most effective means of enforcing international law. See, e.g., Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 276–77 (1997); Laurence Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 22 (2004).

Although there have been some significant developments within the context of TRIPS concerning public health, the issue of an appropriate balance remains a pressing problem. For example, despite a unanimous declaration concerning the importance of considering public health with respect to TRIPS, as well as a waiver of one TRIPS requirement to enable imports of lower cost drugs,⁵ developing countries and public health advocates have criticized such actions as inadequate, modest reforms.⁶ Moreover, wealthier countries that have resisted greater consideration of public health within TRIPS may, ironically, be unduly constrained in addressing their own domestic crises if they face unexpected national epidemics.⁷ In addition, existing and pending international agreements subsequent to TRIPS have introduced heightened levels of patent protection that further prevent nations from considering public health needs.⁸ The increasing proliferation of such agreements, commonly dubbed “TRIPS-plus” agreements for their heightened requirements, underscores the critical need to reevaluate the global balance of patent rights and public health.

Thus far, there has been a lack of balanced scholarship considering the potential effects of increasing patent rights on both developing and devel-

5. See World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 5(a), (c), WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Public Health Declaration]; General Council Decision of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003) [hereinafter 2003 General Council Decision].

6. See, e.g., Rachel Kiddell-Monroe, *Canada's Generic Drug Law Is All Talk, No Action*, GLOBE & MAIL, Aug. 14, 2006, at A13 (reporting that not only is the WTO waiver unworkable, but that even after Canada passed legislation to implement the waiver, no drugs have been exported despite a standing two-year request by Doctors Without Borders); Oxfam International, *Patents Versus Patients: Five Years After the Doha Declaration* 19–20 (Oxfam Briefing Paper No. 95, 2006) (declaring the Paragraph 6 solution one “wrapped in red tape”); see also Ellen ‘t Hoen, *A Guide to the Post-2005 World: TRIPS, R&D and Access to Medicines*, MSF, Feb. 25, 2005, <http://www.msf.org/msfinternational/content/advocacy/accesstoessentialmedicinescampaign/index.cfm> (follow “A guide to the post-2005 world: TRIPS, R&D and access to medicines” hyperlink) (last visited Apr. 24, 2007) (suggesting that the paragraph 6 solution is “needlessly complex” and that the TRIPS flexibilities require political will on a national level); Robert Weisman, *The WTO: Areas of Concern, and What We Are Doing*, ESSENTIALACTION.ORG, Aug. 21, 2006, <http://www.essentialaction.org/access/index.php?/archives/49-The-WTO-Areas-of-Concern,-and-What-We-Are-Doing.html> (last visited Apr. 24, 2007).

7. See, e.g., Letter from Henry A. Waxman, Sherrod Brown & Thomas H. Allen to Rob Portman, U.S. Trade Representative (Dec. 5, 2005), available at <http://oversight.house.gov/Documents/20051205181731-42316.pdf> [hereinafter Waxman Letter] (arguing that the United States should not foreclose the possibility of compulsory licensing in case of a public health emergency); CPTECH Statement to the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Committee on Appropriations—Possible Avian Bird Flu Pandemic Highlights Flaws in U.S. Trade Policy (Nov. 2, 2005), available at <http://www.cptech.org/ip/health/tamiflu/cptech11022005.doc> (suggesting that the United States trade position may hinder domestic health in the event of an avian flu crisis and requesting the United States Trade Representative (“USTR”) reconsider its position); see also *infra* note 71 (describing an altered interpretation of TRIPS requirements by the United States and Canada in the face of the 2001 anthrax “crisis” in North America).

8. See *infra* note Part II.

oped countries. TRIPS-plus agreements have typically been negotiated and endorsed by government trade representatives under the strong influence of the large pharmaceutical companies that are the primary beneficiaries of increased patent rights.⁹ In addition, although some have criticized TRIPS, as well as TRIPS-plus agreements, proposals to either eliminate TRIPS or to impose a moratorium on new agreements are likely too radical to be readily embraced¹⁰—at least while the United States continues to be under a strong mandate to secure ever-increasing levels of patent protection.¹¹ This is especially true for countries that are strongly attracted to the prospect of increased market access in wealthy countries, even if it is at the cost of future public health needs.

This Article aims to provide a timely and realistic assessment that will help promote positive development for all countries. It attempts to move beyond polarized past discussions to highlight not only current pitfalls, but also how to better address the growing disconnect between patent rights and public health. In particular, this Article hopes to underscore that reconsideration of TRIPS-plus requirements is critical at this juncture, since these requirements may unduly restrict the national flexibilities of even developed countries that are currently strong patent-right advocates. Although no single scholarly piece is likely to provide a comprehensive solution to balancing patent rights and public health, this Article hopes to better illuminate existing problems and issues for all countries with the aim of improving future discussions.

Part I of this Article begins with a discussion of TRIPS, not only because of its extensive reach, but also because it provides a useful point of comparison with subsequent agreements involving patent rights and public health. This part first introduces the inherent flexibilities in TRIPS, as well as the Doha Public Health Declaration, which reaffirms the importance of respecting these flexibilities for public health interests. Then, the specific

9. See generally SUSAN K. SELL, *PRIVATE POWER, PUBLIC LAW: THE GLOBALIZATION OF INTELLECTUAL PROPERTY RIGHTS* 39–53 (2003) (describing the successful efforts of major industries in software, entertainment, and pharmaceuticals in influencing the trade position of the United States).

10. See, e.g., *Undermining Access to Medicines: Comparison of Five US FTAs*, OXFAM BRIEFING NOTE (Oxfam Int'l, Boston, Mass.), June 2004; see also *infra* notes 137–51 and accompanying text (discussing proposed agreements to both establish minimum standards of access and forego dispute resolution under existing treaties, the Access to Knowledge Treaty, and the Medical Research Development Treaty Proposal).

11. The USTR has a strong mandate to continue to negotiate and implement trade agreements with ever-stronger terms for intellectual property laws. See, e.g., Trade Act of 2002 § 2102(b)(4)(a)(i)(II), 19 U.S.C. § 3802(b)(4)(A)(i)(II) (2006) (noting that a primary objective of the United States regarding trade-related intellectual property rights is to ensure that “provisions of any multilateral or bilateral trade agreement . . . entered into by the United States reflect a standard of protection similar to that found in United States law”).

patent requirements and exceptions are delineated, including opportunities for countries to maximize public health considerations.

Part II of this Article then turns to TRIPS-plus agreements and how they further compromise consideration of public health issues. Part II takes a topical approach to these agreements to highlight new trends, including new requirements of what must be patented, extended patent terms and limited exceptions to patent rights. In addition, this part discusses the growing use of a new form of protection over data submitted to national regulatory agencies.

Part III provides a perspective on methods to address and overcome the growing TRIPS-plus requirements. This part reviews current international and domestic efforts to preserve public health considerations, as well as technology-based options.

I. TRIPS

TRIPS is the cornerstone of global intellectual property laws because it sets forth minimum standards for all WTO member countries, composed of a majority of both developed and developing countries. While the term “minimum standards” may not seem intrusive, mandating patent standards was a major issue for nations that previously provided limited, or in some cases no, patent protection. Indeed, agreement to TRIPS is often described as a package deal whereby developing countries acceded to TRIPS requirements in exchange for other benefits of WTO membership, including increased access to foreign markets.¹² Although TRIPS requirements reflect the laws of developed countries, developing countries may have initially believed that there was sufficient flexibility within the framework of TRIPS to preserve their ability to foster public health interests. For example, the preamble to TRIPS explicitly recognizes that there are “underlying

12. See, e.g., Ruth L. Gana, *The Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development*, 18 LAW & POL'Y 315, 334 (1996) (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”); Donald P. Harris, *Carrying a Good Joke Too Far: TRIPS and Treaties of Adhesion*, 27 U. PA. J. INT'L ECON. L. 681, 724–38 (2006) (arguing that TRIPS is analogous to a contract of adhesion of which developing countries had little choice to accept); Helfer, *supra* note 4, at 2–3 (noting that TRIPS is defended as a package deal); Arie Reich, *The WTO As a Law-Harmonizing Institution*, 25 U. PA. J. INT'L ECON. L. 321, 362 (2004) (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); Gregory Shaffer, *Power and Global Governance: The Need for A Comparative Institutional Approach*, in POWER AND GLOBAL GOVERNANCE 8 (Michael Barnett & Bud Duvall eds., 2004). In addition, developing countries believed that by signing onto WTO and TRIPS, they could avoid unilateral actions by developed countries. See, e.g., CARLOS M. CORREA, *INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES* 11 (2000).

public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives.”¹³

Within the body of TRIPS, there are articles entitled “objectives” and “principles” that address societal policies beyond intellectual property rights. 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.”¹⁴ 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.¹⁵

The appropriate balance between patent rights and other social policies has been of continued importance since the conclusion of TRIPS. In the years immediately after TRIPS was signed, there was some debate concerning the interpretive value of provisions relating to social policies such as public health.¹⁶ The controversy has somewhat abated in light of the 2001 Doha Declaration on Public Health, unanimously agreed to by all WTO member countries present at the Doha Ministerial Conference. In particular, the Declaration states affirmatively that “[i]n applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”¹⁷ Although the Doha Public Health Declaration is not an official amendment to TRIPS, it does have interpretative value and supports the argument that the principles and objectives set out in Articles 7 and 8 of TRIPS, such as balancing patent rights with development goals, are relevant.¹⁸

13. TRIPS, *supra* note 1, pmb1.

14. *Id.* art. 7.

15. *Id.* art. 8(1).

16. See, e.g., J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 35 (1997) (suggesting that under “appropriate circumstances” Articles 7–8 of TRIPS could be used as independent ad hoc exceptions).

17. Doha Public Health Declaration, *supra* note 5, ¶ 5(a).

18. See James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 301–07 (2002); see also JEROME H. REICHMAN & CATHERINE HASENZAH, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA 16 (2003) (noting that although the legal status is “uncertain,” on a practical level, the Declaration could be an authority from which future panels could “draw guidance” when deciding cases).

The Doha Public Health Declaration is also important with respect to patents and public health for several other reasons. For example, the Declaration affirmatively states that

[w]e agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.¹⁹

On the other hand, this positive affirmation does not provide specific guidance on *how* the TRIPS provisions can be interpreted so as to promote public health, with the result that parties may be in the same position of arguing over the appropriate scope of flexibility under TRIPS.²⁰

Now that some of the overarching policy issues and controversies have been framed, the specific patent requirements of TRIPS will be delineated, including their impact on public health. First, what must be typically patentable under TRIPS will be explained, together with the scope of some limited exceptions. Then, the scope of patent rights will be defined, together with exceptions to such patent rights. With respect to the scope of patentability as well as patent rights, the exceptions are often critical to providing an avenue to preserve national sovereignty in determining the appropriate balance between the rights of creators and users of patented inventions. However, even with explicit exceptions, differing interpretations of the scope of the exceptions have led to disputes between member states, as will be discussed.

A. Patentability

TRIPS requires that patents be available for all "inventions" in all fields of technology if they comply with the other requirements of TRIPS. In addition, TRIPS specifies that patents must be available for products and processes.²¹ This requirement forces some countries to effectuate a major change in patent laws with an impact on public health. For example, prior to TRIPS, India provided patents, but provided only process patents on

19. Doha Public Health Declaration, *supra* note 5, ¶ 4.

20. Of course, controversies remain under the guidance and oversight of the Dispute Settlement Understanding that governs all agreements pursuant to the WTO. DSU, *supra* note 3, app. 1 (noting TRIPS as one of the agreements covered by the DSU). This procedure favors mutually agreed resolutions, but will nonetheless convene a judicial-type panel if member states fail to reach an agreement. The existence of this process is an important factor in promoting resolution, because failure to comply carries heavy penalties, including the potential for trade sanctions. *Id.* art. 3(7).

21. TRIPS, *supra* note 1, art. 27(1).

pharmaceuticals so as to promote low cost drugs and greater innovation. However, under TRIPS, so long as an invention meets the technical requirements of patentability, a patent must be granted for an inventive product, including a pharmaceutical compound, even if it would negatively impact the accessibility of drugs.²² On the other hand, since the term “invention” is not defined in TRIPS, countries have some flexibility to exclude undesired subject matter by more narrowly defining an invention.²³ For example, although Western countries tend to adopt a very broad definition of what constitutes an invention—considering it satisfied if a substance in nature is isolated or purified—TRIPS does not require member states to follow such standards.²⁴

The relevant technical requirements mandate that inventions be “new, involve an inventive step and are capable of industrial application,” or—stated differently—new, non-obvious, and useful.²⁵ Additionally, the patent application must adequately disclose the invention such that a person of similar technical skill could carry out the invention.²⁶ Importantly, the lack of an explicit definition of what constitutes “new” allows member states to self-define these terms, which for some countries means not changing their existing definitions.

Because of the lack of a definition for “new,” TRIPS does not produce *uniform* standards for what types of invention will be considered new. Rather, it allows countries to continue with standards that have differing impacts. For example, in many European countries, “new” requires that an invention not have been previously known anywhere in the world.²⁷ On the other hand, the United States considers an invention “new” even if it is known outside the United States—so long as the knowledge is not documented in writing.²⁸

22. See generally *id.* art. 27 (providing no exclusion for inventions that impact accessibility of drugs).

23. See *id.* (providing no definition for “invention”).

24. See, e.g., Carlos M. Correa, *Patent Rights*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT* 189, 198 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998) (noting disparate treatment as applied to biotechnology-related inventions).

25. TRIPS, *supra* note 1, art. 27(1); see also *id.* n.5 (noting that “[f]or the purposes of this Article, the terms ‘inventive step’ and ‘capable of industrial application’ may be deemed by a Member to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively”).

26. *Id.* art. 29. Both the technical requirements of the invention and the patent application are not further defined in TRIPS, but are understood to be identical to Western patent laws.

27. See Convention on the Grant of European Patents, art. 54(2), Oct. 5, 1973, 1065 U.N.T.S. 199 [hereinafter EPC], available at <http://www.european-patent-office.org/legal/epc/>.

28. Under the United States rules, an invention may be deemed new, and thus patentable, even if it is known in another country—so long as the knowledge is not documented in any fixed writing. See 35 U.S.C. § 102(a) (2000). However, there are proposals to amend the U.S. patent laws. See, e.g., Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 3(b)(1) (2005).

The differing standards on what inventions are considered “new” affects what might be patentable. In particular, with a narrower standard, such as the one in Europe, the scope of patentable subject matter is narrower, with the corollary result that more is publicly available and accessible because it is not subject to patent. In addition, as a preview to changes under TRIPS-plus agreements, the lack of a definition of “new” under TRIPS enables some countries to deny patents on new uses of previously known compounds. For example, if scientists discover that a patented compound initially used for heart disease is actually useful for minimizing wrinkles, then that new use need not be patented. If the new use is not patented, it becomes freely available because no single producer will have the right to exclude others from such use.

Available to member states are several possible exceptions to the general rule that patent protection be available for all inventions. There are a few categorical subject matters that are exempted, as well as one broad-based exemption, although all have implications for public health. First, members may, but need not, exclude methods of medical diagnosis and treatment for humans and animals.²⁹ Accordingly, countries may exclude methods of medical diagnosis and treatment, thereby lowering health care costs with respect to such technology. In addition, members may exclude plants and animals “other than micro-organisms” from patentability, although “plant varieties [must be protected] either by patents or by an effective *sui generis* system.”³⁰ This exclusion was controversial when the

29. TRIPS, *supra* note 1, art. 27(3)(a) (noting that members may exclude “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”). This exception is similar to the rule in both the EPC and Japan; however, since the exclusion is merely permissive, it also allows the United States to maintain its patent laws that have no such exclusion.

30. *Id.* art. 27(3)(b). This exception bears some facial similarity to the previous law in Europe and Japan that varieties need not be protected, but for the first time requires some alternative system of protection. Although TRIPS does not define what constitutes an “effective” *sui generis* system, many commentators have assumed that international agreements protecting plant varieties that existed at the time of TRIPS would be pertinent. *See, e.g.,* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 225 (2d ed. 2003) (suggesting that TRIPS negotiators assumed UPOV-type protection—and in particular, UPOV (1991)—would be considered adequate); Correa, *supra* note 24, at 197 (noting that the reference to *sui generis* may be interpreted to refer to the Union for the Protection of Plant Varieties (“UPOV”) convention, although also suggesting that the language provides an opportunity to develop other *sui generis* protection). Moreover, this ambiguity may be more of a theoretical issue since subsequent agreements have often specified the exact agreement that must be adopted. *See, e.g.,* DAVID VIVAS-EUGUI, REGIONAL AND BILATERAL AGREEMENTS AND A TRIPS-PLUS WORLD: THE FREE TRADE AREA OF THE AMERICAS (FTAA) 3–4, 18–19 (2003), available at <http://www.quno.org/geneva/pdf/economic/Issues/FTAs-TRIPS-plus-English.pdf>. Other agreements strongly suggest or even require patent protection. *E.g.,* Central America-Dominican Republic-United States Free Trade Agreement, art. 15.9(2), Aug. 5, 2004 [hereinafter CAFTA], available at http://www.ustr.gov/Trade-Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html (technically preserving a *sui generis* option, yet mandating “reasonable efforts” be made to provide patent protection); U.S.-Austl. Free Trade Agreement, art. 17.9(1)–(2), U.S.-Austl., May 18, 2004, T.I.A.S. No. 6422 [hereinafter Australia FTA], available at http://www.ustr.gov/Trade_Agree-

TRIPS negotiations were concluded because some members opposed providing any protection on life forms (whether through patents or another system). In addition, if some types of plants are provided patent protection, that protection may impede a state's ability to access those plants that provide nutritional and health benefits, because the plants' protected status will increase their market costs. Because of the heated dispute, the final agreement provided that it was to be reviewed four years after its conclusion, with parties contemplating possible changes of the provision at that time.³¹ However, this controversy has not abated; rather it has increased with respect to the new issue of whether patents should be granted for biologically based material that is derived from plant resources or the traditional knowledge of indigenous people.³²

The final exception to the general scope of patentability under TRIPS lies in Article 27(2). This article does not categorically exclude any particular subject matter. Rather, it permits members to exclude an invention if the member believes that the prevention of *commercial exploitation* of the invention within the member country "is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment."³³ However, an invention cannot be excluded "merely because the exploitation is prohibited by . . . law."³⁴ The inclusion of health would seem to suggest that this provision could be of utility in balancing patent rights against public health. However, to date countries do not seem to have attempted to utilize this provision to exclude subject matter from patentability for the purposes of promoting public health. In addition, the provision is presumed to apply only to specific inventions, rather than entire categories of inventions.³⁵ The inclusion of the phrase "*ordre public*" invokes fundamental principles of society. Notably, similar language in previous patent laws has generally failed to preclude patents on biotechnology on the grounds that the inven-

ments/Bilateral/Australia_FTA/Final_Text/Section_Index.html (requiring patent protection for plants); U.S.-Jordan Free Trade Agreement, art. 4(17)-(18), U.S.-Jordan, Oct. 24, 2000, 41 I.L.M. 63 (requiring patent protection for plants).

31. TRIPS, *supra* note 1, art. 27(3)(b); *see also* GERVAIS, *supra* note 30, at 227-34 (providing a historical perspective of the text and noting that discussions of this provision have been among the "most controversial" for the TRIPS council).

32. *See generally* Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433 (2006) (providing a history of the conflict, as well as current proposals).

33. TRIPS, *supra* note 1, art. 27(2).

34. *Id.*

35. GERVAIS, *supra* note 30, at 250 (suggesting that compulsory licenses must be granted "only on a case-by-case basis" since categorical licenses "would seem to violate this provision").

tion was not objectionable to the entire society so that it violated *ordre public*.³⁶

B. Patent Rights

1. Exclusive Rights—Article 28

TRIPS provides that a patent confers on its owner “exclusive rights” to prevent unauthorized persons from certain activities. In general, unauthorized individuals are precluded from making, using, selling, offering for sale, or importing the patented product or process.³⁷ These rights are consistent with existing patent law doctrine in Western countries that provide a right to exclude others, but not an affirmative right to use.³⁸ Although unstated in TRIPS, generally someone who desires to use his or her patented invention must determine whether there is either a preexisting patent that would bar use (without first obtaining a license), or whether there are additional laws with which the person must comply. For example, in most countries, a patented drug typically cannot be sold without governmental marketing approval.³⁹

The term of rights under TRIPS is a minimum of twenty years, calculated from the date of filing of the patent application. In other words, the patent term is twenty years minus the time the Patent and Trademark Office (“PTO”) takes to examine the application.⁴⁰ Although the examination

36. A similar exception under the European Patent Convention was held to require concrete evidence of serious prejudice to the environment beyond speculation of possible harm. *Greenpeace Ltd. v. Plant Genetic Systems N.V.*, T 0356/93-3.3.4, 1995 O.J. E.P.O. 545, ¶¶ 18–19. In addition, the exception may be further limited by the scope of the *claimed* invention—the formal language concerning the legal scope of what is patented—as offensive; an invention can not be excluded from patentability based on abstract conceptions of offensive uses, or even if offensive uses of the invention are described in the patent, but not claimed. *See In re Transgenic Plant/Novartis AG*, G 0001/98, 1999 O.J. E.P.O. 111, ¶ 3.3.3.

37. TRIPS, *supra* note 1, art. 28(1)(a). Moreover, for patented processes, the patent owner may also exclude others from importing the product obtained “directly” from the patented process. *Id.* art. 28(1)(b).

38. *E.g.*, 35 U.S.C. § 271(a) (2000); *id.* § 154(a)(1).

39. In the United States, the Food and Drug Administration (“FDA”) must approve all new drugs before they can be sold in interstate commerce. 21 U.S.C. § 355(a). Similarly, in the EU, the European Medicines Agency (“EMA”) must approve drugs before they are sold. *See About EMA—Structure*, <http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm> (last visited Apr. 21, 2007). In Canada, Health Canada must approve drugs. *See Health Canada, Drugs & Health Products*, http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html (last visited Apr. 21, 2007).

40. *See* TRIPS, *supra* note 1, art. 33; 35 U.S.C. § 154(a)(2). The patent term period is an issue of huge significance, as underscored by a separate WTO dispute involving the U.S. and Canada. *See Panel Report, Canada—Term of Patent Protection*, WT/DS170/R (May 5, 2000), *aff’d*, Appellate Body Report, *Canada—Term of Patent Protection*, WT/DS170/AB/R (Sept. 18, 2000). Although Canada’s rules did not consistently provide a TRIPS-consistent patent term, its positive impact on speeding up the introduction of generic drugs was not given much consideration by the WTO dispute panel. It instead

period varies for different types of inventions, the average time is slightly over two years, such that the average patent term is probably around seven-teen to eighteen years, although it may be considerably shorter if the examination time is lengthy.⁴¹ Moreover, the *effective* patent term may be shorter for patented pharmaceuticals that require a separate governmental approval process. This is often the case, not because of government inaction, but rather because the information required for regulatory approval may not yet exist at the time that a patent application is filed. When this occurs, there is a gap in the time periods between filing the application and regulatory approval.⁴² Although some countries provide “extensions” of patent terms to make up for delays with either the patent examination process or regulatory approval process, TRIPS imposes no such extension.⁴³ On the other hand, such extensions are mandated under some TRIPS-plus agreements, as discussed in the next section.

2. Exceptions to Patent Rights

Two explicit provisions of TRIPS articulate exceptions to the standard patent rights. In particular, TRIPS permits a “limited exception” to patent rights under Article 30, if certain, ambiguously stated requirements are met.⁴⁴ In addition, Article 31 of TRIPS also permits use without the authority of the patent holder in cases where Article 30 is not met *and* more than ten procedural conditions are satisfied.⁴⁵ Either of these provisions permits an exception to the usual scope of patent rights—with respect to either the exclusive rights over the patented invention or the patent term. However, because each provision has some complexities, they will be separately discussed.

applied a very rule-based analysis in finding that Canada’s rules must be changed, with the concomitant result of extending the patent term of some blockbuster drugs and delaying entry of related generics.

41. U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE AND ACCOUNTABILITY REPORT: FISCAL YEAR 2003, at 19 (2003) (noting average pendency to patent issuance or abandonment in 2003 as 26.7 months).

42. *See, e.g.*, CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY ch. 4 (1998) (noting that the average “effective” patent term is about eleven to twelve years); Center for Drug Evaluation and Research, Frequently Asked Questions on the Patent Term Restoration Program, http://www.fda.gov/cder/about/smallbiz/patent_term.htm (last visited Mar. 15, 2007) (providing an explanation of the effective patent term for pharmaceuticals is often shortened due to FDA requirements).

43. *Compare* 35 U.S.C. §§ 154(b), 155–156 (2000) (providing for extensions of patent terms based on the delay of the PTO or based on delays in regulatory review), *with* TRIPS, *supra* note 1, arts. 27–31 (providing no such patent right).

44. TRIPS, *supra* note 1, art. 30.

45. *Id.* art. 31.

a. *Article 30—A “Limited Exception” to Patent Rights*

Article 30 is a very short provision that on its face seems to provide a means to balance the needs of rights owners against the needs of users, especially because it specifically refers to the interests of parties beyond patent owners.⁴⁶ In particular, Article 30 provides, “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”⁴⁷

Although member states initially had varied interpretations of the scope of flexibility of this provision, such interpretations have been largely limited by a WTO panel decision interpreting the scope of Article 30. In *Canada—Patent Protection of Pharmaceutical Products*,⁴⁸ a WTO panel interpreted Article 30 as having three separate and distinct requirements, which were cumulative in nature based on the interpretative guidelines of the Dispute Settlement Understanding that governs all WTO agreements.⁴⁹ First, the panel interpreted the “limited exception” phrase to be a distinct requirement separate from the rest of Article 30. To pass muster, an exception first must be very narrowly tailored from the general patent rights under Article 28.⁵⁰ Second, the limited exception must not “unreasonably conflict with normal exploitation” of the patent. Third, the limited exception must not “unreasonably prejudice” the “legitimate interests of the patent owner,” taking into account the “legitimate interests of third parties.”

To best understand the WTO interpretation, a brief background of the factual context may be helpful. Two provisions in Canada’s patent law were challenged as violating the patent owner’s right to exclude all others

46. See, e.g., Correa, *supra* note 24, at 207–08 (noting that TRIPS Article 30 uses very general wording, especially in comparison to more specific proposals that were made and rejected during the negotiations process).

47. TRIPS, *supra* note 1, art. 30.

48. Panel Report, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000) [hereinafter Panel Report, *Canada Generics*].

49. 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.* ¶¶ 7.20–21. In dissecting each requirement, the panel noted that it was applying the customary international law for interpreting international treaties, as mandated under WTO rules. See *id.* ¶ 4.13 n.40; DSU, *supra* note 3, 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), May 23, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679.

50. In interpreting this exception, the panel relied on definitions from the *Oxford English Dictionary* to support its definition that there must be a very “narrow exception” that involves a “small diminution of the rights in question.” Panel Report, *Canada Generics*, *supra* note 48, ¶¶ 7.30–31 & n.393.

from making the patented invention during the (Article 28) patent term.⁵¹ One provision, commonly known as the “regulatory review exception,” enabled the manufacture of patented drugs during the patent term for the purpose of obtaining regulatory approval for sale *after* patent expiry to expedite the entry of generic drug marketers.⁵² Although only Canada’s laws were challenged,⁵³ many WTO member states with similar legal provisions based on the same policy of accelerating public access to lower-cost generic drugs closely watched the case.⁵⁴ The second provision, known as the “stockpiling exception,” enabled the same companies that qualified for regulatory approval to manufacture unlimited quantities of the patented drug during the last six months of the patent term; however, sales were not permissible until the day the patent expired.⁵⁵

Although Canada conceded that its laws were facially inconsistent with the Article 28 right to exclude requirements, Canada argued that the provisions were “limited exceptions” permissible under Article 30.⁵⁶ In both instances, Canada argued that its laws were limited incursions on patent rights that were justified in promoting public health. In particular, by permitting an exception for the manufacture of patented drugs for regulatory approval of generics, Canada could accelerate by several years the Canadian public’s access to cheaper drugs after the patent expired. In addition, Canada could prevent a *de facto* extension of the patent term that would otherwise occur if a generic manufacturer had to wait until patent expiry to obtain regulatory approval. As for the stockpiling provision, Canada asserted its necessity, explaining that without the provision, consumers would be forced to wait several months after the patent expired for manufacturers to start producing generic versions, resulting in an unfair, *de facto* extension of the patent term.⁵⁷

51. The EU cited three specific TRIPS provisions that were violated: the Article 28 right to exclude, the Article 33 patent term, and the nondiscrimination requirement of Article 27. *Id.* ¶ 3.1.

52. *Id.* ¶¶ 2.1, 7.2 (citing Canadian Patent Act § 55.2(1)).

53. Indeed, Canada argued that there was an understanding during the TRIPS negotiations that the regulatory review provision would be permissible under TRIPS, since negotiating members such as the United States had such provisions in their laws and intended to keep them. Similarly, Canada argued that similar laws adopted by member states after the conclusion of TRIPS provided further support pursuant to principles of treaty interpretation that permit consideration of subsequent practice of the parties. *Id.* ¶ 4.15.

54. Although WTO panel decisions technically have no *stare decisis* effect and are only binding on parties to the dispute, WTO members closely follow them and subsequent panels frequently rely upon prior panel decisions, even if not legally required to do so.

55. *Id.* ¶¶ 2.1, 7.8–10 (citing Canadian Patent Act § 55.2(2)).

56. *Id.* ¶ 7.12.

57. *Id.* ¶¶ 4.14, 7.12.

The panel found that the regulatory review exception was a “limited exception” under Article 30, but that the stockpiling exception was not.⁵⁸ In particular, it found that the regulatory review exception was a “limited exception” because it was restricted to conduct necessary for regulatory approval, with no commercial use made of resulting products.⁵⁹ On the other hand, the panel found that the stockpiling provision was *not* appropriately limited because of the lack of any limits on the quantity of production. This finding resulted in the panel never contemplating the Article’s other two requirements, particularly whether the stockpiling provision interfered with normal exploitation of the patent owner’s rights.⁶⁰

After finding that the regulatory review provision was appropriately limited, the panel then considered the other two elements of the exception before ultimately concluding that the regulatory review was a permissible exception under Article 30. The panel concluded that the regulatory review provision did not unreasonably conflict with “normal exploitation”⁶¹ based on its determination that normal exploitation did not include the *de facto* exclusivity that would occur without the provision as a result of the time needed to obtain regulatory approval to sell a patented drug.⁶² The panel also found that the regulatory review period did not unreasonably prejudice the “legitimate interests” of the patent owner.⁶³ The panel found that pharmaceutical patent owners had no “legitimate interest” in maintaining an effective patent term equivalent to that of patent owners who did not need regulatory approval to make use of their respective inventions.⁶⁴

58. *Id.* ¶ 8.1.

59. *Id.* ¶ 7.45.

60. *Id.* ¶¶ 7.34–.36. The fact that the provision was limited with respect to only occurring in the last six months of the patent term was not adequate. In addition, although the stockpiling provision as written was considered to be impermissible, the panel left open the possibility that a stockpiling provision *could* be permissible if there were some limits set on the amount of production. *Id.* ¶ 7.37.

61. The panel once again looked to the dictionary definition of “normal” to conclude that the normal practice for a patent owner would include the “more or less brief” period of market exclusivity that typically exists after the patent expired. *Id.* ¶¶ 7.53–.55.

62. *Id.* ¶¶ 7.56–.57.

63. As a matter of interpretation, the panel referred initially to the common definition of “legitimate” in evaluating the final prong of Article 30. *Id.* ¶ 7.68 (citing two definitions from the *Oxford Dictionary*). The panel rejected the EC’s attempt to equate legitimate interests with the full range of legal interests under Article 28 as emasculating the final provision of Article 30. *Id.* The panel noted that the exception was derived in part from the Berne Convention, which had slightly different interests at issue, and concluded that the only sensible definition of “legitimate” must encompass more than merely Article 28 interests. *Id.* ¶ 7.71.

64. 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” *Id.* ¶ 7.82 (emphasis added). Moreover, the panel noted that although some countries had regulatory review provisions at the time TRIPS was being negotiated, the fact that these exceptions “were apparently not clear enough, or compelling enough, to make their way explicitly into

In addition to the findings specific to the legality of Canadian laws, the WTO panel decision provided further insights into the balance between patent rights and public health. First, the finding that the regulatory provision was compatible with TRIPS suggests that patent rights under TRIPS are not absolute. Indeed, even though the stockpiling provision was deemed incompatible, the panel decision left open the possibility that a differently worded stockpiling provision could be permissible; for example, one that limited production of the patented product by quantity, rather than merely duration.⁶⁵ Although Canada elected to eliminate stockpiling altogether, the panel's reception to a more narrowly tailored provision should not be overlooked. The panel also hinted that the popular doctrine of experimental use—providing researchers with the ability to use patented inventions in the course of research—would be permissible under Article 30.⁶⁶

On the other hand, despite a lengthy panel decision, the full scope of flexibility allowed by Article 30 remained undefined. For example, the panel never reached the question of how the interests of third parties (such as consumers) should be balanced against the patent owners' interests—an issue of obvious interest to many. In addition, the panel did not directly address many of the arguments made by third parties concerning the utility of using the TRIPS preamble—as well as Articles 7 and 8—to interpret substantive provisions such as Article 30.

b. Article 31—“Other Use”

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. Many commentators refer to this provision as authorizing compulsory licensing, although the term “compulsory licensing” does not appear in the actual provision.⁶⁷ Generally, a state must attempt to negoti-

the recorded agenda of the TRIPS negotiations” suggested that they should not be considered part of the legitimate interests. Stated differently, the panel noted that adjudication should not be utilized to decide a “normative policy issue that is still obviously a matter of unresolved political debate.” *Id.* Accordingly, the panel concluded that it was not necessary to conclude what would constitute “unreasonable prejudice,” nor how third party interests should be balanced against the patent owner's legitimate interests, other than to opine that legitimate interests must include something broader than legal interests. *Id.* ¶ 7.71.

65. *See id.* ¶¶ 7.30–36.

66. *Id.* ¶ 7.69 (noting that the panel purports to assert no opinion on the permissibility of experimental use under Article 30, although it agrees with the “general meaning of the term legitimate interest” contained in legal analysis involved in considering whether scientific experiments would be legitimate interests).

67. *See, e.g.*, UNCTAD-ICTSD, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 460–62 (2005); Correa, *supra* note 24, at 208.

ate for a license directly from the patent holder before imposing a compulsory license.⁶⁸ However, this negotiation may be waived in cases of “national emergency,” or other circumstances of “extreme urgency” or “public non-commercial use.”⁶⁹ Although some initial controversy emerged concerning what constitutes a national emergency under this provision,⁷⁰ the 2001 Doha Declaration on Public Health clarified that individual countries have “the right to determine what constitutes a national emergency or other circumstances of extreme urgency.”⁷¹ Moreover, it specifically noted that it is “understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.”⁷²

The exception to patent owner negotiation was recently an issue when Thailand issued a five-year compulsory license for Merck’s patented drug Efavirenz, a common AIDS treatment for patients who develop immunity

68. TRIPS, *supra* note 1, 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”).

69. *Id.* 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.” *Id.*

70. For example, the use of compulsory licensing to address AIDS epidemics was initially challenged by the United States. However, roles became reversed when Canada and the United States suggested using compulsory licensing to address an anthrax threat that clearly was not an actual epidemic. Geoff Dyer & Adrian Michaels, *A Bitter Pill for Drug Makers*, FIN. TIMES (London), Oct. 23, 2001, at 27 (noting a double standard between U.S. action concerning Cipro versus action against South Africa and Brazil); *Patent Abuse*, FIN. TIMES (London), Oct. 22, 2001, at 20 (noting that “western governments are guilty of double standards” in comparison of the eleven confirmed cases of anthrax infection versus the 25 million people faced with dying of AIDS in Africa for lack of medical treatment). Indeed, the timing of the anthrax threat in the fall of 2001 likely aided the unanimous agreement on the Doha Declaration on Public Health since the U.S. and Canada were accused of hypocrisy in the wake of the Doha negotiations. *See, e.g.*, Paul Blustein, *Drug Patent Dispute Poses Trade Threat: Generics Fight Could Derail WTO Accord*, WASH. POST, Oct. 26, 2001, at E1 (noting the global implications of the Cipro patent fight, including WTO negotiations scheduled to take place at Doha); Sarah Boseley, *Drug Dealing*, GUARDIAN, Oct. 24, 2001, available at <http://education.guardian.co.uk/businessofresearch/comment/0,,579977,00.html> (comparing the three anthrax deaths to the thousands of daily deaths in Africa from AIDS in the context of U.S. hypocrisy in enforcing patents in developing countries such as South Africa).

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

72. *Id.* However, since this time, controversy concerning the scope of public health crises that would justify the waiver of voluntary negotiations has continued. In particular, the U.S. has contended that these are the *only* possible emergencies, while developing countries have argued for a broader interpretation. *See, e.g.*, MARY MORAN, *RENEGING ON DOHA* (2003), available at <http://www.cptech.org/ip/wto/p6/msf052003.pdf>; Brook K. Baker, *Doha Redux—U.S. Enters New Phase of Bad Faith Bargaining*, CPTECH.ORG, July 2, 2003, <http://www.cptech.org/ip/wto/p6/hgap07022003.html> (last visited Feb. 13, 2007); CPTech, Oxfam, & Third World Network, *Deadlock over Scope of Diseases Threatens to Kill Solution*, CPTECH.ORG, Nov. 27, 2002, <http://www.cptech.org/ip/wto/p6/ngos11272002.html> (last visited Feb. 13, 2007); Chakravarthi Raghavan, *TRIPS Consultations on Implementing Doha Recessed*, THIRD WORLD NETWORK, Nov. 29, 2002, <http://www.twinside.org.sg/title/5246a.htm> (last visited Feb. 13, 2007).

to off-patent therapeutics.⁷³ Thailand asserted that it was within its WTO rights to issue a compulsory license without prior negotiation to address its own public health crisis, but Merck asserted that it was entitled to an initial consultation period.⁷⁴ The situation became even more complex when Thailand announced two additional compulsory licenses over the AIDS drug Kaletra, as well as the heart drug Plavix.⁷⁵ The compulsory license regarding Plavix was particularly controversial to some who suggested that heart disease could not satisfy the national emergency requirement.⁷⁶ However, TRIPS permits waiver of prior negotiation with the patent owner not only where there is an emergency, but also for “public, noncommercial use.”⁷⁷ To address the criticism, Thailand issued a white paper to explain

73. Thai. Dep’t of Disease Control, Ministry of Pub. Health, Announcement on the Public Use of Patent for Pharmaceutical Products (Nov. 29, 2006) [hereinafter Thailand Announcement], available at <http://www.cptech.org/ip/health/c/thailand/thaic14efavirenz.html>.

74. See, e.g., Andrew Jack & Amy Kazmin, *Thailand Breaks Patent for AIDS Drug to Cut Costs*, FIN. TIMES (London), Nov. 30, 2006, at 9. The United States Trade Representative Office also pressured Thailand to withdraw the license. Tove Iren S. Gerhardsen, *Thailand Compulsory License on AIDS Drug Prompts Policy Debate*, IP-WATCH, Dec. 22, 2006, available at <http://www.ip-watch.org/weblog/index.php?p=499> (noting that a source indicated the USTR had pressured Thailand to withdraw the license, as well as more ambiguous quotes from USTR officials that they had not provided “specific advice,” but expected Thailand to “follow certain steps,” with the suggestion that the patent owner Merck should have first been contacted); Letter to Secretary of State Condeleeza Rice and Ambassador Susan Schwab (Dec. 21, 2006), available at <http://www.cptech.org/ip/health/c/thailand/riceschwabthailand21dec06.pdf> (requesting that the USTR not pressure Thailand into negotiations with patent holders before issuing compulsory licenses for manufacturing generic AIDS drugs). Several members of congress also lobbied the USTR to “respect” the Thai government’s actions and not to intervene. Letter from Tom Allen et al. to Susan Schwab (Jan. 10, 2007), available at <http://www.cptech.org/ip/health/c/thailand/congressional-schwabletter-thailand-10jan06.pdf>. The USTR denied involvement, but suggested that Thailand should “respond to any requests for direct discussions by concerned stakeholders, including, among others, the patent holder.” Letter from Susan Schwab to Thomas Allen (Jan. 17, 2007), available at <http://www.cptech.org/ip/health/c/thailand/letter.pdf>.

75. Thai. Dep’t of Disease Control, Ministry of Pub. Health, Decree Regarding Exploitation of Patent on Drugs & Medical Supplies by the Government on Combination Drug Between Lopinavir & Ritonavir (Jan. 29, 2007), available at http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf; Thai. Dep’t of Disease Control, Ministry of Pub. Health, Announcement Regarding Exploitation of Drugs and Medical Supplies for Clopidogrel (Jan. 25, 2007), available at http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf.

76. See, e.g., Tove Iren S. Gerhardsen, *Drug Company Reacts to Thai License; Government Ready to Talk*, IP-WATCH, Feb. 16, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=538&res=1280&print=0> (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*, WALL ST. J. (Asia), Mar. 7, 2007 (noting that “heart disease isn’t a ‘national emergency’”); Ronald A. Cass, *Thai Patent Turmoil*, WALL ST J., 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”); see also *Pharmaceuticals: A Gathering Storm*, ECONOMIST.COM, June 7, 2007, http://www.economist.com/business/displaystory.cfm?story_id=9302864 (last visited July 5, 2007) (noting that Joe Pender, of GlaxoSmithKline suggests that while compulsory licenses are permissible under TRIPS, they are meant to be used as a “last resort” in “limited circumstances, such as national health emergencies,” and only after consultation with the patent owner).

77. TRIPS, *supra* note 1, art. 31(b); see also Medicines sans Frontieres, MSF’s Response to *Wall Street Journal* Editorial on Compulsory Licenses in Thailand (Mar. 12, 2007), available at

its rationale behind the compulsory licenses.⁷⁸ Although Thailand continued to negotiate with the patent owner, controversy continued. Abbott withdrew requests to register seven new medicines in Thailand, including a heat-stable version of the AIDS drug Kaletra that would be well-suited to the Thai climate.⁷⁹ In addition, Thailand was placed on the United States Special 301 watch list.⁸⁰ The report noted the compulsory licenses as “indications of a weakening of respect for patents.”⁸¹ Thailand’s experience suggests that despite the clear language in TRIPS, prior negotiation with the patent owner is not required in all cases before a compulsory license is issued; this step may nonetheless be expected.

Even when there is no question about prior negotiation with a patent owner, countries may still encounter criticism for using compulsory licenses. For example, when Brazil invoked its first ever compulsory license for the AIDS drug Efavirenz, the patent owner, Merck, admitted that there were prior negotiations.⁸² Nonetheless, Merck issued a press release stating

http://www.doctorswithoutborders.org/publications/openletters/wsj_03-12-2007.cfm (noting that “[i]t is a common misunderstanding perpetuated by editorials like yours that [compulsory licenses] can only be used in the case of an emergency”); KEI, Notes from March 16, 2007, U.S. Capitol Briefing on Thailand’s Compulsory Licenses, available at http://www.keionline.org/index.php?option=com_content&task=view&id=37 (providing summaries of speaker statements that reflect both the view that Thailand’s license of Plavix was permissible non-commercial use, as well as the opposing view that the licenses were neither emergency nor non-commercial use).

78. Thai. Ministry of Pub. Health & Nat’l Security Office, Facts and Evidence on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand (2007), available at <http://www.cptech.org/ip/health/c/thailand/thai-cl-white-paper.pdf>; see also Martin Vaughan, *In Clash with Activists, Critics Charge Thailand Violation of Trade Rules*, IP-WATCH, Mar. 19, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=569&res=1280&print=0>

79. See, e.g., Bruce Jaspen, *AIDS Controversy Dominates Abbot Labs’ Annual Meeting*, CHI. TRIB., Apr. 27, 2007; Tove Iren S. Gerhardsen, *Thailand Presents Report on Compulsory Licensing Experience*, IP-WATCH, Mar. 12, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=563&res=1280&print=0>. After public criticism and controversy, Abbott did offer to directly sell Kaletra to Thailand at a discounted rate, but did not change its decision to withhold other drugs from Thailand. See, e.g., Nicholas Zamiska, *Abbott’s Thai Pact May Augur Pricing Shift*, WALL ST. J., Apr. 23, 2007; Jaspen, *supra* (noting Abbott’s continued decision to withhold drugs from Thailand despite protests at Abbott’s Annual Stockholders meeting); *AIDS Activists Call for Boycott of Abbott Products*, ABBOTT’S GREED, Apr. 25, 2007, www.abbottsgreed.com/index.php?title=AIDS_activists_call_for_boycott_of_Abbott_products (last visited July 5, 2007) (noting calls for boycotts of Abbott products).

80. OFFICE OF THE U.S. TRADE REPRESENTATIVES, 2007 SPECIAL 301 REPORT 27 (2007) [hereinafter 2007 SPECIAL 301 REPORT]. However, some members of Congress have suggested that Thailand’s priority status is unwarranted. See Letter from Henry A. Waxman et al. to Susan C. Schwab (June 20, 2007).

81. 2007 SPECIAL 301 REPORT, *supra* note 80, at 27.

82. Press Release, Merck & Co., Statement on Brazilian Government’s Decision to Issue Compulsory License for Stocrin (May 4, 2007), available at http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html [hereinafter Merck Statement on Brazil Licenses]. Public health advocates, on the other hand, noted that Brazil’s action demonstrates that issuing a compulsory license, rather than merely threatening to do so—as Brazil had in the past—achieves the lowest price. See, e.g., Tove Iren S. Gerhardsen, *Brazil Takes Steps to Import Cheaper AIDS Drug Under Trade Law*, IP-WATCH, May 7, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=614&res=1280&print=0>.

that Brazil's action is "not in the best interests of patients in Brazil and around the world."⁸³ The press release made no mention of whether Brazil's action was consistent with TRIPS; indeed, it did not mention TRIPS. Rather, Merck characterized the compulsory license as an "expropriation of intellectual property" that "sends a chilling signal to research-based companies . . . potentially hurting patients who may require new and innovative life-saving therapies."⁸⁴ In addition, the Special 301 Report issued by the USTR also criticized Brazil's discussion with patent holders.⁸⁵

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.⁸⁶ For example, conditions governing the grant of a license include that use shall be "considered on its individual merits,"⁸⁷ and that the scope and duration of the use must be "limited" to the authorized purpose.⁸⁸ Additional mandatory procedural safeguards also exist in the form of judicial or other independent review of the use authorization.⁸⁹ 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."⁹⁰ As with the review of the use authorization, remuneration decisions are subject to judicial or other independent review.⁹¹

Despite the long list of procedural requirements beyond initial consultations, compliance with these requirements has not generally been an issue. Although Thailand was strongly criticized for failing to negotiate with patent owners prior to issuance of the compulsory license, whether the licenses were granted for "limited" scope and duration relative to the purpose of the compulsory license, and whether the remuneration was "adequate" were not directly addressed. For example, is the license on efavirenz until December 2011 limited in duration if AIDS is less of an issue before

83. Merck Statement on Brazil License, *supra* note 82.

84. *Id.*

85. 2007 SPECIAL 301 REPORT, *supra* note 80, at 30 (noting that the "United States underscores the importance of Brazil engaging in open and transparent discussions with all relevant stakeholders . . . in the interest of reaching mutually satisfactory outcomes").

86. In addition, other grounds include non-commercial use, dependent patents, and anti-competitive practices. See TRIPS, *supra* note 1, art. 31(a)-(l).

87. *Id.* art. 31(a).

88. *Id.* art. 31(c). For example, in the Thailand license of Efavirenz, the license is arguably limited with respect to quantity since the license specifies that it is to be used on not more than 200,000 patients per year and only for certain individuals. See Thailand Announcement, *supra* note 73.

89. TRIPS, *supra* note 1, art. 31(i).

90. *Id.* art. 31(h). For example, Thailand considers a royalty rate of 0.5% of the total sale value to be compliant. See, e.g., *Thailand to Break HIV drug Patent*, NATION, Nov. 30, 2006, available at <http://www.nationmultimedia.com/search/page.news.php?clid=2&id=30020346>.

91. TRIPS, *supra* note 1, art. 31(j).

that time?⁹² Arguably the scope could be considered limited in that the license states that it shall not exceed 200,000 patients entitled to medical benefits—especially since national law provides for universal access to essential medicine, as well as the fact that TRIPS only requires the license to be limited relative to the *purpose* of the license.⁹³ Also, is a royalty of 0.5 percent of the total sale value adequate?⁹⁴ Discussion of the Thai licenses has focused more on whether Thailand should be entitled to use any compulsory licenses as a middle-income country, rather than on whether the specific requirements of TRIPs are satisfied. In responding to concerns of some members of Congress, Susan Schwab noted that “[w]e have not suggested that Thailand has failed to comply with particular national or international rules.”⁹⁵ Similarly, the Special 301 report that criticizes Thailand’s compulsory licenses does not refer to any specific TRIPs provisions that are violated.⁹⁶

Prior to the compulsory licenses of Thailand and Brazil, the most controversial requirement of Article 31 was that use be authorized “predominantly for the supply of the domestic market of the Member authorizing such use.”⁹⁷ The controversy over this provision has primarily centered on the inability of some developing countries, such as South Africa, to take advantage of compulsory licenses because of a lack of sufficient manufacturing capacities, while other countries with strong generic manufacturing industries, such as India, would be precluded from exporting inexpensive drugs. The problem was first universally recognized in 2001 when member states included a provision in the Doha Public Health Declaration explicitly recognizing the problem and instructing the Council of TRIPS to find an “expeditious solution” by the end of 2002.⁹⁸ The Council did ultimately provide a solution on the eve of a Ministerial Conference in Cancun in August 2003. The solution consisted of a waiver of the domestic use requirement together with additional procedural requirements.⁹⁹

The Council’s waiver was crafted as a temporary solution that would be replaced by an official amendment to TRIPS. Although the Council had

92. See Thailand Announcement, *supra* note 73.

93. *Id.*

94. *Id.* One commentator suggested that compulsory licenses generally provide “far less than a reasonable economic return.” Ronald A. Cass, *Drug Patent Piracy*, WALL ST. J., May 7, 2007.

95. Letter from Susan Schwab to Thomas Allen, *supra* note 74.

96. 2007 SPECIAL 301 REPORT, *supra* note 80, at 27 (suggesting that “the lack of transparency and due process exhibited in Thailand represents a serious concern,” without any mention of whether the process actually violates any specific TRIPS provision).

97. TRIPS, *supra* note 1, art. 31(f).

98. Doha Public Health Declaration, *supra* note 5, ¶ 6.

99. 2003 General Council Decision, *supra* note 5, ¶ 2.

hoped for adoption within six months, many member countries stymied adoption of the initial waiver because of its perceived onerous procedural requirements. In addition, a group of African countries submitted an alternative proposal to remove many of the waiver's procedural requirements—a move welcomed by civil society and many other developing countries as a constructive step forward.¹⁰⁰ On the other side, industrialized countries focused on limiting the set of diseases included for compulsory licensing.¹⁰¹ Ultimately, the original waiver was replaced with a proposed amendment to TRIPS on the eve of the 2005 WTO Ministerial Conference without any of the proposed changes.¹⁰² The waiver remains in effect until

100. Communication from Nigeria on Behalf of the African Group, *Implementation of Paragraph 11 of the 30 August 2003 Decision*, ¶ 3, IP/C/W/437 (Nov. 30, 2004); see also 2nd Ordinary Session of the Conference of African Ministers of Health, Gaborone, Botswana, Oct. 10–14, 2005, *Gaborone Declaration: On a Roadmap Towards Universal Access to Prevention, Treatment and Care*, CAMH/Decl.1(II), ¶ 4 (calling upon ministers of trade to seek a “more appropriate” permanent solution that “removes all constraints, including procedural requirements” for the export and import of generic medicines under TRIPS). In addition, in proposals that preceded the 2003 Council Decision, there were simpler solutions proposed that focused on interpretations of Article 30. E.g., Proposal from a Group of Developing Countries, *Draft Ministerial Declaration on the TRIPS Agreement and Public Health*, ¶ 9, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) (suggesting that under Article 30, members may “authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members”); see also Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859, 868–70 (2002) (discussing the relative political ease with which an Article 30 amendment can be made); Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPS Agreement*, 21 B.U. INT’L L.J. 101, 112–22 (2003) (discussing the strengths and weaknesses of four alternative solutions involving Articles 30 and 31). However, this proposal was rejected by scholars and countries. See, e.g., Second Communication from the United States, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 31, IP/C/W/358 (July 9, 2002) (suggesting that interpreting Article 30 to allow members to permit compulsory licenses to export patented products would unreasonably prejudice the legitimate interests of the patent owner); Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries* 29 (Comm’n on Intell. Prop. Rights, Study Paper No. 2a, 2002) (suggesting that the Article 30 export solution might unreasonably prejudice the interests of the patent holder and thus fail to satisfy Article 30); Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT’L L. 47, 52 (2002) (denying that developing countries had even suggested that they could rely on Article 30). In addition, other options that were proposed initially included a moratorium on disputes, as well as an amendment to Article 31. For an overview of these options, see Jacques H.J. Bourgeois & Thaddeus J. Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution*, 5 J. WORLD INTELL. PROP. 835, 846–52 (2002).

101. See, e.g., MORAN, *supra* note 72, at 3.

102. Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Proposal for a Decision on an Amendment to the TRIPS Agreement*, IP/C/41 (Dec. 6, 2005) [hereinafter *Proposed Paragraph 6 Amendment*]. Part of the problem was that a debate over whether a statement read by the General Council Chairman at the time the waiver was adopted—concerning eleven advanced developing countries that intended to use the waiver only in cases of national emergency—should be part of a formal amendment. See, e.g., Zoellick Vows to Work for TRIPS Deal, Lays Out U.S. Conditions, INSIDE U.S. TRADE, Aug. 1, 2003, at 7, 7; *WTO Members Re-Open Fight over Substance of TRIPS-Health Agreement*, INSIDE U.S. TRADE, Mar. 12, 2004, at 1, 18–19; see also WTO General Council, *Minutes of Meeting: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 29, WT/GC/M/82 (Nov. 13, 2003) (providing text of the original statement by General Coun-

two-thirds of the membership ratifies the amendment (as is the case with any TRIPS amendment), with the anticipated ratification date recently extended until 2009.¹⁰³

The larger issue is that only a single country, Rawanda, has attempted to use the waiver in the four years since it has been in effect.¹⁰⁴ Some have suggested that the waiver has not been used because countries were uncertain regarding its permanence.¹⁰⁵ The underutilized waiver could theoretically be a function of when the full impact of TRIPS requirements became effective; some countries with strong generic production, such as India, did not have patents on pharmaceuticals until 2005, such that compulsory licensing was not even a possibility.¹⁰⁶ Moreover, even for WTO members who have had full patent protection in place, enactment of domestic laws to permit compulsory licenses for exportation has been slow. Only a handful of countries have even modified their laws to enable compulsory licensing

cil Chairman). In addition, some countries were opposed to incorporating the 2003 waiver into an amendment without further consideration of better alternatives in light of the fact that no country had used the 2003 waiver. *See, e.g.*, Joint statement by NGOs on TRIPS and Public Health: WTO Members Should Reject Bad Deal on Medicines (Dec. 3, 2005), available at <http://www.cptech.org/ip/wto/p6/ngos12032005.html> (recommending that WTO members reject the proposal to adopt the 2003 amendment for its lack of workability, as well as failure to consider proposed alternatives); Ruth Mayne, *The Recent Agreement on WTO Patent Rules and Access to Medicines: A Flawed Deal?*, COURIER, Nov.–Dec. 2003, at 30. To supposedly resolve the debate, the General Council Chair re-read the same statement that was read in 2003. *See, e.g.*, Tove Iren S. Gerhardsen, *WTO Strikes Agreement on TRIPS and Public Health on Eve of Ministerial*, IP-WATCH, Dec. 6, 2005, available at <http://www.ip-watch.org/weblog/index.php?p=168&print=1&res=1024&print=1>; *see also* WTO General Council, *Minutes of Meeting: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, ¶¶ 28–29, WT/GC/M/100 (Mar. 27, 2006).

103. Press Release, World Trade Org., Members OK Amendment to Make Health Flexibility Permanent, Press/426 (Dec. 6, 2005); *see also* Marrakesh Agreement Establishing the World Trade Organization, art. X(3), Apr. 15, 1994, 33 I.L.M. 1144 (1994) (providing for two-thirds voting requirement); William New, *TRIPS Council Extends Health Amendment; Targets Poor Nations' Needs*, IP-WATCH, Oct. 23, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=798> (noting extension of ratification deadline from the end of 2007 to the end of 2009 after only 11 countries had adopted it); *see Ratification of TRIPS Health Amendment Languishes, With Five Months to Go*, BRIDGES WKLY. TRADE NEWS DIG., June 27, 2007, available at <http://www.ictsd.org/weekly/07-06-27/story4.htm> (noting that only seven member states have ratified the amendment with less than six months before the targeted goal).

104. World Trade Org., TRIPS and Public Health: Notifications by Importing WTO Members, http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited Oct. 17, 2007); Laura MacInnis, *Rawanda Launches Key Test of WTO Drug Patent Waiver*, REUTERS, July 20, 2007, <http://www.reuters.com/article/healthNews/idUSL2088068720070720> (last visited Nov. 12, 2007); Tove Iren S. Gerhardsen, *Rwanda Pioneers Use of WTO Patent Flexibility for HIV/AIDS Drug*, IP-WATCH, July 20, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=696&res=1280&print=0>.

105. *See, e.g.*, Cecilia Oh, *Will the TRIPS Amendment on Compulsory Licensing Work?*, BRIDGES, Jan.–Feb. 2006, at 22, 23.

106. *Id.* at 23; *see also* The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, ¶ 15 (India), available at http://www.ipindia.nic.in/ipr/patent/patent_2005.pdf.

of drugs for export since the 2003 waiver.¹⁰⁷ In addition, much diversity lies amongst the domestic enactment of laws, resulting in complexity beyond that already complained of in the WTO decision. For example, in Canada, drugs for export must be included on a list of acceptable products. The WTO requirement that both the importing and exporting countries be involved creates barriers for organizations such as Doctors Without Borders, which would ordinarily prefer to purchase drugs directly from a supplier.¹⁰⁸

Even if countries amend their laws to permit compulsory licenses for export, there remain some serious hurdles to overcome. For a country to import patented drugs, they must first be an “eligible importing member,” which is defined as any least-developed country member, or a member that has notified the TRIPS Council of its intention to use the system as an importer.¹⁰⁹ Before importation occurs, the eligible importing member must

107. See, e.g., Use of Patented Products for International Humanitarian Purposes Regulations (Patent Act) SOR/2005-143 (Can.) (amending Patent Act and implementing August 30, 2003, decision of WTO General Counsel); Council Regulation 816/2006, Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, 2006 O.J. (L157/1) 1; The Patents (Amendment) Act ¶ 55 (India) (adding new section 92A); Consultation—Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in Norwegian Law, Mar. 2, 2004, available at http://www.regjeringen.no/en/dep/ud/Documents/lover_regler/reglement/2004/Consultation--Implementation-of-paragraph-6-of-the-Doha-Declaration-on-the-TRIPS-Agreement-and-Public-Health.html?id=420597 (describing the addition of a paragraph to the Patent Regulations of December 20, 1996 to state that “[a] compulsory licence shall be issued mainly with a view to supplying the domestic market. The King may by regulations prescribe rules that deviate from this.”); Swiss Federal Inst. of Intellectual Prop., Conformation of Swiss Law to the WTO Decision of 30 August 2003 Concerning the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Nov. 23, 2005), available at <http://www.ige.ch/E/jur-info/documents/j10019e.pdf>; Jung-Ae Suh & In H. Kim, *Korea Revises Its Compulsory License Rules*, MANAGING INTELL. PROP., Nov. 2005, at 100; Ellen ‘t Hoen and Suerie Moon, *China: State Intellectual Property Office Order #37*, <http://cptech.org/ip/wto/p6/china-order37.html> (last visited Feb. 15, 2007) (unofficial translation of Chinese Patent Act with commentary); see also Tove Iren S. Gerhardsen, *TRIPS Public Health Amendment Questioned; China Implements Decision*, IP-WATCH, Dec. 14, 2005, available at <http://www.ip-watch.org/weblog/index.php?p=178> (noting that China has implemented the WTO waiver and now joins the EU, India, Norway, Korea, and the Netherlands as countries that have implemented—or are on the verge of implementing—the waiver). In addition, the United States has proposed, but not yet enacted any legislation. See Life-Saving Medicines Export Act of 2006, S.3175, 109th Cong. § 2(a) (2006).

108. Kiddell-Monroe, *supra* note 6.

109. *Proposed Paragraph 6 Amendment*, *supra* note 102, at 5, ¶ 1(b) (defining an eligible importing member). Certain countries have stated that they will not use the system under any circumstances as importing members; the noted members include Australia, Canada, EU and its member states, Japan, New Zealand, Norway, Switzerland, and the United States. *Id.* at 5, ¶ 1(b) n.5. Other countries have indicated that they would utilize the system only in extremely urgent or emergency situations, in particular China, Israel, Korea, Kuwait, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. However, despite these stated agreements within the context of the WTO, some U.S. senators have suggested that the U.S. position to never utilize compulsory licensing is an “untenable position, especially in light of the current threat of an avian flu pandemic,” and argued that the United States should not foreclose the possibility of compulsory licensing in case of a public health emergency. Waxman Letter, *supra* note 7, at 3–4.

confirm that it lacks sufficient manufacturing capacity and intends to follow the guidelines.¹¹⁰ It must also specifically notify the TRIPS Council of the name of the desired product, as well as the expected quantity, with the information to be publicly available on a dedicated WTO webpage.¹¹¹ The importing member must then hope that several other conditions beyond its control exist. First, some other country must have amended its laws to enable compulsory licensing of patented drugs for export, and a manufacturer in that country must be willing to manufacture drugs for export. Assuming such a manufacturer exists, the exporting country must issue a narrowly tailored compulsory license that provides “only the amount necessary” to meet the requested needs, and the exported products must be “clearly identified” through “specific labelling or marking.”¹¹² Before these distinctly packaged items may be exported, the manufacturer must post on a website the exact quantities shipped, as well as any distinguishing features. Finally, the exporting member country must specifically notify the TRIPS Council of the licensed manufacturer and certain other details.¹¹³

C. Patent “Plus” Protection: Test Data

Beyond the specific patent provisions of TRIPS, Article 39 provides protection from “unfair competition” with respect to “information” that is provided to governmental agencies, but otherwise “undisclosed” to third parties. In particular, Article 39 provides,

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.¹¹⁴

However, what is deemed “unfair competition” or “unfair commercial use” has been subject to dispute since it is not explicitly defined. Multinational pharmaceutical companies and the countries where such companies dominate (such as the U.S. and EU) consider this term to preclude regula-

110. *Proposed Paragraph 6 Amendment*, *supra* note 102, at 5, ¶ 2(a)(ii); *see also id.* at 6, ¶¶ 3–4 (noting that eligible importing members shall take “reasonable measures” to prevent re-exportation of products and provide “effective legal means” to prevent any importation not explicitly authorized under the annex).

111. *Id.* at 5, ¶ 2(a)(i).

112. *Id.* at 6, ¶ 2(b).

113. *Id.* at 6, ¶ 2(b)–(c).

114. TRIPS, *supra* note 1, art. 39(3).

tory bodies from using any of the data submitted by an originator company for a “reasonable” period of time; this interpretation results in delays in the application and approval procedures for a generic version.¹¹⁵ Others have argued that the provision does not provide exclusive rights—and, indeed, that such an approach was suggested and rejected in the TRIPS negotiations—such that it should not bar regulatory agencies from relying on data originally submitted by an originator company in deciding to approve a generic version.¹¹⁶

A DSU panel has never clarified the precise parameters of this provision despite initial disputes alleging that it was violated.¹¹⁷ This requirement marks the first time an international standard was created to provide protection for information that is not independently protected by patents or any other type of intellectual property.¹¹⁸ For countries that are bound only to TRIPS and not subject to Free Trade Agreements (“FTAs”) that dictate higher norms, the scope of Article 39 could remain important.¹¹⁹ However, for the many countries that are obligated by norms in FTAs, this article’s importance is primarily as a new norm in the international scheme. In particular, it provides a floor from which member countries have since argued for higher and more specific requirements for protection of such regulatory information. This is further described in the following section on TRIPS-plus agreements.¹²⁰

115. See, e.g., Carlos Maria Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT’L L. 69, 77–78 (2002).

116. *Id.* at 78.

117. 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 Org., *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). However, for an interesting review of the background leading to the TRIPS provision, including limitations to its interpretation, see generally Jerome H. Reichman, *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective* (presented at UNCTAD-ICTSD, Dialogue on Moving the Pro-Development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Nov. 29–Dec. 3, 2004), available at http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004-2/bell4_documentation.htm.

118. E.g., GERVAIS, *supra* note 30, at 274 (noting that TRIPS is the first multilateral agreement to address the issue).

119. Indeed, India is currently facing this issue. For a thorough and thoughtful discussion of various interpretations of Article 39(3), see TAHIR AMIN ET AL., *THE IMPACT OF ARTICLE 39.3 IN INDIA: A PRACTICAL PERSPECTIVE* (2006), available at http://imak.org.googlepages.com/l-MAK_Article39.pdf.

120. In addition, the existence of TRIPS-plus agreements that dictate higher standards has promoted arguments for interpreting this provision to create a liability-based regime where generic applications could be submitted and some compensation is provided to the patent owner. See *id.* at 11–17.

II. TRIPS-PLUS

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 FTAs negotiated between a major industrialized country (such as the U.S. or Canada) and a developing country.¹²¹ In addition, industrialized countries are not immune—Australia has also signed a FTA that may impede its historic ability to provide relatively low cost drugs to its citizens.¹²² As with the WTO Agreement (of which TRIPS is a part), these subsequent agreements involve countries agreeing to higher intellectual property standards as part of a bargain for increased market access. Although negotiations over TRIPS-plus agreements continue, counter-trends aiming to highlight the health implications of such agreements have evolved. Before the counter-trends are discussed further, however, this section provides an overview of the types of TRIPS-plus requirements that are presently being imposed. In particular, this part highlights some typical requirements of FTAs regarding patentability, patent rights, and data protection.¹²³

121. 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. *See, 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 a draft treaty on standards of patentability, the Substantive Patent Law Treaty (“SPLT”). Standing Committee on the Law of Patents, *Draft Substantive Patent Law Treaty*, WIPO Doc. SCP/9/2 (Mar. 3, 2003) [hereinafter SPLT Treaty]; *see also* *WIPO Moves Toward “World” Patent System*, GRAIN, July 2002, at 3, available at http://www.grain.org/briefings_files/wipo-patent-2002-en.pdf (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, so it is not a focus of this section, although it is discussed in the next section on countering TRIPS-plus trends, since a primary reason for the current stalemate in negotiations relates to opposition to its TRIPS-plus standards. *See, e.g.*, Standing Committee on the Law of Patents, *Summary by the Chair*, ¶ 7, WIPO Doc. SCP/10/10 (May 14, 2004). According to the summary of the Chair of the Committee, a number of delegations expressed support for the proposal, but others opposed the proposal, “emphasizing the need to consider . . . the interrelationship of those provisions . . . such as the disclosure of the origin of genetic resources and traditional knowledge, public health, patentability criteria and the general exceptions.” *Id.*

122. *See* Australia FTA, *supra* note 30, art. 17.

123. *See, e.g.*, Free Trade Agreement, art. 17.9, U.S.-Chile, June 6, 2003 [hereinafter Chile FTA], available at http://www.ustr.gov/Trade_Agreements/Bilateral/Chile_FTA/Final_Text/Section_Index.html; Free Trade Agreement, art. 15.9, U.S.-Morocco, June 15, 2004 [hereinafter Morocco FTA], available at http://www.ustr.gov/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/Section_Index.html. 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, Eur. Cmty.-Morocco, art. 39, Feb. 26, 1996, 2000 O.J. (L 70) 2, 11; Agreement on Trade, Development and Cooperation, Eur. Cmty.-S. Afr., art. 46, Oct. 11, 1999, 1991 O.J. (L 311) 3, 17.

A. Patentability

Whereas TRIPS allowed countries flexibility in defining the terms of patentability to meet their individual needs, subsequent FTAs infringe on that flexibility. For example, TRIPS explicitly notes that member states may choose to exclude medical procedures and treatments from patentability, but TRIPS-plus agreements may eliminate this option.¹²⁴ Patents on medical treatments can substantially increase the cost of health care and its accessibility. In the United States, where there is no such exclusion from patentability, health care costs are a major issue, with some physicians (and patients) complaining about the negative impacts patents have on medical treatment.¹²⁵

Also, whereas TRIPS allows countries to define what constitutes “new” and “patentable,” some TRIPS-plus agreements explicitly limit national discretion to define these terms. For example, some agreements specify that a new use of a previously known compound is *per se* patentable subject matter.¹²⁶ The United States permits patents on new uses of such compounds, without regard for their impact on public health.¹²⁷ 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.¹²⁸ While this is consistent with United States law, it is a more permis-

124. For example, the draft SPLT similarly contains no such exceptions. See SPLT Treaty, *supra* note 121, art. 2; see also IPR Text Proposed by U.S. to Thailand, Patents, sec. 2(b) (2006), [hereinafter Draft Thailand FTA], available at http://bilaterals.org/article-print.php3?id_article=3677 (explicitly requiring patents be granted on medical treatments and procedures).

125. See, e.g., Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601 (2000). Indeed, even some Justices of the Supreme Court were sufficiently disturbed by the impact of patent rights on public health that they *sua sponte* suggested that the scope of patentable subject matter be reconsidered in a case where no party had ever raised this issue. *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, No. 04–607, slip op. at 14–15 (U.S. June 22, 2006) (Breyer, J., dissenting from dismissal of certiorari petition).

126. See, e.g., Free Trade Agreement, U.S.–Oman, art. 15.8(1)(b), Jan. 19, 2006 [hereinafter Oman FTA], available at http://www.ustr.gov/Trade-Agreements/Bilateral/Oman_FTA/Final_Text/Section_Index.html (stating that the agreement “confirms that . . . patents [are] available for . . . known product[s] . . . for the treatment of particular medical conditions”); U.S.–Korea Free Trade Agreement, art. 18.8(1), U.S.–Korea, June 30, 2007 [hereinafter Korea FTA], available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Republic_of_Korea_FTA/Draft_Text/asset_upload_file273_12717.pdf (stating that “each Party confirms that patents shall be available for any new uses or methods of using a known product”).

127. See 35 U.S.C. §§ 101–103 (2000).

128. See, e.g., U.S.–Pan. Trade Promotion Agreement, art. 15.9(7), U.S.–Pan., June 28, 2007 [hereinafter Panama TPA], available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Panama_FTA/Draft_Text/asset_upload_file131_10350.pdf (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 an inventive step); Korea FTA, *supra* note 126, 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).

sive standard, resulting in more patents—which could negatively impact public health—than what TRIPs requires.¹²⁹

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.¹³⁰ Not only might this result in more patent issuances, but if issued patents have a presumption of validity, and patents will also be more difficult to challenge.

B. Patent Rights

There are several aspects of patent rights that are generally extended through TRIPS-plus agreements. For one, many (if not most) agreements extend the patent term, slowing the availability of lower cost generic drugs. Other agreements limit compulsory licensing during the patent term, taking away a traditional tool nations utilize to address public health concerns during the patent term. These agreements may compromise the availability of generic drugs during a health crisis, which could lead to a major problem if present fears of global pandemics, such as avian flu, become realized. Still other agreements limit parallel imports—the ability of a country to import a patented drug that was previously the subject of an authorized sale in another country—as a way to purchase patented drugs at the lowest possible cost.

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.¹³¹ 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

129. See 35 U.S.C. § 102(b) (providing a grace period for disclosures that exist one year prior to the patent application).

130. See, e.g., Korea FTA, *supra* note 126, art. 18.8(4) (noting that if opposition proceedings are provided to third parties, “the Party shall not make such proceedings available before the grant of the patent”).

131. 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, A REVIEW OF EXISTING DATA EXCLUSIVITY LEGISLATION IN SELECTED COUNTRIES, at intro. (4th rev. ed. 2005).

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.¹³²

The patent term in many TRIPS-plus agreements goes beyond the TRIPS requirement of twenty years from the date of application (minus the period of examination). In particular, many agreements allow for extension of the patent term if there are “unreasonable delays” in the patent examination.¹³³ “Unreasonable delays” may be as few as four years from the date of filing or two years from the request for examination.¹³⁴ 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.¹³⁵ The required patent term extensions under TRIPS-plus agreements 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.¹³⁶ 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.¹³⁷ However, for countries that are

132. 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.

133. See, e.g., Oman FTA, *supra* note 126, art. 15.8(6)(a); Trade Promotion Agreement, U.S.-Peru, art. 16.9(6)(a), Apr. 12, 2006 [hereinafter Peru TPA], available at http://www.ustr.gov/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/Section_Index.html; Australia FTA, *supra* note 30, art. 17.9(8)(a); Korea FTA, *supra* note 126, 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).

134. See, e.g., Peru TPA, *supra* note 133, 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, *supra* note 30, art. 17.9(8)(a); Oman FTA, *supra* note 126, art. 15.8(6)(a).

135. See, e.g., Free Trade Agreement, U.S.-Sing., art. 16.8(4)(a), May 6, 2003 [hereinafter Singapore FTA], available at http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html; Chile FTA, *supra* note 123, art. 17.10(2)(a); CAFTA, *supra* note 30, art. 15.9(6)(b); Korea FTA, *supra* note 126, 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., Singapore FTA, *supra*, art. 16.7(8).

136. See *supra* note 48 and accompanying text.

137. 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

members to TRIPS-plus agreements, this panel finding is *de facto* inapplicable.

Recent FTAs also provide *de facto* patent term extensions in other ways. For example, some FTAs entitle the patent owner to a commercial monopoly if the patent term expires before the period of data protection.¹³⁸ 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.¹³⁹

1. Limited Compulsory Licensing During Patent Term

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.¹⁴⁰ The Singapore agreement, for example, limits compulsory licensing to remedying anti-competitive behavior, public non-commercial use, and national emergencies.¹⁴¹ In addition, the compensation due patent owners is “reasonable and entire” compensation, rather than “adequate compensation” under TRIPS.¹⁴² Moreover, some FTAs entirely omit any provision that is analogous to the compulsory licensing provision of TRIPS Article 31; rather, the

compelling nor so widely recognized that it could be regarded as a ‘legitimate interest’ within the meaning of Article 30.” Panel Report, *Canada Generics*, *supra* note 48, ¶ 7.82 (emphasis added). Moreover, the panel noted that although some countries had regulatory review provisions at the time TRIPS was being negotiated, the fact that these exceptions “were apparently not clear enough, or compelling enough, to make their way explicitly into the recorded agenda of the TRIPS negotiations” suggested that they should not be considered part of the legitimate interests. *Id.* Stated differently, the panel noted that adjudication should not be utilized to decide “a normative policy issue that is still obviously a matter of unresolved political debate.” *Id.*

138. *See, e.g.*, Korea FTA, *supra* note 126, art. 18.9(4); U.S.-Colom. Trade Promotion Agreement, art. 16.10(2), U.S.-Colom., Nov. 22, 2006 [hereinafter Colombia TPA], available at http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Colombia_FTA/Final_Text/asset_upload_file776_10142.pdf.

139. *See, e.g.*, Peru TPA, *supra* note 133, art. 16.10.2; Columbia TPA, *supra* note 138, art. 16.10.2; Panama TPA, *supra* note 128, art. 15.10.2.

140. 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, *supra* note 5, ¶ 5(b).

141. Singapore FTA, *supra* note 135, art. 16.7(6)(a) (anti-competitive practices); *id.* 16.7(6)(b) (public non-commercial use or national emergencies).

142. *Id.* art. 16.7(6)(b)(ii); *see also* Free Trade Area of the Americas, Third Draft Agreement, ch. XX, subsec. B.2.e, art. 6.1(c), Nov. 21, 2003, FTAA.TN/w/133/Rev.3 [hereinafter FTAA] (also requiring “reasonable and entire compensation”).

only exception to patent rights is a provision similar to the more ambiguous TRIPS Article 30.¹⁴³

Even for FTAs that do not have provisions explicitly governing compulsory licensing, other provisions may impede such use of patented inventions. In particular, compulsory licensing may be a non-issue if a generic drug company cannot obtain the regulatory approval necessary because of data protection 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.”¹⁴⁴ 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.¹⁴⁵ 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.¹⁴⁶

143. See, e.g., Korea FTA, *supra* note 126, art. 18.8(3), Panama TPA, *supra* note 128, art. 15.9(3); Colombia TPA, *supra* note 138, 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).

144. TRIPS, *supra* note 1, art. 39(3); see also *supra* note 114 and accompanying text.

145. See, e.g., North American Free Trade Agreement, art. 1711(6), U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) (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, *supra* note 123, art. 17.10(1) (requiring five years of data protection of pharmaceutical products that use a “new chemical entity”); Singapore FTA, *supra* note 135, 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, *supra* note 30, art. 15(10) (providing five years of protection for pharmaceutical products); FTA, *supra* note 142, 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, *supra* note 126, art. 15.9(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Peru TPA, *supra* note 133, art. 16.10(1)(a) (providing at least five years for pharmaceuticals and ten years for agricultural chemical products); Australia FTA, *supra* note 30, art. 17.10 (providing at least five years for new pharmaceutical products and ten years for agricultural chemical products).

146. See, e.g., 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), available at http://ustr.gov/assets/Document_Library/Fact_Sheets/2006/asset_upload_file151_9980.pdf; Russian Accession: New Potential Hurdle with EU: TRIPS-plus IP Commitments with US, BRIDGES WKLY. TRADE NEWS DIG., Nov. 29, 2006, at 4, 5.

2. Limits on Parallel Imports

Restrictions on parallel imports—imports of patented drugs previously subject to an authorized sale in another country—constitute a major difference between TRIPS and subsequently negotiated trade agreements. Before delineating the differences, it is first important to clarify the concept of parallel imports and their significance to public health interests.

Permitting parallel importation (alternatively referred to as the doctrine of international exhaustion)¹⁴⁷ favors consumer interests and access to medicine, because countries are free to import products from the country where they are legitimately sold for the lowest possible price. Pharmaceutical manufacturers are strongly opposed to international exhaustion since their business model relies upon price differentiation amongst different countries. If consumers could freely buy the cheapest product available, companies would not be able to discriminate amongst different markets.

At the time of the TRIPS negotiation, the topic of parallel importation was hotly contested.¹⁴⁸ While countries hotly debated whether to explicitly permit or prevent parallel imports, the final agreement merely states that the topic will be excluded for the purposes of dispute settlement under WTO proceedings.¹⁴⁹ In addition, the recent Doha Public Health Declaration states that TRIPS is intended to “leave each Member free to establish its own regime for such exhaustion without challenge.”¹⁵⁰

While member countries may continue to debate whether TRIPS controls the issue of parallel imports, 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

147. According to the concept of international exhaustion, once a legal copy of a patented product is circulated (i.e., with permission of the patent holder) somewhere in the world, patent rights for that product are exhausted, such that the patent owner cannot protest subsequent importation of the patented product to a different country. This concept stems from the more universally recognized principle of domestic exhaustion, or doctrine of first sale. Essentially, within an individual country, the first sale of a patented product exhausts the patent owner's rights regarding that product. The duly authorized purchaser of the product may then use or dispose of the product as he or she wishes, including re-selling it. In addition, in the case of the European Union, the domestic exhaustion principle is extended through the entire European Community such that a single authorized sale of a patented product *anywhere* within the European Community exhausts the patent owner's rights with regard to that product.

148. See GERVAIS, *supra* note 30, at 111–15.

149. TRIPS, *supra* note 1, art. 6 (providing that “[f]or the purposes of dispute settlement . . . nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights”).

150. Doha Public Health Declaration, *supra* note 5, ¶ 5(d).

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.¹⁵¹

C. *Tension Within TRIPS-Plus Agreements and Negotiations*

Although the next section focuses exclusively on activity that counters the TRIPS-plus trend, some elements within the existing and pending agreements indicate a possible trend against automatic adoption of new TRIPS-plus norms.

In addition to the specific changes to patentability and patent rights, certain notable elements are *not* included in many TRIPS-plus agreements. Importantly, the objectives and principles of TRIPS, as stated in Articles 7 and 8 of TRIPS, are generally not included in any of the FTAs. Their omission could be important, because whereas the TRIPS requirements are to be interpreted *in light of* the objectives and principles of Articles 7 and 8, no similar interpretative framework supporting public health exists in the FTAs. In light of this omission, some countries have tried to reinstitute the thrust of the two articles with side letters to TRIPS-plus agreements that declare some type of right to consider public health.¹⁵² Noble as these efforts may be, they may not allow countries to take full advantage of flexibilities under TRIPS and the Doha Public Health Declaration, because the interpretative weight of side letters will likely be minimal even if they contain similar language.¹⁵³

However, in a very important new development, some previously negotiated FTAs between the U.S. and other countries are expected to now

151. Singapore FTA, *supra* note 135, art. 16.7(2)–(3); Morocco FTA, *supra* note 123, art. 15.9(4); *see also* FTAA, *supra* note 142, 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).

152. *See* Understanding Regarding Certain Public Health Measures, Aug. 5, 2004, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf (understanding of chapter fifteen of CAFTA, *supra* note 30); Understandings Regarding Certain Public Health Measures, Apr. 12, 2006, *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file485_9506.pdf (understanding of chapter sixteen of the Peru TPA, *supra* note 133); Letters between Minister Taïb Fassi Fihri, Delegate for Foreign Affairs and Cooperation, Kingdom of Morocco, and Robert B. Zoellick, Trade Representative, United States (June 15, 2004), *available at* http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/asset_upload_file258_3852.pdf (courtesy translation of the understanding of chapter fifteen of the Morocco FTA, *supra* note 123).

153. *See* RUTH MAYNE, REGIONALISM, BILATERALISM, AND “TRIP PLUS” AGREEMENTS: THE THREAT TO DEVELOPING COUNTRIES 7 (2005) (suggesting that the impact of side letters “will be at best to muddy the ability of countries to use the TRIPS flexibilities confirmed by the Doha Declaration and the WTO August 30th decision on access to medicines, and at worst undermine their implementation”).

incorporate such language within the main text of the agreements, rather than merely in side letters. In particular, the United States Trade Representative announced new trade rules for FTAs with developing countries that aim to strike a better balance between promoting innovation and public health rights.¹⁵⁴ The new rules are to apply to pending agreements with Peru and Panama; but not to Korea and Russia.¹⁵⁵ 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 FTAs.¹⁵⁶

Although the bipartisan agreement to scale back intellectual property provisions is certainly a major development, the ultimate details may not provide substantial change from the original text. Many of the agreed changes are relatively modest. For example, instead of mandating that patent terms be extended for “unreasonable delay” in either patent or marketing approval, the new proposal states that Peru and Panama *may* do so.¹⁵⁷ However, although *may* seems less restrictive than the original wording of “shall,” the new proposal also contains new language that requires Peru and Panama to make “best efforts” to be expeditious.¹⁵⁸ Thus, this seems to at least leave the door open to criticism and pressure if patents or marketing approvals are not granted in the fashion desired by major pharmaceuticals. Similarly, although the new proposal no longer requires the national drug approval agency to withhold approval of generic drugs unless the agency can certify that no patent rights are violated, there are now new rules that procedures and remedies must exist for “expeditiously adjudicating” whether a patent is infringed.¹⁵⁹ In addition to these examples, there is the

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

155. Office of the U.S. Trade Representative, Trade Facts—Intellectual Property (May 2007) (noting that modified provisions relating to medicines and health only apply to “developing country partners”). In addition, the pending agreement with Colombia may ultimately join Peru and Panama, but is currently stalled because of violence against trade unionists. See Letter from Charles Rangel & Sander Levin, *supra* note 154.

156. 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 8 (May 10, 2007), available at http://www.cpath.org/sitebuildercontent/sitebuilderfiles/2007_new_trade_policy_details5-10-07.pdf.

157. *Id.* at 7.

158. *Id.*

159. *Id.* at 7-8.

possibility of a general addition to the agreements that could require periodic review of the national intellectual property rights.¹⁶⁰

The most notable change to the FTAs, beyond the fact that there was a scaling back of the FTAs' terms, is probably the change in status of the initial side letters on public health. The new proposal directly addresses the previous criticism of the side letters—namely, that they failed to provide adequate legal protection because they were not official parts of the agreement.¹⁶¹ The revised FTAs should now affirm commitment to the Doha Public Health Declaration, as well as contain some language to clarify that the FTA “does not and should not prevent the Parties from taking measures to protect public health or from utilizing the TRIPS/health solution.”¹⁶² On the other hand, having similar language in the WTO/TRIPS context, as well as in United States laws, has not ended United States pressure on countries that attempt to use TRIPS flexibilities.¹⁶³

Another potentially important development to the TRIPS-plus movement beyond the activities described in the next section is the stalling of some FTAs that were previously in negotiation. For example, the United States was unsuccessful in completing the Andean FTA and resorted to negotiating individual agreements with individual countries. The United States has successfully concluded agreements with Peru and Columbia, but has not yet done so with Ecuador or Bolivia.¹⁶⁴ While some may perceive this piecemeal approach dangerous to the leveraging position of developing countries, it can also be viewed more optimistically as progress to the extent that the United States cannot easily replicate identical agreements with the countries of its choice.¹⁶⁵ In addition, the Free Trade Agreement of the

160. *Id.* at 8 (noting that the “FTA could include a provision calling for the periodic review of the implementation and operation of the IPR Chapter, and giving the Parties an opportunity to undertake further negotiations”).

161. *See, e.g.*, Letter from Henry A. Waxman et al. to Susan Schwab (Mar. 12, 2007), available at <http://www.oversight.house.gov/Documents/20070312150354-57129.pdf> (noting that side letters in recent FTAs signed by the US inadequately protect public health needs).

162. Peru & Panama FTA Changes, *supra* note 156, at 8.

163. *See, e.g.*, Letter from Henry A. Waxman et al., *supra* note 80 (stating that the recent listing of Thailand in the Special 301 Report in response to Thailand's TRIPS-complaint compulsory licenses “calls into question the United States' commitment to the Doha declaration”); Letter from Henry A. Waxman et al., *supra* note 161 (noting that recent FTAs signed by the U.S. “appear to undermine” the Doha Declaration, as well as the Trade Promotion Authority Act directing the Administrative branch to adhere to the Doha Declaration).

164. *See Back to the Drawing Board*, ANDEAN GROUP REP., Nov. 29, 2005, at 5 (noting that Colombia and Ecuador announced that they were ending negotiations for an Andean free trade agreement); *US Congress Agrees to Extend Series of Trade Preferences*, BRIDGES WKLY. TRADE NEWS DIG., Dec. 13, 2006 (noting that the U.S. had failed to conclude FTAs with Ecuador or Bolivia).

165. In addition, although trade representatives of the United States have successfully concluded negotiations, actual approval by Congress of these agreements remains unclear or, at least, subject to renegotiation to include tougher labor standards. *See* Eoin Callan, *Industry Drive to Save Trade Deals*,

Americas (“FTAA”)—originally scheduled to be completed by January 2005—has stalled, with no draft texts since 2003 and no start date set for relaunching negotiations.¹⁶⁶

Negotiations have also stalled on a FTA between the United States and Thailand. Although the reasons are complicated by the recent compulsory licenses, as well as the lack of a democratic government, Thailand raised interesting issues of broader applicability. For example, Thailand found the proposed FTA inconsistent with human rights and national sovereignty not only because of the negative impact on medicines, but because acceptance of unilateral terms was considered to cede sovereignty to the United States.¹⁶⁷ These issues apply to other FTAs that are negotiated using the same template by USTR.

III. MOVING BEYOND TRIPS-PLUS

Although countries are continuing to negotiate TRIPS-plus agreements, there is a global movement running counter to the trend of ever-increasing intellectual property right norms. In particular, a wide variety of actors—including developing countries, non-governmental organizations, and individuals—are taking actions to emphasize the importance of public health in relation to patent rights.

A. *International Activity*

At the international organization level, the biggest issue under current discussion is a proposal for the World Intellectual Property Organization (“WIPO”) to adopt a development agenda. WIPO agreements are not formally part of the WTO framework. Yet, to the extent that they become part of international law, they can still influence interpretation of WTO agreements such as TRIPS. Argentina and Brazil first proposed a development agenda for WIPO in August 2004.¹⁶⁸ The initial proposal laid out a variety

FIN. TIMES, Dec. 28, 2006; Mark Drajem, *Panama, U.S. Sign Trade Deal / Pact Awaits Tough Opposition from Democrats*, HOUS. CHRON., Dec. 20, 2006, at Business 7.

166. See Office of the U.S. Trade Representative, FTAA Ministerials, http://www.ustr.gov/Trade_Agreements/Regional/FTAA/FTAA_Ministerials/Section_Index.html (last visited Feb. 15, 2007).

167. See, e.g., *Thai Human Rights Commission Criticises FTA with US*, BILATERALS.ORG, Jan. 26, 2007, http://www.bilaterals.org/article.php?id_article=7012 (last visited July 6, 2007).

168. World Intellectual Prop. Org. Secretariat, *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/11 (Aug. 27, 2004) [hereinafter *WIPO Proposal*]. In addition, even before formal WIPO activity, debate and momentum to internationally address development issues began after the UK Commission on Intellectual Property Rights published a report critical of the application of intellectual property rights to development. SISULE F. MUSUNGU, *RETHINKING INNOVATION, DEVELOPMENT AND INTELLECTUAL PROPERTY IN THE UN: WIPO AND BEYOND* 12 (2005).

of ideas for WIPO members to consider. On the broad framework of intellectual property—the mission of WIPO—the proposal suggested that intellectual property should be a “policy instrument” and that greater attention should be paid to ensure that costs do not outweigh benefits. More specifically, the proposal suggested that intellectual property norm setting should actively embrace a perspective of developing countries consistent with a variety of other international activity, including the UN Millennium Development Goals and the WTO Doha Development Agenda.¹⁶⁹ The proposal suggested that if negotiations on the draft Substantive Patent Law Treaty (“SPLT”) were informed by a development perspective, future discussions would consider the entirety of the treaty (as previously proposed by developing countries), proposals to include public interest flexibilities, and language mirroring Articles 7 and 8 of TRIPS. In addition, beyond the political “hot potato” of the SPLT, the Argentina-Brazil proposal laid out additional suggestions, ranging from more committees within WIPO and greater participation of civil society, to a “high level” declaration on the development aspect and a new treaty on access to knowledge and technology.

The initial proposal for a development agenda has spawned a variety of activity under the auspices of WIPO, as well as other fora. Although initial meetings did not seem promising—since discussions included debates about the propriety and scope of a specific development committee¹⁷⁰—most recent meetings have been hailed as achieving remarkable progress. This section will provide highlights of activity fostered by the initial WIPO proposal. First, shortly after the proposal for a development agenda, a Declaration on the Future of WIPO was pronounced at Geneva. The Declaration was supported by developing countries and hundreds of civil society organizations (such as Medicines Sans Frontières), scientists, academics, and others.¹⁷¹

A proposed Treaty on Access to Knowledge (“A2K”) was crafted in 2005 and has been the subject of continued discussion.¹⁷² The essence of

169. *WIPO Proposal*, *supra* note 168, annex at 1–2 (noting that the WIPO norm-setting activities “largely exceed existing obligations under . . . TRIPS . . . while . . . countries are still struggling with the costly process of implementing TRIPS itself”).

170. See William New & Tove Iren S. Gerhardson, *WIPO Development Agenda Talks End with No Agreement for Now*, IP-WATCH, June 30, 2006, available at <http://www.ip-watch.org/weblog/index.php?p=346> (noting conclusion of recent round of negotiations without agreement).

171. Geneva Declaration on the Future of WIPO 3–14 (Oct 4, 2004), available at <http://www.cptech.org/ip/wipo/futureofwipodeclaration.doc>.

172. For example, Yale Law School has hosted two major conference on A2K that brought together academics as well as activists. See Yale Access to Knowledge Conference, <http://research.yale.edu/ip/eventsa2k.html> (last visited Feb. 16, 2007). Additional information about the substance of the

A2K is to ensure a balance between intellectual property owners and users not only in patents, but in all intellectual property disciplines. The current draft framework mirrors the minimum standards of TRIPS, but in the reverse direction; whereas TRIPS requires all members to adopt certain minimum levels of protection, A2K suggests all members adopt certain minimum standards of *access*.¹⁷³ 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.¹⁷⁴

In addition, A2K challenges some present interpretations concerning the scope of patentable subject matter as well as patent rights under TRIPS. In particular, A2K suggests excluding higher life forms from patentability.¹⁷⁵ 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.¹⁷⁶ 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. While seemingly reasonable from a health perspective, compassionate use is much broader than the present laws of some nations. For example, in the United States there is no statutory safe harbor, and common law exclusions for experimental use have been narrowly interpreted.¹⁷⁷ Compassionate use as an exception to infringement seems inimical to present United States patent laws that not only permit the patenting of medical procedures and technologies, but also enable patent owners to recover from those who contribute to patent infringement.

conference and subsequent discussions is available on a wiki at http://research.yale.edu/isp/a2k/wiki/index.php/Yale_A2K_Conference (last visited Feb. 16, 2007).

173. Draft Treaty on Access to Knowledge, art 1-2, May 9, 2005, *available at* <http://www.cptech.org/a2k/consolidatedtext-may9.pdf>.

174. *Id.* art. 1-3(c).

175. *Id.* art. 4-1(a)(viii).

176. *Id.* arts. 4-1(b)(ii), (iv).

177. *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, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) (discussing the problems surrounding the experimental use exception); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000) (proposing a fair use defense comparable to that found in copyright law).

The concrete A2k proposals have fostered discussion that challenges TRIPS-plus provisions. For example, draft text for a “Paris Accord,” discussed at a meeting of the Transatlantic Consumer Dialogue (“TACD”) in June 2006, builds upon some of the principles of A2K.¹⁷⁸ The goal of the Accord is to establish an “agreement between creative communities and the public.” While the language is stated to be “far from final,” its principles are nonetheless interesting in reflecting additional movement away from TRIPS-plus requirements.

For example, it echoes A2K in declaring that “science depends upon access to knowledge” and that intellectual property rules “should not prevent experimental use.”¹⁷⁹ Although the terms “data protection” or “data exclusivity” are not specifically invoked, they are nonetheless addressed. 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.”¹⁸⁰ In other words, rules providing data exclusivity that are premised on the necessity to protect financial 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 research¹⁸¹ and specifically rejects the traditional business model of multinational pharmaceutical companies that uses high drug prices to finance research.¹⁸²

Most recently, some A2K goals entered mainstream political discussions within 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.”¹⁸³ In addi-

178. Draft Paris Accord, June 17, 2006, available at <http://www.cptech.org/a2k/pa/ParisAccord-june17draft.pdf>. 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).

179. Draft Paris Accord, *supra* note 178, at 2.

180. *Id.*

181. *Id.* (noting that “[g]overnments must support global agreements to share in the costs of evaluating new medicines”).

182. *Id.* (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”).

183. See, e.g., Tove Iren S. Gerhardsen, *Negotiators Agree to Add Access to Knowledge to WIPO Mandate*, IP-WATCH, June 14, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=654&res=1280&print=0> (internal quotations omitted).

tion, the member states agreed that WIPO should “promote norm-setting activities related to IP that support a robust public domain.”¹⁸⁴ 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.¹⁸⁵ 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.”¹⁸⁶

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.¹⁸⁷ 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.¹⁸⁸

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 health-needs driven research and development” that would include a range of incentive

184. *Id.* (internal quotations omitted).

185. See *WIPO Members Agree on Development Agenda*, BRIDGES WKLY. TRADE NEWS DIG., June 20, 2007, available at <http://www.ictsd.org/weekly/07-06-20/story1.htm>.

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

187. See, e.g., Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*, 2 PLoS BIOLOGY 147 (2004).

188. Medical Research and Development Treaty, art. 2.3 (Discussion Draft 4, Feb. 7, 2005), available at <http://www.cptech.org/workingdrafts/rndtreaty.html>.

mechanisms.¹⁸⁹ 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.¹⁹⁰ On the other hand, past experience suggests that the WHO may have difficulty in developing proposals that satisfy all parties. For example, reactions were mixed in response to a recent report authored by a commission of the WHO on promoting innovation that would address the needs of developing countries.¹⁹¹ Public health sympathizers argued that the report failed to go far enough in its recommendations, whereas the pharmaceutical industry largely opposed the substance of the report for reaching too far.¹⁹²

While it is too early to determine whether the WHO will achieve its goal in promoting long-term development of drugs and access to drugs, it has already taken an important step towards fostering access. In particular, at the same annual WHO summit, member states reached a preliminary agreement that promotes use of TRIPS flexibilities. A present draft urges member states to "provide, whenever necessary, in their legislation for use, to the full, of the flexibilities contained in . . . [TRIPS] in order to promote access to pharmaceutical products."¹⁹³ This language is stronger than language that was supported by the United States, Switzerland, and Japan, that suggested that countries should *consider* whether to adapt legislation to enable TRIPS flexibilities.¹⁹⁴

189. *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. Despite the resolution, the U.S. has disassociated itself from the decision. See *WHO Members Adopt Resolution on Pharmaceutical Innovation*, BRIDGES WKLY. TRADE NEWS DIG., May 23, 2007, available at <http://www.ictsd.org/weekly/07-05-23/story2.htm>.

190. See, e.g., *WHO Members Divided over Plan for Promoting Pharmaceutical Innovation*, BRIDGES WKLY. TRADE NEWS DIG., Apr. 25, 2007, available at <http://www.ictsd.org/weekly/07-04-25/story3.htm> (noting controversy over whether WHO should deal with TRIPS and bilateral trade agreements, as well as controversial funding mechanisms for pharmaceutical innovation).

191. WORLD HEALTH ORG., PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH 171-88 (2006).

192. See, e.g., Elen 't Hoen, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health: A Call to Governments*, 84 BULL. WORLD HEALTH ORG. 421, 422 (2006) (criticizing the report for failing to provide better proposals); *Reactions Strong but Mixed to WHO Report on IP and Medicines Access*, IP-WATCH, Apr. 4, 2006, available at <http://www.ip-watch.org/weblog/index.php?p=261&print=1> (noting criticisms from both health groups and pharmaceutical interests).

193. Tove Iren S. Gerhardsen, *WHO Members Reach Preliminary Agreement on TRIPS and Malaria*, IP-WATCH, May 21, 2007, available at <http://www.ip-watch.org/weblog/index.php?p=624&res=1280&print=0> (brackets in original) (internal quotations omitted).

194. *Id.*; see also World Health Org., *Malaria, Including a Proposal for Establishment of World Malaria Day*, at 2, EB120.R16 (Feb. 1, 2007), available at http://www.who.int/gb/ebwha/pdf_files/EB120/B120_R16-en.pdf (stating that member states are urged to "consider, whenever neces-

B. Domestic Efforts

Another alternative to TRIPS-plus provisions lies in the newly amended patent laws of India. Thus far, India has resisted the temptation of compromising public health through enhanced patent rights in exchange for greater market access in other sectors. Although India recently had to amend its patent laws to comply with the TRIPS requirement to provide patents to pharmaceutical products, its amendments took some novel approaches that could serve as a useful illustration to other countries with respect to how to balance patent rights and public health needs. For example, India carved new exceptions to its scope of patentable subject matter in an attempt to avoid overprotection of pharmaceutical drugs that are of little improved therapeutic value. Unlike some FTAs, India's Patent Act specifically states that the discovery of new uses or properties of known substances are not patentable if they do not enhance efficacy.¹⁹⁵ Another novel characteristic of India's patent laws is that patent protection granted based upon patent grants in other jurisdictions (filed under the "mailbox" provision of TRIPS) are only enforceable *prospectively* from the date of patent issuance. Generic companies that were making and selling the now-patented drug prior to the grant are permitted to continue producing such generic drugs under a *de facto* compulsory license, which provides a reasonable royalty to the patent owner.¹⁹⁶ Thus, India still permits some generic production of currently patented drugs.

Another important option that individual countries may take is to challenge patents and even patent applications more aggressively, especially in combination with more rigorous standards of patentability. India provides one model of enabling third parties to oppose not only issued patents, but also patent applications before they are granted.¹⁹⁷ In fact, India recently

sary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights").

195. Compare The Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005, ¶ 3(d), with Oman FTA, *supra* note 126, art. 15.8(1)(b) (confirming that patents are available for known products for the treatment of medical conditions).

196. However, this is only available for generic manufacturers that have made a substantial investment and sold the drug from January 1, 2005, to the present. The Patents (Amendment) Act ¶ 10(c) (India).

197. The first successful pre-grant opposition was used in March 2006 by the Indian Network for People Living with HIV/AIDS (INP+) against a drug by GlaxoSmithKline. The challenge was based on Section 3(d) of the 2005 Indian patent law and claimed that the drug was merely a combination of two existing drugs. Following the opposition, GlaxoSmithKline withdrew its patent applications for the drug. See, e.g., Médecins Sans Frontières, Briefing Note, *A Key Source of Affordable Medicines Is at Risk of Drying Up 4* (Dec. 2006). In addition, there are a number of other pre-grant oppositions currently filed, including some by generic companies. See, e.g., Noemie Bisserbe, *Local Pharma Strikes First in Patent War*, ECON. TIMES, Oct. 24, 2006 (noting that generic companies have filed over one hundred pre-grant oppositions and that after four or five cases, the patent office has ruled in favor of the

reinstated the pre-grant opposition period to encourage early challenges to inventions that should not be patented.¹⁹⁸ This additional opportunity was successfully utilized by the Cancer Patient Aid Opposition, which convinced the Indian patent office to deny a patent for Novartis's anti-cancer drug Gleevac.¹⁹⁹ In particular, the patent office found the application unpatentable in light of the 2005 Indian Patent Act, which excludes pharmaceutical derivatives from patentability unless they differ significantly from the original compound with regard to efficacy.²⁰⁰ This standard of patentability is striking in comparison to most other patent laws that have no requirement that a compound show increased efficacy. Indeed, the compound that was rejected in India has been granted a patent in over forty countries. The provision is no accident; rather, it reflects India's attempt to comply with TRIPS's requirement of patents on pharmaceutical products while simultaneously recognizing a historical sensitivity to the impact of patents on health care. Prior to TRIPS, India permitted patents on processes of making pharmaceuticals, but not on the products themselves in an attempt to spur generic production and enhance the availability of drugs. In addition, the provision at issue here, Section 3(d), was designed to prevent "evergreening," a common practice used by drug companies to obtain additional patents for small improvements to previously patented compounds. Although evergreening is recognized as an issue worldwide due to its negative impact in delaying introduction of lower-cost generic drugs, no country before India had attempted to directly bar the practice through heightened patentability requirements.

Whether India's patent requirement of increased efficacy for pharmaceutical derivatives will be a model for balancing patents and public health,

opposition each time); Amelia Gentleman & Hari Kumar, *AIDS Groups in India Sue to Halt Patent for U.S. Drug*, N.Y. TIMES, May 12, 2006, at A4 (noting that two patients-rights groups challenged Gilead Science's patent application on the antiretroviral drug Viread as not sufficiently new under India's law).

198. The time for opposition has been extended to a minimum period of six months from publication (instead of the older three month period) with expanded grounds, as well as an opportunity for a hearing. Press Release, India Ministry of Commerce & Indus., Important Changes Incorporated in the Patents (Amendment) Bill, 2005 as Compared to the Patents (Amendment) Bill, 2003, at ¶¶ 7-10 (Mar. 23, 2005), available at <http://pib.nic.in/release/release.asp?relid=8906>.

199. The Gleevac application was not a standard application. Rather, under TRIPS rules, Novartis had initially requested an exclusive marketing right for Gleevac in 1998, based upon TRIPS rules that permit a company to request patent-like rights in a country where product patents are not yet available for pharmaceuticals. Novartis succeeded in obtaining such exclusive marketing rights in 2003. Novartis then promptly sued generic makers of its compound based on the exclusive marketing rights, with conflicting results in the courts. Meanwhile, third-party oppositions challenged the patent.

200. The Patents (Amendment) Act ¶ 3 (India) (providing that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance 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" is not patentable).

or an example of the difficulties of attempting to do so, remains to be seen. Novartis has challenged the Indian Patent Act as unconstitutional and in violation of TRIPS.²⁰¹ According to Novartis, India should not be entitled to establish requirements for patentability beyond the traditional standards of novelty, non-obviousness, and utility. Despite pleas and negative publicity from public health organizations, Novartis is persisting in its challenge.²⁰² If successful, generic versions of drugs in India will be delayed, as they currently are in other countries.

C. Technology Solutions

1. Working with the Existing Patent System

Even in nations that do not currently embrace an opposition system for third parties (either before or after a patent issues), current technology provides means to aid patent examiners in minimizing the number of over-broad patents where there is prior art. For example, in the United States, which has discussed, but not yet enacted, any form of opposition system, the pilot “Peer to Patent” project, sponsored by corporate giants such as IBM and Microsoft, aims to use peer review and a Wiki-based network to help official patent examiners locate and consider relevant prior art.²⁰³ While the project was conceived to improve prior art searches, this model could be used in conjunction with the current opposition system in India to assist patent offices in locating the best prior art, thereby limiting the issuance of invalid patents. This opportunity may be particularly important because once patents are issued in the United States, they carry a presumption of validity in litigation, with few opportunities for administrative opposition.²⁰⁴

201. See, e.g., *Novartis Files 2 Patent Suits in Chennai Court*, TIMES OF INDIA, Aug. 18, 2006.

202. See, e.g., Press Release, Médecins Sans Frontières, MSF Urges Novartis to Drop its Case Against the Indian Government (Dec. 20, 2006), available at <http://www.accessmed-msf.org/prod/publications.asp?scntid=20122006113976&contenttype=PARA&>.

203. Press Release, Peer to Patent Project, Community Patent Review Project Will Open Patent Examination Process to Online Peer Review, Using Web-Based Technologies to Connect Scientific Experts and the Patent Office (Aug. 29 2006), available at http://dotank.nyls.edu/communitypatent/pressrelease_082906.html. For the theoretical background behind this new project, see Beth Simone Novek, “Peer to Patent”: *Collective Intelligence, Open Review, and Patent Reform*, 20 HARV. J.L. & TECH. 123 (2006).

204. 35 U.S.C. § 282 (2000) (presumption of validity). Moreover, in light of the fact that there is no serious means to challenge patents outside the litigation context, borderline patents may be unfairly used by patent trolls to extort money from health care providers.

2. Solutions Outside the Patent System

Some scientists are turning to open-source research as an alternative to the traditional patent system. Open research in lieu of patent protection has been, and continues to be, globally considered.²⁰⁵ Most prominently, the World Health Organization has been addressing medium-term approaches to sustaining a global approach of researching and developing drugs that predominantly impact the developing world. These multi-faceted approaches explicitly consider open-source, open-access, and other types of collaborations.²⁰⁶ Some Western countries, including members of the European Union, have expressly supported the idea of patent pooling at WHO meetings.²⁰⁷ Although the support at this point is only for the general principle, rather than a specific proposal, movement along this line is a marked contrast to the bilateral agreements entered into by the EU and other countries that specifically mandate TRIPS-plus levels of patent protection.

Some open-source projects already exist, ranging from projects that operate on an international scale, spanning multiple countries, to more domestic projects.²⁰⁸ In many cases, participants agree to release data into the public domain to promote access and avoid the problem of patent thickets. One ambitious project aims to not only use open-source access, but also to promote web-based research and development in areas of particular interest to developing countries. For example, the Tropical Disease Initiative, established in 2004, relies on the volunteer efforts of scientists using electronic bulletin boards and blogs as building blocks.²⁰⁹ Any promising research results are then sent to “virtual pharmas,” charity-based groups that will contract with corporate partners to produce and market drugs. The goal is to drastically decrease the costs of drug development by using both

205. For example, the draft Paris Accord previously referred to similarly supports open research projects that would enable follow-on innovation. Draft Paris Accord, *supra* note 178, at 2.

206. World Health Organization Intergovernmental Working Group on Public Health, Innovation & Intellectual Property, *Elements of a Global Strategy and Plan of Action*, WHO Doc. A/PHI/IGWG/1/5 (Nov. 2, 2006).

207. See, e.g., Tove Iren S. Gerhardsen, *WHO Members Take Small Steps with New Medicine R&D Plan in Novel Exercise*, IP-WATCH, Dec. 7, 2006, available at <http://www.ip-watch.org/weblog/index.php?p=482> (noting that France supported the idea of patent pooling and that the EU was open to exploring patent pooling as well).

208. For information about the HapMap project, see, for example, International HapMap Consortium, *The International HapMap Project*, 426 NATURE 789 (2003); International HapMap Project Home Page, <http://www.hapmap.org> (last visited Feb. 16, 2007). Alternatively, for information on CAMBIA's project, see CAMBIA Biological Open Source (BiOS) Initiative Home Page, <http://www.bios.net/daisy/bios/home.html> (last visited Feb. 16, 2007).

209. Stephen M. Maurer, Arti Rai & Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source the Answer?*, 1 PLOS MED. 180 (2004); see also Tropical Disease Initiative Home Page, <http://www.tropicaldisease.org> (last visited Feb. 16, 2007).

volunteer workers and a not-for-profit organization.²¹⁰ At a minimum, this project is designed on a very different framework than the “blockbuster” model of pharmaceutical development and profit maximization that most large drug companies currently utilize. This project pays great attention to promoting drugs that will likely be highly lucrative, without regard to whether they promote maximal global needs.

CONCLUSION

Patents and public health in a post-TRIPS world is an exciting but uncertain issue. Although news stories frequently trumpet new developments, it seems nearly impossible to maintain the current perspective with so much push and pull between the interests of developed and developing countries. Although the trend towards TRIPS-plus agreements is disconcerting to the interest and ability of countries to maintain public health interests, the strong counter-movements are highly encouraging. The global attention to the important intersection of patents and public health has the potential to lead to important discussions, as well as an eventual balance that all nations can tolerate.

210. Maurer, Rai & Sali, *supra* note 209, at 180.