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INDIA'S USE IT OR LOSE IT: TIME TO REVISIT TRIPS?

LEVON BARSOUMIAN

ABSTRACT

India is one of a number of countries which impose a “local working” requirement on patented inventions. This finds its source in sections 83, 84, and 89 of India’s Patent Act. A recent decision by the Controller of Patents granting a compulsory license to Natco for a Bayer-patented anti-cancer drug confirms that importation will not satisfy this requirement. Corporations seeking to produce and market products for international sale will receive varying degrees of patent protection from different nations. This comment proposes an amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) defining what local working requirements are permitted, and requiring that nations meet and confer when making decisions on compulsory licenses against foreign patent-holders.

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LEVON BARSOUMIAN*

INTRODUCTION

Over the past hundred years, modes of shipping have improved.¹ The world population growth in that same time has provided a large market to buy and sell goods.² Lowering barriers to international trade is the World Trade Organization (“WTO”).³ Intellectual property rights are crucial to international trade.⁴ Patent rights are important to the international trade of goods.⁵ The Patent Cooperation Treaty (“PCT”) and Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) together form a framework for international patent prosecution and patent protection.⁶ The TRIPS agreement has a pending amendment, the Doha Ministerial Declaration of 2004.⁷

India is a rapidly developing country, with a growing population exceeding 1 billion.⁸ This puts India in an attractive position for trade with the United States.⁹

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¹ See generally Liav Orgad, *Illiberal Liberalism Cultural Restrictions on Migration and Access to Citizenship in Europe*, 58 AM. J. COMP. L. 53, 54–59 (2002) (discussing advent of cheap travel and how it has contributed to immigration); see also Anna Gekht, *Shared but Differentiated Responsibility: Integration of International Obligations in Fight Against Trafficking in Human Beings*, 37 DENV. J. INT'L. L. & POL'Y. 29, 33 (2008) (noting advancements in transportation as contributing to increases in human trafficking).

² See U.N. POPULATIONS FUND, STATE OF THE WORLD POPULATION 2001 (2001), available at <http://www.unfpa.org/swp/2001/english/ch01.html#1c> (noting that the population had doubled between 1960 and 2001 to 6.1 billion); see also POPULATION REFERENCE BUREAU, WORLD POPULATION GROWTH (2010), available at <http://www.prb.org/Educators/TeachersGuides/HumanPopulation/PopulationGrowth.aspx> (outlining population growth from ancient times to present day).

³ See generally Marrakesh Agreement Establishing the World Trade Organization, The Results of the Uruguay Round of Multilateral Trade Negotiations, art. X, April 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 [hereinafter WTO Agreement].

⁴ See generally SHUBHA GHOSH ET AL., INTELLECTUAL PROPERTY: PRIVATE RIGHTS, THE PUBLIC INTEREST, AND THE REGULATION OF CREATIVE ACTIVITY 228–31 (Thompson/West 2007) (describing historical development of patent rights and rights covered).

⁵ See Alice O. Martin & Sendil K. Devadas, *Patents with an “I” = Patients*, 188 ANN. HEALTH L. 261, 269–70 (2009) (noting that without a patent system, investors may stay away).

⁶ See Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, art. 17, Apr. 15, 1994, 33 I.L.M. 1125, 1869 U.N.T.S. 299 [hereinafter TRIPS], available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf; see also Patent Cooperation Treaty, June 19, 1970, 9 I.L.M. 978.

⁷ See Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 P4 (Nov. 14, 2001) [hereinafter Doha Declaration].

⁸ CENT. INTELLIGENCE AGENCY, THE WORLD FACTBOOK (2010), available at <https://www.cia.gov/library/publications/the-world-factbook/geos/in.html> (noting Indian population in excess of 1.1 billion as of July 2010 estimates).

It is therefore important to have an understanding of the patent laws of India and how they will apply to an American corporation seeking to do business in India.¹⁰

The focus of this comment is a provision in the Indian Patent Law which requires a patent to be worked in the territory of India.¹¹ If a patent is not worked in the territory of India, compulsory license may be granted upon application and approval by the patent controller.¹² A compulsory license is defined by Black's Law Dictionary as a license created by statute that allows others to use an invention in exchange for a reasonable royalty without the consent of the patentee.¹³ Working of a patent is not defined within the text of the Indian Patent Law.¹⁴ A recent decision of the Controller of Patents, however, has elucidated the meaning of the local working requirement as it pertains to the Indian Patent Law.¹⁵ This comment will focus on the impact of the local working requirement on an American corporation.

First, this comment will introduce and explain the respective patent laws of India and the United States. The local working requirement will be introduced and explained. Next, the comment introduces the TRIPS agreement, the PCT, and the Doha Declaration will be introduced. The comment analyzes the TRIPS text and TRIPS decisions in order to determine if a "use it or lose it" provision predicated on local working is permitted by the TRIPS agreement. The comment presents a revision to TRIPS as a solution to the uncertainty faced by a company seeking to conduct work in India.

I. BACKGROUND

Over the past hundred years, the United States and India have become important trade relations.¹⁶ With increased interaction between nations India and the United States, having an understanding of the current relationship between two countries and their patent laws become important.¹⁷

⁹ See generally Peter K. Yu, *Access to Medicines, BRICS Alliances, and Collective Action*, 34 AM. J. L. AND MED. 345, 348 (2008) (discussing the attractiveness of partnerships with BRICS alliance countries).

¹⁰ See Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J. L. & TECH. 198, 217 (2010).

¹¹ See The Patents Act, No. 39 of 1970, INDIA CODE (1999), § 84(1) (amended 2005). [hereinafter Indian Patent Act].

¹² *Id.*

¹³ BLACK'S LAW DICTIONARY (9th ed. 2009) (defining a compulsory license as "a statutorily created license that allows certain people to pay a royalty and use an invention without the patentee's permission"). See generally Andrew C. Mace, *TRIPS, eBay, and Denials of Injunctive Relief: Is Article 31 Compliance Everything?*, 10 COLUM. SCI. & TECH. L. REV. 232, 243-45 (2009).

¹⁴ See Indian Patent Act, § 84.

¹⁵ Natco Pharma. Ltd. & Bayer Corp. (Mar. 12, 2012) (India).

¹⁶ U.S. CENSUS BUREAU, REPORT ON U.S. INTERNATIONAL TRADE IN GOODS AND SERVICES Exhibit 6a (2009) [hereinafter 2009 REPORT ON INT'L TRADE].

¹⁷ See Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J. L. & TECH. 198, 217 (2010).

A. Trade between the United States and India

India is a major trade partner of the United States.¹⁸ In 2009, the United States exported a total of \$1.1 trillion in goods,¹⁹ importing \$1.6 trillion in goods.²⁰ In the same time period, the United States exported \$16.4 billion worth of goods and services to India,²¹ while importing \$21.2 billion worth of goods and services.²² In the field of advanced technology products,²³ a highly patent-dependent field,²⁴ the United States exported \$244 billion worth of products,²⁵ while importing some \$300 billion worth of products and services in 2009.²⁶ The same year, India was the 15th ranked importer to the United States.²⁷ Patent protection can have a huge impact on two nations that have extensive trade relationships with one another, and impact manufacturing and marketing choices.²⁸

Further complicating this picture is outsourcing. A large number of companies in the United States develop their technologies domestically while outsourcing manufacturing.²⁹ To add to these companies, a large number of companies in the United States also outsource product development processes overseas.³⁰ Cheap foreign labor overseas, inexpensive shipping, and improved trade relations between nations have lowered the barriers to outsourcing operations.³¹ With a population of over one billion and growing, some have questioned why it would be so attractive for

¹⁸ 2009 REPORT ON INT'L TRADE, *supra* note 16, at Exhibit 6a.

¹⁹ U.S. CENSUS BUREAU, REPORT ON U.S. INTERNATIONAL TRADE IN GOODS AND SERVICES Exhibit 5 (2010) [hereinafter 2010 REPORT ON INT'L TRADE].

²⁰ *Id.* at Exhibit 5.

²¹ *Id.*.

²² *Id.*, at Exhibit 5.

²³ 2009 REPORT ON INT'L TRADE, *supra* note 16, at Exhibit 6a.

²⁴ See *Advanced Technology Product Definitions*, U.S. CENSUS BUREAU, <http://www.census.gov/foreign-trade/reference/glossary/a/atp.html#general> (last visited June 5, 2012) (including as part of its General Advanced Technology Product Definitions Biotechnology, Life Science, Opto-Electronics, Information & Communications, Electronics, Advanced Materials, Aerospace, and Nuclear Technology).

²⁵ *Id.*

²⁶ *Id.*

²⁷ 2009 REPORT ON INT'L TRADE, *supra* note 16, at Exhibit 6a.

²⁸ See Kamal Nath's Statement on the Ordinance Relating to Patents (Third) Amendment (Dec. 27, 2004), available at http://commerce.nic.in/pressrelease/pressrelease_detail.asp?id=1309 (indicating Kamal Nath's, Union Cabinet Minister of Commerce and Industry, views on the positive economic effects of the TRIPS agreement and India's amendments to its patent laws).

²⁹ See Joseph Straus, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMP. & INT'L L. 91, 94-99 (1998) (discussing companies which allocate manufacturing overseas).

³⁰ *Id.* (discussing companies which allocate research and development overseas). This article also emphasizes the importance of there being no discrimination based on country of origin for international trade. *Id.*

³¹ See Mark B. Baker, "The Technology Dog Ate My Job": *The Dog-Eat-Dog World of Offshore Labor Outsourcing*, 16 FLA. J. INT'L L. 807, 814-18 (2004) (outlining some of the advantages and disadvantages of outsourcing, including labor wages); see also Michael G. Owen, *Legal Outsourcing to India: The Demise of New Lawyers and Junior Associates*, 21 PAC. MCGEORGE BUS. & DEV. L. J. 175, 176 (2008) (discussing the current state of the legal industry and pros and cons of outsourcing legal work to India).

a company to market its products in India, and conduct manufacturing operations there.³²

B. Territoriality of Patent Laws

In order to be able to develop, manufacture, or sell a product in a particular country, it is crucial to understand the local patent laws.³³ Patent laws are territorial, in that they do not extend outside the territory where they have been granted.³⁴ This necessitates a detailed examination of the patent laws in India and the United States to understand the extent of the rights granted by a patent in each country, respectively.

C. The United States Patent Law

The United States has had a statutory scheme governing patents since the adoption of the United States Constitution.³⁵ The Constitution empowered Congress to create laws on patents.³⁶ The current iteration of patent laws rests in the America Invents Act ("AIA").³⁷ The United States Patent and Trademark Office is the body which reviews and grants patents.³⁸

³² See Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. PITT. L. REV. 491, 495 (2008) (noting India as the world's largest democracy); see also Mark Landler, 'India Everywhere' in the Alps, N.Y. TIMES, Jan. 17, 2006, at C3 (contrasting India's free-market democracy to China's Communist regime).

³³ See generally Vincent J. Napoleon, *Impact of Global Patent and Regulatory Reform on Patent Strategies for Biotechnology*, 9 PITT. J. L. & POL'Y. 1, 10–12 (2008).

³⁴ See GHOSH, *supra* note 4, at 228–31; 35 U.S.C. § 154 (2006) (granting to the patentee the right to exclude others from making, using, selling the patented subject, or importing it to the United States); *Microsoft Corp. v. A T & T*, 550 U.S. 437, 454–55 (2007) (noting the court's "presumption against extraterritoriality" in patent cases, the court goes on to say, "the presumption that United States law governs domestically but does not rule the world applies with particular force in patent law."); see also *Deepsouth Packing Co. v. Laitrap Corp.*, 406 U.S. 518, 531 (1972) ("Our patent system makes no claim to extraterritorial effect . . . and we correspondingly reject the claims of others to such control over our markets."); *Brown v. Duchesne*, 60 U.S. 183, 195 (1856) ("[T]hese acts of Congress do not, and were not intended to, operate beyond the limits of the United States," and "the use . . . outside the jurisdiction of the United States is not an infringement of his rights.").

³⁵ See 1 Stat. 109 (1790).

³⁶ See U.S. CONST. art. I, § 8, cl. 8 (granting the power to Congress to "Promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries").

³⁷ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.) [hereinafter AIA].

³⁸ See 35 U.S.C. § 1 (2006) (establishing the United States Patent and Trademark Office). See also *id.*, § 2 (vesting the responsibility to grant and issue, and disseminate to the public information regarding, patents); *id.*, § 3–13.

The threshold requirement for patentability is that the subject matter of the patent in question be eligible under section 101.³⁹ If the invention is patentable, it still must satisfy three substantive requirements: novelty,⁴⁰ utility,⁴¹ and non-obviousness.⁴² Even if an invention is novel, useful, and non-obvious, there is no guarantee that a patent will result.⁴³

Once these requirements and other reporting requirements are met,⁴⁴ a patent may be granted.⁴⁵ A U.S. Patent grants the holder right to exclude others from making, selling, or marketing the product within the territory of the United States,⁴⁶ for twenty years from the date of application.⁴⁷ Upon expiration of twenty years from the date of application, a patentee can generally not prevent others from making, using, selling, or marketing the patented item within the territory of the United States.⁴⁸

D. The Indian Patent Law

Indian Patent Law is based on British Patent Law.⁴⁹ Substantively, Indian Patent Law is similar to the United States Patent Law.⁵⁰ In the United States, an

³⁹ See AIA, § 33 (to be codified at 35 U.S.C. § 101) (noting that the AIA prohibits any patents from issuing “on a claim directed to or encompassing a human organism.”).

⁴⁰ *Id.* § 3(b) (to be codified at 35 U.S.C. § 102) (outlining the following requirements for novelty: that “the claimed invention was [not] patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . .”).

⁴¹ *Id.* § 33 (to be codified at 35 U.S.C. § 101) (describing the invention or the improvement as useful).

⁴² See *id.* § 3(c) (to be codified at 35 U.S.C. § 103). The AIA describes the requirement for non-obviousness as follows:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Id.

⁴³ See *id.* § 3(b) (to be codified at 35 U.S.C. § 102) (outlining reasons outside of novelty for a patent application to be rejected).

⁴⁴ See 35 U.S.C. §§ 21–26 (2006); see also 35 U.S.C. §§ 131–67.

⁴⁵ U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 700 et. seq. (8th ed. 8th rev. 8, July 2010).

⁴⁶ See 35 U.S.C. § 154.

⁴⁷ *Id.* The Patent Act also provides for extension of the term of the patent provided that certain conditions are met. *Id.* § 154(b).

⁴⁸ See *id.* § 154.

⁴⁹ See Martin J. Adelman & Sonia Baldia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India*, 29 VAND. J. TRANSNAT’L L. 507, 518–19 (1996) (outlining the history of the development of the Indian Patent Law).

⁵⁰ Compare 35 U.S.C. §§ 101–102 to The Patents (Amendment) Act, No. 38 of 2002, INDIA CODE (2002), § 3 [hereinafter Indian Patent Act of 2002].

invention has to fall under one of the categories of patentable subject matter.⁵¹ In addition, the Indian Patent Law imposes three substantive requirements on inventions in order to be patented:⁵² novelty,⁵³ utility,⁵⁴ and an “inventive step.”⁵⁵

A significant difference between the patent laws of the United States and India is the requirement that a patent be worked within the territory.⁵⁶ Failure to do so may result in the grant of a compulsory license.⁵⁷ After the grant of a compulsory license, it is possible for a patent to be revoked altogether.⁵⁸

E. TRIPS, the PCT, and the Doha Declaration

The content of TRIPS was negotiated from 1986 to 1994 and finally signed on April 15, 1994.⁵⁹ The purpose behind TRIPS is to harmonize the patent laws for member nations.⁶⁰ In addition to patents, the treaty covers copyright, trademark, and other intellectual property rights.⁶¹ TRIPS is enforced by the World Trade Organization (“WTO”).⁶² At its foundation, TRIPS requires member nations to treat

⁵¹ See Indian Patent Act of 2002, § 4 (outlining as unpatentable inventions “the primary or intended use . . . of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment,” as well as a “business method . . . *per se*.”).

⁵² *Id.*, § 3.

⁵³ *Id.*

⁵⁴ *Id.* (defining utility as being “capable of industrial application,” which is further defined as “capable of being made or used in industry.”).

⁵⁵ *Id.* (defining “inventive step” as “a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance.”).

⁵⁶ See Indian Patent Act, § 84 (linking the requirements of affordability and working the patent within the territory of India):

At any time after the expiration of three years from the date of the sealing of a patent, any person may make an application to the Controller for grant of compulsory licence on patent on any of the following grounds, namely: . . .

(b) that the patented invention is not available to the public at a reasonably affordable price, or

(c) that the patented invention is not worked in the territory of India.

Id.

⁵⁷ See Indian Patent Act of 2002, § 84. See also Rajnish Kumar Rai, *Scare of Avian Flu Revisits India: A Bumpy Road Ahead*, 8 PITT. J. TECH. L. & POL'Y. 7, 7 (2008) (noting that India has “one of the broadest and most comprehensive compulsory licensing systems,” going “much beyond national emergency . . . public health . . . and anti-trust situations.”).

⁵⁸ See Indian Patent Act, § 85 (outlining the process for loss of patent right completely):

Where, in respect of a patent, a compulsory licence has been granted, the Central Government or any person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order *revoking the patent* on the ground that the patented invention has not been worked in the territory of India.

Id.

⁵⁹ See TRIPS, *supra* note 6.

⁶⁰ See *id.*, art. 1 (“members shall be free to determine the appropriate method of implementing the provisions of this agreement within their own legal system and practice.”).

⁶¹ See *generally id.*, part II, sec. 1 (covering copyright protection); *Id.*, part II, sec. 2 (covering trademark protection).

⁶² See WTO Agreement, *supra* note 3, art II.

all member nations equally with regards to intellectual property rights.⁶³ TRIPS imposes a patent protection period of 20 years.⁶⁴ Further, it requires member nations to confer the same rights to member nations that they have granted to non-member nations.⁶⁵

TRIPS imposes substantive requirements for patent grants which track the patent laws of the United States and India, among others.⁶⁶ The three substantive requirements are novelty,⁶⁷ an “inventive step”,⁶⁸ and capability of industrial application.⁶⁹ Patentable subject matter is left up to member nations.⁷⁰ Importantly, TRIPS explicitly authorizes compulsory licensing.⁷¹ In addition, it provides certain exclusive rights that shall be conferred with a patent.⁷²

TRIPS is further modified by the Doha Declaration.⁷³ The Doha Declaration was promulgated by the Ministerial Conference on November 14, 2001.⁷⁴ One of the topics discussed at the Doha Ministerial Conference was public health.⁷⁵ The Doha

⁶³ TRIPS, *supra* note 6, art. 3 (describing “national treatment,” article 3 says “each member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property”). The TRIPS agreement goes further, requiring “most-favored nation” treatment for its member nations. *Id.*, art. 4. “Most-favored nation” is defined as follows: “with regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other members.” *Id.*

⁶⁴ *Id.*, art. 33 (setting term of protection at twenty years from the date of filing an application).

⁶⁵ *Id.*, art. 4.

⁶⁶ *Id.*, art. 28.

⁶⁷ *Id.*

⁶⁸ *Id.* (defining the term “inventive step” to be synonymous with “non-obvious”).

⁶⁹ *Id.* (defining the term “capable of industrial application” as synonymous with the term “useful”).

⁷⁰ *Id.*, art. 27 (describing generally the requirements for patentability, and granting member nations the right to exclude from patentability inventions that it would be necessary to prevent in the interest of public order, morality, to protect human life, or to protect the environment).

⁷¹ *Id.*, art. 31 (authorizing the issuance of compulsory licenses, but imposing various safeguards):

[E]ach compulsory license has to be considered on its merits; the proposed user has to have made unsuccessful efforts to obtain authorization on fair terms prior to the grant of the compulsory license, with the exception of the cases of natural emergency or “other situations of extreme urgency;” the scope will be limited to the reason for the grant of the compulsory license; the license will not be exclusive; the license will not be assignable; the license should be terminated when the conditions for its grant cease to exist; the right-holder will be paid; and the grant and terms of the license will be subjected to judicial review.

Id.

⁷² *Id.*, art. 28 (breaking down patent rights conferred by product and process, and conferring the rights to exclude from making, using, offering for sale, selling, or importing, products without the owner’s consent; and conferring the rights to exclude from using the process, and to exclude others from selling, offering for sale, or importing the product obtained by the process in the case of a process patent).

⁷³ See Doha Declaration, *supra* note 7.

⁷⁴ *Id.*; see also WTO Agreement, *supra* note 3, art. IV (describing the make-up of the Ministerial Conference, to consist of representatives of all members, and prescribing that the Ministerial Conferences shall take place at least once every two years).

⁷⁵ *Id.*

Declaration authorizes compulsory licensing in stronger terms than TRIPS, especially as the compulsory licensing pertains to public health.⁷⁶

The Patent Cooperation Treaty ("PCT") is an international treaty governing patent application itself.⁷⁷ Established in 1970, the PCT was most recently revised in 2001.⁷⁸ The PCT provides for an international patent application.⁷⁹ The PCT also provides for international searches.⁸⁰ To accomplish the international application and search, the PCT establishes an international search authority.⁸¹ The application is then reviewed by the international patent review body.⁸² These three treaties and administrative bodies work together to attempt to harmonize the patent process and patent laws around the world.

II. ANALYSIS

This section will first analyze the meaning of the local working provision of the Indian Patent Law, and how this definition is informed by international treaties, decisions, and other sections of the patent law. The section will then analyze the impact of the local working requirement on an American corporation. Finally, this section will analyze the legality of the local working requirement within the TRIPS framework.

⁷⁶ Doha Declaration, *supra* note 7, para. 5 (iterating that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted," and that "each member has the right to determine what constitutes a national emergency"); *see also id.* 7, para. 6 (requiring the Council for TRIPS to devise a solution for countries who have no or insufficient manufacturing capabilities and thus granting compulsory licenses would not help in providing product).

⁷⁷ *See* Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 (amended 2001), available at <http://www.wipo.int/pct/en/texts/pdf/pct.pdf> [hereinafter PCT].

⁷⁸ *Id.*

⁷⁹ *Id.*, art. 3 (describing the requirements of the international application). *See also id.*, art. 4.

⁸⁰ *See id.*, art. 15 (describing the international search process). *See also id.*, art. 16 (describing the international search authority); *id.*, art. 17 (describing the procedure before the international search authority); *id.* art. 18 (describing report generated by the international search authority).

⁸¹ *See id.*, art. 16.

⁸² *See generally id.*, ch. II (regarding the International Preliminary Examination process); *id.*, art. 31 (describing the process by which the preliminary examination is requested); *id.*, art. 32 (describing the body that will be performing the preliminary examination); *id.* art. 33, para. 1 (describing the preliminary examination as being a "non-binding opinion on the questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), and to be industrially applicable."); *id.*, art. 33, paras. 2–4 (describing novel as not anticipated by the prior art; involving an inventive step as being "not, at the prescribed relevant date, obvious to a person skilled in the art;" and industrially applicable as capable of being "made or used . . . in any kind of industry."); *id.*, art. 35 (describing the contents of the preliminary report, and noting that the report will not state whether or not the claimed invention is patentable according to any national law, but will indicate whether it finds each claim to be novel, involve an inventive step, and industrially applicable).

A. The Meaning of “Working in the Territory of India”

The first point to be analyzed is the meaning of section 84 of the Indian Patents Act, requiring that a patent be worked in the territory of India.⁸³ On its face, section 84 does not give any guidance regarding the meaning of local working.⁸⁴ However, taken together with section 89, the local working requirement will not be satisfied by importation alone.⁸⁵ The recent grant of a compulsory license to Natco Pharmaceutical Limited (“Natco”) on one of Bayer’s patented pharmaceuticals confirms this suspicion.⁸⁶ The Controller of Patents granted Natco a compulsory license on Bayer’s patents because, inter alia, the quantities imported by Bayer were “grossly inadequate,” priced out of most Indian patients’ means, and Bayer does not manufacture the drug in India.⁸⁷ The Controller applied the standard, “worked to the fullest extent that is reasonably practicable” to Bayer’s practices,⁸⁸ but only stated this standard at the beginning and the end of his analysis on the local working requirement.⁸⁹ During his analysis of the issue of the local working requirement, the Controller stated that: “[s]ection 83(b) states that patents are not granted merely to enable patentees to enjoy a monopoly for importation of the patented article. Upon a reading of this provision, it becomes amply clear to me that mere importation cannot amount to working of a patented invention.”⁹⁰ Section 27 of TRIPS, however, seems to indicate that this result should not be the case.⁹¹ If read together with article 27 of TRIPS, importation should satisfy the local working requirement of the Indian Patent Law.⁹² India’s Manual of Patent Practice and Procedure (“MPPP”) provides additional guidelines for the patent controller to consider when entertaining an application for a compulsory license.⁹³ Both the Indian Patent Law and the MPPP explicitly recognize that patent rights should not be granted solely for the purpose of importation.⁹⁴ Therefore, the local working requirement within the Indian patent system excludes requires local manufacturing.⁹⁵

⁸³ See Indian Patent Act, § 84.

⁸⁴ *Id.*

⁸⁵ See Indian Patent Act, § 89.

⁸⁶ See Natco Pharma. Ltd. & Bayer Corp. (Mar. 12, 2012) (India).

⁸⁷ *Id.* The Controller found the small volumes of the drug imported into the country to be “neglectful . . . as far as India is concerned.” *Id.* In terms of availability, the Controller found that “the mandate of law is not just to supply the drug in the market but to make it available in a manner such that [a] substantial portion of the public is to reap the benefits of the invention.” *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.* The Controller also found that patentees are “obliged to contribute towards the transfer and dissemination of technology.” *Id.* The only options for a patentee to “work” a patent in India are to manufacture it in India, or to grant a license so that another party can manufacture the invention in India. *Id.*

⁹¹ TRIPS, *supra* note 6, art. 27.

⁹² See Indian Patent Act, § 84. See also, TRIPS, *supra* note 6, art. 27.

⁹³ See Indian Patent Office, Manual of Patent Practice and Procedure (2008) [hereinafter MPPP], available at <http://www.ipindia.nic.in/ipr/patent/manual/main%20link.htm>.

⁹⁴ See TRIPS, *supra* note 6, art. 27 (stating that patent rights shall be enjoyable without discrimination as to the place of invention or the field of technology).

⁹⁵ See Natco Pharma. Ltd. & Bayer Corp. (Mar. 12, 2012). See also MPPP, *supra* note 93; Indian Patent Act, § 89.

B. Is a Local Working Requirement Legal under TRIPS?

The next point to analyze is the legality of India's local working requirement within the TRIPS framework. Article 27 of the TRIPS agreement does not allow discrimination based on the place of invention.⁹⁶ Article 27 also does not allow discrimination based on whether the products are imported or locally produced.⁹⁷ On its face, the TRIPS agreement seems to prohibit a local working requirement which only protects patents that are manufactured within the nation, denying protection to patented products which are only imported into the nation.⁹⁸ However, article 30 also permits limited exceptions to the exclusive rights conferred by grant of a patent.⁹⁹ In addition, article 31 of the TRIPS agreement permits certain uses, such as compulsory licenses, without the authorization of the patent holder.¹⁰⁰

C. Dispute Settlement Board Decisions

The WTO Dispute Settlement Board ("DSB") is the adjudicative body of the WTO that handles disputes.¹⁰¹ To date, the DSB has heard thirty-one cases pertaining to the TRIPS agreement.¹⁰² Ten of the disputes have pertained to article 27 of the TRIPS agreement.¹⁰³ None have pertained to article 30 of the TRIPS agreement.¹⁰⁴ Three have pertained to article 31 of the TRIPS agreement.¹⁰⁵ The United States brought forward six of the ten disputes pertaining to article 27.¹⁰⁶

In DS196,¹⁰⁷ the United States alleged that Argentina did not include safeguards while granting of compulsory licenses on the basis of inadequate working.¹⁰⁸ This dispute was ultimately not decided by the DSB, as both the United

⁹⁶ See TRIPS, *supra* note 6, art. 27.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*, art. 30 (allowing members to provide "limited exceptions" to the rights conferred by patents, provided that the exceptions don't unreasonably interfere with "normal exploitation of the patent" and do not "unreasonably prejudice the legitimate interests of the patent owner," all while taking into account the legitimate interests of third parties).

¹⁰⁰ *Id.*, art. 31 (allowing "other use without authorization of the right holder," subject to limitations such as unassignability, non-exclusivity, and a hearing on the merits of the request).

¹⁰¹ See WTO Agreement, *supra* note 3, art. IV.3 (establishing the Dispute Settlement Body of the World Trade Organization). See also *id.*, annex 2 (describing the authority granted to the DSB, describing the consultation process, and describing the makeup of the DSB and general provisions concerning the DSB). See also THOMAS A. ZIMMERMAN, NEGOTIATING THE REVIEW OF THE WTO DISPUTE SETTLEMENT UNDERSTANDING (2006).

¹⁰² See *Dispute Settlement: Index of Disputes by Agreement Cited*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#selected_agreement (last visited June 5, 2012) (listing all disputes made citing the TRIPS agreement).

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ See *Argentina – Certain Measures on the Protection of Patents and Test Data (U.S. v. Argentina)*, Dispute DS196 (WT/DS196/1) (June 6, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds196_e.htm.

¹⁰⁸ *Id.* The complaint alleged that Argentina violated its TRIPS obligations on numerous grounds, including failure to protect unfair uses of data that must be disclosed as part of regulatory

States and Argentina mutually agreed that Argentina's compulsory licensing provisions were compliant with TRIPS.¹⁰⁹

Two disputes were brought relating to the same transaction. DS408, lodged by India against members of the European Community, had to do with seizure of infringing articles at ports in Europe, and has not yet been decided by the DSB.¹¹⁰ DS409 is part of DS408, but was brought forward by Brazil, with respect to generic drugs imported from India.¹¹¹ Both DS408 and DS409 have been joined by Brazil, Canada, China, Ecuador, Japan, and Turkey.¹¹²

In 2000, the DSB had occasion to make a decision on whether local working requirements are legal within the TRIPS framework.¹¹³ The United States disputed a provision in Brazil's patent law requiring local working of patents in Brazil in DS199.¹¹⁴ The DSB ultimately did not have to make a decision on the complaint made by the United States, as Brazil and the United States resolved the dispute among themselves and the United States withdrew the complaint.¹¹⁵ The United States and Brazil, however, did agree that Brazil would confer with the United States prior to making compulsory licensing decisions that affected corporations from the United States.¹¹⁶

The DSB also had occasion to declare how far TRIPS article 30 extends in 1997, with DS114.¹¹⁷ Canada's patent laws provided that pharmaceutical producers could use products patented by others for regulatory purposes, such as obtaining approval

approvals; improperly excluding microorganisms from patentability; failure to provide for preliminary injunctions to prevent infringement during trial; failure to protect product-by-process patents and the exclusive right of importation; failure to provide safeguards in granting compulsory licenses, particularly those granted for failure to work the patent; shifting the burden of proof in civil proceedings improperly; and failing to provide adequate protection for certain transitional applications. *Id.*

¹⁰⁹ See *id.* (including both DS171 and DS196 in the same mutually agreed upon compromise).

¹¹⁰ See European Union and a Member State – Seizure of Generic Drugs in Transit (India v. E.U.), Dispute DS408 (WT/DS408/1) (May 19, 2010), *available at* [www.worldtradelaw.net/cr/ds408-1\(cr\).pdf](http://www.worldtradelaw.net/cr/ds408-1(cr).pdf). India alleges that the European Union, and the Netherlands in particular, have been seizing shipments of generic drugs traveling through their ports on patent infringement grounds. *Id.* India alleges that these seizures are inconsistent with the 2003 Decision on TRIPS and Public Health. *Id.*

¹¹¹ See European Union and a Member State – Seizure of Generic Drugs in Transit (Brazil v. E.U.), Dispute DS409 (WT/DS409/1) (May 19, 2010), *available at* [www.worldtradelaw.net/cr/ds409-1\(cr\).pdf](http://www.worldtradelaw.net/cr/ds409-1(cr).pdf). Brazil's complaint mirrors India's complaint. *Id.* However, Brazil's complaint differs in that it places itself and "third countries" as the eventual recipients of the generic drugs originating in India. *Id.*

¹¹² See European Union and a Member State – Seizure of Generic Drugs in Transit (India v. E.U.), Dispute DS408 (WT/DS408/8) (June 18, 2010), *available at* http://trade.ec.europa.eu/doclib/docs/2011/january/tradoc_147471.pdf (noting the European Union's acceptance of Canada, China, Ecuador, India, Japan, and Turkey to join the consultations).

¹¹³ See Brazil – Measures Affecting Patent Protection (U.S. v. Brazil), Dispute DS199 (WT/DS199/1) (June 8, 2000), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ See Canada – Patent Protection of Pharmaceuticals (E.C. v. Canada), Dispute DS114 (WT/DS114/1) (Jan 12, 1998), *available at* http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm [hereinafter Canada 1998].

for a generic.¹¹⁸ In addition, the patent laws provided for a “stockpiling” exception to the patent protection on making and using another’s patented invention six months prior to expiration of the patent.¹¹⁹ During this dispute, the DSB found that the grant of compulsory licenses is subject to the section 27 requirement that prohibits discrimination based on place of invention.¹²⁰ Furthermore, the DSB accepted both Canada’s and the European Union’s advanced definitions of working the patent, which included sale and licensing of patented items.¹²¹

Although many disputes that made their way through the DSB were ultimately resolved outside of the dispute process, two of the cases contain information useful in determining whether India’s local working requirement is legal under TRIPS.¹²² Applying the definition put forward by both Canada and the European Union in DS114, a requirement of local working of a patent which encompasses selling locally would not literally violate of the TRIPS agreement.¹²³ However, continuing with the DSB’s further statements, that article 27 prohibits discrimination as to whether products are imported or produced locally, appears to definitively rule that local working requirements which limit the definition of local working to manufacturing are against TRIPS.¹²⁴ The board goes one step further, inferring that the text of article 27.1 implies that a local working provision may go against the spirit of the TRIPS agreement.¹²⁵ So, according to the DSB history, a local working requirement would probably not comply with the letter or the spirit of the TRIPS agreement.¹²⁶

¹¹⁸ *Id.* The contested provision of the Canadian patent law permitted a third party to use a patented invention to carry out tests required for marketing approval of a patented pharmaceutical prior to the expiration of the patent, without the rights-holder’s consent. *Id.*

¹¹⁹ *Id.* The contested provision of the Canadian patent law permitted a third party to stockpile the patented item for six months prior to the expiration of the patent. *Id.* The third party would then be able to sell the now off-patent item immediately upon expiration of the patent. *Id.*

¹²⁰ *See id.* The panel went on to say, “article 27.1 prohibits discrimination as to enjoyment of ‘patent rights’ without qualifying the term,” and continues, saying, “the acknowledged fact that the [a]rticle 31 exception for compulsory licences and government use is understood to be subject to the non-discrimination rule of 27.1.” *Id.*, at 170.

¹²¹ *See* Canada – Patent Protection of Pharmaceuticals (E.C. v. Canada), Dispute DS114 (WT/DS114/R) (Mar. 17, 2000), available at www.wto.org/english/tratop_e/dispu_e/7428d.pdf [hereinafter Canada 2000].

¹²² *See* Brazil, *supra* note 113; Canada 1997, *supra* note 117.

¹²³ *See* Canada 2000, *supra* note 121.

¹²⁴ *Id.* The panel stated, “article 27 prohibits only discrimination as to the place of invention, the field of technology, and whether products are imported or produced locally.” *Id.*, at 172.

¹²⁵ *See id.* Speaking specifically on discrimination as to the field of technology, the panel stated that “to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain . . . national policies . . . that fact may well constitute a *deliberate limitation rather than a frustration of purpose*.” *Id.* at 171 (emphasis added). The panel went further, saying that “it is quite plausible, as the EC argued, that the TRIPS agreement would want to require governments to apply exceptions in a non-discriminatory manner, in order to ensure that governments do not succumb to domestic pressures to limit exceptions to areas where right holders tend to be foreign producers.” *Id.* at 171.

¹²⁶ *See* India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, Dispute DS79 (E.U. v. India) (WT/DS79/R) (1996), available at www.wto.org/english/tratop_e/dispu_e/79r.pdf (stating that DSB decisions are not binding on subsequent panels, but may be considered).

D. Impact of Local Working Requirement on Patented Inventions

The final point to be analyzed is the effect of the Controller of Patents' interpretation of the local working requirement on the different phases of an American corporation's product. Since importation will not satisfy the local working requirement, three years after grant of the patent, a party will be able to successfully obtain a compulsory license if a foreign company's only commercial activity in India consists of importing the patented good.¹²⁷ That local party could successfully seek and obtain a compulsory license on the foreign company's patent while it is still importing its product and prior to beginning manufacturing operations in India, provided that it has not commenced manufacturing operations within three years of grant of the patent. If, however, importation does satisfy the local working requirement, a foreign company will be able to defend the patented item from compulsory licensing.¹²⁸ The Controller of Patents' current interpretation of India's local working requirement seems to be violative of India's TRIPS commitments. However, TRIPS is a treaty that is based on compliance.¹²⁹ As such, it is not guaranteed that the Indian patent office will interpret the TRIPS provisions or its own patent law in compliance with TRIPS. Therefore, it is most likely that the foreign company will lose its patent rights to an applicant for a compulsory license after three years pass and it is still only importing its product, with the possibility of complete loss of right after an additional two years. Clarification of India's patent provision requiring local working will help the foreign company understand its rights over its patents in India.

III. PROPOSAL

The TRIPS framework has been a part of international law for approximately ten years.¹³⁰ In addition, India's patent amendments bringing the Indian Patent Law into compliance with TRIPS have been in effect for the past five years.¹³¹

TRIPS is a living document, as evidenced by the modifications that are in the process of ratification embodied in the Doha Declaration.¹³² A good way to put pressure on India¹³³ to make the country more open to outside investment in the patent system would be a change to the TRIPS agreement itself. Such a change will clarify the expectations of foreign companies seeking to invest in India. A working framework for determining the appropriateness of granting a compulsory license would serve to encourage foreign companies to apply for patents and conduct business in India. In addition, modifying the TRIPS agreement will impact all

¹²⁷ See Indian Patent Act, § 84.

¹²⁸ See, e.g., Canada 2000, *supra* note 121.

¹²⁹ See TRIPS, *supra* note 6, art. 1 (giving members the authority to implement whatever methods they deem appropriate to come into compliance with the TRIPS agreement).

¹³⁰ See *id.* (noting signed date of Apr. 15, 1994).

¹³¹ See Indian Patent Act 2005 (noting signed date of Apr. 5, 2005).

¹³² See Doha Declaration, *supra* note 7 (noting adoption date of Nov. 14, 2001).

¹³³ And other countries which have compulsory licensing procedures centered around local working requirements.

member nations, and provide some of the same by-products as those provided to India.

First, a clause in TRIPS defining local working will be part of an appropriate solution to the ambiguity surrounding TRIPS' stance on the local work requirement. The definition of local working should be satisfied by on-shore manufacturing, as well as importing, licensing to import, licensing to manufacture, and licensing to sell within the country.¹³⁴ By defining local working within the TRIPS agreement, individual signatories will be unable to dispute the legality of a local working requirement imposed by another nation, and individual signatories will also be forced to adhere to a single interpretation of the meaning "worked in the territory." This will give a certain degree of confidence to foreign inventors when choosing to pursue patent applications in countries that have local working requirements.

The second requirement would be a clause in TRIPS requiring countries granting compulsory licenses to first confer with the government of the corporation's home country and report to an international review board prior to granting a compulsory license.¹³⁵ This would give both countries an equitable forum in which to voice concerns.¹³⁶

This would be an appropriate solution for a number of reasons. First, requiring a "face-to-face" meeting between the two countries most interested in the protection or exercise of the patent would strike a balance between the interests of the two countries. Coupling this with reporting to a review board would place a check on countries with disparate bargaining power exerting excessive influence on others. Both countries would have an opportunity to voice concerns over why the rights should continue to be protected as monopoly rights, and what public interests play into the request for a compulsory license. Second, the review process would further the stated mission of the TRIPS agreement, which was established to "reduce distortions and impediments to international trade."¹³⁷ Third, requiring a bilateral review of compulsory licensing requests would force an international dialogue

¹³⁴ This amendment would be most appropriate as part of article 27 of the TRIPS agreement, immediately at the end of section 1, and should read as follows:

A patent will be considered to be worked within a territory if it is manufactured within the territory, sold within the territory, licensed for sale within the territory, licensed for manufacture within the territory, or imported to the territory.

¹³⁵ The proposed amendment will modify article 31 of the TRIPS agreement, and add the following language:

(m) when the rights holder is the national of another signatory nation, the nation seeking to grant the compulsory license must confer with the home nation of the rights holder prior to such use.

and

(m)(i) the results of such conferences will be reported to the Council on TRIPS.

(m)(ii) the Council on TRIPS will review the conference records annually.

¹³⁶ See Brazil, *supra* note 113.

¹³⁷ See TRIPS, *supra* note 6, preamble (noting that the TRIPS agreement desires to "reduce distortions and impediments of trade," a "need to promote effective . . . protection of intellectual property rights," and that the "procedures to enforce intellectual property rights do not . . . become barriers to . . . trade"). See also *id.*, art. 7 (indicating that "intellectual property rights should contribute to the promotion of . . . innovation and . . . transfer and innovation of technology," "to the mutual advantage of producers and users . . . conducive to social and economic welfare.") (emphasis added).

between nations that would have the potential to further the underlying policy behind TRIPS.¹³⁸ Fourth, there is international precedent already existing in the accords reached between the United States and Brazil on this same requirement, founded upon Brazil's local working requirement and establishing that the two countries will confer with one another when granting compulsory licenses on patents belonging to persons originating in the other.¹³⁹ Also, adding a requirement that the countries confer with one another prior to granting compulsory licenses, and provided that countries do in fact follow this process, will create a body of international records that will help to inform parties when making decisions to patent overseas. Finally, requiring that conference results be reported to the WTO for review will get an extra set of eyes looking at the final agreement, which will potentially help develop future policy regarding compulsory licensing.

This change to the TRIPS framework, however, cannot be implemented without overcoming a number of obstacles. The first issue confronting a proposed change to TRIPS is the history behind the drafting of TRIPS.¹⁴⁰ During the negotiation of the TRIPS agreement, the local working requirement, in particular, was hotly contested between different nations who had alternate approaches to a local working requirement and different national interests.¹⁴¹ In addition to the substance, the particular wording will become an issue with one hundred and fifty three signatory nations being a party to the TRIPS agreement.¹⁴²

The second hurdle that an amendment to TRIPS will face is a procedural hurdle: the requirement that two thirds of the signatory parties must ratify an amendment to TRIPS.¹⁴³

This sets up the third obstacle, which is brought about by the nature of the TRIPS agreement: actual implementation.¹⁴⁴ India, for example, took almost ten years between signing onto the TRIPS agreement and implementing all of its requirements.¹⁴⁵

The fourth issue facing any amendments to the TRIPS agreement is the existence of competing domestic interests of the individual signatories.¹⁴⁶ A developed country and a developing country will have different objectives and interests involving patent rights, particularly as countries get closer to the opposite ends of the spectrum.

¹³⁸ *Id.*

¹³⁹ See Brazil, *supra* note 113.

¹⁴⁰ See, e.g., Paul Champ & Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S. - Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 373–80 (2002) (describing the negotiation process).

¹⁴¹ *Id.*

¹⁴² See WORLD TRADE ORG., <http://www.wto.org> (follow the hyperlink titled "153 members" for a list of all 153 member countries).

¹⁴³ See WTO Agreement, *supra* note 3.

¹⁴⁴ See TRIPS, *supra* note 6, art. 1 (noting that "members shall give effect to the provisions of [TRIPS]"); see also *id.*, art. 8 (noting that members can adopt "measures necessary to protect public health").

¹⁴⁵ See Indian Patents Act of 2005.

¹⁴⁶ A very wealthy country, for example, will have drastically different concerns in the area of intellectual property rights, from a very poor country struggling to feed its citizenry.

A fifth obstacle is rooted in the legislative history behind TRIPS itself.¹⁴⁷ A consensus was not reached during the Uruguay round with regards to the inclusion or exclusion of a local working requirement.¹⁴⁸ It is possible that this same deadlock will face the WTO as it attempts to amend the text of the TRIPS agreement to make it more difficult for countries to grant compulsory licenses.¹⁴⁹ In addition, a change requiring that two nations meet and report the meeting to the WTO will likely meet similar criticism to that met by the Doha declaration, namely that the requirements are too onerous to pursue a compulsory license.¹⁵⁰

Despite these obstacles, an amendment to TRIPS still appears to be the best solution to address the concerns of foreign companies who are trying to develop global marketing or outsourcing plans. The problems presented by amendment to an international treaty like TRIPS are surmountable if the WTO dedicates itself to negotiation and resolution of the amendment, and potential catching points are outweighed by the benefits. Many companies which want to conduct business in India will want to know what they are getting into before embarking on its plan to develop, manufacture, and sell products in India. In addition to understanding the patent laws of India, having the relevant provisions pertaining to the company's rights and knowing that there is a safety valve in case of an application for compulsory license will serve to assure similarly situated corporations that their patented inventions will be protected outside of the United States, and in turn, to increase their investment in countries like India.

IV. CONCLUSION

In the past fifteen years, TRIPS became a part of international law and signed on to by one hundred fifty-three countries.¹⁵¹ The United States and India are two

¹⁴⁷ See Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania, Uruguay, and Pakistan, part II, chap. II, art. 5, GATT Doc. MTN.GNG/NG11/W/71 (May 14, 1990), available at http://www.wto.org/gatt_docs/English/SULPDF/92100147.pdf.

¹⁴⁸ See Champ & Attaran, *supra* note 140, at 373–80 (describing the negotiation process).

¹⁴⁹ This is based on using the legislative history as a real-world example of the negotiating process and an assumption that the competing interests of signatory nations will fall along similar lines to the original WTO and TRIPS negotiations.

¹⁵⁰ See *Little-used 'Par.6' System Will Have its Day*, WORLD TRADE ORG., http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm (last visited June 5, 2012) (describing proceedings at October 26-27 TRIPS Council meeting). Only one case has been reported since the Doha declaration and ensuing years, with Canada being the exporter and Rwanda being the importer. *Id.* Canada presented its experience implementing the system and in practice in that one instance during the meeting. *Id.* A number of countries at the meeting criticized the system as overly burdensome. *Id.* India chimed in with an account regarding a recent experience with compulsory licensing under the Paragraph 6 exception as well. *Id.* India's contribution reflected that an Indian company had sought compulsory licenses in order to export pharmaceuticals to Nepal. *Id.* Ultimately, however, the company dropped its request for the compulsory license. *Id.* According to the Indian representative, the company dropped its request for a compulsory license because Nepal "found the conditions for using the system too onerous to proceed." *Id.*

¹⁵¹ See WORLD TRADE ORG., <http://www.wto.org> (follow the hyperlink titled "153 members" for a list of all 153 member countries).

innovating nations with large populations that signed on to the TRIPS agreement.¹⁵² In its Patent Law, India has included a provision requiring that patents be worked within the territory of India, or on sale at a reasonable price.¹⁵³ The legality of a local working requirement was heavily contested during the drafting of the TRIPS agreement,¹⁵⁴ and the United States has gone on to dispute the legality of more than one country's local working requirement since the TRIPS agreement was finalized and adopted.¹⁵⁵ In addition to the local working requirement, the Indian Patent Law has substantive differences from the patent law of the United States.¹⁵⁶ This creates uncertainty for foreign inventors in India at the outset because a patentable invention elsewhere may not be patentable in India. In addition, the potential penalty for failing to work a patent in India is the grant of a compulsory license.¹⁵⁷ This compulsory license may ripen into a permanent revocation of the patentee's patent rights. A revision to the TRIPS agreement, within the spirit of the agreement, will be important in order to guarantee further clarity in the rights of parties such as Megatech Corporation seeking to patent inventions in India as well as other countries with similar provisions in their patent laws.

¹⁵² *Id.* The United States and India are among the countries that became members on January 1, 1995. *Id.*

¹⁵³ See Indian Patents Act 2005, § 84(c) (outlining the local working requirement).

¹⁵⁴ See, e.g., Champ & Attaran, *supra* note 140, at 373–80 (describing the negotiation process).

¹⁵⁵ See Brazil, *supra* note 113 (describing the dispute brought by the United States and the accord reached by the United States and Brazil to terminate the dispute). See also, Champ & Attaran, *supra* note 140, at 373–80.

¹⁵⁶ See, e.g., Indian Patent Act, § 3 (requiring “increased efficacy” for patentability).

¹⁵⁷ See generally, *id.*, § 84 (outlining possible reasons for granting compulsory licenses, including the failure of a patent be worked in the territory of India, unavailability of the patented item in India for a “reasonably affordable price,” and lack of meeting the requirements of the public). See also, The Patents Act 2005, § 92 (enabling the grant of compulsory licenses for export of pharmaceuticals to countries that are unable to do so, as authorized by the Doha Declaration); *id.* § 89 (outlining factors that the patent controller should take into account when considering a section 84 application for compulsory license, including the nature of the invention, the amount of time that has passed since the patent issued, and the actions taken by the patentee in attempting to work the patent in the territory of India).