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Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Damaging to the United States Healthcare Industry

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RENEWING HEALTHY COMPETITION: COMPULSORY LICENSES AND WHY ABUSES OF THE TRIPS ARTICLE 31 STANDARDS ARE MOST DAMAGING TO THE UNITED STATES HEALTHCARE INDUSTRY

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I. Introduction	119
II. Background and Overview of Compulsory Licenses	121
A. The Modern Patent System	121
B. Compulsory Licenses	123
III. Implications of Compulsory Licensing to the United States	128
A. Creating an Environment for Innovation.....	128
B. Bilateral Investment Treaties and the United States	130
C. Need for Better Governance of Compulsory Licenses	132
IV. Recent Uses of Compulsory Licenses and How Article 31 <i>bis</i> Application Could Prove to be Particularly Harmful.....	134
A. Recent Uses	134
B. Significance of Article 31 <i>bis</i>	137
V. Suggested Reformation of Article 31 and Potential Claims for Indirect Expropriation under Bilateral Investment Treaties	139
A. Alternatives to Compulsory Licenses.....	140
B. Recommendations: WTO Amendments	141
C. The Use of Bilateral Investment Treaties for United States Investors Abroad	143
i. General Considerations	143
ii. Practical Guidance for Investors	147
VI. Conclusion	149

I. INTRODUCTION

Imagine you are the owner of a large pharmaceutical company in the United States. You have spent enormous amounts of money and time in developing a new and useful drug. Patent ownership provides protection for your business so that as your company grows, you have more money to invest in research and development of new drugs. To your surprise, you find that you are slowly losing control of your patent because you are being forced by foreign governments to allow others to use

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your patented products without your consent. As a result, profits are diminished and control of your product weakened. This is an example of what results when governments abusively issue compulsory licenses. Regardless of how one thinks healthcare within the United States should be provided for, in the area of healthcare innovation, the United States has contributed more than any other country.² Because of this fact, the United States healthcare industry stands to be disproportionately burdened unless changes are made to international compulsory licensing procedures and investors start critically analyzing the policies of the countries where they choose to invest.

A compulsory license is a controversial legal instrument, which provides a unique exception to copyright law. Essentially, a compulsory license is an involuntary contract between a willing buyer and an unwilling seller, which is enforced by a state government.³ Generally under a compulsory license, authorization is given to a manufacturer to produce a patented product without the patent-holder's permission.⁴ This severe limitation on the rights of patent holders has increasingly been used in the health care arena by countries wishing to produce pharmaceuticals at a reduced cost in the name of public health.⁵ With the addition of an amendment ("Article 31bis") to the World Trade Organization ("WTO") framework,⁶ developed countries are now allowed to grant compulsory licenses to domestic manufacturers who can then export pharmaceuticals to developing countries – one of the main problems that patent systems are designed to protect against.⁷ While compulsory licenses may be needed in dire situations, there is a risk that vague language within compulsory licensing law will allow the system to be misused and abused. Ultimately, the United States pharmaceutical industry will absorb the greatest burden.

With that in mind, this note will examine why the international compulsory

² JOSEPH DiMASI, THE TRUTH ABOUT DRUG INNOVATION: THIRTY-FIVE SUMMARY CASE HISTORIES ON PRIVATE SECTOR CONTRIBUTIONS TO PHARMACEUTICAL SCIENCE (2008), available at http://www.manhattan-institute.org/html/mpr_06.htm (noting that from 1982-2003 American drug makers produced a greater number of first-in-class drugs than European producers, despite Europe's larger population).

³ See Gianna Julian-Arnold, *International Compulsory Licensing: The Rationales and The Reality*, PTC Research Foundation of the Franklin Pierce Law Center, IDEA: J.L. & TECH. (1993); Carlos M. Correa, *Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?* (Aug. 2004), <http://www.grain.org/briefings/?id=186> ("A compulsory license is an authorization given by the government for the use by a third party, without consent of the right holder, of a patent or other intellectual property rights"); Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 283 n.1 (2008) ("The term 'compulsory license' can refer to any compelled relaxation of an intellectual property owner's right to exclude in exchange for a licensee's payment").

⁴ See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 133 (2008).

⁵ See Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT'L L. 331 (2004).

⁶ See Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73 (2004) (the November 2001 Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001. It reaffirmed flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines.).

⁷ See *id.*

licensing failures will disproportionately effect the United States pharmaceutical industry in the future, why more comprehensive and defined guidelines for implementation are needed, and how pharmaceutical companies can protect themselves using bilateral investment treaties. To this end, Section I provides a general description of intellectual property rights as they currently exist worldwide. Next, Section II provides an overview of the WTO compulsory licensing scheme and its amendment, Article 31*bis*. Section III explores the implications specific to American pharmaceutical companies. Against this backdrop, Section IV outlines the recent uses of compulsory licenses that have been harmful to pharmaceutical businesses in the United States, and how Article 31*bis*'s application could be abused. Finally, Section V will provide general policy suggestions for making amendments that will allow for increased protection of patent rights, and how bilateral investment treaties can be used as an alternative means of settling disputes for American companies investing abroad.

II. BACKGROUND AND OVERVIEW OF COMPULSORY LICENSES

A. *The Modern Patent System*

While organized patent systems are relatively modern developments, the basic rights trace back hundreds of years and were first recognized in 15th century Venice as an essential innovation in property law.⁸ Today, the patent system in the United States is given effect by the Constitution.⁹ Article I, Section 8, authorizes Congress to grant exclusive rights to authors and inventors for their respective discoveries for a limited time.¹⁰ A patent in the United States, grants the patent holder a twenty-year monopolistic right over his invention, during which time no one, absent authorization by the patent holder, may make, use, or sell the patented product.¹¹ In exchange for this exclusive right, the patent holder pays his due to society by disclosing the technical specifications relating to how the invention was created, and at the end of the twenty-year period, the protection expires allowing the patented invention to enter the public domain for open production and non-exclusive use.¹²

Outside of the United States, many countries have similar patent protections, the enforcement of which is governed by national laws and international treaties.¹³ Most businesses from the United States making investments in foreign countries rely on national patent laws, bilateral investment treaties ("BITs"), and other international investment agreements, including the WTO, to protect private investments.¹⁴ Most BITs provide a comprehensive listing of the types of

⁸ See ROBERT P. MERGES ET AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 118 (4th ed. 2007).

⁹ See *id.*

¹⁰ U.S. CONST. art. I, § 8, cl. 8 (authorizing Congress to "promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").

¹¹ See MERGES ET AL., *supra* note 8, at 118.

¹² See *id.*

¹³ See *id.*

¹⁴ *Id.*

protected intellectual property as well as detailed arbitration clauses.¹⁵ However, the extent to which rights guaranteed through BITs are actually enforced and protected is unclear as there has yet to be a publicly reported decision concerning an intellectual property right protected within a BIT.¹⁶ Nonetheless, as foreign investments and the number of treaties increase, future arbitration in this area is inevitable.¹⁷ In our increasingly globalized world, intellectual property, especially in the realm of pharmaceuticals, has become a huge business.¹⁸ Indeed, it has been suggested that international patent rights “have never been more economically and politically important . . . than they are today.”¹⁹

In the area of foreign direct investment intellectual property rights empower pharmaceutical companies with the legal protection required to stay profitable in foreign markets.²⁰ The exclusivity provided by the patent is unique in its ability to protect foreign investors from illegal copying, and is therefore essential for pharmaceutical companies investing abroad.²¹ One commentator observed that for a single drug to enter the market, an average of one billion dollars is spent first in research and development.²² The cost of production, distribution, and marketing of a drug usually pales in comparison to this front-end investment making the pharmaceutical industry particularly vulnerable to patent infringement and compulsory licensing.²³ Having the ability to leverage a product through patent protection is essential for pharmaceutical companies who rely primarily on innovative research and development to stay competitive.²⁴

¹⁵ In most BITs, the term “investment,” incorporates almost any kind of business related activity. See Mahnaz Malik, *Recent Developments in the Definition of Investment in International Investment Agreements*, available at www.iisd.org/pdf/2008/dci_recent_dev.pdf.

¹⁶ Correa, *Investment Protection*, *supra* note 5, at 352; Tsai-Yu Lin, *Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements – Are There Issues Beyond the TRIPS Agreement?*, 40 INT’L REV. INTELL. PROP. & COMPETITION L. 152 (2009) (noting that to date “no claim regarding compulsory licenses has been brought before investor-state arbitration and led to an arbitral award”).

¹⁷ *Id.*

¹⁸ See Correa, *Investment Protection*, *supra* note 5, at 333.

¹⁹ FREDERICK M. ABBOTT, UNCTAD-ICTSD PROJECT ON IPRs AND SUSTAINABLE DEVELOPMENT, INTELLECTUAL PROPERTY PROVISIONS OF BILATERAL AND REGIONAL TRADE AGREEMENTS IN LIGHT OF U.S. FEDERAL LAW, Issue Paper No. 12 (Feb. 2006).

²⁰ See Antony Taubman, *Rethinking TRIPS: ‘Adequate Remuneration’ for Non-Voluntary Patent Licensing*, 11 J. INT’L ECON. L. 927, 937 (2008).

²¹ Christopher S. Gibson, *Globalization and the Technology Standards Game: Balancing Concerns of Protectionism and Intellectual Property in International Standards*, 22 BERKELEY TECH. L.J. 1403, 1428 (2007) (explaining the importance of patent protection for businesses whose primary product is rooted in intellectual property).

²² Ronald A. Cass, *Compulsory Licensing of Intellectual Property: The Exception that Ate the Rule?* 16-17 (D.C. Legal Found., Working Paper Series No. 150, 2007), available at <http://www.wlf.org/upload/casswpCover.pdf>.

²³ See *id.*; Richard J. Hunter, *Compulsory Licensing: A Major Issue in International Business Today?*, 11 EUR. J. SOC. SCI. 370 (2009) (noting that because of the increasing complexity of the chronic and degenerative diseases that have become the main targets of pharmaceutical research and development, it now takes an average of ten to fifteen years to bring a new drug from the laboratory to market, at a cost of more than \$500 million); see also Daniel Benoliel & Bruno Salama, *Towards an Intellectual Property Bargaining Theory: The Post-WTO Era*, 32 U. PA. J. INT’L L. ____ (forthcoming Fall 2010) (explaining that “[t]he pharmaceutical industry is [a] prototypical patent-sensitive industry”).

²⁴ See Hunter, *supra* note, 23 at 371.

B. Compulsory Licenses

A compulsory license provides a government with the authority to exercise one or more of the exclusive rights without having to obtain the patent holder's permission to do so.²⁵ The use of compulsory licensing has been recognized internationally for more than 125 years, however in recent years there has been a distinct expansion in scope.²⁶ The Paris Convention, dating from 1883,²⁷ first recognized compulsory licensing as a means to address the abusive exercise of patent rights on "failure to work" grounds, thereby justifying issuance in limited cases.²⁸ Through a compulsory license, a government authority interferes directly with a privately owned patent to authorize its use by the government or by one or more third parties, subject to certain terms.²⁹ For example, a compulsory license might be issued by a government agency with conditions, such as removing restrictions on the use for which the license is authorized, specifying which third parties are entitled to use the patent, imposing time restrictions on the use, and

²⁵ See Cahoy, *supra* note 4, at 133.

²⁶ ADRIAN JOHNS, *PIRACY: THE INTELLECTUAL PROPERTY WARS FROM GUTENBERG TO GATES* 274 (University of Chicago Press 1st ed. 2009) (noting that while the idea of compulsory licensing "seems to have originated as a serious proposition in the 1830s . . . [its] predecessors can be traced back into the eighteenth century").

²⁷ MERGES ET AL., *supra* note 8, at 120; Paris Convention for the Protection of Industrial Property art. 5(A), Mar. 20, 1883, 21 U.S.T. 1538 provides that:

- (1) Importation by the patentee into the country where the patent has been granted of articles manufactured in any of the countries of the Union shall not entail forfeiture of the patent.
- (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.
- (3) Forfeiture of the patent shall not be provided for except in cases where the grant of compulsory licenses would not have been sufficient to prevent the said abuses. No proceedings for the forfeiture or revocation of a patent may be instituted before the expiration of two years from the grant of the first compulsory license.
- (4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license.

Id.

²⁸ Paris Convention for the Protection of Industrial Property art. 5(A), Mar. 20, 1883, 21 U.S.T. 1538. The Paris Convention originally sought to prevent the patentee from denying public access to novel intellectual property, where to withhold such information would be unreasonable or contrary to public policy. *Id.* Under Article 5 of the Paris Convention, an applicant could apply for a nonexclusive, nontransferable compulsory license for the use of an invention in the public interest on the grounds of "failure to work" or "insufficient working" before the expiration of three years from the date of application for the patent, or four years from the date of the grant of the patent whichever period expires last. *Id.* However, the Paris Convention allowed a compulsory license application to be denied if the patentee justifies his inaction by legitimate reasons. *Id.*

²⁹ Cahoy, *supra* note 4, at 133.

specifying payment of compensation to the IP owner.³⁰ The purpose of a compulsory license, in the pharmaceutical context, is presumably to increase access to essential medicines by providing a broader use of the invention than intended by the original patent holder.³¹ As a result however, the patent holder is forced to give up a large amount of control of the patent for the alleged benefit of the larger public.³²

Despite the centrality of exclusive rights within the intellectual property system, the compulsory license claims to provide a safety valve for occasions where there is an overriding public interest.³³ The compulsory license thus enables a government to make an exception to the exclusive protection by allowing usage of the patent for itself or a third party on certain conditions it deems appropriate.³⁴ Given the powerful nature of compulsory licenses, it is easy to see that if misused, there is a potential threat to the security of private property, as well as innovation.³⁵ In this regard, a compulsory license can be compared to a governmental taking of real property by use of eminent domain power as seen in the United States Supreme Court decision *Kelo v. City of New London*.³⁶ Like a governmental taking, a compulsory license can considerably erode the confidence in private property and protected innovations.³⁷

The use of a compulsory license often triggers WTO trade law considerations. Most of the scholarly commentary concerning the use of compulsory licensing has focused on international trade laws and public health issues.³⁸ The most relevant commentary is focused on the WTO's Trade-Related Aspects of Intellectual Property Agreement ("TRIPS Agreement"), which sets conditions for the issuance of a compulsory license in Article 31.³⁹ Additionally,

³⁰ See Taubman, *supra* note 20, at 947.

³¹ Correa, *Investment Protection*, *supra* note 5, at 331.

³² Cahoy, *supra* note 4, at 141-42.

³³ See Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

³⁴ See *id.*

³⁵ See Gibson, *supra* note 21, at 1-3 (an expansion of interference by a government polity through compulsory licensing has the potential to substantially diminish security in intellectual property rights).

³⁶ *Kelo v. City of New London*, 545 U.S. 469 (2005). In *Kelo*, the Supreme Court ruled that state and local governments should be given broad deference in deciding to take private property to use for private economic development projects. *Id.*

³⁷ Cass, *supra* note 22, at 2 (comparing the government interference in private property to the effects of indirect expropriation through the use of a compulsory license and noting that "the security of private property is substantially reduced if government can take it by force for any and every use the authorities want").

³⁸ See, e.g., Sandra Bartelt, *Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health*, 6 J. WORLD INT'L PROP. 283 (2003); KOMMERSKOLLEGIUM SWEDISH NATIONAL BOARD OF TRADE, THE WTO DECISION ON COMPULSORY LICENSING: DOES IT ENABLE IMPORT OF MEDICINES FOR DEVELOPING COUNTRIES WITH GRAVE PUBLIC HEALTH PROBLEMS? (2008), available at http://www.kommers.se/upload/Analysarkiv/Arbet_somr%C3%A5den/WTO/Handel%20och%20skydd%20f%C3%B6r%20immateriella%20r%C3%A4ttigheter%20-%20TRIPS/Rapport%20The_WTO_decision_on_compulsory_licensing.pdf [hereinafter National Board of Trade].

³⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S. 299, Marrakesh Agreement Establishing the World Trade Organization, available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS Agreement]. The TRIPS Agreement was created as a result of the 1986-1994 Uruguay Round of international trade negotiations and contains rules on patents and other forms of intellectual property. *Id.* Adherence to the TRIPS

the Doha Declaration on the TRIPS Agreement and Public Health (“Article 31*bis*”), a statement of intent adopted by the WTO in 2001, serves as a companion to the TRIPS Agreement, although there has yet to be a formal amendment.⁴⁰ Article 31*bis* clarifies and confirms that member states have the right to grant compulsory licenses to protect public health and gives broad discretion to do so.⁴¹

The general purpose of Article 31 is to allow any WTO Member to issue a compulsory license after fulfilling certain requirements⁴² – many of which are unclear or subject to broad interpretation.⁴³ Interestingly, nowhere within Article 31 of the TRIPS Agreement do the words “compulsory license” appear.⁴⁴ However, in reference to patent usage Article 31 does allow for “use without authorization of the right holder,” thus allowing a compulsory license to be issued.⁴⁵ Before a country can grant a compulsory license each license must be “considered on its individual merits;”⁴⁶ attempts to obtain authorization from the right holder on reasonable commercial grounds must have failed;⁴⁷ the compulsory license must be limited in scope and duration to the purpose for which it was issued;⁴⁸ the license must be used “predominantly for the supply of the domestic market” of country issuing the license;⁴⁹ and lastly the owner of the patent must be “paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”⁵⁰ These requirements are much too lenient and imprecise to protect the interests of countries with legitimate pharmaceutical patents.

Agreement means that all WTO member states, in theory, must maintain a minimum level of intellectual property protection. Cass, *supra* note 22, at 12-13. The TRIPS Agreement was developed in response to “concerns in developed nations that the intellectual property rights of their nationals were not sufficiently respected internationally and that remedies for addressing derogations from intellectual property rights were not sufficiently strong.” *Id.* The TRIPS Agreement “is to date the most comprehensive multilateral agreement on intellectual property.” See World Trade Organization, Overview: The TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Oct. 18, 2010).

⁴⁰ World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001, ¶ 5, WT/MIN(01)/DEC/2 (2001) [hereinafter Doha Declaration]; see also Catherine Saez, *Drug Access Waiver Debate Looms for June TRIPS Council Meeting*, Intellectual Property Watch, available at <http://www.ip-watch.org/weblog/2010/05/31/drug-access-waiver-debate-looms-for-june-trips-council-meeting/> (commenting on recent consultations between WTO members who are discussing expanding the scope the Doha Declaration, and noting the difficulties of holding a technical workshop to evaluate the “paragraph 6” amendment because of the widely differing views on the outcome).

⁴¹ See World Trade Organization, Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Sept. 2003) [hereinafter Implementation of Paragraph 6]. The 2003 decision ratified the Doha Declaration and created a special mechanism for compulsory licenses to enhance access to patented pharmaceuticals by countries with limited manufacturing capabilities. See Bartelt, *supra* note 38.

⁴² See National Board of Trade, *supra* note 38.

⁴³ Hunter, *supra* note 23, at 372.

⁴⁴ See generally TRIPS Agreement, *supra* note 39, art. 31.

⁴⁵ World Trade Organization, Fact Sheet: TRIPS and Pharmaceutical Patents, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm (last visited Oct. 18, 2010) [hereinafter Fact Sheet].

⁴⁶ TRIPS Agreement, *supra* note 39, art. 31(a).

⁴⁷ See *id.*, art. 31(b).

⁴⁸ See *id.*, art. 31(c)-(e), (g).

⁴⁹ *Id.* art., 31(f).

⁵⁰ *Id.* art., 31(h).

The language of Article 31 gives wide deference to WTO members in deciding what grounds a compulsory license can be used, no longer referring strictly to failure to adequately use the patent in the market as the only justification.⁵¹ In addition to this broad deference, Article 31 provides several potential reasons for authorizing a compulsory license. First, Article 31(b) suggests that a national emergency, circumstances of extreme urgency, or public non-commercial use could justify issuance of a compulsory license.⁵² Next, Article 31(k) provides that a compulsory license may be used to correct anti-competitive behavior such as “failure to work.”⁵³ And lastly, Article 31(l) allows a compulsory license for the use of an essential “second patent,” which cannot be exploited without infringing on another “first patent.”⁵⁴ In this case, the compulsory license is allegedly justified only where the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.⁵⁵

The use of a compulsory license will only be permitted if there have been unsuccessful efforts to obtain authorization from the patent holder – which requires reasonable commercial terms and the commencement of negotiations for a reasonable period of time.⁵⁶ However, the requirement of a reasonable negotiation period will be waived for a WTO Member country under three scenarios: (1) in the case of a national emergency, (2) other circumstances of extreme urgency, or (3) in cases of public non-commercial use.⁵⁷ Lastly, and possibly most contentious, Article 31(f) of the TRIPS Agreement states that after a WTO Member nation is authorized to issue a compulsory license, the use must be limited to the “supply of the domestic market.”⁵⁸

Article 31(f) has been sharply criticized as being too restrictive because pharmaceutical production is predominantly concentrated in high-income countries, and many developing countries lack the capacity for pharmaceutical production entirely.⁵⁹ Article 31(f), therefore, allegedly acted to prevent countries with insufficient or non-existent pharmaceutical manufacturing capabilities from

⁵¹ See generally TRIPS Agreement, *supra* note 39. Notably, Article 30 of the TRIPS Agreement clarifies that a WTO member state’s national law may provide “limited exceptions” to exclusive rights, “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.” Such exceptions include *de minimis* and educational uses. See *id.*

⁵² See *id.*, art. 31(b), (k), (l). While these exceptions provide some guidance, it is worth noting that nowhere in the text of Article 31 does the WTO provide definitions for “national emergency,” “circumstances of extreme urgency,” or “public non-commercial use.” See generally *id.*

⁵³ See *id.*, art. 31(k).

⁵⁴ See *id.*, art. 31(l).

⁵⁵ *Id.*

⁵⁶ National Board of Trade, *supra* note 38, at 7.

⁵⁷ TRIPS Agreement, *supra* note 39, art. 31(b).

⁵⁸ *Id.*, art. 31(f).

⁵⁹ Vera Zolotaryova, *Are We There Yet? Taking “TRIPS” To Brazil and Expanding Access to HIV/AIDS Medication*, 33 BROOK. J. INT’L L. 1099, 1103 (2008) (noting that because certain non-epidemic conditions are now seen as an urgent enough health emergency to necessitate a compulsory license, the use of compulsory licenses is likely to increase worldwide to the exclusion of countries with little or no manufacturing capabilities).

issuing compulsory licenses.⁶⁰ In response to the human rights activists' outcry on this matter, the Ministerial Conference of the WTO met in Doha Qatar in 2001, and developed a Declaration of the TRIPS Agreement and Public Health, commonly known as the Doha Declaration.⁶¹ The Doha Declaration was made effective in 2005 when an amendment was added to Article 31 known as Article 31*bis*, inserting the language from the Doha Declaration and an Annex to the WTO Article 31 framework.⁶² The amendment was composed of three waivers under Article 31.⁶³ The result of these waivers was to significantly ease the requirements that production be "predominantly for the supply of the domestic market."⁶⁴ This change is significant because the exporting countries' duty under Article 31(f) is now waived, thereby allowing compulsory licenses to be produced in one country and then exported to another.⁶⁵ Additionally, under this new framework, only the exporting country is responsible for adequate remuneration.⁶⁶ The result is that multiple countries are benefiting from the compulsory license, but the responsibility is borne solely by the exporting country – thus creating an incentive for countries with manufacturing capabilities to urge those without to acquire compulsory licenses. Similarly, re-export of the pharmaceutical produced under the license is allowed among members of a regional trade agreement.⁶⁷ This

⁶⁰ *Id.* at 1107. WTO member countries with no manufacturing capabilities were unable to make use of the compulsory licensing scheme for lack of production capabilities. *Id.* at 1108. Without the ability to manufacture pharmaceuticals within their own country a compulsory license did not serve to alleviate the problem. *Id.* at 1107.

⁶¹ Doha Declaration, *supra* note 40.

⁶² The Doha Declaration was implemented shortly after the U.S. considered issuing a compulsory license in order to get sufficient amounts of Anthrax antibiotics claiming an epidemic situation. *See* Fact Sheet, *supra* note 35.

⁶³ TRIPS Agreement, *supra* note 39, at 7.

⁶⁴ *See* Implementation of Paragraph 6, *supra* note 41.

⁶⁵ *See* Doha Declaration, *supra* note 40, at 6 (stating that "[t]he TRIPS Agreement does not and should not prevent [WTO] 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. Paragraph 6 of the Doha Declaration emphasized "recogni[tion] that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.").

⁶⁶ Implementation of Paragraph 6, *supra* note 41. The WTO General Council affirmed that Paragraph 6 should be implemented to allow countries with limited manufacturing capabilities, to issue compulsory licenses to other countries who have manufacturing capabilities and who could then export the pharmaceuticals to countries lacking production facilities. Notably, under the General Council's orders "[t]he obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence [sic] to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)...." *Id.*

⁶⁷ *See id.*

[W]here a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable [sic] Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or

practice expands the reach of Article 31 and diminishes the capacity for the patent owner to profit in foreign markets – which can lead to a decrease in total foreign investment.⁶⁸ These changes create the possibility for compulsory licenses to be granted such that one country can produce pharmaceuticals for another, opening the floodgates for potential misuse and further loss of patent control.

Although there had been some debate about whether the grounds on which a compulsory license can be issued under Article 31 were exclusive, the Doha Declaration confirmed that member states have the “freedom to determine the grounds upon which such licenses are granted.”⁶⁹ This “freedom” creates a great deal of subjective power resting with developing nations in the determination of whether to issue a compulsory license.⁷⁰ Similarly, under the new WTO framework, each member shall have the right to determine what constitutes a national emergency or other circumstance of extreme urgency.⁷¹ This deference to WTO members is far too broad and subjective, and will allow countries to claim circumstances requiring issuance of compulsory licenses without adequate need or an unbiased analysis of the situation.

The response to the Doha Declaration in the developed world has not been positive. The United States agreed not to use the amendment as an importing member, because it saw the need to protect investments from unauthorized usage⁷² – this is the correct approach to protect long-term goals of innovation. The broad text of the TRIPS Agreement was intended to grant each nation the authority to promote public health, but the new loosely defined language lacks objective guidelines, and thereby creates an atmosphere for further patent abuses worldwide.

III. IMPLICATIONS OF COMPULSORY LICENSING TO THE UNITED STATES

A. *Creating an Environment for Innovation*

The United States has contributed to more top diagnostic and therapeutic innovations than any other country.⁷³ Similarly, in the area of pharmaceutical innovations, the United States has produced more than the European Union and

imported under a compulsory licence [sic] in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.

Id.

⁶⁸ Cass, *supra* note 22, at 22 (explaining the importance of intellectual property protection as a key factor to the enormous contribution that innovators have made in recent history, particularly in the area of human health).

⁶⁹ Doha Declaration, *supra* note 40, at para. 5(b).

⁷⁰ Brent Savoie, *Thailand's Test: Compulsory Licensing in an Era of Epidemiological Transition*, 48 VA. J. INT'L L. 211, 219 (2007); *see also* Doha Declaration, *supra* note 56, at para. 6.

⁷¹ *See* Doha Declaration, *supra* note 40, at para. 6.

⁷² Bird & Cahoy, *supra* note 3, at 158 n.86. Many countries agreed not to use Article 31 *bis* as importing members because of the fear that implementation would detrimentally diminish patent protections abroad.

⁷³ Tyler Cowen, *Poor U.S. Scores in Health Care Don't Measure Nobel and Innovation*, N.Y. TIMES, Oct. 5, 2006 (noting that the “cream of the crop” in contributions to basic medical science is to count the number of Nobel prizes in medicine and physiology. Of the ninety-five Nobel Prize recipients for medical related innovations in the past forty years, fifty-seven of them, roughly sixty percent of the total, were from the United States).

Switzerland combined – in spite of having a smaller total population.⁷⁴ The innovator-friendly environment created by a protective patent system in the United States directly answers the question of why the United States contributes disproportionately to the production of pharmaceuticals.⁷⁵ For example, approximately forty percent of the United States economic growth is dependent upon intellectual property protection of some kind.⁷⁶ A great example is the Pfizer Company, currently the world's largest research-based pharmaceutical company, employing over 85,000 people, and investing almost sixty billion dollars each year in the pursuit of new and beneficial treatments.⁷⁷

Although many factors are surely relevant to how the United States has managed to create such a healthy environment for intellectual property, the predominant contributor is monetary compensation.⁷⁸ Individuals and firms will tend to invest more in medical innovation when they can expect larger returns, the returns sustain for a longer period of time, and when profits are realized without undue delay.⁷⁹ These three factors all directly relate to the ease of use and protective nature of the patent system in the United States, which allows exclusive protection for twenty years to patent holders.⁸⁰ In recent years, the United States has accounted for forty-five percent of worldwide pharmaceutical sales, as compared to Europe's twenty-seven to thirty percent and Japan's nine to twelve percent.⁸¹ The United States attracts high quality innovators mainly because of monetary incentives.⁸² The population of Europe is one hundred and fifty percent larger than the United States, and Japan is forty-two percent larger, so the greater contribution of the United States cannot be attributed to its population size alone.⁸³ Additionally, the United States is over-represented as a base of operations for top pharmaceutical firms.⁸⁴ Of the top fifteen pharmaceutical firms, measured by pharmaceutical revenues, eight are based in the United States, six in Europe, and one in Japan.⁸⁵ These factors are unlikely to be a coincidence. Although the firms may have located in the United States for historic reasons, it is most likely that a superior business climate cultivated by strong patent protection is a major factor –

⁷⁴ Iain Cockburn & Rebecca Henderson, *Public-private Interaction and the Productivity of Pharmaceutical Research* (Cambridge Nat'l Bureau of Econ. Research, Working Paper No. 6018, 1997); DiMASI, *supra* note 2 (analyzing a list of "impact drugs" as those having the most impact on therapeutic science between 1965 and 1992, combined with a list of the twenty-five most prescribed drugs in the world).

⁷⁵ *Id.*

⁷⁶ Cowen, *supra* note 73, at 5 (explaining that intellectual property is used in many areas of business, but carries significant importance in the pharmaceutical industry).

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ See Jenna Greve, *Healthcare in Developing Countries and the Role of Business: A Global Governance Framework to Enhance the Accountability of Pharmaceutical Companies*, CORP. GOVERNANCE 2008 WLNR 16938575 (Sep. 7, 2008) (noting that the monopoly power created by a patent is the cornerstone of many pharmaceutical companies which rely on intellectual property to survive).

⁸⁰ *Id.*

⁸¹ JOHN NORTHRUP, *THE BUSINESS OF HEALTH CARE INNOVATION* (Lawton Robert Burns ed., Cambridge University Press 2005).

⁸² *Id.*

⁸³ CENT. INTELLIGENCE AGENCY, *THE WORLD FACTBOOK* (1994).

⁸⁴ NORTHRUP, *supra* note 81, at 2-3.

⁸⁵ *Id.*

a factor that must also be taken into account when investing abroad.⁸⁶

B. Bilateral Investment Treaties and the United States

After the Doha Declaration and creation of Article 31 *bis*, the landscape upon which a compulsory license could be granted changed significantly.⁸⁷ A major question arises: how will the application of Article 31 *bis* affect the future of the pharmaceutical industry in the United States? In the wake of the Doha Declaration, much attention was given to investment treaty arbitration, but much less was written about intellectual property issues arising under BITs,⁸⁸ and even less so in relation to claims for expropriation after the issuance of a compulsory license.⁸⁹ Thus, pharmaceutical companies must now be careful both when investing within the United States, and especially when participating in foreign direct investments abroad.

Increasingly, investors from the United States may be able to seek recourse through alternative means of dispute settlement because of threats to business through the use of compulsory licensing abroad.⁹⁰ The WTO's Understanding on Rules and Procedures Governing the Settlement of Disputes⁹¹ provides for settlement of trade claims between states, and may be relevant if the state authorizing the compulsory license has failed to comply with the TRIPS Agreement's requirements.⁹² However, the investor from the United States may also wish to consider bringing a claim in investor-state arbitration directly against the host state under the terms of a BIT.⁹³ As compulsory licensing becomes more common, investors should weigh the benefits of investment arbitration and potential claims for indirect expropriation.

A majority of intellectual property disputes involve the patent owner suing a non-contracting party for alleged infringement of the owner's exclusive patent

⁸⁶ Rudolph Dolzer, *New Foundations of the Law of Expropriation of Alien Property* (1981) 75 AM. J. INT'L L. 553, 580 (especially for international investors, reliance and legitimate expectations contribute to "a continuous and increased international flow of capital, which... is crucial for the development and stabilization of the international economy in general, and the economy of developing countries in particular").

⁸⁷ *Id.* at 581.

⁸⁸ Correa, *Bilateral Investment*, *supra* note 3; UNCTAD, *Intellectual Property Provisions in International Investment Agreements on Regulations and Enforcement of Intellectual Property Rights*, INTELL. PROP. Q. UPDATE, at 2 (2006).

⁸⁹ Bird & Cahoy, *supra* note 3, at 285.

⁹⁰ *Id.* at 286. Bird and Cahoy note that the current dispute-settlement framework provided through bilateral investment treaties between nations might be the best way to insure greater protections for United States pharmaceutical companies investing abroad. *Id.* Bird and Cahoy suggest that in light of the overly flexible requirements of the WTO's Article 31, the use of bilateral investment treaties should be considered as a better means of increased protection. *Id.*

⁹¹ *Id.*; see World Trade Organization Agreement, Understanding on Rules and Procedures Governing Settlement of Disputes, Annex 2, available at http://www.wto.org/english/tratop_e/dispu_e/dsu_e.htm (explaining that "[t]he rules and procedures of this Understanding shall also apply to consultations and the settlement of disputes between Members concerning their rights and obligations under the provisions of the Agreement Establishing the World Trade Organization... and of this Understanding taken in isolation or in combination with any other covered agreement").

⁹² Bird & Cahoy, *supra* note 3, at 286-87.

⁹³ *Id.*

rights.⁹⁴ Most of these disputes are resolved through litigation between private parties in the courts of a country where the patent owner has registered with the national patent office.⁹⁵ In many cases, the parties to the private litigation have no prior interaction and have not decided on a settlement framework.⁹⁶ Without a prior agreement the parties usually default to private litigation through the national court system in the country where the investment was made, which may be nationalistic and generally unfavorable to foreign investors.⁹⁷

Understanding the dispute settlement framework will be helpful for investors from the United States. The possibility of investor-state arbitration offers a unique avenue to protect intellectual property for pharmaceutical companies engaged in foreign investment.⁹⁸ For example, in a claim arising from a WTO member's conduct that infringes on exclusive patent usage, such as the use of a compulsory license, the BIT may provide protection to support a claim brought directly against the WTO member in an international tribunal.⁹⁹ Most BITs, which are first negotiated by two separate government states, contain a dispute resolution clause in which the contracting governments agree that if an investment dispute arises with a foreign investor from another contracting state, they will submit to an international tribunal for arbitration.¹⁰⁰ It has been recognized that this significant increase of consent to arbitration between foreign investors and their host states is one of the most significant developments in international law in the past forty years.¹⁰¹ Regardless of the widespread adoption of BITs, there has yet to be a published case of an investor-state arbitration that has reached a settlement under the terms of a BIT in an international tribunal.¹⁰² Thus to ensure protection, investors should be particularly aware of whether their patent has been registered

⁹⁴ *Id.*

⁹⁵ See 8 CHRISTOPHER GIBSON, *ARBITRATION IN INTERNATIONAL INTELLECTUAL PROPERTY DISPUTES*, THE CALIFORNIA INTERNATIONAL PRACTITIONER (1997).

⁹⁶ *Id.*

⁹⁷ See DAVID W. PLANT, *RESOLVING INTELLECTUAL PROPERTY DISPUTES*, 15 (1999) (noting that without an arbitration agreement in place at the time of a dispute, the chances of avoiding the national court systems are rare); see also Andrew Newcombe, *The Boundaries of Regulatory Expropriation in International Law*, 20:1 ICSID REV. – FOREIGN INVESTMENT L.J. 34, 34-35 (2005) (explaining that foreign investors are especially susceptible to regulatory takings because first, “the investor typically lacks representation in the political process and may not have any input into decisions that significantly affect its investment. Second, receiving reciprocal advantages in the long-run will not mitigate the burdens of regulation where the [foreign] investor hopes to recoup its investment in the short term and to leave the jurisdiction. Third, where government measures result in very severe losses, it is unlikely that adequate subsequent benefits will be obtained to off-set losses. For example, nationalization policies are often predicated on the assumption that the foreign investor will be excluded from future economic participation in the economy. Fourth, economic nationalism is often a popular domestic policy. The nationality of the foreign investor makes the foreign investment a target for government measures. Finally, payments of compensation to a foreign investor may be viewed as a political failure, and are unlikely to be widely supported by the domestic political constituency.”).

⁹⁸ See Newcombe, *supra* note 97, at 35.

⁹⁹ See Susan Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521, 1528-32 (2005).

¹⁰⁰ LUCY REED, JAN PAULSSON & NIGEL BLACKABY, *GUIDE TO ICSID ARBITRATION* 40-45 (2004) (explaining that the majority of BITs contain provisions allowing for some form of privatized dispute settlement).

¹⁰¹ R. DOAK BISHOP, *FOREIGN INVESTMENT DISPUTES, CASES, MATERIALS AND COMMENTARY* 31 (2005).

¹⁰² *Id.*

within the host state, as well as the nature of the investment itself and whether the type of investment has been subject to investor-state arbitration in the past.¹⁰³ In the event that a compulsory license is issued, the investor should look to whether the host-state either violated the broader WTO treaty requirements or whether there is a more specific claim available under an applicable BIT.¹⁰⁴

C. Need for Better Governance of Compulsory Licenses

Some form of compulsory licensing statute is common in the national systems of many countries, even if not often put to use.¹⁰⁵ The United States is an example of a country with a *limited* compulsory licensing structure.¹⁰⁶ The American Intellectual Property Law Association, in comments during the FTC proceedings concerning Dell, stated that:

The appearance of a United States government agency imposing a compulsory patent license, especially a royalty-free compulsory license, must be avoided except in response to egregious conduct. Other countries could cite such an action as the basis for imposing broad and onerous compulsory licensing requirements upon United States patentees abroad.¹⁰⁷

The various compulsory licensing schemes abroad may have different legal bases and be authorized subject to varying executive, and administrative or judicial procedures.¹⁰⁸ In practice, sometimes the mere threat of using a compulsory license is enough to force compliance or a settlement with a pharmaceutical company.¹⁰⁹ The danger of ambiguous compulsory licensing systems resulting in the loss of intellectual property investments can be seen in an example from Egypt. Egypt is a country with moderate income and unlimited potential for growth, yet in spite of this seeming promise, the amount of intellectual property investment from foreign companies has significantly decreased in the last twenty years.¹¹⁰ In the

¹⁰³ See United Nations Conference on Trade and Development, Mar. 7-11, 2005, *Commission on Investment, Technology, and Related Financial Issues*, available at http://www.unctad.org/en/docs/c2d62_en.pdf. In the arbitration context, despite the significant expansion of patent-based investments worldwide disputes between foreign investors and a national government have been limited to construction, banking, telecommunications, residential utilities, and various other high risk or hazardous activities. *Id.* at para. 11.

¹⁰⁴ *Id.*

¹⁰⁵ In 2008, there were at least one hundred countries that had licensing laws permitting the government to authorize compulsory licenses in some form. Bird & Cahoy, *supra* note 3, at 292. Compulsory licenses have been granted only in limited circumstances in the United States, usually in relation to antitrust concerns, such as making the compulsory licensing of a patent a condition for approval of a merger between two competing businesses within a single market, or ordering a patent license in order to avoid violations of federal law prohibiting unfair competitive practices. *Id.*

¹⁰⁶ See Federal Trade Commission, American Intellectual Property Law Association, <http://www.ftc.gov/opp/global/aipal.shtm> (last updated June 25, 2007).

¹⁰⁷ *Id.*

¹⁰⁸ Bird & Cahoy, *supra* note 3, at 292-93.

¹⁰⁹ See Jerome Reichman, *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J.L. MED. & ETHICS 247, 249-50 (2009) (describing how a number of governments have “quietly begun to use the threat of compulsory licenses to rein in the prices of selected medicines”).

¹¹⁰ See *International Enforcement of Intellectual Property Rights: Hearing before the S. Comm. on Fin.*, 110th Cong. 2 (2008) (transcript of Senator Max Baucus, Chairman, S. Comm. on Fin.) available at <http://finance.senate.gov/newsroom/chairman/release/?id=2f938a1a-7683-4de8-9a3a-022c04251365>.

Middle East, Egypt has one of the worst records in protecting intellectual property rights, which has been devastating to its ability to increase trade opportunities and attract foreign investors.¹¹¹ Two months after Pfizer entered the Egyptian market, the Egyptian Health Ministry decided to grant a compulsory license to produce Viagra to all Egyptian companies who applied for the rights to produce the generic version.¹¹² The generic version of the drug was to be sold at one-twentieth of the price of Pfizer's market price.¹¹³ These actions by the Egyptian government diminished Egypt's capacity to attract future foreign investment. As a result, Pfizer canceled plans to build an additional production facility in Egypt,¹¹⁴ and pharmaceutical company PhRMA followed suit cancelling a three-hundred million dollar investment.¹¹⁵

The increasing costs of pharmaceuticals come from the expensive research and development process, which is needed to produce effective and safe drugs.¹¹⁶ For context, approximately fifty-six percent of funding for global pharmaceutical research is provided for by the private sector, costing over one-hundred billion dollars per annum.¹¹⁷ Moreover, most research in the pharmaceutical industry does not result in patented medicine; therefore pharmaceutical companies must secure earnings that not only cover their research and development costs, but also the costs of unsuccessful research.¹¹⁸ A decrease in research would most likely reduce the rate of medical progress and innovation across the globe.¹¹⁹ The monopoly power created by a patent is essential for pharmaceutical companies to earn enough money to stay in business and to finance subsequent research and development projects.¹²⁰

When a compulsory license is issued, the private funds have already been invested into the product, so once the license takes effect, the investment cannot be taken back.¹²¹ Compulsory licenses are retroactive by nature, meaning that the pharmaceutical is already patented and the patent holder only loses his exclusive right over the patented product after the compulsory license is issued.¹²² The underlying problem occurs because once the compulsory license is issued, the incentive to invest in the future is reduced. This foreseeable reduction in investment could also have a major impact on global health.

Under the Article 31 amendments, each WTO member has the authority to

¹¹¹ See Abeer Allam, *Seeking Investment Egypt Tries Patent Laws*, N.Y. TIMES, Oct. 4, 2002, available at <http://www.nytimes.com/2002/10/04/business/seeking-investment-egypt-tries-patent-laws.html> (noting that Egypt's compulsory licensing statute is overly broad, creating weak protections for intellectual property).

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ Bird & Cahoy, *supra* note 3, at 306.

¹¹⁵ *Id.* at 308.

¹¹⁶ See Greve, *supra* note 79 (explaining that research and development is one of the most time consuming and costly components of a successful pharmaceutical company).

¹¹⁷ *Id.* (noting that funding is not primarily coming from the public sector or the government, but rather from private industry).

¹¹⁸ *Id.* at 8.

¹¹⁹ *Id.*

¹²⁰ *See id.*

¹²¹ Bird & Cahoy, *supra* note 3.

¹²² *Id.*

grant a compulsory license, and has great discretion for doing so.¹²³ Generally, developing nations have weaker intellectual property protections and are therefore more likely to issue compulsory licenses on patented pharmaceutical products than are developed countries.¹²⁴ For fear of not regaining the cost of research and development, United States pharmaceutical companies will stop devoting their time and energy into discovering new cures for diseases, which are ironically most needed in the developing world, and instead focus on more profitable endeavors.¹²⁵

IV. RECENT USES OF COMPULSORY LICENSES AND HOW ARTICLE 31 *BIS* APPLICATION COULD PROVE TO BE PARTICULARLY HARMFUL

A. *Recent Uses*

Most countries have some national compulsory licensing system in place, even if rarely used.¹²⁶ Global health projections leave little doubt that chronic diseases are rapidly overtaking infectious diseases, such as malaria, AIDS and tuberculosis, as the world's deadliest diseases; a shift emphasized by recent World Health Organization (WHO) reports on global health.¹²⁷ Many of these chronic diseases, such as obesity, are best regulated through education, healthy eating, and regular exercise.¹²⁸ Yet, in a culture which demands a "quick fix" for everything, the use of compulsory licenses to fix these chronic problems is not surprising.

While many countries have adopted compulsory licensing statutes and claim to protect foreign investors, there has been much uncertainty in many cases about whether a national statute providing for compulsory licenses is in compliance with the standards from Article 31 of the TRIPS Agreement.¹²⁹ To date, there have been relatively few high-profile grants of compulsory licenses by governmental authorities for reasons other than antitrust concerns.¹³⁰ One of the most

¹²³ Doha Declaration, *supra* note 40, at 6.

¹²⁴ See Office of the U.S. Trade Representative, 2008 Special 301 Report 37 (2008), available at http://www.ustr.gov/sites/default/files/asset_upload_file553_14869.pdf. The special report is a tool used to pinpoint problems in intellectual property rights protection in countries that are engaged in trade with the United States. *Id.* A significant number of countries the United States has placed on the Watch List are developing nations. *Id.*

¹²⁵ See Baucus, *supra* note 110.

¹²⁶ See Bird & Cahoy, *supra* note 3, at 292.

¹²⁷ The WHO report said populations are aging partly due to success against infectious diseases, and changing patterns of food, alcohol and tobacco consumption. World Health Organization, Fact Sheet No. 311: Obesity & Overweight, <http://www.who.int/mediacentre/factsheets/fs311/en/index.html> (last visited Jan. 19, 2011). Fact Sheet No. 311 emphasizes that while deaths from infectious diseases, maternal conditions and poor nutrition would fall by three percent in the next decade; deaths from chronic disease will increase by seventy-one percent. *Id.* Cases of diabetes, heart disease and stroke, for which major weight gain is a big risk factor, are predicted to rise rapidly as the obesity epidemic takes hold in the developing world. *Id.*

¹²⁸ See Fact Sheet, *supra* note 45.

¹²⁹ See Ching-fu Lin, *Filling in the Gaps of the TRIPS Agreement: Reflections on the Taiwan-Philips CR-R Compulsory License Case*, 3 ASIAN J. WORLD TRADE ORG. & INT'L HEALTH L. & POL'Y 557 (2008) (Lin describes Taiwan's issuance of a compulsory license under Article 76 of Taiwan's Patent Act with respect to Philips' recordable compact disk patents and argues that both the issuance of the license and Taiwan's Patent Act were valid and consistent with Article 31 of the TRIPS Agreement). Additionally, the article notes that there has yet to be a WTO arbitration settlement or official report that directly interprets the language of Article 31. *Id.*

¹³⁰ *Id.*

contentious recent instances involves a compulsory license issued by the Brazilian government.¹³¹ In May 2007, Brazilian President Luiz Inacio Lula de Silva signed a document, which established a compulsory license to enable Brazil to make or import a generic version of the patented HIV treatment drug, Efavirenz.¹³²

This case is significant for a number of reasons, one being that before the compulsory license was issued, Brazil had rejected an offer by the patent owner, Merck & Co., to voluntarily discount the price for its drug by thirty percent.¹³³ These decisions by governments unwilling to negotiate on price have been viewed as controversial, raising concerns by the United States Trade Representative.¹³⁴ Rather than claiming a failure to comply with Article 31 of the TRIPS Agreement, Merck issued a statement focusing on foreign investment, characterizing the Brazilian government's decision to issue the compulsory license as a form of indirect expropriation.¹³⁵ Merck stated that "[t]his expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world," and harshly emphasized that "[t]his decision. . . will have a negative impact on Brazil's reputation as an industrialized country seeking to attract inward investment. False"¹³⁶

Brazil's issuance of a compulsory license sets a bad example for other nations because it encourages the use of compulsory licensing provisions for countries with middle-class income levels purely to lower the cost of pharmaceuticals.¹³⁷ Further, Brazil has the twelfth largest economy in the world,¹³⁸ a relatively low rate of HIV/AIDS infection, and is better situated to pay for or produce the medications needed itself compared to poorer countries that are suffering from HIV/AIDS on an epidemic proportion.¹³⁹ In spite of the pharmaceutical industry's backlash at Brazil's actions in issuing compulsory licenses for its citizens, Brazil has recently proposed expanding the scope of compulsory licensing under the TRIPS framework, making it easier to compel any kind of drug on the market for generic production at lower cost.¹⁴⁰ Regardless of

¹³¹ Jon Cohen, *Brazil, Thailand Override Big Pharma Patents*, 316 SCI. MAG. 816 (May 11, 2007), <http://www.sciencemag.org/content/316/5826/816.full.pdf?sid=6ce9c1ef-fa09-4e95-8062-c192d3288a26> (last visited May 2005).

¹³² Keith Alcorn, *Brazil Issues Compulsory License on Efavirenz*, AIDS MAP NEWS (May 7, 2007), <http://www.aidsmap.com/page/1427206/>.

¹³³ *Id.*

¹³⁴ In April 2007 the U.S. Trade Representative cited the issuing of compulsory licenses as one reason for elevating countries like Brazil to the Priority Watch List, a U.S. government warning to countries it judges do not adequately protect intellectual property rights. *Id.* Indeed, being placed on the U.S. Trade Representative's watch list has the effect of deterring future investment and could potentially lead to increases of export tariffs. *Id.*

¹³⁵ *Id.*

¹³⁶ Merck & Co., Inc., *Statement on Brazilian Government's Decision to Issue Compulsory License for Stocrin* (May 2007) <http://www.drugs.com/new/merck-amp-co-inc-statement-brazilian-government-s-decision-issue-compulsory-license-stocrin-6088.html>.

¹³⁷ Vera Zolotaryova, *Are We There Yet? Taking "TRIPS" To Brazil and Expanding Access to HIV/AIDS Medication*, 33 BROOK. J. INT'L L. 1099, 1120 (2008).

¹³⁸ International Center for Trade and Sustainable Development, *Brazil Grants Compulsory License*, 11 NEWS & ANALYSIS (May 2007) available at <http://ictsd.net/i/news/bridges/11643>.

¹³⁹ *Id.*

¹⁴⁰ Stephen J. Thiru, *Brazil's Proposal at WIPO on Patent Limitations and Exceptions* (SCP/14/7), <http://keionline.org/node/769>. On January 20, 2010, Brazil submitted a proposal to the Standing

Brazil's intentions and claims of suffering from a legitimate emergency, the requirement under Article 31, that countries must first try to negotiate with patent owners before granting compulsory licenses should not be so easily waived or should, at the very least, require additional objective standards.

Likewise, in Thailand the government has issued compulsory licenses for multiple kinds of pharmaceutical drugs. The first was for the same drug used in Brazil, Efavirenz; next it was for Kaletra, which is also used to treat HIV/AIDS, and lastly for Plavix, which is used to treat cardiovascular conditions such as heart disease.¹⁴¹ The issuance of a compulsory license for Plavix in Thailand is significant for a number of reasons. First, Thailand, like Brazil, is a middle-income country, and better situated to pay the market price for needed medications.¹⁴² However, nowhere in the TRIPS Article 31 framework does the WTO consider the income level of member states when determining whether to issue a compulsory license.¹⁴³ Secondly, Thailand's compulsory license for Plavix was the first of its kind issued for a chronic disease rather than an infectious disease.¹⁴⁴ Breaking ground in this area, the Thai government has lowered the bar to allow all kinds of patented medications to be considered for compulsory licensing.¹⁴⁵ Furthermore, Thailand issued the compulsory license for Plavix under Article 31's exception for public non-commercial use rather than the national emergency exception,¹⁴⁶ which is yet to be defined by the WTO.¹⁴⁷

This usage, therefore, has significantly widened the scope in terms of which ailments are considered severe enough by the WTO to compel an unwilling patent owner to issue a license.¹⁴⁸ To make matters worse, at the time Thailand issued the compulsory license for Kaletra, the pharmaceutical company who owned the patent was already selling the drug to Thailand at a discounted price.¹⁴⁹ Interestingly, because Thailand issued the compulsory license under the public non-commercial use exception, Article 31(b) waives the normal WTO requirement that the member state must first make reasonable efforts to participate in negotiations with the patent holder before issuing a compulsory license.¹⁵⁰

Committee on the Law of Patents, citing the historically limited use of currently existing patent exceptions as justification for expansion of compulsory licensing. *Id.*

¹⁴¹ See Press Release, *Abbott Laboratories, Thailand Abbott Laboratories Won't Introduce New Drugs in Thailand due to Breaking of Patent* (Mar. 14, 2007), <http://www.aegis.org/news/ads/2007/AD070549.html> [hereinafter Abbott Press Release].

¹⁴² Zolotaryova, *supra* note 137, at 1108.

¹⁴³ See generally TRIPS Agreement, *supra* note 39.

¹⁴⁴ See Abbott Press Release, *supra* note 141. The significance of issuing compulsory licenses for chronic illnesses, such as heart disease, is that these diseases are found worldwide and are best treated by changes in diet and exercise. *Global Strategy on Diet, Physical Activity and Health*, WORLD HEALTH ORGANIZATION, <http://www.who.int/dietphysicalactivity/en/index.html>; see also *infra* Section IV.B.

¹⁴⁵ *Id.*

¹⁴⁶ Zolotaryova, *supra* note 137, at 1109.

¹⁴⁷ Simon Montlake, *Thailand Widens Scope of Generic Drugs*, CHRISTIAN SCI. MONITOR (Jan. 31, 2007), <http://www.csmonitor.com/2007/0231/p07s02-woap.html>.

¹⁴⁸ *Id.*

¹⁴⁹ See Abbott Press Release, *supra* note 141.

¹⁵⁰ See generally TRIPS Agreement, *supra* note 39, Article 31(b) (explaining that WTO members are not required to negotiate with the lawful patent holder if the country is using the patent for a "public non-commercial use").

The examples from Thailand and Brazil display the unfortunate truth that the compulsory licensing system under the WTO framework has the potential to infringe on the proper functioning of the pharmaceutical markets and world health.¹⁵¹ As pharmaceutical companies realize the potential for patents to be used without their consent, they may follow the example of Abbott Laboratories, which decided to divest from the Thai market awaiting national patent system reform.¹⁵² Abbott withdrew seven pending patent registration applications for new medicines in Thailand in response to compulsory licensing.¹⁵³ As a result of the withdrawal of investment within these countries, citizens will suffer because hesitant pharmaceutical companies may no longer wish to invest or introduce new and useful medicines.¹⁵⁴

B. Significance of Article 31bis

With the addition of Article 31bis¹⁵⁵ and the statement on the implementation of the Doha Declaration,¹⁵⁶ parameters for the issuance of compulsory licenses are increasingly unclear. The Doha Declaration stood for the proposition that developing nations who are unable to manufacture pharmaceuticals should be authorized to import generic versions of drugs from nations with more developed manufacturing capabilities.¹⁵⁷ In addition to the obvious issues relating to dilution of investment, another problem with importing generic drugs under a compulsory license is that the drugs likely would originate from countries such as India and China,¹⁵⁸ which have limited quality-control inspection abilities.¹⁵⁹ These potentially unsafe generic drugs can cause serious harm when they enter into a market and become hard to control.¹⁶⁰

i. Broad deference

Article 31bis affirms that “[e]ach [WTO] member has the right to determine what constitutes a national emergency or other circumstance of extreme urgency.”¹⁶¹ This language is problematic because it gives wide discretion to each WTO member to decide under which circumstances a compulsory license may be

¹⁵¹ Montlake, *supra* note 147, at 5.

¹⁵² See Abbott Press Release, *supra* note 141.

¹⁵³ Savoie, *supra* note 70, at 219.

¹⁵⁴ See Zolotaryova, *supra* note 137, at 110.

¹⁵⁵ See TRIPS Agreement, *supra* note 39.

¹⁵⁶ Doha Declaration, *supra* note 40.

¹⁵⁷ *Id.* It should be noted that the original TRIPS agreement was in fact initiated for opposite purposes – namely to protect the intellectual property rights of international investors whose rights were not being sufficiently protected by developing countries. *Id.*

¹⁵⁸ Marc Kaufman, *FDA Scrutiny Scant in India, China as Drugs Pour into U.S.*, WASH. POST, June 17, 2007, http://www.nipcweb.com/FDA_Scrutiny_%20India_China.pdf (noting that since 2001 India and China have become major suppliers in the international generic drug market).

¹⁵⁹ *Id.* (noting that quality-control inspections are rarely conducted by the Food and Drug Administrations in India and China. For comparison, in 2005, the Food and Drug Administration (“FDA”) conducted over 1,200 quality inspections in the United States, but only 200 inspections were done in China and India in the last seven years.)

¹⁶⁰ *Id.*

¹⁶¹ Doha Declaration, *supra* note 40, at para. 5(c).

appropriate.¹⁶² The amendment also claims 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.”¹⁶³ The terms “national emergency” and “circumstances of extreme urgency” have been used to describe a variety of situations within countries wishing to issue a compulsory license.¹⁶⁴ While the WTO has recognized that a national emergency may include public health crises such as AIDS, tuberculosis, malaria, there is no clear definition or standard for determining which other emergencies would justify the issuance of a compulsory license.¹⁶⁵ While any of these listed emergencies may create a legitimate need for intervention, the trend has been toward issuing compulsory licenses to countries suffering from diseases treatable through preventative measures, such as some cardiovascular diseases.¹⁶⁶ For example, the WHO has recognized that obesity has reached “epidemic” proportions in many Western countries, while also acknowledging that obesity is best treated through changes in diet and exercise.¹⁶⁷ If cardiovascular diseases are most effectively treated through lifestyle changes, there should not be a way for compulsory licenses to be issued for cardiovascular medications merely for cost saving purposes. Such naivety cloaked in good will creates an atmosphere where countries are able to abuse the system in order to obtain cheaper drugs, even when there is no clear and immediate need.

ii. Re-exportation

This broad deference given to WTO member countries under Article 31 *bis*, also allows re-exportation among members of a regional trade agreement and raises potential public policy concerns by creating ulterior anti-competitive motives for countries to issue compulsory licenses.¹⁶⁸ If a country is a member to a regional trade agreement, Article 31 *bis* waives the requirements that the compulsory license be predominantly for the supply of the domestic market of the country granting the license.¹⁶⁹ The amendment thus allows members of a regional trade agreement who import generic drugs under a compulsory license to also export them to other states so long as those states suffer from the same medical problems.¹⁷⁰ While the proposed amendment states that “[i]t is understood that this will not prejudice the territorial nature of the patent rights in question,” the amendment fails to outline detailed requirements for countries privy to a regional trade before becoming eligible to receive imports under the

¹⁶² See Jamie Feldman, *Compulsory Licenses: The Dangers Behind the Current Practice*, 8 J. INT’L BUS. & L. 137, 142-43 (explaining the dangers of compulsory licensing abuse).

¹⁶³ See Doha Declaration, *supra* note 40.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ Correa, *Investment Protection*, *supra* note 5.

¹⁶⁷ *Global Strategy on Diet, Physical Activity and Health*, WORLD HEALTH ORGANIZATION, <http://www.who.int/dietphysicalactivity/en/index.html>.

¹⁶⁸ Doha Declaration, *supra* note 40.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

compulsory license.¹⁷¹ Leaving these kinds of requirements to the discretion of each country further expands the scope of Article 31 and diminishes the capacity for the patent owner to profit in foreign markets, ultimately leading to a decrease in foreign investment.¹⁷² Without detailed provisions on the circumstances in which a compulsory license can be issued, there is a risk that countries participating in regional trade agreements will be able to siphon off generic pharmaceuticals without showing true need.

iii. Adequate Remuneration

Lastly, adequate remuneration for the patent owner under a compulsory license is a problem because only the exporting country is responsible for payment under Article 31*bis*.¹⁷³ Because two countries are involved, both the exporting country and the importing country, the responsibility should be borne by both parties. This deference to WTO members is far too broad, and will allow countries to claim circumstances requiring issuance of compulsory licenses without adequate need or an analysis of the situation by a neutral third party. The United States joined with thirty-two other countries in agreeing not to use the Article 31*bis* amendment as an importing member because of the need to protect investments from unauthorized usage.¹⁷⁴ This is the correct approach to protect long-term goals of innovation within the pharmaceutical industry.

V. SUGGESTED REFORMATION OF ARTICLE 31 AND POTENTIAL CLAIMS FOR
INDIRECT EXPROPRIATION UNDER BILATERAL INVESTMENT TREATIES

The history of the TRIPS Agreement negotiations reveal that, behind the language of Article 31, are two basic rationales for government intervention: to safeguard against a severe epidemic and to ensure the proper functioning of the markets.¹⁷⁵ These are legitimate goals, but the ends do not justify the means if there is inconsistency in interpretation of the standards. While the WTO continues to amend its compulsory licensing statute, foreign governments should consider alternatives to compelling a patent against the will of the patent owner. Investors should also consider new methods of patent protection and dispute settlement under BITs in international arbitration.

¹⁷¹ *Id.*

¹⁷² Correa, *Investment Protection*, *supra* note 5.

¹⁷³ Doha Declaration, *supra* note 40.

¹⁷⁴ Bird & Cahoy, *supra* note 3, at 158 n.86. The countries other than the United States that agreed not to use Article 31*bis* as an importing member include: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. *Id.* With the expansion of the European Union, the list now includes ten more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia. *Id.*

¹⁷⁵ See Anthony Taubman, *Rethinking TRIPS: "Adequate Remuneration" for Non-Voluntary Patent Licensing*, 11:4 J. INT'L ECON. L. 927, 947 n.91 (2008) (noting that during the TRIPS Agreement negotiations, members of the Swiss Delegation suggested that compulsory licenses may be needed to serve overriding public interests, such as in the case of a health epidemic, or to safeguard the proper functioning of the markets by overriding the temporary monopoly of a patent holder who is withholding use entirely).

A. *Alternatives to Compulsory Licenses*

i. *Anticipating Volatility*

Some pharmaceutical firms are beginning to lower drug prices for poorer nations, hoping to smooth access to faster-growing emerging markets, and make up for sluggish growth in the United States, Japan and Europe.¹⁷⁶ Taking alternative measures to increase access to medicines may be a proactive step pharmaceutical companies can take to avoid the harsh consequences of compulsory licensing. For example, GlaxoSmithKline and Sanofi-Aventis have both promised to cut prices in some developing countries, selling at half or a quarter of the price they are receiving in the developed world.¹⁷⁷ These price-cuts provide a better way for markets to work, and yet still supply those in need with the most cutting edge medications.

Similarly, China is facing new challenges in the area of pharmaceutical patent protection. In 2009, China's State Intellectual Property Office issued more than 580,000 patents – up forty-one percent from a year earlier.¹⁷⁸ This large increase in innovation resulted in substantial revisions to China's national patent laws.¹⁷⁹ Because of the perception of weak international patent protection, China's new laws have been criticized as being overly protectionist, granting more patents to national companies and discriminating against foreign companies wishing to invest in China's growing economy.¹⁸⁰ Additionally, United States companies like Pfizer, who have significant research and development investments in China, may be negatively impacted by the new regulations, which force patent holders to license their patents to other producers if patents aren't "fully exploited" or if patent owners are deemed to be using the patents in an anti-competitive manner.¹⁸¹ It is unclear how China will determine whether a patent is being misused, or how much patent owners will be paid if they are forced to license their patent under a compulsory license.¹⁸² This recent example from China shows how changes in national patent law might be in conflict with the TRIPS Article 31 requirements,

¹⁷⁶ Ben Hirschler, "Silent Pandemic" Will Force Drug Price Rethink, (Jan. 20, 2010) <http://www.reuters.com/article/idUSTRE60J36O20100120> (explaining that "Drugs for diseases which were previously dominant only in the rich, well-fed world, such as diabetes, heart disease and cancer, are increasingly in demand in poorer nations in Asia and Africa, whose populations are now living longer"). Worth noting is the author's warning of the compulsory licensing systems' effect on competition, suggesting that when countries:

[d]iscount[] prices for poorer countries, a move already made by some big drug firms... pharmaceutical bosses will also be under pressure to join patent pools to promote downward price pressure on drugs for major chronic diseases by increasing the number of producers, and may face legal challenges to force them to allow in more generic competition.

Id.

¹⁷⁷ *Id.*

¹⁷⁸ Loretta Chao, *China Issued a Record Number of Patents in 2009*, WALL ST. J., Feb. 4, 2010, available at <http://online.wsj.com/article/SB100014240527/>.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.* China's new laws will allow China to issue a compulsory license if the government decides that a patent is being underutilized. *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

and provides an example of the need for a more protective and predictable system worldwide.¹⁸³

ii. Patent Linkage

Patent linkage is another option that large pharmaceutical companies like Bayer have utilized. Patent linkage occurs where a country's food and drug regulatory arm is petitioned to agree to an order delaying the introduction of a generic version of a patented drug until the expiration of the original drug's patent.¹⁸⁴ While linkage strategies will create better protection for patent holders, the practice is generally seen by public health activists as a hostile attempt to prevent generic medicines from reaching those who need them most.¹⁸⁵ A more effective method might be for pharmaceutical companies to work with generic drug manufacturers within developing countries to prevent the need for compulsory licensing while remaining profitable.¹⁸⁶ If pharmaceutical companies take the lead on creating legitimate generic medicines, these drugs will more likely reach those who need them, thus preventing the threat of a compulsory license, and allowing patent holders to retain control.

B. Recommendations: WTO Amendments

Given the current potential for misuse of the compulsory licensing law as well as the difficulties faced by countries with legitimate need but with no manufacturing capabilities of their own, other options could be suitably explored so as to attain proper balance between the humanitarian efforts and competitive needs of the pharmaceutical sectors in developing countries. Contrary to the belief of many humanitarian activists, there is no evidence that an overly protective IP policy necessarily will lead to less competition.¹⁸⁷ Statistical analysis of modern trends in foreign investment reveals that the more protections and incentives countries give to innovators, the more likely they are to invest time and money discovering new life-saving medications.¹⁸⁸ While bringing the fruits of

¹⁸³ Jingyuan Sun, *China's State Council Publishes New Implementing Rules for the New Patent Law*, LEXOLOGY, Jan. 22, 2010, available at <http://www.lexology.com/library/>.

¹⁸⁴ Priyanka Golikeri, *While Bayer Pushes Patent, EU Parliamentary Group Opposes*, DNA INDIA, (Feb. 16, 2010) http://www.dnaindia.com/money/report_while-bayer-pushes-patent-eu-parliamentary-group-opposes_1348342 (explaining that a European parliamentary group is planning to call on the EU and European Commission, the executive arm of the EU, to not push for provisions such as patent linkage in developing countries).

¹⁸⁵ *The Pharma Letter, Bayer's Patent Linkage Appeal to be Heard by India's Supreme Court*, (Mar. 2010) <http://www.thepharmaletter.com/file/28478/bayers-patent-linkage-appeal-to-be-heard-by-indias-supreme-court.html>.

¹⁸⁶ William O. Duperon, *Global Competition Versus Regional Interests: FDI and Pharmaceuticals in India*, 5 J. INT'L L. & TECH. (2010) (noting that by working to promote legitimate generic drugs (as opposed to forced compulsory licensing), the "progression of the pharmaceutical industry into generic markets may present the possibility of patent protection and affordable drugs coexisting").

¹⁸⁷ See Arnold, *supra* note 3, at 3.

¹⁸⁸ Greve, *supra* note 79. WILLIAM D. NORDHAUS, INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE 70 (1969) (explaining that patent systems and the protection they provide create incentives to innovate by conferring monopoly power for a limited time).

pharmaceutical innovation to the wider public is a noble pursuit, the WTO compulsory licensing scheme, as it is today, is not a balanced answer. There must be reform to ensure that patent owners are protected and innovators have incentives to continue creating the life-saving medications our world needs.

i. Moderated Deference

First, the resulting amendment from the Doha Declaration - Article 31*bis* - essentially allows WTO members complete discretion in determining whether to grant a compulsory license.¹⁸⁹ Instead of paving an avenue for potential abuse, the WTO should set guidelines for determining whether a country is legitimately suffering a “national emergency” or “circumstance of extreme urgency.” Additionally, the decision of whether a WTO member state is actually encountering a national emergency or circumstance of extreme urgency should not rest solely in the hands of the country issuing the compulsory license. Rather, it should rest with a WTO commission that has experience and can work with the nation to take an unbiased look at their situation, and make a decision as to whether there is legitimate need for a compulsory license to be issued.

Furthermore, Article 31(b) should be amended to include detailed descriptions of the circumstances under which its exceptions should apply. As written, Article 31(b) waives the requirement that there be reasonable negotiations with the patent owner under circumstances of ‘national emergency,’ ‘other circumstances of extreme urgency,’ or ‘public non-commercial use.’¹⁹⁰ It is unclear under Article 31(b) whether these terms are to be read in the conjunctive or whether any of the three would fulfill the requirements and activate the waiver of reasonable negotiations.¹⁹¹ Without clear definitions from the WTO of these terms, and authentication from the WTO on all decisions regarding “national emergenc[ies],” “extreme urgency,” and “public non-commercial use,” countries will increasingly be able to issue compulsory licenses for any type of drug, and for any perceived need.

ii. Price Reduction

The need to provide more affordable pharmaceuticals has been addressed by both private pharmaceutical producers and countries wishing to provide better healthcare to their citizens. GlaxoKlineSmith has taken a unique approach to the problem by taking the offense in trying to provide greater access to medicines in poor countries.¹⁹² The company plans to create a patent pool for tropical diseases, reinvest twenty percent of profits from medicines sold in least developed countries, and reduce prices in those countries by seventy-five percent.¹⁹³ Whether

¹⁸⁹ See Doha Declaration, *supra* note 40.

¹⁹⁰ TRIPS Agreement, *supra* note 39 art. 31(b).

¹⁹¹ *Id.*

¹⁹² John Davis, *Glaxo's Witty Tries to Fix an Industry Problem*, THE INVIVO BLOG (Jan. 20, 2010) <http://invivoblog.blogspot.com/2010/01/glaxos-witty-tries-to-fix-industry.html>.

¹⁹³ *Id.*

GalxoKlineSmith's plan is partially a public relations ploy to undo negative public perception about large pharmaceutical companies, or a response to threats of monetary losses through compulsory licenses, the new proposals set the stage for a sea change in the way pharmaceutical companies operate under current international protections.

Similarly, the governments of some countries are attempting to intervene in the free market to provide cheaper drugs for their citizens.¹⁹⁴ The Philippine government has been increasingly pushing for drug companies to voluntarily halve the prices on a series of life-saving medications.¹⁹⁵ Officials at the Philippines Department of Health have targeted twenty drugs, which cost two to three times more than in some other Asian countries, as potential candidates for the program.¹⁹⁶ Last August, Philippine President Gloria Macapagal Arroya imposed mandatory price controls on a number of hypertension and cancer medications, all of which were produced by companies from the United States.¹⁹⁷ The choice to rely on a law enacted in 2008, allows the Philippine government to impose price controls to force drug manufacturers into voluntarily lowering prices.¹⁹⁸ This case in the Philippines is an example of how some countries are trying alternatives to compulsory licensing to lower prices. Whether these and other alternatives will eventually deter investors is yet to be seen.

C. The Use of Bilateral Investment Treaties for United States Investors Abroad

i. General Considerations

American pharmaceutical producers investing abroad will benefit by familiarizing themselves with licensing policy developments, as these investors are the parties who will be most significantly impacted.¹⁹⁹ One huge policy development is the increased use of BITs between nations wishing to increase trade and create better investment protection.²⁰⁰ Most BITs provide that disputes between an investor and the host state can be settled in arbitration, and can provide additional protection not found in the vague language of the WTO's TRIPS Article 31.²⁰¹ Protection under the terms of a BIT mean the difference between having to

¹⁹⁴ James Hookway, *Philippines Seeks Voluntary Drug-Price Cuts*, WALL ST. J., Jan. 19, 2010, available at <http://www.online.wsj.com/article/SB1000142405274870362660457>.

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.* The Philippines, a country of ninety-million people, has been influenced in 2010 by upcoming presidential elections, where making medications more affordable is a key issue for the outgoing political party. *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ ANDREAS F. LOWENFELD, INTERNATIONAL ECONOMIC LAW 484 (2d ed. 2002) (explaining the expansion of patent-based investments abroad and their unique susceptibility to changes in compulsory licensing policy).

²⁰⁰ See Franck, *supra* note 99, at 1522 (noting that in the past twelve years, countries have entered into approximately 1500 new bilateral investment treaties in order to attract foreign investors and create flexibility in the resolution of investment disputes).

²⁰¹ *Id.* This additional protection, above and beyond that found in the WTO framework is often referred to as "TRIPS-plus." *Id.* Most BITs contain arbitration provisions allowing for private arbitration should a dispute arise relating to the investment. *Id.*

wait on a lengthy process under the WTO's settlement procedures, or being able to bring a case directly against a foreign government in investor-state arbitration under the terms of the BIT.²⁰² Additionally, a BIT provides the opportunity for two countries to negotiate for protection above and beyond that provided under multilateral treaties like the WTO.²⁰³

It is important for investors to know that virtually all BITs contain provisions on expropriation in closely parallel if not identical wording.²⁰⁴ Since a compulsory license does not actually take away the legal title from the patent holder, investors will not have a claim for *direct* expropriation, but they may have a claim for *indirect* expropriation if their property right is diminished substantially - the effects of which would be tantamount to full expropriation.²⁰⁵ It is generally recognized in international law that regulatory actions taken by a state government can interfere with privately held property rights to such an extent that these rights are rendered so useless that they must be deemed to have been expropriated - even though the WTO member state does not intend to expropriate the rights and the legal title to the property formally remains with the original patent owner.²⁰⁶ Intellectual property scholars Jan Paulsson and Zachary Douglas have written extensively on the area of indirect expropriation and suggest two stages of analysis, first looking at the magnitude of the interference to the property right, and second to whether that interference rises to the level of expropriation as referenced in the treaty.²⁰⁷ In Christopher Gibson's article *Compulsory Licensing: The Case of Indirect Expropriation* he suggests analyzing a third factor, namely the character and motive behind the regulatory government action on a case-by-case basis.²⁰⁸ These three factors have been incorporated into Annex B of the U.S. Model BIT for determining whether an indirect expropriation has occurred under the terms of the BIT.²⁰⁹ In theory, as Paulson, Douglas and Gibson explain, these factors

²⁰² *Id.*

²⁰³ See Ermias Tekeste Biadgleng, *IP Rights Under Investment Agreements: The TRIPS-Plus Implications for Enforcement and Protections of Public Interest* 18 (South Centre Research Paper No. 8, Aug. 2006) available at http://www.southcentre.org/index2.php?option=com_content&do_pdf=1&id=86 (explaining that the adoption of investment treaties "leave government measures open for challenge by utilising[sic] the mechanisms for the settlement of investment disputes."); see also TRIPS Agreement, *supra* note 39, art. 1(1) (explaining that WTO members may "implement in their law more extensive protection" than that provided by under Article 31).

²⁰⁴ Jan Paulsson & Zachary Douglas, *Indirect Expropriation in Investment Treaty Arbitrations*, in 19 *ARBITRATING FOREIGN INVESTMENT DISPUTES: PROCEDURAL AND SUBSTANTIVE LEGAL ASPECTS* 145 (Norbert Horn ed., Kluwer Law International 2004).

²⁰⁵ *Id.* at 152 (explaining that most bilateral investment treaties do not define the meaning of indirect expropriation and often simply refer to government measures that are the "same," "equivalent to," or "tantamount to" direct expropriation); see also Newcombe, *supra* note 97, at 8.

²⁰⁶ See Newcombe, *supra* note 97, at 9-10 (quoting *Starrett Housing Corporation v. Islamic Republic of Iran*, 4 U.S. C.T.R. 122, 154 (1983)).

²⁰⁷ See Paulsson & Douglas, *supra* note 204, at 148-49.

²⁰⁸ Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: the Case of Indirect Expropriation*, 25 *AM. U. INT'L L. REV.* 357, 382-83 (2010).

²⁰⁹ See 2004 United States Model Bilateral Investment Treaty, Annex B, <http://www.ustr.gov/sites/default/files/U.S.%20model%20BIT.pdf> [hereinafter U.S. Model BIT]. The United States Model Annex suggests the following language for an analysis of indirect expropriation:

- (a) The determination of whether an action or series of actions by a Party, in a specific fact situation, constitutes an indirect expropriation, requires a case-by-case, fact-based inquiry that considers, among other factors:

would be sufficient for a finding of indirect expropriation in the case of a compulsory license, however in practice the BITs using this language could be improved to create even greater protection for investors abroad.²¹⁰

First, BITs should not merely reference the WTO standards as a minimum baseline.²¹¹ As Gibson points out, there has been a trend in recent U.S. BITs to incorporate the WTO Article 31 standards directly into the expropriation analysis.²¹² One example of this trend is found in the recent U.S.-Uruguay BIT.²¹³ While the U.S.-Uruguay BIT includes the helpful three-factor analysis from the U.S. Model BIT, it also includes a provision excluding the possibility that a compulsory license could amount to expropriation so long as the license is in accordance with the TRIPS Agreement standards.²¹⁴ This provision essentially incorporates the WTO standards into the BIT, which can prove to be problematic given the ambiguous nature of Article 31.²¹⁵ Moreover, merely incorporating the standards from Article 31 will not provide any additional protection for investors.²¹⁶ Under this framework, so long as a compulsory license is Article 31 compliant, it will not violate the terms of the BIT. A better idea would be to include a provision that specifically relates to when a compulsory license will be allowed and under what terms, allowing tribunals to focus on a more comprehensive set of factors for determining whether an indirect expropriation occurred.²¹⁷

Second, while the three-factor analysis of an indirect expropriation provides some guidance for tribunals, it pales in comparison to the detail provided for in

(i) the economic impact of the government action, although the fact that an action or series of actions by a Party has an adverse effect on the economic value of an investment, standing alone, does not establish that an indirect expropriation has occurred;

(ii) the extent to which the government action interferes with distinct, reasonable investment-backed expectations; and

(iii) the character of the government action.

Id. at Annex B, para. 4.

²¹¹ Agreement on the Encouragement and Reciprocal Protection of Investments, U.S.-Uru., Nov. 4, 2005, available at http://www.unctad.org/sections/dite/ia/docs/bits/US_Uruguay.pdf [hereinafter U.S.-Uruguay BIT].

²¹² See Gibson, *Compulsory License*, supra note 208, at 396-97 (analyzing significant developments in the U.S.-Uruguay BIT, which incorporates the standards set forth in Article 31).

²¹³ See U.S.-Uruguay BIT supra, note 211.

²¹⁴ *Id.* at 397. The relevant portion of the U.S.-Uruguay BIT reads: “to the extent that a compulsory license is TRIPS Agreement compliant, the expropriation provisions in...[the] U.S.-Uruguay BIT will not apply at all.” *Id.*

²¹⁵ See supra Section IV (discussing the problems with the language and implementation of Article 31*bis*).

²¹⁶ See Newcombe, supra note 97, at 41 (explaining that the addition of a factor-based analysis found in Article 31 of the TRIPS Agreement will not add anything new to the already existing body of international law).

²¹⁷ See *id.*

Article 31.²¹⁸ Thus, inclusion of standards for what constitutes a national emergency, who makes those decisions, and analysis of a contracting state's socio-economic status would go a long way toward ensuring that patents are protected from unfounded and abusive compulsory licensing.²¹⁹ Additionally, adequate remuneration standards in United States BITs should take into account the full "market value" of the investment, not just the "economic value" as required by Article 31 and many of the currently existing BITs.²²⁰ By considering the economic status of the country seeking a compulsory license, existence of legitimate need, as well as any offers to reduce purchase price, a tribunal will have a better chance of coming to a balanced decision on whether expropriation has occurred.²²¹

Lastly, to insure protection under BITs entered into by the United States, the treaties should be renegotiated to provide more detail and much needed guidance for investors on how the standard should be applied in a case against a government issuing a compulsory license.²²² It has been observed that this lack of clear guidance on what regulatory actions amount to indirect expropriation can make arbitration under modern BITs regarding compulsory licenses particularly tricky.²²³ Regardless, given the potential to resolve disputes quickly and ensure protection, measures to increase the applicability of BIT's should be seriously considered. Indeed, it is surprising that the United States has entered into relatively few BITs compared to other countries.²²⁴

While the use of BITs to protect against misuses of the compulsory licensing mechanism seems ideal, the high degree of deprivation needed to support a claim for indirect expropriation, as it is currently defined in many BITs, makes the possibility of fully protecting patent rights on this basis unrealistic. Pharmaceutical companies should place a renewed emphasis on urging the United States Trade Representative to renegotiate current BITs to specifically define parameters for indirect expropriation in the case of a compulsory license.

²¹⁸ See Gibson, *Compulsory License*, *supra* note 208, at 400 n.158 (comparing the detailed provisions regarding use of a patent without the right-holder's authorization, with the minimal advisory language offered in the U.S. Model BIT).

²¹⁹ See Feldman, *supra* note 162 (suggesting that a more comprehensive approach, including comparative analysis of income levels and medical programs, will be helpful when determining whether a country has objectively sufficient need for a compulsory license).

²²⁰ See Gibson, *Compulsory License*, *supra* note 108, at 415 (explaining a scenario where a BIT requiring adequate remuneration that differs from the requirements of Article 31 (i.e. fair market value) could act as a form of "discipline" for the host state as it considers the amount of remuneration it will pay).

²²² See Newcombe, *supra* note 97, at 19 (explaining that "indirect expropriation" is the same as a "regulatory taking" in the expropriation context, and noting that a major problem with most investment treaties is that they "typically do not define the meaning of expropriation and often simply refer to government measures that are the 'same' or 'equivalent' to expropriation or are 'tantamount to expropriation'").

²²³ See Gibson, *Compulsory License*, *supra* note 108, at 396 (explaining that the language found in most BITs present a difficult case for arbitration in the context of a claim for indirect expropriation from a pharmaceutical compulsory license because of the clash between opposing interests - namely the government's interest in protecting public health and the patent holder's interest to protect their investment).

²²⁴ See *id.*

ii. Practical Guidance for Investors

When considering whether a claim for indirect expropriation exists under a BIT, investors should undertake a two-part analysis.²²⁵ First, “the analysis should focus on the nature or magnitude of the interference to the investor’s property interest in the investment caused by measures attributable to the Host State to determine whether those actions amount to a taking.”²²⁶ Second, “there should be a determination of whether this taking or interference rises to the level of an expropriation by reference to the relevant treaty standard.”²²⁷ This analysis is similar to the factors set out in the United States Model BIT, which contains provisions about whether the economic impact of government action amounts to expropriation.²²⁸

During the first stage of analysis, investors should realize that a compulsory license has the potential to undercut one of the fundamental incentives of an intellectual property investment – namely the right to exclusive patent usage within the foreign market.²²⁹ At worst, a compulsory license could substantially affect the ability of pharmaceutical producers to turn a profit, thus significantly reducing the value of the investment. Thus, it has been observed that there is an obvious assumption the issuance of a compulsory license can “cause an adverse effect on the economic value of a patented product and interfere with the patent holder’s ability to use or enjoy its patent in a given market.”²³⁰ However, the extent of interference will be dependent upon the compulsory license’s terms, including the duration and length of the license, any subsequent remuneration to be paid to the investor owning the patent, and whether the parties authorized by the government to make use of the patent actually turn a profit from the license.²³¹ A traditional analysis of a taking in the direct expropriation context requires that there be a “substantial deprivation” to the investor.²³² However, any one of these factors alone will not always be determinative, but rather they should be weighed in the totality. For example, if an investor is offered a low level of compensation under a compulsory license and the parties authorized by the government to use the compulsory license are in fact making a huge profit, there is a greater likelihood that a “taking” has occurred.²³³ By considering the practical effects of compulsory licensing, including a comprehensive valuation of the investment, international

²²⁵ Paulsson & Douglas, *supra* note 204, at 147-48.

²²⁶ *Id.*

²²⁷ *Id.* at 148.

²²⁸ See U.S. Model BIT, *supra* note 209. Under Annex B of the U.S. Model BIT, the determination of whether a measure constitutes an indirect expropriation requires consideration of three factors: the economic impact of the government action; the extent to which the government action interferes with distinct, reasonable investment-backed expectations; and the character of the government action. *Id.*

²²⁹ Paulsson & Douglas, *supra* note 204, at 154.

²³⁰ Michael Ewing-Chow, *Thesis Antithesis and Synthesis: Investor Protection in BITs, WTO and FTAs*, 30(2) U. NEW S. WHALES L.J. 548, 556 (2007). Ewing-Chow proposes that the level of deprivation is predominantly a question of degree for investors in the indirect expropriation analysis. *Id.* The answer to this question, he suggests, turns entirely on the duration, scope, and remuneration offered for any given patent use. *Id.*

²³¹ *Id.*

²³² *Id.*

²³³ Lowenfeld, *supra* note 199, at 476.

arbitral tribunals confronted with an investor-state dispute should be well equipped to determine whether an indirect taking has occurred.²³⁴

The second stage of analysis requires the investor to ask whether the taking is sufficient to constitute an indirect expropriation. To determine if an indirect expropriation has occurred, international tribunals will consider (1) specific representations or actions regarding a promise of protection on the part of the foreign government, and (2) legitimate or reasonable expectations and reliance on the part of the investor.²³⁵ A situation in which both factors exist, presents a significantly different scenario from one in which no state representations or promises of protection are made to the investor directly.²³⁶ One such example of the former would be where some facially non-discriminatory legislation is passed, such as an increase in economic regulation, in which an investor may have no legitimate expectation of an unchanging government regulatory structure.²³⁷ Without some additional representation of patent protection from the state, an investor would have a hard time arguing indirect expropriation under the BIT, and would have a better chance pursuing a claim through the WTO framework, challenging the issuance of the compulsory license directly instead of seeking a settlement award in arbitration. This use of BIT arbitration is still evolving, but a careful analysis of the above factors, in conjunction with the possibility of future health crises, drug pricing and other market considerations, an investor should have a better chance of preserving her investment and saving money down the road.

Before investing internationally, pharmaceutical companies should consider asking questions of a foreign government's patent office about what kinds of protection they can expect, and inquire as to whether or not the granting of patent rights for a particular pharmaceutical qualifies as the type of representation or action toward the investor that will be recognized within the indirect expropriation context. Investors should also consider whether it is reasonable for them to rely on the foreign government's grant of patent protection throughout the term, especially if the pharmaceutical company anticipates any intermittent usage periods during the life of the patent.²³⁸ Additionally, investors should take care to observe what posture a country has taken toward other foreign investors in the past, and make decisions accordingly to fully protect their investments from expropriation.

Lastly, investors should also consider the national patent law of a country in which they are considering an investment and inquire into whether there is a provision regulating compulsory licenses. In most cases, these national laws will provide the terms under which a compulsory license may be granted by the

²³⁴ See Gibson, *Compulsory License*, *supra* note 208, at 385.

²³⁵ See Newcombe, *supra* note 79, at 154 (explaining that a business's legitimate expectation is determined, at least partially, by looking at any investment related treaties or agreements in existence at the time of investment. Concern for this element is reflected in recent U.S. model investment treaty language by requiring arbitral tribunals to weigh the extent of governmental interference with patent rights, against the investor's "distinct, reasonable investment-backed expectations."); see U.S. Model BIT, *supra* note 209.

²³⁶ Newcombe, *supra* note 97, at 153.

²³⁷ See Paulsson & Douglas, *supra* note 185 (discussing a tribunal's finding that an investor had no reasonable expectation that the government regulatory policy would remain perpetually unchanged).

²³⁸ Newcombe, *supra* note 97, at 153.

government.²³⁹ Thus, for an investor, reasonable investment-backed expectations should include the investor's knowledge of the foreign state's patent law system. With the increasing likelihood of a compulsory license being issued under the vague terms of Article 31, investors should consider whether a national patent law allowing increased relaxation of patent protection fundamentally undermines the stability of the patent such that complete reliance by the investor would be unreasonable.²⁴⁰

Moreover, to the extent that a country's national patent law, or government's authorization of a compulsory license is inconsistent with international law, the patent owner, as a foreign investor, may also take into account that it is able to claim rights under international standards through either the WTO system or investment arbitration under a BIT.²⁴¹ While there are many factors that can be used to determine whether indirect expropriation has occurred, these factors should provide an adequate framework for guiding tribunals when considering a government's authorization of a compulsory license.

VI. CONCLUSION

Compulsory licensing of pharmaceutical patents takes on a particularly controversial nature. On the one hand pharmaceutical companies are confronted by serious pressures to extend good will from countries faced with legitimate public health concerns, on the other are the reasonable investment-backed expectations of a patent-based investment rooted in an applicable BIT, national, or international patent laws such as the WTO. With worldwide adoption of an increasingly expansive view of compulsory licensing in the name of public health, there are now good reasons for pharmaceutical companies who are considering investing abroad to explore the potential for dispute settlement either directly under a BIT or through WTO arbitration.

The main issues regarding compulsory licenses are centered around the question of how much latitude governments should be given to take actions that may interfere with intellectual property investments, whether these actions erode the standards of protection established for investors under national patent laws and BITs, and whether such measures are consistent with the requirements set forth in

²³⁹ *Id.* The limitations on patent usage, terms of protection and process for remuneration differs between countries. Often times their overlapping language and procedures can be found in national patent laws, Article 31 and Article 31*bis* of the TRIPS Agreement, and applicable BITs. *Id.*

²⁴⁰ Lin, *supra* note 16, at 157 (emphasizing the common sense explanation that an investor in a state with a compulsory licensing statute should "be in a position to be able to foresee that the compulsory license is applicable and will have associated effects." Investors should "take [compulsory licensing laws] into consideration before making any investment decision[s]."); *cf.* Gibson, *supra* note 208 (recognizing that in the majority of situations, compulsory licenses are only granted in exceptional circumstances, and positing that except in the case of a minority of countries, an investor should not reasonably expect that the existence of a compulsory licensing law will substantially undermine the investors "distinct, reasonable investment-backed expectations").

²⁴¹ *Id.* An investor may opt for direct settlement under a BIT as a sole means for monetary recourse under a claim for indirect expropriation. *Id.* If the investor has reason to believe that the compulsory license was issued in violation of the Article 31 requirements, they may wish to pursue arbitration with the WTO, but will face additional challenges persuading their home country, as the WTO member state, to initiate the proceedings within the WTO framework. *Id.*

Article 31 of the TRIPS Agreement. Because the WTO framework serves as a baseline, the standards should be clear and comprehensive. The realized benefits, in extreme circumstances, that compulsory licenses are meant to provide, are slowly becoming sidelined by a trend toward manipulating the vague language of TRIPS in order to compel licenses for any reason. The language of TRIPS, specifically the amendment Article 31*bis*, needs to create consistent protection for foreign investors. While Article 31*bis* is currently operational, a 2008 decision was made to extend the deadline for formally accepting the TRIPS agreement amendment.²⁴² The deadline was extended until 31 December 2009 or “such later date as may be decided by the Ministerial Conference,” and has yet to be formally ratified.²⁴³ Any future amendments must incorporate strong IP protection, not just for its immediate effect, but also for establishing a long-term sustainable minimum baseline of protection for innovators.

While the usage of BITs to protect foreign direct investment has the potential to be useful for pharmaceutical companies, the law is still evolving, and there is little in the way of precedent or guidance on successfully winning a case for indirect expropriation. Pharmaceutical companies must recognize the continuing and unresolved conflict between the need for strong patent protection and the need to remedy future health emergencies. Until the WTO’s Article 31 more appropriately addresses this balance, pharmaceutical companies will benefit by an increased focus on working with the United States Trade Representative to amend current BITs to provide increased guidance on when an indirect expropriation has occurred. By designing BITs to specifically address indirect expropriation in the case of a compulsory license issued for pure economic gain, pharmaceutical companies investing abroad will have more confidence to innovate and continue foreign investment. If enough BITs reflect this emphasis on increased intellectual property protection, the WTO might be influenced to make the much-needed changes to the lenient standards under Article 31.

Until the WTO makes the necessary changes to its compulsory licensing laws, investors’ main goal for protecting their investment should be to utilize new, direct means of settlement in an effort to avoid WTO arbitration, or for the time being to reconsider investing in certain countries altogether.

²⁴² *Decision on Extension of Formal TRIPS Amendment* (Dec. 18, 2007), <http://docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/L/711.doc>. In order for the decision to have legal effect, two-thirds of the WTO’s 151 Members are required to ratify the agreement. *Id.* While the European Union has formally accepted the amendment, their acceptance only brings the number to 41. *Id.*; see also Saez, *supra* note 40 (noting the struggle to achieve a consensus among WTO members regarding the format for evaluating the language and substance of the TRIPS amendment).

²⁴³ *Id.* In 2008 the Ministerial Conference decided to extend the deadline for accepting the TRIPS agreement amendment to December 31, 2009 or “such later date as may be decided by the Ministerial Conference.” *Id.*