

ARTICLES

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Patrick Wieland, *Why the Amicus Curia Institution is Ill-suited to address Indigenous Peoples' Rights before Investor-State Arbitration Tribunals: Glamis Gold and the Right of Intervention*

NOTES AND
COMMENTS

Petros C. Mavroidis, *Doha, Dohalf or Dohaha? The WTO Licks its Wounds*

Claus D. Zimmermann, *Toleration of Temporary Non-Compliance: The Systemic Safety Valve of WTO Dispute Settlement Revisited*

Melissa Blue Sky, *Developing Countries and Intellectual Property Enforcement Measures: Improving Access to Medicines through WTO Dispute Settlement*

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DEVELOPING COUNTRIES AND INTELLECTUAL PROPERTY
ENFORCEMENT MEASURES: IMPROVING ACCESS TO
MEDICINES THROUGH WTO DISPUTE SETTLEMENT

MELISSA BLUE SKY*

In 2008 and 2009, customs officials in the European Union, alleging patent infringement detained and seized generic medicines in transit from India to Brazil. The two countries requested consultations through the World Trade Organization's Dispute Settlement Understanding based on alleged violations of the Agreement on Trade-Related Aspects of International Property Rights and other international agreements. These disputes are different from all prior ones—they are premised upon the claim that the EU violated the TRIPS agreement through the use of its border measures that went beyond the TRIPS minimum standards, rather than claiming that the other country did not meet those minimum obligations. They also show how developed countries seek to enact such intellectual property standards outside the WTO and limit global access to medicines. This note examines how developing countries can use the DSU to challenge these restrictions, and pursue policies that promote global access to medicines.

* J.D. American University Washington College of Law, LL.M. in Law in Development, University of Warwick. E-mail: melissabluesky[at]gmail.com. The usual disclaimer applies.

TABLE OF CONTENTS

- I. INTRODUCTION
- II. ACCESS TO MEDICINES AND IP FORUM SHIFTING
 - A. *Access to Medicines and Global Health*
 - B. *IP Protection and Access to Medicines*
 - 1. World Intellectual Property Organization
 - 2. WTO – TRIPS
 - 3. TRIPS Flexibilities, Doha Declaration and Paragraph 6 Parallel Importation
 - 4. Existing and Emerging Bilateral and Regional Frameworks
- III. DEVELOPING COUNTRIES, WTO DISPUTE SETTLEMENT AND TRIPS
 - A. *Dispute Settlement Generally*
 - B. *IP Disputes*
- IV. DEVELOPING COUNTRY CHALLENGES TO IP MEASURES LIMITING ACCESS TO MEDICINES
 - A. *EU Seizure of Generic Drugs in Transit*
 - 1. 2010 Requests for Consultations by India and Brazil
 - 2. The Case Against EC Regulation 1383/2003 before a future WTO Panel
 - (i) TRIPS Articles 51 and 52
 - (ii) TRIPS Article 41
 - B. *US Section 301*
 - C. *Anti-Counterfeiting Trade Agreement*
 - D. *Bilateral TRIPS-plus Measures*
 - E. *Trans-Pacific Partnership Agreement*
- V. CONCLUSION

I. INTRODUCTION

In the fall of 2010, Anand Grover, the United Nations Special Rapporteur on the Right to Health, posed a question to presenters at a public consultation on trade, medicines, and health on whether they had considered filing a complaint before the Dispute Settlement Body (“DSB”) of the World Trade Organization (“WTO”) after the United States’ Special 301 Report under its Trade Act, 1974 accused their countries of deficient intellectual property (“IP”) protections.¹ Country and NGO representatives seemed vaguely supportive of the idea, but hesitant because of the risk of suspension of discretionary trade preferences or having detrimental foreign policy actions taken against them.²

¹ *Public Consultation on Trade, Access to Medicines and the Right to Health with Anand Grover*, U.N. *Special Rapporteur on the Right to Health*, Oct. 28, 2010, available at: <http://www.wcl.american.edu/pijip/go/events/un-special-rapporteur-on-the-right-to-health> (select “VIEW WEBCAST”).

² *Id.* (statements of Isabella Albornoz, General Counsel, Embassy of Ecuador, Kannikar Kijtiwachakul, Health Consumer Protection Program, Chulalongkorn

The U.S. Special 301 Report and other IP enforcement measures³ promote policies that seek to restrict access to medicines. Although there are risks for developing countries, this is the ideal moment to strategically and opportunistically use the Dispute Settlement Understanding (“DSU”) of the WTO to challenge the restrictive IP standards and enforcement agenda by the developed countries that are shifting IP out of the WTO multilateral trading system, further limiting access to medicines.

In the ‘Access to Medicines’ movement, developing countries and activists have succeeded in addressing their concerns with the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”), at least to some degree, in the context of the WTO. The Doha Declaration on Access to Medicines⁴ and the 2003 Decision on Implementation of Paragraph 6,⁵ support the right of a country to gain access to medicines and recognize that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”.⁶ Despite these successes, there is a wide consensus that countries still face challenges within the heightened intellectual property protections introduced by TRIPS.⁷

Moreover, while developing countries have been able to incorporate means to protect public health into declarations in the WTO multilateral context, developed countries and pharmaceutical companies are working outside the WTO to advance their agenda of imposing standards above that required by TRIPS (“TRIPS-plus”)

University, Thailand, and Amit Sengupta, Peoples Health Movement and the All India Peoples Science Network, India).

³ These enforcement measures include EC Regulation 1383/2003, the Anti-Counterfeiting Trade Agreement, Regional Trade Agreements, and the Trans-Pacific Partnership, all discussed in this article.

⁴ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) (hereinafter Doha Declaration).

⁵ World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1 (2003) (hereinafter Paragraph 6 Implementation).

⁶ Doha Declaration, *supra* note 4, ¶ 4.

⁷ See U.N. Human Rights Council, Eleventh Session, June 2-19, 2009, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Anand Grover, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (hereinafter *Report of the Special Rapporteur*); CAROLYN DEERE, THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND THE GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES (Oxford Univ. Press 2008) (hereinafter DEERE).

through a series of bilateral treaties,⁸ discretionary national programs (for example, the U.S. Section 301 Report that was discussed above),⁹ domestic laws that conflate generic medicines with counterfeit medicines and give customs agents rights which were once reserved for judges,¹⁰ and the recently finalized Anti-Counterfeiting Trade Agreement,¹¹ and Trans-Pacific Partnership (“TPP”) currently under negotiation.¹²

Although it has been widely recognized that a shift to incorporate IP protections into the WTO began in the 1980s and that in recent years there has been a shift out of the WTO (“forum shifting”),¹³ the capacity of developing countries to shift the focus back to the WTO to protect their interests has not been a focal point of the debate. Scholars have also noted achievements of some developing countries in winning claims before the WTO’s DSB on a wide range of

⁸ See, e.g., Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, (Oct. 24, 2000) 41 I.L.M. 63.; U.S.-Peru Trade Promotion Agreement, Apr. 12, 2006.

⁹ For the most recent Report, see OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2011 SPECIAL 301 REPORT (Apr. 2011), available at: http://www.ustr.gov/webfm_send/2841 (last visited Nov. 8, 2011) (hereinafter 2011 SPECIAL 301 REPORT).

¹⁰ The regulation allows customs authorities to detain goods *suspected* of infringing on intellectual property rights under certain circumstances. These determinations often involve legal determinations as to whether the goods may infringe on a property right, and in some cases goods may be destroyed even *without* a finding of a property right violation (Art. 11 “Member States may provide . . . for a simplified procedure . . . which enables customs authorities to have such goods abandoned for destruction under customs control, without there being any need to determine whether an intellectual property right has been infringed under national law”). See Council Regulation 1383/2003, 2003 O.J. (L 196/7) (EC), available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF> (last visited Nov. 9, 2011) (hereinafter EC Regulation 1383/2003).

¹¹ Anti-Counterfeiting Trade Agreement, formally adopted on April 15, 2011, opened for signature on May 1, 2011 until May 2013 (hereinafter ACTA), available at: http://trade.ec.europa.eu/doclib/docs/2011/may/tradoc_147937.pdf (last visited Nov. 8, 2011).

¹² See *Trans-Pacific Partnership*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, available at: <http://www.ustr.gov/tpp> (last visited May 30, 2011).

¹³ See, e.g., Susan K. Sell, *Cat and Mouse: Forum-Shifting in the Battle over Intellectual Property Enforcement*, (Draft, prepared for IGIS research seminar 2010), available at: <http://www.gwu.edu/~igis/Sell Paper.doc> (last visited Nov. 8, 2011); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1 (2004) (hereinafter Helfer). Part II of this article discusses forum shifting and access to medicines in greater detail.

issues including agriculture¹⁴ and the imposition of anti-dumping and countervailing duties.¹⁵ However, they have not yet done so for IP challenges related to access to medicines.¹⁶ In using the dispute settlement procedures to their advantage, developing countries have succeeded in using the rules of the WTO to level the playing field in other areas, and have been able to incorporate some of their concerns regarding access to medicines at the WTO through the Doha Declaration. This note suggests that, developing countries should also use dispute settlement of the WTO to challenge unilateral and regional instruments that infringe upon the WTO agreements to improve access to medicines in developing countries and ultimately, worldwide health.

The article first considers the evolution of international intellectual property rights (“IPR”) standards within the World Intellectual Property Organization (“WIPO”), the barriers to access to medicines constructed by the TRIPS Agreement, and the degree to which these barriers have been lifted by subsequent WTO declarations. Challenges to improving access to medicines within the WTO are briefly considered before the focus turns to laws and agreements outside the WTO, which seek to raise IP protections above the standards contained in TRIPS agreement. The article then considers the potential challenges to the following at the WTO: TRIPS-plus measures in bilateral treaties, U.S. Section 301 Report, EC Regulation 1383/2003, ACTA, and the TPP. While it will not be possible to constrain all IP enforcement measures through WTO challenges, developing countries can take steps leading up to and including recourse to the DSB to temper negotiations or modify existing instruments that hinder access to medicines. The article then concludes by recommending that developing countries bring select

¹⁴ See, e.g., Appellate Body Report, *United States – Subsidies on Upland Cotton*, WT/DS267/AB/R (Mar. 3, 2005), Appellate Body Report, *European Communities – Export Subsidies on Sugar*, WT/DS265/AB/R, WT/DS266/AB/R, WT/DS283/AB/R (Apr. 28, 2005).

¹⁵ See, e.g., Appellate Body Report, *United States – Measures Relating to Shrimp from Thailand and United States – Customs Bond Directive for Merchandise Subject to Anti-Dumping/Countervailing Duties*, WT/DS343/AB/R, WT/DS345/AB/R (July 17, 2008); Todd Allee, *Developing Countries and the Initiation of GATT/WTO Disputes* (2008), available at: http://www.cis.ethz.ch/events/past_events/PEIO2008/Allee_Developing.Countries.WTO.Disputes (last visited Nov. 8, 2011); David Evans & Gregory Shaffer, *Introduction: The Developing Country Experience in WTO Dispute Settlement*, in *DISPUTE SETTLEMENT AT THE WTO: THE DEVELOPING COUNTRY EXPERIENCE* (Gregory Shaffer & Ricardo Meléndez-Ortiz eds., 2010) (hereinafter Evans & Shaffer).

¹⁶ The exception is that both Brazil and India requested consultations regarding the seizure by the European Union of generic medicines in transit in 2010; however, the parties resolved the dispute in the consultation proceedings. This dispute is considered further in Part IV of this article.

claims at the WTO that are ultimately likely to improve their ability to manufacture and import medicines needed for the health of their people.

II. ACCESS TO MEDICINES AND IP FORUM SHIFTING

A. *Access to Medicines and Global Health*

Limited access to medicines contributes to chronic illness and death of millions of people in developing countries. As a result of high drug prices and low availability, progress has not been made towards reaching the United Nations Millennium Development Goal (“UN MDG”) 8.E that states that developed countries must provide access to medicines in developing countries, in cooperation with pharmaceutical companies.¹⁷ On an average, the proportion of people in developing countries with sustainable access to affordable essential medicines has not improved since the UN began tracking progress towards MDG 8 in 2007.¹⁸ Approximately one-third of the people worldwide still lack access.¹⁹ In developing countries, essential medicines are available at 42% of public facilities (approximately) and at 64% of private facilities,²⁰ at a cost of 270% and 630% higher than the international references prices respectively.²¹ Lives of an estimated 10 million people per year could be saved with existing medicines, but price has been a significant barrier.²²

B. *IP Protection and Access to Medicines*

A wide range of IP protections impact prices of medicines in a variety of ways,²³ but the focus of this note is primarily on patent protections and enforcement in the international realm. International agreements granting patent

¹⁷ Millennium Development Goals, UNITED NATIONS, available at: <http://www.un.org/millenniumgoals/global.shtml> (last visited Nov. 8, 2011).

¹⁸ MDG GAP TASK FORCE, MILLENNIUM DEVELOPMENT GOAL 8 THE GLOBAL PARTNERSHIP FOR DEVELOPMENT AT A CRITICAL JUNCTURE 57 (2010) (hereinafter MDG GAP TASK FORCE).

¹⁹ WORLD HEALTH ORG. & HAI GLOBAL, MEASURING MEDICINE PRICES, AVAILABILITY, AFFORDABILITY AND PRICE COMPONENTS 1 (2d ed. 2008) (hereinafter WORLD HEALTH ORG. & HAI GLOBAL).

²⁰ MDG GAP TASK FORCE, *supra* note 18, at 57.

²¹ Anne Bozik, *Essential Medicines: The Crisis in Developing Countries*, YALE J. MED. & L., Spring 2011, at 13, available at: <http://www.yalemedlaw.com/issues/vol7-issue2.pdf> (last visited Nov. 9, 2011).

²² WORLD HEALTH ORG. & HAI GLOBAL, *supra* note 19.

²³ *Report of the Special Rapporteur*, *supra* note 7.

rights to inventors of new medicines limit the rights of others to produce generic versions, which have lower prices and expand access.²⁴ The patent allows the manufacturer a monopoly and the ability to set higher prices.²⁵

In international negotiations, the goal of pharmaceutical manufacturers, through their developed country proponents, has been to increase and expand rights for patent owners throughout the world.²⁶ Over the past few decades, these efforts have shifted IP from the purview of the WIPO to the WTO,²⁷ and now to bilateral, regional, and other “coalitions of the willing”.²⁸ These shifts have heightened IP protection and limited access to medicines by developing countries.

²⁴ These limits, including extension of the patent term or linking a patent with national registration, are generally contained in bilateral free trade agreements. However, these provisions may be subject to additional enforcement measures by way of ACTA and other agreements. Although footnote 2 of ACTA allows for a party to exclude patents from the section on civil enforcement measures, the default is that patents will be subject to the measures. Anti-Counterfeiting Trade Agreement, *supra* note 11.

²⁵ See *Report of the Special Rapporteur*, *supra* note 7.

²⁶ See, e.g., PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), *Special 301 Submission 2010*, available at: <http://keionline.org/sites/default/files/USTR-2010-0003-0245.1.pdf> (last visited Nov. 9, 2011) (PhRMA, in this report, notes that some countries are falling short of TRIPS obligations and FTA obligations, and calls upon the United States to exert pressure through the Special 301 process); PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), *Bilateral and Multilateral FTA Negotiations: Opportunities for Improved IP Protection and Market Access*, available at: <http://www.cptech.org/ip/health/phrma/301-01/301-01-fta-appendix.pdf> (last visited Nov. 9, 2011) (noting that the strong IP provisions in the US-Jordan Free Trade Agreement should be the new minimum for future US FTA negotiations).

²⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1197 (1994) (hereinafter TRIPS Agreement).

²⁸ See USTR, Free Trade Agreements, available at: <http://www.ustr.gov/trade-agreements/free-trade-agreements> (last visited Nov. 9, 2011), for a list of U.S. agreements in force and pending. See EU Trade Commission, Overview of Regional Trade Agreements, available at: http://trade.ec.europa.eu/doclib/docs/2006/december/tradoc_111588.pdf (last visited Nov. 9, 2011). There are, of course, additional overlapping international IP agreements and institutions, see Laurence R. Helfer, *Regime Shifting in the International Intellectual Property System*, 7 PERSP. ON POL. 39 (2009). This article, however, identifies the principle forums in which developed countries have heightened IP protections and developing countries have sought to limit those increases.

1. World Intellectual Property Organization

In the late 1800s, developed countries began to negotiate agreements to strengthen national and international IP laws,²⁹ and the secretariat for the conventions, the WIPO, was created in 1967.³⁰ The developing countries were largely uninvolved in the development of international IP agreements, but concerns began to emerge in the post-colonial era.³¹ They saw the international conventions as limiting their access to IP, and their attempts in the 1980s to secure preferential treatment, by a revision of the Paris Convention, were unsuccessful.³²

2. WTO – TRIPS

As a result of developing country recalcitrance, WIPO's lack of capability to enforce its conventions, and the fact that each country within the WIPO had one vote, the United States and the EU sought to shift IP protection from WIPO to another international forum—the General Agreement on Tariffs and Trade (“GATT”, the precursor to the WTO).³³

Including IPRs in a multilateral trade framework was, and continues to be, controversial. Patents and other IP protections do not immediately implicate a relationship with trade, and in drafting the Punta del Este Ministerial Declaration,³⁴ the section was entitled “Trade Related Aspects of Intellectual Property rights, Including Trade in Counterfeit Goods”.³⁵ Although some developing countries

²⁹ Most importantly the Paris and Berne Conventions, which sought to extend protections for IP holders in foreign jurisdictions through the principle of “National Treatment”, whereby signatories would extend the same privileges, rights, and legal remedies to nationals of other signatories. DEERE, *supra* note 7, at 36. For a timeline of the core IP agreements, *see id.* at 330.

³⁰ Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3.

³¹ *See* DEERE, *supra* note 7, at 37-40 (detailing regional IP approaches in developing countries after independence).

³² Helfer, *supra* note 13, at 20; DEERE, *supra* note 7, at 43-45.

³³ Helfer, *supra* note 13, at 19-20; DEERE, *supra* note 7, at 46-48 (providing the historical context and dissatisfaction of U.S. and European companies with the limited patent protections in other countries). In spite of the regime shift from WIPO to the WTO, WIPO remains an important organization for IP worldwide and established the WIPO development agenda at the request of Argentina and Brazil in 2004. Helfer, *supra* note 13, at 24-26.

³⁴ World Trade Organization, Ministerial Declaration of Sept. 20, 1986, MIN(86)/W/19, 25 I.L.M. 1623 (1986) (Punta del Este Declaration, launching the Uruguay Round).

³⁵ Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 Hous. L. Rev. 979,

opposed the inclusion of IP in the GATT negotiations and others believed that they could limit the agreement to only IP issues relating to trade in counterfeit goods and other trade-related issues, this was not to be.³⁶

The foundation for incorporating IPRs within the GATT system was set at the beginning of the Uruguay Round of negotiations, which also created the WTO.³⁷ IP was brought into the trade framework by developed countries as a bargaining tool to extract commitments on IP from developing countries in exchange for opening up market access in goods and other concessions.³⁸ The GATT had two other specific benefits for the U.S. and Europe: due to their strength as trading partners, they had significant negotiating power and the dispute settlement system was perceived to be more effective than the various, unused convention procedures overseen by WIPO.³⁹

Throughout the following eight years of negotiations, multinational companies encouraged creation of a coalition of the U.S., Europe, and Japan to champion their interests in requiring all members to adopt high levels of patent protection.⁴⁰

983 (2009) (hereinafter Yu—*Objectives and Principles*).

³⁶ *Id.* at 984; Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 25 U. PA. J. INT'L ECON. L. 1079, 1093 (2004) (hereinafter Weissman); DEERE, *supra* note 7, at 52.

³⁷ Yu—*Objectives and Principles*, *supra* note 35, at 982. *See also*, Weissman, *supra* note 36, at 1085-88, 1092-94 (2004) (describing the role of the pharmaceutical industry in encouraging the US to push for the inclusion of IP in the GATT).

³⁸ DEERE, *supra* note 7, at 51. For changes strengthening IP protections at the WTO, *see* Uruguay Round negotiating history, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Draft Agreement To Discourage the Importation of Counterfeit Goods, MTN.GNG/NG11/W/9, 25 June 1987, *available at*: http://ipmall.info/hosted_resources/lipa/trips/W9.pdf (last visited Nov. 9, 2011); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Trade in Counterfeit Goods: Compilation of Written Submissions And Oral Statements, MTN.GNG/NG11/W/23, 26 Apr. 1988, *available at*: http://ipmall.info/hosted_resources/lipa/trips/W23.pdf (last visited Nov. 9, 2011); Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Status of Work in the Negotiating Group, Chairman's Report to the GNG, MTN.GNG/NG11/W/76, 23 July 1990, *available at*: http://ipmall.info/hosted_resources/lipa/trips/W76.pdf (last visited Nov. 9, 2011); TRIPS Agreement, *supra* note 27.

³⁹ Helfer, *supra* note 13, at 11-22.

⁴⁰ DEERE, *supra* note 7, at 53-55. INTELLECTUAL PROPERTY COMMITTEE (IPC), BASIC FRAMEWORK OF GATT PROVISIONS ON INTELLECTUAL PROPERTY, STATEMENT OF

The U.S. and Europe also worked outside the GATT framework to create bilateral agreements with high IP protections, and exert pressure on the remaining reluctant developing countries.⁴¹ To finalize negotiations on a range of agreements on different issues, the “single undertaking” principle that all agreements had to be approved as a package meant that it could not be opposed without forfeiting gains in market access despite the fact that less than 20 developing countries participated in the IP negotiations.⁴²

The result was the 1994 TRIPS agreement, which “enhanced the substantive rules found in pre-existing agreements negotiated within WIPO and included them within a single treaty that imposed a comprehensive set of intellectual property protection standards. The obligation to provide such protection extended to the entire WTO membership, including many developing states whose previous commitment to intellectual property protection was nonexistent or at best, equivocal.⁴³

The TRIPS agreement incorporates principles of the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary and Artistic Works; provides for National Treatment and Most-Favored Nation Treatment; establishes minimum standards for copyright, trademark, patents, and other IP rights; creates an enforcement mechanism; and sets out binding dispute settlement procedures.⁴⁴

Nearly all developing countries had to enact new or update existing IP laws to comply with TRIPS obligations, including the grant of patents for 20 years from the inventor’s filing date for any product or process in all fields of technology.⁴⁵ In contrast to many WTO and other international agreements granting “special and

VIEWS OF THE EUROPEAN, JAPANESE AND UNITED STATES BUSINESS COMMUNITIES (1988). For a timeline of industry actions, see PETER DRAHOS & JOHN BRAITHWAITE, INFORMATION FEUDALISM xi-xv (2002).

⁴¹ *Id.* at 54-56. This included, *inter alia*, use by the US of its Special 301 to “name and shame” countries in its annual report, along with the resulting imposition of sanctions for those countries falling below the US standards. Europe also began to change its approach, which culminated in an EU IP enforcement strategy in 2004. Strategy for the Enforcement of Intellectual Property Rights in Third Countries, 2005 O.J. (C 129/03) (EC).

⁴² *Id.* at 56.

⁴³ Helfer, *supra* note 13, at 23.

⁴⁴ TRIPS Agreement, *supra* note 27. See also, JOHN H. JACKSON, THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS 310-13 (2d ed. 1997); DEERE, *supra* note 7, at 64-68 (detailing the TRIPS provisions, obligations, and timeframes for implementation).

⁴⁵ TRIPS Agreement, *supra* note 27, art. 33; DEERE, *supra* note 7, at 11.

differential treatment” to developing countries, the TRIPS agreement has only three special provisions for developing countries: the implementation period for coming into compliance is longer,⁴⁶ the requirement that developed countries transfer technology to developing countries,⁴⁷ and a commitment by developed countries to provide capacity-building and technical assistance to developing countries.⁴⁸

The first group of developing countries had to implement TRIPS by 2000. With the deadline nearing, many countries had difficulty enacting all the required legislations and increasingly felt that they had been coerced into accepting an agreement that held only costs and no benefits for them.⁴⁹ Against the backdrop of growing resentment related to TRIPS implementation, the U.S. aggressively pursued perceived violations of the TRIPS agreement both within the WTO and unilaterally, leading to further opposition to the IP protections advanced by the developed countries.⁵⁰

3. TRIPS Flexibilities, Doha Declaration, and Paragraph 6 Parallel Importation

After failing to start a new round of trade negotiations at the 1999 Seattle Ministerial Conference, developed countries realized that they would have to make broad concessions in the next round of WTO negotiations, which came in the form of the 2001 Doha “Development” Round.⁵¹ Prior to this round, a group of

⁴⁶ TRIPS Agreement, *supra* note 27, arts. 65, 66.

⁴⁷ *Id.* art. 66(2).

⁴⁸ *Id.* art 67.

⁴⁹ See Declaration of the Group of 77 and China on the Fourth WTO Ministerial Conference at Doha, Qatar (Oct. 22, 2001), *available at*: <http://www.g77.org/doc/Doha.htm> (last visited Oct. 9, 2011); Havana Programme of Action, Group of 77 South Summit, Havana, Cuba, Apr. 10-14, 2000, (stating “[w]e are distressed that since the Ministerial Meeting in Marrakech held in 1994 establishing the WTO, little has been done to develop an effective program of concrete measures to assist the integration of [developing] countries into the multilateral trading system.”), *available at*: http://www.g77.org/summit/ProgrammeofAction_G77Summit.htm (last visited Nov. 9, 2011).

⁵⁰ See generally Susan K. Sell, *TRIPS and the Access to Medicines Campaign*, 20 WIS. INT’L LJ 481, 496-514 (2001-2002) (outlining the advancement of the Access to Medicines Campaign in response to the post-TRIPS actions taken by the United States to introduce TRIPS-plus provisions in trade agreements and limiting countries’ abilities to take advantage of compulsory licensing flexibilities permitted by Articles 30 and 31 of TRIPS) (hereinafter Sell).

⁵¹ World Trade Organization, Ministerial Declaration of 14 November 2001,

80 developing countries proposed the ‘Declaration on the TRIPS Agreement and Public Health’ (“Doha Declaration”), which was ultimately adopted in 2001.⁵² The Declaration “reaffirm[ed] the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility . . . to protect public health and, in particular, to promote access to medicines for all”.⁵³

Although the TRIPS obligations are the same for all WTO members, aside from the three exceptions noted above, countries are given the flexibility to implement the provisions “within their own legal system and practice”.⁵⁴ Though the flexibilities have been inherent in the TRIPS agreement since 1994, the Declaration provided reassurance that they would not be targeted for using TRIPS flexibilities to protect public health in light of the aggressive action taken by developed countries against countries employing compulsory licensing.

An important flexibility in the TRIPS agreement, reaffirmed by the Doha Declaration, includes the ability to issue compulsory licenses⁵⁵ in connection with the determination of what constitutes a national emergency or a circumstance of extreme urgency.⁵⁶ Additional flexibilities related to access to medicines and public health include the ability for each country to determine whether the exhaustion of IPR is national/regional or international,⁵⁷ to determine the scope of patentability and specific limited exclusions,⁵⁸ and the scope of enforcement measures.⁵⁹

Paragraph 6 of the Doha Declaration recognized that some countries did not have the manufacturing capacity in the pharmaceutical sector and “could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”.⁶⁰ However, it postponed any remedial action until 2002.⁶¹ The

WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002).

⁵² Doha Declaration, *supra* note 4. *See also*, Sell, *supra* note 50 at 516 (describing the 80 developing countries’ proposed declaration and negotiations leading up to the Doha meeting).

⁵³ *Id.* ¶ 4.

⁵⁴ TRIPS Agreement, *supra* note 27, art. 1(1).

⁵⁵ *Id.* art. 31.

⁵⁶ Doha Declaration, *supra* note 4, ¶ 5(c) (national emergencies can include public health crises such as “HIV/AIDS, tuberculosis, malaria and other epidemics”).

⁵⁷ *Id.* ¶ 5(d); TRIPS Agreement, *supra* note 27, art.6; DEERE, *supra* note 7, at 75-76 (discussing the concept of exhaustion of the primary property owner’s right and when it can no longer be enforced).

⁵⁸ TRIPS Agreement, *supra* note 27, art. 27, 30; DEERE, *supra* note 7, at 76-81.

⁵⁹ TRIPS Agreement, *supra* note 27, pt. III; DEERE, *supra* note 7, at 95.

⁶⁰ Doha Declaration, *supra* note 4, ¶ 6

⁶¹ *Id.*; *see also* DEERE, *supra* note 7, at 75-76 (listing countries and different parallel

subsequent Decision on the Implementation of Paragraph 6 set forth the procedures and obligations for both exporting and importing parties.⁶² However, the requirements under it are cumbersome⁶³ and have been used successfully only once for exports from Canada to Rwanda.⁶⁴ Although a number of countries have accepted the amendment, others have provided interventions to the TRIPS Council that the Paragraph 6 procedures still need to be revised.⁶⁵

While developing countries have achieved some successes in the context of the WTO, many have not implemented TRIPS flexibilities due to lack of capacity, being party to other agreements with TRIPS-plus obligations, or pressure from developed countries.⁶⁶ Such implementation of TRIPS and TRIPS-plus obligations without recourse to the flexibilities can add significant costs for governments and limits access to medicines.⁶⁷ Moreover, the progress made in context of the TRIPS agreement may not be able to achieve the real progress needed to expand access to medicines, particularly as developed countries shift away from the WTO as the primary forum for expansion of IP protections.⁶⁸

imports laws).

⁶² Paragraph 6 Implementation, *supra* note 5.

⁶³ Vanessa Bradford Kerry & Kelley Lee, *TRIPS the Doha Declaration and Paragraph 6 Decision: What are the Remaining Steps for Protecting Access to Medicines?*, 3 GLOBALIZATION & HEALTH, no. 3, 2007, available at: <http://www.globalizationandhealth.com/content/3/1/3> (last visited Nov. 8, 2011).

⁶⁴ George Tsai, Note, *Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063 (2009).

⁶⁵ See, e.g., *Positions Unchanged on Biodiversity Issues, "Para 6" System*, THIRD WORLD NETWORK (Mar. 10, 2011), available at: <http://www.twinside.org.sg/title2/wto.info/2011/twninfo110305.htm> (last visited Nov. 9, 2011); *Review of "Para 6" System, ACTA Feature at TRIPS Council*, THIRD WORLD NETWORK (Nov. 2, 2011), available at: http://www.twinside.org.sg/title2/intellectual_property/info.service/2011/ipr.info.111101.htm (last visited Nov. 9, 2011) (noting that while Argentina, Indonesia, and New Zealand accepted the amendment, Ecuador and Cuba do not believe that it will address the problems faced by countries in effectively employing compulsory licensing).

⁶⁶ *Report of the Special Rapporteur*, *supra* note 7, ¶ 26. DEERE, *supra* note 7, at 74-98. Both Brazil and Argentina allow the flexibility of compulsory licensing under a broad range of circumstances, while Pakistan and Cambodia allow it in more limited situations and Jordan, due to its FTA with the U.S. "imposed TRIPS-plus procedural requirements and other limitations on the issuance of compulsory licenses, including restricting the use of compulsory licenses to emergencies or epidemics only". See DEERE, *supra* note 7, at 82.

⁶⁷ Rudolf V. Van Puymbroeck, *Basic Survival Needs and Access to Medicines – Coming to Grips with TRIPS: Conversion + Calculation*, 38 J.L. MED. & ETHICS 520, 541-42 (2010).

⁶⁸ Susan K. Sell, *Cat and Mouse: Forum-Shifting in the Battle over Intellectual Property Enforcement* (Draft, prepared for IGIS research seminar, 2010), at 6, available at:

4. Existing and Emerging Bilateral and Regional Frameworks

The TRIPS Agreement has not been able to achieve all that the developed countries and pharmaceutical companies hoped for and have thus shifted the forum once again. This time, the shift is to bilateral and other agreements where developed countries are able to enact TRIPS-plus measures amongst themselves or with compliant developing countries. Little progress and no end in sight have made the WTO Doha Round of negotiations an unattractive forum for pharmaceutical manufacturers to advance their interests. The U.S., EU, and other developed countries are instead turning to negotiating free trade agreements, or relying on domestic laws such as the U.S. Special 301 and the EU border measures. These considerations have been discussed in more detail in Part IV of this note.

To be able to expand access to intellectual property and medicines, developing countries need to confront the IP anti-counterfeiting and enforcement agenda. The WTO dispute settlement system may be one tool available to developing countries in shifting the enforcement balance from ever-expanding public protections for privately held IPR to one that includes “exceptions and limitations, fair use, due process, civil rights, privacy rights, and antitrust (or competition policy)”.⁶⁹

III. DEVELOPING COUNTRIES, WTO DISPUTE SETTLEMENT, AND TRIPS

A. Dispute Settlement Generally

The Uruguay Round that created the TRIPS agreement also produced the DSU, which requires members to approach the multilateral forum for violations of WTO agreements rather than taking unilateral action.⁷⁰ Countries must also abide by the decision reached by the Panel, or on appeal, by the Appellate Body. If a member fails to do so, they may have to pay compensation to the complainant or risk having their concessions suspended by the prevailing party, with the approval of the DSB.⁷¹

Many developed country members saw the binding decisions and recourse to sanctioned retaliation in the event of non-compliance as significant improvements over the GATT panel, which had no enforcement mechanism, and particularly over the WIPO secretariat for IPR matters.

www.gwu.edu/~igis/Sell%20Paper.doc (last visited Nov. 8, 2011).

⁶⁹ *Id.* at 30.

⁷⁰ Understanding on Rules and Procedures Governing the Settlement of Disputes art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 (hereinafter DSU).

⁷¹ *Id.* arts. 21, 22.

Over 400 claims have been filed with the DSB since the DSU came into force in 1995; however, most are settled between parties during the consultation phase.⁷² Of the total, an *ad hoc* panel considers less than half of the filed disputes and the Appellate Body then hears about 70% of the Panel decisions on appeal.⁷³

Although developing countries face considerable challenges in filing disputes, primarily related to costs,⁷⁴ approximately 40% of all claims have been filed by developing countries.⁷⁵ Moreover, the trend of developing countries filing for dispute settlement in the WTO is increasing, while for developed countries it is declining.⁷⁶ Out of the top eleven most frequent complainants, seven are developing countries, highlighting the fact that once a developing country has participated in a dispute, either as a complainant or respondent, they are more likely to initiate a future claim at the WTO.⁷⁷ However, the majority of developing countries have never filed a complaint.⁷⁸

B. IP Disputes

The TRIPS agreement also contains a provision on dispute settlement, which applies the DSU and Articles XXII and XXIII of the GATT.⁷⁹ A moratorium on filing non-violation complaints based on TRIPS provisions remains in effect, although it was initially set to expire in 2000.⁸⁰ The United States and Switzerland

⁷² Joost Pauwelyn, *The Dog That Barked But Didn't Bite: 15 Years of Intellectual Property Disputes at the WTO*, 1(2) J. INT'L DISP. SETTLEMENT 389, 393-394 (2010) (hereinafter Pauwelyn).

⁷³ *Id.* at 6.

⁷⁴ See, e.g., Hunter Nottage, *Developing Countries in the WTO Dispute Settlement System* (U. C. Oxford, GEG Working Paper 2009/47, 2009) available at: <http://www.globaleconomicgovernance.org/wp-content/uploads/nottage-working-paper-final1.pdf>, (identifying and evaluating the commonly-identified constraints to developing country participation in WTO disputes including lack of expertise in WTO law or resources to hire legal counsel, inability to enforce decisions through cross-retaliation, lack of capacity to identify violations or trade barriers, and others).

⁷⁵ Evans & Shaffer, *supra* note 16, at 2.

⁷⁶ Chad P. Bown & Rachel McCulloch, *Developing Countries, Dispute Settlement and the Advisory Centre on WTO Law* (World Bank, Policy Research Working Paper 5168, 2010).

⁷⁷ Christina L. Davis & Sarah Blodgett Bermeo, *Who Files? Developing Country Participation in GATT/WTO Adjudication*, 71 J. POL. 1033, 1047 (2009).

⁷⁸ Evans & Shaffer, *supra* note 16, at 2.

⁷⁹ TRIPS Agreement, *supra* note 27, art. 64.

⁸⁰ TRIPS: 'Non-Violation' Complaints (Article 64.2), WORLD TRADE ORG., Dec. 3, 2009, available at:

would like to allow such complaints. However, an apprehension that these countries could limit the ability of other countries to use TRIPS flexibilities persists among a majority of members. Thus, the lifting of the ban is strongly opposed.⁸¹ Out of more than 400 claims filed at the WTO, only 29 have included TRIPS provisions,⁸² and less than one-third of those have been heard by a Panel.⁸³ The United States and the European Communities have been the primary complainants in the majority of disputes; Canada, Australia, India, and Brazil have each filed a request for consultations with the EC; Brazil also filed a request for consultations with the US.⁸⁴

Until recently, developing countries have participated in TRIPS almost exclusively as defendants, in claims that allege violations of the minimum standards under TRIPS. In fact, the first TRIPS dispute *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*⁸⁵ led to the establishment of a Panel with India as the respondent state.⁸⁶ Somewhat surprisingly, claims have been brought against developing countries in less than one-third of the TRIPS complaints filed, and the majority of the consultations occur between developed countries.⁸⁷

Recently, a slight shift has occurred within the framework of the DSU—beginning with the Panel report in a claim related to protection and enforcement of IPRs brought by the United States in *China – Measures Affecting the Protection and*

http://www.wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm (last visited Nov. 9, 2011).

⁸¹ See *id.* A non-violation complaint would allow a country to bring a suit not on the basis of a specific breach of the TRIPS agreement, but rather because of an imbalance or a benefit the complainant believes it is owed. For a detailed analysis on potential problems of non-violation claims in the TRIPS realm, see MATTHEW T. STILLWELL & ELISABETH TUERK, CTR. FOR INT'L ENVTL. LAW, NON-VIOLATION COMPLAINTS AND THE TRIPS AGREEMENT: SOME CONSIDERATIONS FOR WTO MEMBERS (May 2001), available at: http://www.ciel.org/Publications/Nonviolation_Paper1.pdf (last visited Nov. 9, 2011).

⁸² *Intellectual Property (TRIPS), Disputes by Agreement*, WORLD TRADE ORG., available at: http://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A26#selected_agreement (last visited June 2, 2011) (hereinafter *TRIPS–Disputes by Agreement*).

⁸³ Pauwelyn, *supra* note 72, at 2, 10-35 (analyzing the TRIPS disputes that have been heard by a panel or appellate body, whether the disputes directly concern IP issues, and resulting interpretations of the TRIPS Agreement by the DSB).

⁸⁴ *TRIPS–Disputes by Agreement*, *supra* note 82.

⁸⁵ *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50, Sept. 5, 1997.

⁸⁶ Peter K. Yu, *TRIPS and Its Achilles' Heel*, 18 J. INTELL. PROP. L. 479(2011).

⁸⁷ *TRIPS–Disputes by Agreement*, *supra* note 82.

Enforcement of Intellectual Property Rights,⁸⁸ and continuing with the requests for consultation with the European Communities submitted by India and Brazil⁸⁹—towards the recognition that IP protections that exceed TRIPS obligations have the potential to violate both the spirit and the letter of the agreement.

The 2009 Panel report in *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*⁹⁰ included US claims that China was not meeting its TRIPS obligations of criminalizing IP infringements, disposal of confiscated goods infringing IP rights, and protecting rights holders of materials not authorized for publication or distribution in China. Although Panel reports do not set precedents within the WTO dispute settlement system and do not bind anyone but the parties, they are often cited in subsequent Panel and Appellate Body reports and may also influence negotiations on similar issues.⁹¹ While the Panel decided some issues in favour of the U.S. and others for China, “less developed countries might have become the dispute’s ultimate winner”.⁹²

In the Panel report, there are several potential gains for developing countries both with regard to bringing DSU challenges to external agreements and IP enforcement negotiations in and out of the WTO to protect their access to medicines. First, the Panel repeatedly recognized that the TRIPS agreement contains minimum standards, and allows for countries to use flexibilities inherent in the agreement, particularly with regard to criminal enforcement, but also reinforced, as many previous Panel and AB reports have done, that “Article 1.1 does not permit differences in domestic legal systems and practices to justify any derogation from the basic obligation to give effect to the provisions on enforcement”.⁹³

⁸⁸ Panel Report, *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R, Jan. 26, 2009 (hereinafter *China – IP*).

⁸⁹ Request for Consultations by India, *European Union and a Member State – Seizure of Generic Drugs in Transit*, WT/DS408/1 (May 19, 2010) (hereinafter *India’s Request for Consultations*); *European Union and a Member State – Seizure of Generic Drugs in Transit*, WT/DS409/1 (May 19, 2010) (hereinafter *Brazil’s Request for Consultations*).

⁹⁰ Panel Report, *China – IP*, *supra* note 88.

⁹¹ *Id.* at 11.

⁹² Peter K. Yu, *TRIPS Enforcement and Developing Countries*, 26 AM. U. INT’L L. REV. 727, 782 (2011), available at: <http://www.auilr.org/pdf/26/26.3.6.pdf> (last visited Nov. 8, 2011) (hereinafter Yu–*TRIPS Enforcement*).

⁹³ Panel Report, *China – IP*, *supra* note 88, ¶ 7.513. At issue is the third sentence of Article 1.1 of TRIPS, which states “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice”.

The Panel also invokes the recognition that IP rights are private rights from the preamble of the TRIPS when determining that the phrase “competent authorities shall have the authority to order the destruction or disposal of infringing goods”⁹⁴ does not require a member country to undertake an action without a request or application.⁹⁵ This is significant for developing countries, because, unlike ACTA and numerous bilateral treaties, TRIPS does not require seizure of goods believed to infringe the obligations of the agreement.⁹⁶

An additional action by the Panel that may benefit developing countries is that the Panel would not accept a bilateral agreement as evidence of subsequent practice to which the complainant was a party but the defendant was not. This is because TRIPS-plus measures to which the complainant is a party but the respondent country is not, cannot be imposed on developing countries.⁹⁷ Furthermore, the Panel took local conditions into consideration in its determination of the scope of counterfeiting or piracy on a commercial scale, examining the Chinese market in detail.⁹⁸ This is also important for developing countries because determinations of alleged violations of TRIPS should not be compared to some universal standard, but should rather take the local context into consideration. Finally, the Panel requested substantive evidence, rather than industry sources or claims without supporting data from a government, to resolve the dispute.⁹⁹ Being respondents in a majority of disputes, this may also serve developing countries if developed country complainants are required to present authoritative evidence to proceed with their claims.¹⁰⁰ Collectively, the Panel report touches upon several issues of great import for developing countries in future IP disputes. Signalling that, Yu says “in an area where developed countries have historically dominated, such as intellectual property protection and enforcement, developing countries are now doing much better in the WTO dispute settlement process than they did in the early days of the TRIPS Agreement”.¹⁰¹ This may provide a foundation for developing countries to challenge developed country IP measures as violative of TRIPS.

⁹⁴ TRIPS Agreement, *supra* note 27, art. 59.

⁹⁵ Panel Report, *China – IP*, *supra* note 88, ¶ 7.247; Yu–TRIPS *Enforcement*, *supra* note 92, at 749-50.

⁹⁶ Yu, *supra* note 92, at 749-50.

⁹⁷ *Id.* at 754-757.

⁹⁸ *Id.* at 757-760.

⁹⁹ Panel Report, *China – IP*, *supra* note 88, ¶ 7.629

¹⁰⁰ *Id.* at 763.

¹⁰¹ *Id.* at 764.

IV. DEVELOPING COUNTRY CHALLENGES TO IP MEASURES LIMITING ACCESS TO MEDICINES

A complex and overlapping array of institutions and agreements govern international IP.¹⁰² While some are more responsive to concerns of developing countries, others seek the highest possible IP enforcement measures. The TRIPS agreement, particularly, imposes the broadest obligations on all of its members and has a binding dispute settlement procedure. Although most TRIPS disputes have sought to compel countries to meet their minimum standards obligations, there is a growing recognition that the agreement does contain several maximum standards, and that some new laws and agreements imposing additional obligations on WTO members may cause them to violate TRIPS.¹⁰³ This flows from the reading of Article 1(1) of the TRIPS, which provides, “[m]embers may, but shall not be obliged to, implement in their law more extensive protection than is required by the Agreement, provided that such protection does not contravene the provisions of this agreement”.¹⁰⁴

In addition to the efforts by developed countries to raise enforcement protections for IP comes a shift in terminology, which seeks to obfuscate legitimate trade in generic medicines by including it within measures aimed against counterfeiting and piracy.¹⁰⁵ This trend may be most apparent in the Anti-Counterfeiting Trade Agreement, which is neither limited to counterfeiting, nor to trade. While the final text of ACTA is much improved from prior drafts because it excludes patents from some of its more draconian provisions, it still requires parties to ensure that domestic law provides for enforcement provisions for “any act of infringement of intellectual property rights” covered by ACTA.¹⁰⁶ This,

¹⁰² Helfer, *supra* note 13, at 39.

¹⁰³ See generally, Annette Kur & Henning Grosse Ruse-Khan, *Enough is Enough – The Notion of Binding Ceilings in International Intellectual Property Protection*, (Max Planck Inst. for Intell. Prop., Competition & Tax Law, Research Paper Series No. 09-01, 2009); Henning Grosse Ruse-Khan, *Time for a Paradigm Shift? Exploring Maximum Standards in International Intellectual Property Protection*, 1 TRADE L. & DEV. 56 (2009) (exploring the ideal of maximum standards in international IP law, rather than the commonly accepted understanding of TRIPS as representing the minimum standard upon which all TRIPS-plus norms may stand).

¹⁰⁴ TRIPS Agreement, *supra* note 27, art. 1.

¹⁰⁵ See Shashank P. Kumar, *European Border Measures and Trade in Generic Pharmaceuticals: Issues of TRIPS, Doha Declaration and Public Health*, 15(6) INT'L TRADE L. & REG. 176, 181-82 (2009) (hereinafter Kumar).

¹⁰⁶ Anti-Counterfeiting Trade Agreement, *supra* note 11, art. 6(1). For an analysis of how ACTA applies to more than counterfeit or pirated goods, see Henning Grosse Ruse-Khan, *A Trade Agreement Creating Barriers to Trade? ACTA Border Measures and Goods in Transit*

along with other FTA measures and USTR (United States Trade Representative) actions under Section 301, has the potential to limit legitimate trade in generic medicines, rather than achieving the purported goal of protection against unsafe medicines.

Some of these measures have been analyzed in this section. The section also discusses the possible outcome of the decisions challenging such measures.

A. EU Seizure of Generic Drugs in Transit

Customs regulation has been used by the EU to move to higher levels of enforcement of IP rights, which began in 1986 and increased with the enactment of Council Regulation 1383 of 2003 (“EC Regulation”).¹⁰⁷ The Regulation *requires* that countries extend border measures to transit goods (exported from a country outside the EU and destined for importation also by a country outside the EU). The Regulation has also increased the scope of infringement to include suspected violation of IP rights *other than* copyright or patent, and enables customs agents to detain, and in some cases, destroy goods upon suspicion of infringement.¹⁰⁸

1. 2010 Requests for Consultations by India and Brazil

In the case of seizures of generic medicines in transit, the seizures of 19 shipments of generic drugs that were “either destroyed or returned” by the Netherlands in 2008 and 2009 pursuant to EC Regulation 1383/2003 are at issue.¹⁰⁹ The seizures were remarkable as they were applied on the basis of alleged infringements of patents in the transit European countries, rather than the exporting or importing country. Both India and Brazil filed requests under the WTO’s DSU for consultations with the EU in 2010.¹¹⁰

Brazil and India have alleged that, the EC Regulation on border measures as well as related EU and Dutch laws and regulations violate, *inter alia*:

14-26 (MAX PLANCK INST. FOR INTELL. PROP., COMPETITION & TAX L., Research Paper Series No. 10-10, 2010) (hereinafter Grosse Ruse-Khan).

¹⁰⁷ Xavier Seuba, *Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border* 4 (INT’L CTR. FOR TRADE & SUSTAINABLE DEV., Issue Paper No. 27, 2010) (hereinafter Seuba).

¹⁰⁸ *Id.* at 4-5.

¹⁰⁹ *India’s Request for Consultations*, *supra* note 89; EC Regulation 1383/2003, *supra* note 10.

¹¹⁰ *India’s Request for Consultations*, *supra* note 89; *Brazil’s Request for Consultations*, *supra* note 89.

- Articles V and X of the GATT;
- Article XVI:4 of the Marrakesh Agreement Establishing the World Trade Organization;
- Articles 1(1), 2, 7, 8, 28, 31, 41, 42, 50, 51, 52, 53, 54, 55, 58 and 59 of the TRIPS Agreement;
- Article 4*bis* of the Paris Convention of 1967;
- Decision of 2003 on the Implementation of Paragraph 6.¹¹¹

The allegations by India and Brazil are noteworthy in that, they alleged that the EC violated the agreement not by failing to apply adequate standards, but rather by exceeding what the TRIPS and other WTO agreements require:

[I]t is a complaint by India and Brazil against the EC, arguing that the EC violates GATT and TRIPS by enforcing IP rights *too strictly*, in particular, as against generic drugs in transit, patented within the EC, but on their way from India to Brazil where they are not patent-protected. This is not a case brought by big pharma or the IP lobby [but rather] a case filed on behalf of the generic drug industry against IP protection *beyond* minimum standards.¹¹²

India and Brazil grounded their claims in GATT Article V on freedom of transit “because the measures at issue, inter alia, are unreasonable, discriminatory and interfere with, and impose unnecessary delays and restrictions on, the freedom of transit of generic drugs lawfully manufactured within, and exported from, India by the routes most convenient for international transit”,¹¹³ and GATT Article X on the publication and administrative regulations, alleging the border measures “are not administered in a uniform, impartial and reasonable manner”.¹¹⁴

Brazil also based its complaint upon the Marrakesh Agreement that each Member’s laws and regulations must be in conformity with obligations in the annex agreements, including TRIPS in this case.¹¹⁵ India further alleges that Article

¹¹¹ *Brazil’s Request for Consultations*, *supra* note 89; *India’s Request for Consultations*, *supra* note 89. For additional analysis of each of the claims and counterarguments, as well as relevant European Court of Justice case law, *see* Seuba, *supra* note 107; Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare*, 1 WORLD INTELL. PROP. ORG. J. 43 (2009); Kumar, *supra* note 105.

¹¹² Pauwelyn, *supra* note 72, at 428-29.

¹¹³ *India’s Request for Consultations*, *supra* note 89.

¹¹⁴ *Id.*

¹¹⁵ *Brazil’s Request for Consultations*, *supra* note 89.

28 read together with Article 2 of the TRIPS Agreement, Article 4*bis* of the Paris Convention, 1967 and the last sentence of paragraph 6(i) of the Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the “August 30, 2003 Decision”) were violated by such a border enforcement measure. A cumulative reading of the aforementioned provisions confirms, *inter-alia*, that the rights conferred on the owner of a patent cannot be extended to interfere with the freedom of transit of generic drugs lawfully manufactured within, and exported from, India.¹¹⁶

The other claims that Brazil and India relied upon in their request for consultations were that the stricter European border measures were inconsistent with TRIPS (Article 1.1), create barriers to legitimate trade and were unnecessarily burdensome (Articles 41 and 42), and authorized interference with parallel imports (contra Article 31 and the 2003 Decision on Implementation of Paragraph 6).¹¹⁷

Although the EU committed to revise its border measure regulation during the process of negotiations and consultations, had the countries been unable to resolve the dispute, India and Brazil should have requested the establishment of a Panel. That it interferes with the free transit principles of GATT and TRIPS, imposes unnecessary restrictions and undue delays, and confers rights on patent holders (in Europe) not contemplated by the TRIPS agreement are some of the many issues that the DSB would likely have found problematic with the EC Regulation 1383/2003 in a potential dispute.¹¹⁸

2. The Case Against EC Regulation 1383/2003 before a future WTO Panel¹¹⁹

A future dispute on the compatibility of the EC Regulation with WTO law would likely centre around two key issues: (1) whether the border measure provisions do “not contravene” TRIPS Article 51, and the related issue of the meaning of importation under Article 52; and (2) whether the regulation creates barriers to “legitimate” trade in generic medicines under TRIPS Article 41.¹²⁰

¹¹⁶ *Id.*

¹¹⁷ *Brazil's Request for Consultations*, *supra* note 89; *India's Request for Consultations*, *supra* note 89.

¹¹⁸ Seuba, *supra* note 107, at 33.

¹¹⁹ An analysis of potential EU defenses in such a claim are beyond the scope of this article, but can be found in Seuba, *supra* note 107, at 22-9.

¹²⁰ As WTO law is cumulative and since TRIPS also recognizes the obligations of members under pre-existing IP conventions, the arguments against EC Regulation

(i) TRIPS Articles 51 and 52

The specific provisions at issue are within Part III, Section 4 of TRIPS on enforcement of IP rights. Article 51 of TRIPS contains the relevant minimum standards and requirements of IP protection through border measures, and Article 52 sets forth the conditions of action based on Article 51.

“Suspension of Release by Customs Authorities” of Article 51 requires members to enable right holders to request customs authorities to suspend from release into commerce imported “counterfeit trademark or pirated copyright goods” but does not impose the same obligations with regard to goods for export or in-transit goods. However, footnote 13 states that there “shall be no obligation to apply such procedures” with regard to goods in transit.¹²¹ Moreover, Article 51 does allow for the creation of similar measures for infringements of intellectual property rights other than copyrights and trademarks, such as patents, as long as they meet the other requirements of the article.

Article 51 therefore creates minimum requirements for border measures, but also permits enactment of additional measures. The country challenging EC Regulation 1383/2003 as inconsistent with WTO law would note, however, that when countries are authorized to enact broader IP protections than those in the TRIPS Agreement, they may do so only insofar as they do “not contravene the provisions of” TRIPS.¹²²

Relevant to the inquiry of whether the EC Regulation contravenes WTO law as an instrument that imposes border measures beyond those required by TRIPS Article 51, is the Article 52 requirement that the right holder in the importing country must make out a *prima facie* case to trigger Article 51.¹²³

Key to the review is whether the “country of importation” is only that of the goods’ final destination, or if it includes the countries of transit that effectively import for the purpose of directly exporting.¹²⁴ If it is the former, then it would be much more difficult to find the European measure consistent than if it is the

1383/2003’s compatibility with WTO law will include the articles and instruments included in India’s and Brazil’s request for consultations noted above. This article, however, limits its analysis principally to TRIPS Articles 1.1, 41, 51, and 52.

¹²¹ TRIPS Agreement, *supra* note 27, art. 51, n. 13.

¹²² TRIPS Agreement, *supra* note 27, art. 1(1).

¹²³ *Id.* at n.14, art. 52; *see also* Seuba, *supra* note 107, at 12.

¹²⁴ Kumar, *supra* note 105, at 185.

latter.¹²⁵ There is a strong argument to be made, based on distinct uses of “transit” and “importation” throughout TRIPS, as well as in GATT Article V, that the “country of import” does not include trans-shipment countries.¹²⁶ As such, detainment and seizure of goods based on the request of a right holder in a European transit country would not fall within Article 52.

Further, border measures enabling customs agents to seize or detain goods have typically only applied to counterfeit or pirated copyrighted or trademarked goods because it is easier to identify them as infringing.¹²⁷ In contrast, infringement of patents, particularly for medicines, may not be apparent through visual inspection alone.¹²⁸

(ii) TRIPS Article 41

Article 41 sets forth general obligations of members regarding enforcement of TRIPS and notes that implementation of these obligations should “avoid the creation of barriers to legitimate trade”.¹²⁹ While it is apparent that a barrier to trade was created by the detainment and seizure of generic medicines, the country filing the dispute with the WTO would also need to show that the trade was legitimate.

The shipments of pharmaceuticals seized under EC Regulation 1383/2003 abided by their national law in both the initial exporting and the final destination importing countries, creating a presumption of legitimacy.¹³⁰ Additionally, in its report in *Canada—Pharmaceutical Products*, the panel deemed the “legitimate interests” of a patent holder to be defined “as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms”, rather than as strictly legal interests,¹³¹ which may be useful for developing countries that do not have specific codified laws or case-based rights attached to all justifiable normative claims. Moreover, the Doha Declaration and the Decision Interpreting Paragraph 6 have both reaffirmed the

¹²⁵ *Id.*

¹²⁶ *Id.* at 187-190.

¹²⁷ Seuba, *supra* note 107, at 11.

¹²⁸ *Id.*

¹²⁹ TRIPS Agreement, *supra* note 27, art. 41(1). While this language of article 41 has not been interpreted by either a WTO Panel or Appellate Body, see Grosse Ruse-Khan, *supra* note 106, at 13 for a discussion of the provision.

¹³⁰ Kumar, *supra* note 105, at 186.

¹³¹ Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶ 7.69, WT/DS/114/R (Mar. 17, 2009).

need to interpret TRIPS in favour of public health.¹³² The Panel would also take into consideration these decisions of WTO members, through application of the principle of customary international law requiring subsequent agreements to a treaty to be taken into account when interpreting that treaty.¹³³ On this basis, the trade in generic medicines would also be seen as “legitimate.”

B. U.S. Section 301

As part of the broad effort to heighten global IP protections in the 1980s, the U.S. added IP to the U.S. Trade Act of 1974, which included provisions for the President to take action on ‘unfair’ trading practices by other countries.¹³⁴ The USTR was empowered to monitor these trading practices and threaten or impose sanctions.¹³⁵ Although developing countries believed that inclusion of IP in the WTO’s multilateral framework would lessen USTR intrusion, it continued to conduct annual reviews and push aggressively for compliance with IP agreements.¹³⁶ In the late 1990s, the EU challenged Sections 301-310 of the Trade Act, 1974 and USTR actions. The Panel in *United States – Sections 301-310 of the Trade Act of 1974* (“US–Section 301-310 case”) determined that the U.S. could no longer impose unilateral trade sanctions through section 301 because it violated the DSU.¹³⁷ However, the U.S. continued to conduct annual reviews and include countries on “watch lists.”

The USTR includes a review of developing IP issues, and lists countries that it sees as needing higher levels of IPR protection and enforcement in the annual Special 301 Report. The U.S. includes countries on the regular and priority watch lists as a way to exert political pressure on countries to implement TRIPS-plus measures domestically and cease using TRIPS flexibilities.¹³⁸ Despite solicitation of

¹³² Doha Declaration, *supra* note 4; Paragraph 6 Implementation, *supra* note 5 (creating a waiver to Article 31 of TRIPS to allow for parallel importation of medicines in countries with insufficient manufacturing capabilities to undertake compulsory licensing).

¹³³ Seuba, *supra* note 107, at 22 (noting that DSU Article 3.2 requires the application of principles of customary international law, contained in the Vienna Convention on the Law of Treaties, Article 31(3)(a) when interpreting WTO agreements).

¹³⁴ Peter Drahos, *Bilateralism in Intellectual Property*, OXFAM GB, available at: <http://www.maketradefair.com/assets/english/bilateralism.pdf> (last visited May 31, 2011).

¹³⁵ DEERE, *supra* note 7, at 49.

¹³⁶ Sell, *supra* note 50, at 493.

¹³⁷ Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, Dec. 22, 1999 (hereinafter *US–Sections 301-310*); Sean M. Flynn, *Special 301 of the Trade Act of 1974 and Global Access to Medicines* 13 (AM.U., WCL Research Paper No. 2010-25) (hereinafter Flynn).

¹³⁸ Flynn, *supra* note 137. USTR, 2011 SPECIAL 301 REPORT, *supra* note 9 (including the

input from public interest groups, the 2011 report retains many of the same problematic assertions of past years, including the listing of the countries that need to increase enforcement efforts and criminal penalties for IP infringements.¹³⁹

The Case Against Section 301 of the U.S. Trade Act of 1974 Before a Future WTO Panel:

As noted in the introduction, countries should bring new challenges based on the premise that the continued use of Section 301 constitutes unilateral action that violates the DSU. Since the creation of the WTO and DSU in 1994, the U.S. has only initiated proceedings to impose unilateral sanctions once—in an instance of alleged pharmaceuticals patent infringement by Argentina in 1997.¹⁴⁰ Argentina quickly ceded to the U.S. demands and sanctions were never imposed, thus avoiding a potential, direct challenge to the U.S. program.¹⁴¹ The European Communities requested consultations alleging that several sections of the US Trade Act violated the DSU,¹⁴² and the Panel determined that the U.S. could not impose unilateral sanctions on the basis of Section 301, but rather had to proceed through the WTO.¹⁴³

As a result of this decision in the *US–Section 301-310* case, the United States has altered its Section 301 approach to exclude imposition of sanctions on other WTO members, but it still takes unilateral action to try to move countries to enact and enforce higher IP standards.¹⁴⁴ There are two distinct claims based on infringement of DSU Articles 3.1 and 23¹⁴⁵ by the United States. The first claim is

Priority Watch List of China, Russia, Algeria, Argentina, Canada, Chile, India, Indonesia, Israel, Pakistan, Thailand, and Venezuela and varied reasons for their inclusion).

¹³⁹ 2011 SPECIAL 301 REPORT, *supra* note 9; Rashmi Rangnath, *2011 Special 301 Report: Still Oblivious to Public Interest*, PUBLIC KNOWLEDGE POLICY BLOG (May 3, 2011), available at: <http://www.publicknowledge.org/blog/2011-special-301-report-still-oblivious-publi> (last visited Dec. 21, 2011).

¹⁴⁰ Mutually Agreed Solution, *Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WT/DS171/3, June 20, 2002 (hereinafter *Argentina–Pharmaceuticals*); See also SOC. SCI. RESEARCH COUNCIL, MEDIA PIRACY IN EMERGING ECONOMIES 88-89 (Joe Karaganis ed. 2011) (hereinafter SOC. SCI. RESEARCH COUNCIL).

¹⁴¹ SOC. SCI. RESEARCH COUNCIL, *supra* note 140.

¹⁴² *US–Sections 301-310*, *supra* note 137.

¹⁴³ *Argentina–Pharmaceuticals*, *supra* note 140; Flynn, *supra* note 137, at 12; Matthew Turk, Note, *Bargaining and Intellectual Property Treaties: The Case for a Pro-Development Interpretation of TRIPS but Not TRIPS Plus*, 42 N.Y.U. J. INT'L L. & POL. 981 (2010).

¹⁴⁴ Flynn, *supra* note 137.

¹⁴⁵ These articles relate to the agreement of members to work within the WTO multilateral system to settle trade disputes and that Members cannot unilaterally determine

that the administrative adjudications in the form of watch lists, which the USTR undertakes pursuant to Special 301, violate the DSU because they are “a determination to the effect that a violation has occurred”,¹⁴⁶ which is a form of prohibited unilateral trade sanction similar to that considered in the 1999 Panel report.¹⁴⁷

The other claim is that including a country on the Special 301 watch list, and threats resulting from such inclusion constitute violations of the DSU.¹⁴⁸ The Panel in the *US – Special 301* dispute noted that “[a] law reserving the right for unilateral measures to be taken contrary to DSU rules and procedures, may—as is the case here—constitute an ongoing threat and produce a ‘chilling effect’ causing serious damage in a variety of ways”.¹⁴⁹ Among the ways, the Panel noted that threat of unilateral action could effectively be identical to the actual imposition of that action, which would violate Article 3 of the DSU.¹⁵⁰ Once on the watch list, countries remain there until they undertake the actions “suggested” by USTR in the Report. Although the U.S. is no longer able to impose formal unilateral sanctions, other informal political and economic actions are always available to the US government. In 2011, in conjunction with the release of the Special 301 Report, the USTR “invite[d] any country appearing on the Special 301 Priority Watch List or Watch List to negotiate a mutually agreed action plan designed to lead to that country’s removal from the relevant list”, while retaining the caveat that “[a]greement on such a plan will not by itself change a trading partner’s status”.¹⁵¹

B. *Anti-Counterfeiting Trade Agreement*

The ACTA is an IP enforcement agreement negotiated by Australia, Canada, the EU, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland,

whether a measure is inconsistent with WTO agreements. Understanding on Rules and Procedures Governing the Settlement of Disputes, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 (1994).

¹⁴⁶ *Id.* art. 23(2).

¹⁴⁷ *US–Sections 301-310*, *supra* note 137; Flynn, *supra* note 137, at 12-13.

¹⁴⁸ Allegation Letter, United Nations Special Rapporteur on the Right to Health, *In the Matter of Use of the “Special 301” Program, Section 1982 of the Trade Act of 1974, to Limit Access to Medicines in Violation of the International Right to Health*, available at: www.wcl.american.edu/pijip/go/healthgap07202010 (last visited June 2, 2011).

¹⁴⁹ *US–Sections 301-310*, *supra* note 137, ¶ 7.88.

¹⁵⁰ *Id.* ¶ 7.89.

¹⁵¹ Press Release, United States Trade Representative, USTR Releases Annual Special 301 Report on Intellectual Property Rights (May 2011), available at: <http://www.ustr.gov/about-us/press-office/press-releases/2011/may/ustr-releases-annual-special-301-report-intellectual-p>.

and the United States that was announced in October 2007 and finalized in December 2010. These countries were unable to enact the high IP enforcement standards at the WTO¹⁵² and sought to create a new plurilateral agreement of best-practices among a “coalition of the willing”.¹⁵³ Initially, ACTA’s border measures were very similar to those contained in EC Regulation 1383/2003, allowing for detainment of medicines by customs agents on the mere suspicion that they infringed upon right holders in the country of transit.¹⁵⁴

India, China, and other developing countries raised concerns about the ACTA violating the TRIPS Agreement at both the June and October 2010 TRIPS Council Meetings.¹⁵⁵ China’s position in October was that higher protections for rights holders could lead to increased monopoly profits and upset the balance between rights holders and rights users, identified as an element of the TRIPS objective set forth in Article 7.¹⁵⁶ Furthermore, ACTA could lead to abuse of IPRs by rights holders, present an unreasonable obstacle to technology transfer, or restrain trade—all dangers warned against in Article 8 of TRIPS.¹⁵⁷

The final ACTA text is an improvement from previous drafts because patents have been removed from key sections,¹⁵⁸ due in part to the opposition to ACTA limiting the free transit of medicines.¹⁵⁹ In July 2010, the EU stated that patents

¹⁵² Peter K. Yu, *Six Secret (and Now Open) Fears of ACTA* 10-13 (2010), available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1624813 (last visited Nov. 8, 2011).

¹⁵³ *All You Want to Know About the Anti-Counterfeiting Trade Agreement (ACTA)*, EUROPEAN UNION (Oct. 20, 2010), available at: http://trade.ec.europa.eu/doclib/docs/2010/october/tradoc_146792.pdf (last visited Nov. 8, 2011).

¹⁵⁴ Peter Maybarduk, *ACTA and Public Health*, 5 (PIJIP Research Paper No. 9, 2010 AM. U. WASH. C. L.) (hereinafter Maybarduk); Henning Ruse-Khan, *supra* note 106, at 17-18.

¹⁵⁵ *ACTA: Intervention of China to the WTO TRIPS Council*, KNOWLEDGE ECOLOGY INT’L BLOG (Oct. 31, 2010), available at: <http://keionline.org/node/1001> (last visited Nov. 8, 2011).

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ Anti-Counterfeiting Trade Agreement. Section 2 on Civil Enforcement states “[a] Party may exclude patents and protection of undisclosed information from the scope of this Section” and Article 13 on the Scope of Border Measures notes “[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section.” Anti-Counterfeiting Trade Agreement, *supra* note 11.

¹⁵⁹ Urgent ACTA Communiqué: International Experts Find that Pending Anti-Counterfeiting Trade Agreement Threatens Public Interests, AM. UNIV. WASH. COLL. OF LAW (June 23, 2010), available at: <http://www.wcl.american.edu/pijip/go/acta->

would not be covered by ACTA, nor would “cross-border transit of legitimate generic medicines” be hindered.¹⁶⁰ However, the agreement still contains stringent border measures and criminal enforcement procedures, in addition to other TRIPS-plus enforcement measures, which have the potential to hinder access to medicines and infringe upon TRIPS obligations.¹⁶¹

The Case Against ACTA Before a Future WTO Panel

Although there is no immediate opportunity to challenge ACTA in the DSB because it has not yet entered into force,¹⁶² developing countries and NGOs were able to exert pressure through the WTO TRIPS Council by raising concerns that some provisions of ACTA (discussed below) could violate TRIPS and limit access to medicines. ACTA, once in force, may impose obligations on non-parties and lead to upsetting the balance between rights holders and rights users.¹⁶³ This may provide the developing countries with an opportunity to challenge the provisions of ACTA at the WTO.

Although patents have been excluded from ACTA’s border measure enforcement requirements, there are still several ways that trade in generic medicines may be limited by ACTA. Copyright and trademark infringements are not the only IP protected by the Agreement, as ACTA’s definition of IP includes: “all categories of intellectual property that are the subject of Sections 1 through 7

communiqué (last visited Nov. 8, 2011).

¹⁶⁰ Press Release, European Commission, Anti-Counterfeiting Trade Agreement, Report on the 9th Round of Negotiations (July 2, 2010), available at: <http://trade.ec.europa.eu/doclib/press/index.cfm?id=588&serie=352&langId=en> (last visited Nov. 8, 2011).

¹⁶¹ For a detailed discussion of the October 2010 draft text, which was very close to the final December 2010 text, and accompanying analysis of the provisions and potential impacts, see Grosse Ruse-Khan, *supra* note 106.

¹⁶² *Anti-Counterfeiting Agreement Signed in Tokyo*, REUTERS (Oct. 1, 2011) available at: <http://uk.reuters.com/article/2011/10/01/uk-japan-trade-counterfeiting-idUKTRE79018620111001> (last visited Nov. 9, 2011).

¹⁶³ India’s intervention at the October 25, 2011 TRIPS Council highlighted this potential problem, “The MFN provisions of the TRIPS agreement mean that any TRIPS plus protection secured by any trading partner via an RTA or a plurilateral agreement is *ipso facto* applicable to all other WTO members. Thus this agreement will have a direct bearing even on the members not involved in ACTA, but who will subsequently enter into RTAs with ACTA signatories.” *WTO TRIPS Council: India Raises Concerns on ACTA and TPPA on Discussion of “Trends in the Enforcement of IPRs”*, KNOWLEDGE ECOLOGY INTERNATIONAL, Oct. 26, 2011, available at: <http://keionline.org/node/1300>, (last visited Nov. 9, 2011).

of Part II of the TRIPS Agreement".¹⁶⁴ ACTA parties must also provide enforcement of measures related to geographical indications, protected by Article 22 of TRIPS,¹⁶⁵ and protection of data from "unfair use" under Article 39(3) of TRIPS.¹⁶⁶ These requirements could significantly expand IP protections from those contained in TRIPS.

Civil trademark claims can lead to detainment of generic medicines as well, as had occurred in the case of the recent EU seizures. The ACTA requires countries to create procedures for customs officials to detain "suspect" goods.¹⁶⁷ This might be a problem for generic medicines since trademarks of generic medicines are often very similar to the original, and requires a more in-depth legal analysis than often permitted at the border.¹⁶⁸ Such detainment, particularly where in error,¹⁶⁹ would certainly be considered as a barrier to legitimate trade and hence violative of Article 41 of the TRIPS.

Heightened protections for test data under ACTA could also be a barrier to legitimate trade in generic medicines and violate Article 41 of TRIPS. While Article 39 of TRIPS does require that member countries protect test data from right holders "against unfair commercial use", ACTA would obligate parties to have border enforcement measures for "goods which are suspected of infringing domestic test data protection system".¹⁷⁰ If these border measures are also applied to in-transit goods, as ACTA allows,¹⁷¹ then the risks to legitimate trade in generics are even greater.

C. *Bilateral TRIPS-Plus Measures*

Developed countries have negotiated TRIPS-plus agreements outside TRIPS as a way to secure higher patent and other IP protections, such as extending the patent term, introducing data exclusivity, creating patent linkages, and establishing new enforcement mechanisms.¹⁷² Proliferation of these Free Trade Agreements

¹⁶⁴ Anti-Counterfeiting Trade Agreement, *supra* note 11, art. 5(h).

¹⁶⁵ Article 23 of TRIPS provides additional protections for wine and spirits, a category that countries are discussing expanding within TRIPS Council meetings based on the Doha mandate. *Geographical Indications*, WORLD TRADE ORG., available at: http://www.wto.org/english/tratop_e/trips_e/gi_e.htm (last visited June 7, 2010).

¹⁶⁶ Grosse Ruse-Kahn, *supra* note 106, at 24.

¹⁶⁷ Anti-Counterfeiting Trade Agreement, *supra* note 11, art. 16(1).

¹⁶⁸ Grosse Ruse-Khan, *supra* note 106, at 25; Maybarduk, *supra* note 154, at 8.

¹⁶⁹ Maybarduk, *supra* note 154, at 8-9.

¹⁷⁰ Grosse Ruse-Khan, *supra* note 106, at 27.

¹⁷¹ Anti-Counterfeiting Trade Agreement, *supra* note 11, art. 16(2).

¹⁷² See *Report of the Special Rapporteur*, *supra* note 7, at 23; U.S.-Singapore Free Trade

(“FTAs”) increases the minimum standards required by the TRIPS agreement for parties to the FTA and has the potential to undermine the multilateral system. Moreover, there is no express provision allowing FTAs within the TRIPS Agreement,¹⁷³ although they are widely used and accepted.

The Case Against FTAs Before a Future WTO Panel

FTAs have the potential to violate Article 1(1) of the TRIPS Agreement, which provides, “[m]embers may, but shall not be obliged to implement in their law more extensive protection than is required by the Agreement, provided that such protection does not contravene the provisions of this agreement”.¹⁷⁴

However, such an approach to a dispute would not be likely to succeed, even with the support of Articles 7 and 8 of TRIPS in the current multilateral framework unless it violates an additional Article of TRIPS, or a different WTO agreement.

There is the possibility that some older FTAs could be found to violate TRIPS non-discrimination principle, because they contain narrower non-discrimination principles. One example is the US-Dominican Republic-Central American FTA, which limits patent rights to those *available* for any inventions, but does not include a parallel provision to TRIPS Article 27.1 which states that “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced”.¹⁷⁵ The CAFTA discriminates by giving “pharmaceutical patent holders the unique ability to extend the term of their patents for delays in the regulatory approval process and to halt any attempt to manufacture their patented product under compulsory license”.¹⁷⁶

Agreement (May 6, 2003) *available at*: http://www.ustr.gov/sites/default/files/uploads/agreements/fta/singapore/asset_upload_file708_4036.pdf (last visited Dec. 11, 2011); U.S.-Morocco Free Trade Agreement (June 15, 2004) 44 I.L.M. 544.

¹⁷³ Susy Frankel, *Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes*, 12 J. INT'L ECON. L. 1023, 1041 (2009) (hereinafter Frankel).

¹⁷⁴ TRIPS Agreement, *supra* note 27, art. 1.

¹⁷⁵ *Id.* art. 27; DR-CAFTA, ch. 15, Intellectual Property Rights, *available at*: http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf (last visited Nov. 10, 2011).

¹⁷⁶ Maria Victoria Stout, *Crossing the TRIPS Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provisions Violate Trips Article 27.1*, 14 B.U. J. SCI. & TECH. L. 177, 192-8, 200, *available at*: <http://www.bu.edu/law/central/jd/organizations/journals/scitech/volume142/Documents/Stout.pdf> (last visited Nov. 10, 2011)

One proposed alternative that could provide a more successful dispute outcome for developing countries challenging TRIPS-plus measures would be a non-violation complaint.¹⁷⁷ Because countries are often pressured to enter into standard FTAs that have provisions in IP protection, such as second use pharmaceutical patents that go against their own interests, they could show that they are not receiving a benefit that they should receive under TRIPS.

As noted previously, however, there is a moratorium on non-violation disputes in TRIPS, which continues to be renewed because developing countries believe that it would be used against them by the U.S. to limit their ability to use TRIPS flexibilities.¹⁷⁸ While the fears of developing countries may be well-founded, there is a compelling argument that this is the moment for developing countries to collectively use all dispute settlement options available to their advantage. Since the TRIPS Agreement came into force, the push for increased standards takes place in the FTA arena. The FTA negotiations process has been very costly and detrimental to many developing countries and the WTO does not provide a mechanism for developing countries to defend themselves against these pressures. Developing countries, particularly those with little negotiating power, could benefit from the non-violation process as it may provide a rules-based response to the growing and unsustainable pressure to increase intellectual property protection. The non-violation procedure, with proper rules governing it, could very well provide the necessary 'defence' to these pressures.¹⁷⁹

Another possible claim against FTAs, particularly those between the EU and developing countries, would be comparable to that outlined above for EC 1383/2003. Europe has integrated border enforcement measures into its FTAs with a number of countries and they may also violate TRIPS by acting as a barrier to legitimate trade.

D. Trans-Pacific Partnership Agreement

Another effort by the United States to enact trade agreements with TRIPS-plus IP protection is the Trans-Pacific Partnership, which is a multilateral negotiation that is currently underway. The participating countries are Australia, Brunei Darussalam, Chile, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam. The IP chapter of the negotiating text was leaked in February

¹⁷⁷ Frankel, *supra* note 173, at 1055.

¹⁷⁸ *Id.* at 1043-4.

¹⁷⁹ *Id.* at 1045-6.

2011.¹⁸⁰ The draft U.S. position was so extreme that it led some to speculate that it was a negotiating tactic to enable the United States to appear to compromise in the final agreement, while still getting higher standards than in any other agreement.¹⁸¹

The Case Against the TPP Before a Future WTO Panel

The section on public health is still bracketed placeholder text, but the agreement contains no reference to the Doha Declaration or the WHO Global Strategy on Public Health, Innovation, and Intellectual Property.¹⁸² Moreover, a group of U.S. Senators sent the President a letter in May 2011 requesting inclusion of high IP standards, and application to all parties without exception.¹⁸³ At this stage of the negotiations, it is difficult to know what the TPP IP chapter will look like when finalized, and the possibility for dispute settlement is far off.¹⁸⁴ However, developing countries will be able to bring a claim if the final text of TPP's IP chapter includes enforcement measures greater than those in ACTA.

V. CONCLUSION

Reaching the Millennium Development Goal of providing “access to affordable essential drugs in developing countries” in cooperation with pharmaceutical companies recedes with each new step towards the global IP enforcement agenda. The lack of access to medicines and costs many times greater than the international reference price lead to millions of preventable illnesses and deaths each year.

¹⁸⁰ *The Complete Feb 10, 2011 Text of the US Proposal for the TPP IPR Chapter*, KNOWLEDGE ECOLOGY INT'L STAFF BLOG (Mar. 11, 2011), available at: <http://keionline.org/sites/default/files/tpp-10feb2011-us-text-ipr-chapter.pdf> (last visited Nov. 8, 2011).

¹⁸¹ See Rick Shera, *US Wants to Take an Axe to New Zealand IP Law (updated)*, I@W.GEEK.NZ BLOG (Mar. 16, 2011, 3:12pm), available at: <http://lawgeeknz.posterous.com/us-wants-to-take-an-axe-to-new-zealand-ip-law> (last visited Dec. 22, 2011); Melissa de Zwart, *The Trans-Pacific Partnership Agreement (TPPA) IP Chapter*, FORT. REV. OF IP & MEDIA L., available at: <http://fortnightlyreview.info/2011/05/06/the-trans-pacific-partnership-agreement-tpa-ip-chapter/> (last visited Dec. 22, 2011).

¹⁸² *Id.*

¹⁸³ Mike Palmedo, *28 Senators Write Obama Urging Strong IP Chapter in Trans Pacific Partnership* (May 18, 2011), available at: <http://infojustice.org/archives/3430> (last visited Nov. 9, 2011).

¹⁸⁴ USTR, TPP Negotiation Updates, Round 9: Lima, available at: <http://www.ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-negotiation-updates/round-9-lim> (last visited Nov. 10, 2011) (stating that intellectual property was discussed in October 2011 negotiations in Lima, Peru).

One tool available to developing countries in the pursuit of affordable medicines, that may not be immediately apparent, is recourse to the WTO dispute settlement. Developing countries have had some significant achievements in promoting access to medicines within the WTO, from the Doha Declaration in 2001 which reinforces the rights of developing countries to health, to the TRIPS flexibilities to the 2003 Decision on parallel imports. However, as a result of increased power and capabilities of developing countries within the WTO, developed countries are seeking to heighten IP protections and enforcement outside the multilateral forum. It is this very endeavour by developed countries that has given Brazil and India the reason to bring the first claim in the WTO alleging that a law with higher IP standards is in violation of the TRIPS agreement. Developing countries must use their increased capacity and skills with dispute settlement and challenge unilateral, bilateral, and plurilateral measures that seek to limit developing countries right to use TRIPS flexibilities and expand access to medicines.