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

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Melissa Blue Sky*

ABSTRACT

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

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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: had they considered filing a complaint before the Dispute Settlement Body (“DSB”) of the World Trade Organization (“WTO”) based on the United States’ Special 301 Report
allegation of deficient intellectual property ("IP") protections in their countries?\textsuperscript{1} Although country representatives seemed vaguely supportive of the idea, they expressed their desire to work within U.S. law so as not to risk suspension of discretionary trade preferences or have detrimental foreign policy actions taken against them.

The U.S. Special 301 Report and other IP enforcement measures promote policies that see to restrict access to medicines. Although there are risks for developing countries, this is their ideal moment to strategically and opportunistically use the Dispute Settlement Understanding ("DSU") of the WTO to challenge the restrictive IP standards and enforcement agenda, as it shifts out of the WTO multilateral trading system and further limits access to medicines.

In the Access to Medicines movement developing countries and activists have succeeded in having their concerns with the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS") addressed, at least to some degree, in the context of the WTO. The Doha Declaration on Access to Medicines\textsuperscript{2} and the 2003 Decision on Implementation of Paragraph 6\textsuperscript{3} support countries’ rights 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.”\textsuperscript{4} Despite these successes, there is broad agreement that countries still face challenges within the heightened intellectual property protections introduced by

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\textsuperscript{2} 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].


\textsuperscript{4} Doha Declaration, \textit{supra} note 2, para. 4.
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Moreover, while developing countries have been able to incorporate protecting public health into declarations in the WTO multilateral context, developed countries and pharmaceutical companies are working outside the WTO to advance their agenda through a series of bilateral treaties that impose standards above that required by TRIPS (“TRIPS-plus”), discretionary national programs (the U.S. Section 301 Report, for example), domestic laws that conflate generic medicines with counterfeit medicines and give customs agents rights once reserved for judges (EC Regulation 1383/2003), and the recently finalized Anti-Counterfeiting Trade Agreement (“ACTA”), and Trans-Pacific Partnership (“TPP”) currently under negotiation.

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”), the capacity of


developing countries to shift the focus back to the WTO to protect their
interests has not be 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 issues including agriculture, manufactured
goods, and imposition of antidumping and countervailing duties. However, they have not yet done so for IP challenges related to access to
medicines. 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 article 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 IPR
standards within the World Intellectual Property Organization (“WIPO”), to
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 that seek to raise IP protections above the standards contained in

Lawmaking, 29 YALE J. INT’L L. 1 (2004). Part II of this paper discusses forum shifting and
access to medicines in greater detail.

10 See, e.g., Todd Allee, Developing Countries and the Initiation of GATT/WTO
Disputes (2008), available at http://peio.vweb10-test.gwdg.de/files/Allee_Developing.Countries.WTO.Disputes.pdf; David Evans and
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).

11 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
are negotiating and have proceeded to a Panel or Appellate Body Decision. This dispute is
considered further in Part IV of this paper.
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TRIPS agreement. Potential challenges to the following at the WTO will be considered: TRIPS-plus measures in bilateral treaties, US Section 301 of the 1974 Trade Act, 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 selected 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”) 8E, that countries provide access to medicines in developing countries, in cooperation with pharmaceutical companies. The proportion of people in developing countries with sustainable access to affordable essential medicines on average has not improved since the UN began tracking progress towards MDG 8 in 2007\(^1\) and approximately one-third of people worldwide lack access.\(^2\) In developing countries essential medicines are available at public facilities approximately 42% of the time and at private facilities 64% of the time, at a cost 270% and 630% higher than the international references prices respectively.\(^3\) Lives of an estimated 10 million people per year could be saved with existing medicines, but price

\(^{1}\) MDG GAP TASK FORCE, MILLENNIUM DEVELOPMENT GOAL 8 THE GLOBAL PARTNERSHIP FOR DEVELOPMENT AT A CRITICAL JUNCTURE 57 (2010).  
\(^{2}\) WORLD HEALTH ORG. & HAI GLOBAL, MEASURING MEDICINE PRICES, AVAILABILITY, AFFORDABILITY AND PRICE COMPONENTS 1 (2d ed. 2008).  
\(^{3}\) MDG GAP TASK FORCE, supra note 12.
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has been a significant barrier.¹⁵

B. IP Protection and Access to Medicines

A wide range of intellectual property protections impact prices of medicines in a variety of ways,¹⁶ but the focus of this paper is primarily on patent protections and enforcement in the international realm. International agreements granting patent rights to inventors of new medicines limit the rights of others to produce generic versions, which have lower prices and expand access. The patent allows the manufacturer a monopoly and the ability to set higher prices.¹⁷

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. Over the past few decades these efforts have shifted IP from the purview of the World Intellectual Property Organization, to the WTO, and now to bilateral, regional, and other “coalitions of the willing.”¹⁸ These shifts have heightened IP protections and limited access to medicines by developing countries.

a. World Intellectual Property Organization

Beginning in the late 1800s developed countries began to negotiate agreements to strengthen national and international IP laws,¹⁹ and the

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¹⁵ WORLD HEALTH ORG. & HAI GLOBAL, supra note 13.

¹⁶ Report of the Special Rapporteur, supra note 5.

¹⁷ See id.

¹⁸ There are, of course, additional overlapping international IP agreements and institutions, see Laurence R. Helfer, Regime Shifting in the International Intellectual Property System, 7 PERSPECTIVES ON POLITICS 39 (2009). This paper, however, identifies the principle forums in which developed countries have heightened IP protections and developing countries have sought to limit those increases.

¹⁹ 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 5, at 36. For a timeline of the core IP agreements, see id. at 330.
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secretariat for the conventions, the World Intellectual Property Organization (“WIPO”), was created in 1967. The developing countries were largely uninvolved in the development of international IP agreements, but concerns began to emerge in the post-colonial era. Developing countries saw the international conventions as limiting their access to IP and unsuccessfully sought a revision of the Paris Convention in the mid-1980s to grant them preferential treatment.

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

b. WTO-TRIPS

Including IP 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, the section was entitled “Trade-related aspects of intellectual property rights, including trade in counterfeit goods.” Although some developing countries opposed the inclusion of IP in the GATT negotiations, and others believed that they could limit the agreement to only IP issues


21 See DEERE, supra note 5, at 37-40 (detailing regional IP approaches in developing countries after independence).

22 Helfer, supra note 9, at 20); DEERE, supra note 5, at 43-45.

23 Helfer, supra note 9, at 19-20; DEERE, supra note 5, 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 9, at 24-26.

relating to trade in counterfeit goods and other trade-related issues, this was not to be.\textsuperscript{25}

The foundation for incorporating IP within the GATT system was set at the 1986 start of the Uruguay Round of negotiations, which also created the WTO.\textsuperscript{26} IP was brought into the trade framework by developed countries as a bargaining tool to exact commitments on IP from developing countries in exchange for opening up market access in goods and other concessions.\textsuperscript{27} The GATT had two other specific benefits for the United States 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 convention procedures overseen by WIPO, but never used.\textsuperscript{28}

Throughout the following eight years of negotiations, multinational companies encouraged creation of a coalition of the United States, Europe, and Japan to champion their interests in requiring all members to adopt high levels of patent protections.\textsuperscript{29} The United States 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.\textsuperscript{30} To finalize negotiations on a range of agreements on different issues, the “single undertaking” principle that all had to be approved as a package meant that, despite the fact that fewer than 20 developing countries

\textsuperscript{25} 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); DEERE, supra note 5, at 52.

\textsuperscript{26} Yu, supra note 24, at 982. See also, Weissman, supra note 25, at 1085-88, 1092-94 (2004) (describing the role of the pharmaceutical industry in encouraging the United States to push for the inclusion of IP in the GATT).

\textsuperscript{27} DEERE, supra note 5, at 51.

\textsuperscript{28} Helfer, supra note 9, at 11-22.

\textsuperscript{29} DEERE, supra note 5, at 53-54.

\textsuperscript{30} Id. at 54-56.
participated in the IP negotiations, it could not be opposed without forfeiting gains in market access.\textsuperscript{31}

The result was the 1994 TRIPS agreement, which:

- enhanced the substantive rules found in preexisting 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.\textsuperscript{32}

The TRIPS agreement incorporates principles of the Paris and Berne Conventions; provides for National Treatment and Most-Favored Nation Treatment; establishes minimum standards for copyright, trademark, patents, and other IP rights; creates an enforcement mechanism; sets out binding dispute settlement procedures; and contains other provisions.\textsuperscript{33}

Nearly all developing countries must 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.\textsuperscript{34} In contrast to many WTO and other international agreements granting “special and 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, the requirement that developed countries transfer technology to developing countries, and a commitment by developed countries to provide capacity-building and technical assistance to

\textsuperscript{31} Id. at 56.

\textsuperscript{32} Helfer, supra note 9, at 23.

\textsuperscript{33} 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]. \textit{See also}, \textsc{John H. Jackson}, \textsc{The World Trading System} 310-13 (2d ed. 1997); \textsc{Deere}, supra note 5, at 64-68 (detailing the TRIPS provisions, obligations, and timeframes for implementation).

\textsuperscript{34} TRIPS Agreement, supra note 33, art. 33; \textsc{Deere}, supra note 5, at 11.
developing countries.\textsuperscript{35}

The first group of developing countries had to implement TRIPS by 2000; leading up to the deadline many countries had difficulty enacting all the required legislation, and increasingly felt that they had been coerced into accepting an agreement that held only costs and no benefits for them.\textsuperscript{36} Against the backdrop of growing resentment related to TRIPS implementation, the United States aggressively pursued perceived violations of the TRIPS agreement both within the WTO and unilaterally, leading to further opposition to the IP protections advanced by developing countries.\textsuperscript{37}

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

After failing to start a new round of trade negotiations at the 1999 Seattle Ministerial meeting, developed countries realized that they would have to make concessions regarding IP and more broadly, hence the Doha “Development” Round. Prior to the 2001 Ministerial, a group of 80 developing countries proposed the Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”), which was ultimately adopted in 2001.\textsuperscript{38} 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.”\textsuperscript{39}

\textsuperscript{35} DEERE, supra note 5, at 12.

\textsuperscript{36} Helfer, supra note 9, at 24.


\textsuperscript{38} Id. at 516.

\textsuperscript{39} Doha Declaration, supra note 2, para. 4.
Although the TRIPS agreement 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.”\textsuperscript{40} While the flexibilities have been inherent in the agreement since 1994, in light of the aggressive action taken by developed countries against countries employing compulsory licensing, the Declaration provided reassurance that they would not be targeted for using TRIPS flexibilities to protect public health.

An important flexibility in the TRIPS agreement reaffirmed by the Doha Declaration includes the ability to issue compulsory licenses\textsuperscript{41} in connection with the determination of “what constitutes a national emergency or other circumstances of extreme urgency.”\textsuperscript{42} 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,\textsuperscript{43} to determine the scope of patentability and specific limited exclusions,\textsuperscript{44} and enforcement measures.\textsuperscript{45}

Paragraph 6 of the Doha Declaration recognized that some countries might not have manufacturing capacity and would need to be able to import medicines produced under compulsory licensing in another country through parallel importation without having to obtain consent from the patent holder in a third country, but postponed action until 2003.\textsuperscript{46} The subsequent Decision on the Interpretation of Paragraph 6 set forth the procedures and obligations for both exporting and importing parties;\textsuperscript{47} however, the

\textsuperscript{40}TRIPS Agreement, \textit{supra} note 33, art. 1(1).
\textsuperscript{41}\textit{Id.} art. 31.
\textsuperscript{42}Doha Declaration, \textit{supra} note 2, para. 5(c).
\textsuperscript{43}\textit{Id.} art 5(d); TRIPS Agreement, \textit{supra} note 33, art. 6; DEERE, \textit{supra} note 5, at 75-76.
\textsuperscript{44}TRIPS Agreement, \textit{supra} note 33, art. 27, 30; DEERE, \textit{supra} note 5, at 76-81.
\textsuperscript{45}TRIPS Agreement, \textit{supra} note 33, pt. III; DEERE, \textit{supra} note 5, at 95.
\textsuperscript{46}Doha Declaration, \textit{supra} note 2, para. 6; \textit{see also} DEERE, \textit{supra} note 5, at 75-76 (listing countries and different parallel imports laws).
\textsuperscript{47}Paragraph 6 Implementation, \textit{supra} note 3.
requirements are cumbersome\(^{48}\) and have only once been used successfully, for exports from Canada to Rwanda.\(^{49}\) Although a number of countries have provided interventions to the TRIPS Council that the paragraph 6 procedures need to be revised, a solution has yet to emerge.\(^{50}\)

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.\(^{51}\) Implementation of TRIPS and TRIPS-plus obligations without recourse to the flexibilities can add significant costs for governments and limits access to medicines.\(^{52}\) 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,\(^{53}\) particularly as developed countries shift away from the WTO as the primary forum for expansion of IP protections.

d. Existing and Emerging Bi-Lateral and Regional Frameworks

Developed countries and pharmaceutical companies have not achieved


all they hope for through the TRIPS agreement and have shifted the forum once again, this time 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 United States, EU, and other developed countries are turning to negotiating free trade agreements, or relying on domestic laws such as the U.S. Special 301 and the EU border measures, considered in more detail in Part IV of this paper.

To be able to expand access to intellectual property and medicines, developing countries need to confront the IP anti-counterfeiting and enforcement agenda, and its many initiatives. WTO dispute settlement may be one tool available to developing countries to use 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).”

III. DEVELOPING COUNTRIES, WTO DISPUTE SETTLEMENT, AND TRIPS

A. Dispute Settlement Generally

The Uruguay Round that created the TRIPS agreement also produced the Dispute Settlement Understanding, which requires members to proceed in the multilateral forum for violations of WTO agreements rather than taking unilateral action. Countries must also abide by the decision reached by the Panel, or on appeal the Appellate Body, and if a member fails to do so, they may have to pay compensation to the complainant or risk having the prevailing party suspend concessions with approval of the DSB.

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54 Id. at 30.
56 Id. arts. 21, 22.
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 IP matters.

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. Of the total an ad hoc panel considers less than half and the Appellate Body then hears about 70% on appeal.

Although developing countries face considerable challenges in filing disputes, primarily related to costs, approximately 40% of all claims have been filed by developing countries and the trend of developing countries filings for dispute settlement in the WTO is increasing, while for developed countries it is declining. Out of the top eleven most frequent complainants, seven are developing countries, but the majority of developing countries have never filed a complaint. However, once a developing country has participated in a dispute, either as a complainant or respondent, they are more likely to initiate a future claim. Furthermore, the Advisory Centre on

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58 *Id.* at 6.

59 See, e.g., Hunter Nottage, *Developing Countries in the WTO Dispute Settlement System* (University College Oxford, GEG Working Paper 2009/47, 2009) (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).


63 Christina L. Davis & Sarah Blodgett Bermeo, *Who Files? Developing Country
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WTO Law, established in 2001, assisted developing countries in 23 disputes, 19 of which the developing country was the respondent.64

B. IP Disputes

The TRIPS agreement also contains an article on dispute settlement, which applies the DSU and Articles 22 and 23 of the GATT.65 A moratorium on filing non-violation suits based on TRIPS provisions remains in effect, although it was initially set to expire in 2000.66 The United States and Switzerland would like to allow such suits, but because they could limit countries’ ability to use TRIPS flexibilities, the majority of members oppose lifting the ban.67

Out of the more than 400 claims filed at the WTO, only 29 have included TRIPS provisions,68 and less one-third of those have been heard by a panel.69 The United States and 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 European Communities; and Brazil also filed a request for consultations with the


64 Bown & McCulloch, supra note 61, at 14.
65 TRIPS Agreement, supra note 33, art. 64.
67 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.
69 Pauwelyn, supra note 57, 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.
United States.\textsuperscript{70}

Until recently developing countries have participated in TRIPS almost exclusively as defendants in claims that they have not met the minimum standards required by TRIPS, including in the first TRIPS dispute that led to establishment of a panel.\textsuperscript{71} Somewhat surprisingly, claims have been brought against developing countries in less than one-third of the TRIPS complaints filed, however, with the majority of the consultations occurring between developed countries.\textsuperscript{72}

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 IP brought by the United States against China, and continuing with the requests for consultation with the European Communities submitted by India and Brazil—towards the recognition that IP protections that exceed TRIPS obligations have the potential to violate the both the spirit and the letter of the agreement.

The 2009 panel report in \textit{China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights} included a range of issues, some decided in favor of the United States and others for China, but “less developed countries might have become the dispute’s ultimate winner.”\textsuperscript{73} Although panel reports do not set precedent 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.\textsuperscript{74}

In the panel report there are several potential gains for developing countries both with regard to bringing DSU challenges to external

\textsuperscript{70} Intellectual Property (TRIPS), Disputes by Agreement, supra note 68.


\textsuperscript{72} Intellectual Property (TRIPS), Disputes by Agreement, supra note 68.


\textsuperscript{74} Id. at 11.
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agreements and in 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 states, 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.” 75

The panel also invokes the recognition that IP rights are private rights from the TRIPS preamble when finding that “shall have the authority to order the destruction or disposal of infringing goods” from Article 59 does not require a member country to undertake an action without a request or application. 76 This is significant for developing countries, because, unlike ACTA and numerous bilateral treaties, TRIPS does not require seizure of goods believed to infringe on obligations of the agreement. 77

An additional action by the panel that may benefit developing countries is the panel would not accept a bilateral agreement to which the complainant but not the defendant was a party as evidence of subsequent practice. 78 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. 79 Finally, substantive evidence, rather than from industry sources or claims without supporting data from a government, was requested by the panel. 80 Collectively the panel report touches upon several issues of great import for developing


76 Id., para. 7.247; Yu, supra note 73, at 14.

77 Yu, supra note 73, at 14-15.

78 Id. at 17-18.

79 Id. at 19-20.

80 Id. at 21-22.
countries in future IP disputes. Some suggest that it also signifies a potential for progress:

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. The benefits of this process, indeed, have begun to trickle down to less developed countries.81

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

A complex and overlapping array of institutions and agreements govern international IP.82 While some are more responsive to concerns of developing countries and others seek the highest possible IP enforcement measures, the TRIPS agreement 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 overlapping laws and agreements imposing additional obligations on members may violate TRIPS, even if they do not exceed the maximum standards.

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 within measures aimed against counterfeiting and piracy.83 This trend may be most apparent in the Anti-Counterfeiting Trade Act, 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

81 Id. at 23.
82 Helfer, supra note 9, at 39.
provisions, it still requires parties to ensure domestic law provides for enforcement provisions for “any act of infringement of intellectual property rights” covered by ACTA.\(^8^4\) This, along with other FTA measures and USTR actions under Section 301, has the potential to limit legitimate trade in generic medicines rather than achieving the purported goal of protecting against unsafe medicines.

A. **EU Seizure of Generic Drugs in Transit**

Customs regulation has been used by the EU in moving to higher levels of enforcement of IP rights, which began in 1986 and increased with enactment the enactment of Council Regulation 1383 of 2003.\(^8^5\) The Regulation requires that countries extend border measures to in transit goods (exported from a country outside the EU and destined for importation also by a country outside the EU), as well as infringement of IP rights *other than* copyright or patent, and enables customs agents to detain, and in some cases destroy, goods upon suspicion of IP rights infringement upon IP rights.\(^8^6\)

a. **2010 Requests for Consultations by India and Brazil**

In the case of seizures of generic medicines in transit, at issue are 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.\(^8^7\) The seizures were remarkable in that they were applied on the

\(^8^4\) Anti-Counterfeiting Trade Agreement, *supra* note 7, 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* 14-26 (Max Planck Inst. for Intell. Prop., Competition & Tax Law, Research Paper Series No. 10-10, 2010).


\(^8^6\) *Id.* at 4-5.

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basis of alleged infringements of patents in the transit European countries, rather than either the exporting or importing country. Both India and Brazil filed requests under the WTO’s DSU for consultations with the EU in 2010.\(^8^8\) The allegations by India and Brazil are as noteworthy for what they do not claim as for what they do:

[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.\(^8^9\)

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

- 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 4bis of the Paris Convention of 1967;
- Decision of 2003 on the Implementation of Paragraph 6.\(^9^0\)

India and Brazil have grounded their claims in GATT Article V on

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\(^8^8\) *India’s Request for Consultations, supra* note 87; Request for Consultations by Brazil, *European Union and a Member State – Seizure of Generic Drugs in Transit, WT/DS409/1* (May 19, 2010) [hereinafter Brazil’s Request for Consultations].

\(^8^9\) Pauwelyn, *supra* note 57, at 54-55.

\(^9^0\) *Brazil’s Request for Consultations, supra* note 88; *India’s Request for Consultations, supra* note 87. For additional analysis of each of the claims and counterarguments, as well as relevant European Court of Justice case law, see Seuba *supra* note 85; Frederick M. Abbott, *Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare, World Intell. Prop. Org. J.*, No. 1, 2009 at 43; Kumar, *supra* note 83.
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,” and GATT Article X on the publication and administrative regulations, alleging the border measures “are not administered in a uniform, impartial and reasonable manner.”

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.

India continued its infringement claim: Article 28 read together with Article 2 of the TRIPS Agreement, Article 4bis 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”) because a cumulative reading of these provisions confirms, inter alia, that he 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.

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

Although the EU has proposed revising its border measure regulation and bilateral trade negotiations between India and the EU are progressing, DSU consultations between the EU and Brazil and India on this issue are

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91 India’s Request for Consultations, supra note 87.
92 Id.
93 Brazil’s Request for Consultations, supra note 88; India’s Request for Consultations, supra note 87.
ongoing. If the countries are unable to resolve the dispute through negotiations, India and Brazil should request establishment of a panel. There are several issues that the DSB would likely find problematic with the EC Regulation 1383/2003, including 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.\textsuperscript{94} 

b. The Case Against EC Regulation 1383/2003 Before a Future WTO Panel\textsuperscript{95} 

A future dispute on the compatibility of EC Regulation 1383/2003 and WTO would likely center 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; (2) whether the regulation creates barriers to “legitimate” trade in generic medicines under TRIPS Article 41.\textsuperscript{96} 

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

\textsuperscript{94} Seuba, \textit{supra} note 85, at 33. 

\textsuperscript{95} An analysis of potential EU defenses in such a claim are beyond the scope of this paper, but can found in Seuba, \textit{supra} note 85, at 22-29. 

\textsuperscript{96} As WTO law is cumulative, and TRIPS also recognizes members’ obligations under preexisting IP conventions, the arguments against EC Regulation 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 paper, however, limits its analysis principally to TRIPS Articles 1.1, 41, 51, and 52.
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copyright goods,” but does not impose the same obligations with regard to
goods for export or in-transit goods. For infringing goods awaiting export,
members may also provide similar measures, but footnote 13 states that
there “shall be no obligation to apply such procedures” with regard to goods
in transit.97 Moreover, Article 51 does allow for the creation of similar
measures for “other infringements of intellectual property rights” than
copyrights and trademarks, such as patents, as long as they meet the other
requirements of the article. 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.98 In contrast, infringement of patents, particularly for medicines,
may not be apparent through visual inspection alone.99

Article 51 therefore, creates both 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.100

Relevant to the inquiry of whether EC Regulation 1383/2003
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 51.101

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.102 If it is the former,

97 TRIPS Agreement, supra note 33, art. 51, n. 13.
98 Seuba, supra note 85, at 11.
99 Id.
100 TRIPS Agreement, supra note 33, art. 1(1).
101 Id. at n.14, art. 52; see also Seuba, supra note 85, at 12.
102 Kumar, supra note 83, at 10.
then it would be much more difficult to find the European measure consistent than if it is the latter.\textsuperscript{103} 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 “country of import” does not include transshipment countries.\textsuperscript{104} 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.

ii. TRIPS Article 41

The article 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.”\textsuperscript{105} While 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 were legal in both the initial exporting and the final destination importing countries, creating a presumption of legitimacy.\textsuperscript{106} Additionally, in its report \textit{Canada-Pharmaceutical Products}, the panel deemed the “legitimate interests” of a patent holder should 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.\textsuperscript{107} Moreover, the Doha Declaration and the Decision Interpreting Paragraph 6 have both reaffirmed the need to interpret TRIPS in favor of public health.\textsuperscript{108} The panel would also take into consideration these

\begin{flushleft}
\textsuperscript{103} \textit{Id.} \\
\textsuperscript{104} \textit{Id.} at 12-15. \\
\textsuperscript{105} TRIPS Agreement, \textit{supra} note 33, art. 41(1). \\
\textsuperscript{106} Kumar, \textit{supra} note 83, at 11. \\
\textsuperscript{108} Doha Declaration, \textit{supra} note 2; Paragraph 6 Implementation, \textit{supra} note 3
\end{flushleft}
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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.109 On this basis the trade in generic medicines would also be seen as “legitimate.”

B. US Section 301

As part of the broad effort to heighten global IP protections in the 1980s the United States 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.110 The United States Trade Representative (“USTR”) was empowered to monitor these trading practices and threaten or impose sanctions.111 Although developing countries believed that inclusion of IP in the WTO’s multilateral framework would lessen, USTR continued to conduct annual reviews and push aggressively for compliance with IP agreements.112 In the late 1990s the EU challenged the Sections 301-310 and USTR actions. The panel in United States – Sections 301-310 of the Trade Act of 1974 determined that the United States could no longer impose unilateral trade sanctions in non-IP cases through its Section 301 because it violated the DSU.113 However, the United States continued to conduct annual reviews and include countries on “watch lists.”

USTR includes a review of developing IP issues, and lists countries that it sees as needing to have higher levels of IPR protection and enforcement (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).

109 Seuba, supra note 85, 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).
111 DEERE, supra note 5, at 49.
112 Sell, supra note 37, at 493.
in the annual Special 301 Report. The United States 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. Despite solicitation of input from public interest groups, the 2011 report retains many of the same problematic assertions of past years, including that countries need to increase enforcement efforts and criminal penalties for IP infringements.\(^{114}\)

a. 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 challenge based on premise that the continued use of Section 301 constitutes unilateral action that violates the DSU. Since creation of the WTO and DSU in 1994, the United States has only initiated proceedings to impose unilateral sanctions once—in an instance of alleged pharmaceuticals patent infringement by Argentina in 1997.\(^{115}\) Argentina quickly ceded to the U.S. demands and sanctions were never imposed, thus avoiding a potential direct challenge to the U.S. program.\(^{116}\) The European Communities requested consultations alleging that several sections of the U.S. Trade Act violated the DSU, 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.\(^{117}\) This dispute can be viewed as a precursor to the *European Union and a Member State – Seizure of Generic Drugs in Transit* in that it was a challenge to a law used by a member to circumvent WTO law through


\(^{115}\) SOC. SCI. RESEARCH COUNCIL, **MEDIA PIRACY IN EMERGING ECONOMIES** 88-89 (Joe Karaganis ed. 2011).

\(^{116}\) *Id.*

imposing TRIPS-plus standards on countries that had not agreed to be bound by such standards.

As a result of this decision, 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. There are two distinct claims based on infringement of DSU Articles 3(1) and 23 by the United States, one of which is that the informal adjudications USTR undertakes pursuant to Special 301 violate the DSU because they are a form of unilateral trade sanction similar to that considered in the 1999 panel report.\(^{118}\)

The other claim is that including a country on the Special 301 watch list, and continued trade sanctions or threats resulting from that inclusion constitute violations of the DSU.\(^{119}\) Once on the watch list, countries remain there until they undertake the actions “suggested” by USTR in the Report. In 2011, in conjunction with the release of the Special 301 Report, 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.”\(^{120}\) 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

\(^{118}\) Flynn, supra note 113, at 12-13.


produce a ‘chilling effect’ causing serious damage in a variety of ways.”

Among the ways noted by the panel was that the treat of unilateral action could often be effectively identical to the actual imposition of that action.\footnote{Panel Report, \textit{United States – Sections 301-310 of the Trade Act of 1974}, para. 7.88, WT/DS362/R (Dec. 22, 1999) [hereinafter Section 301 Panel Report].}

\textit{C. Anti-Counterfeiting Trade Agreement}

ACTA is an IP enforcement agreement negotiated by Australia, Canada, the EU, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland, and the United States that was announced in October of 2007 and finalized in December 2010. Countries were unable to enact the high IP enforcement standards at the WTO\footnote{\textit{Id.}, para. 7.89.} and sought to create a new plurilateral agreement of best-practices among a “coalition of the willing”\footnote{Peter K. Yu, \textit{Six Secret (and Now Open) Fears of ACTA} 10-13 (2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1624813.} 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.\footnote{Peter Maybarduk, \textit{ACTA and Public Health} 5 (PIJIP Research Paper No. 9, 2010); Henning Ruse-Khan, \textit{supra} note 84, at 17-18.}

India, China, and other developing countries raised concerns about ACTA violating the TRIPS Agreement at both the June and October 2010 TRIPS Council Meetings. 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.\footnote{\textit{All You Want to Know About the Anti-Counterfeiting Trade Agreement (ACTA)}, \textit{EUROPEAN UNION} (Oct. 20, 2010), http://trade.ec.europa.eu/doclib/docs/2010/october/tradoc_146792.pdf.} Furthermore,
ACTA could lead to abuse of IP rights by rights holders, present an unreasonable obstacle to technology transfer, or restrain trade, all dangers warned against in Article 8 of TRIPS.\textsuperscript{127}

The final ACTA text is an improvement from previous drafts because patents have been removed from key sections,\textsuperscript{128} due in part to opposition to ACTA limiting the free transit of medicines.\textsuperscript{129} In July 2010, the EU stated that patents would not be covered by ACTA, nor would “cross-border transit of legitimate generic medicines” be hindered.\textsuperscript{130} However, the agreement enacts stringent border measures and criminal enforcement procedures, in addition to other TRIPS-plus enforcement measures, some of which have to potential to hinder access to medicines and infringe upon TRIPS obligations.\textsuperscript{131}

a. The Case Against ACTA Before a Future WTO Panel

Although there may not be an immediate opportunity to challenge ACTA in the DSB, developing countries and NGOs were able to exert pressure through the WTO TRIPS Council and raising concerns that some provisions of ACTA could violate TRIPS and limit access to medicines to

\textsuperscript{127} Id.

\textsuperscript{128} 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 “The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section.”


\textsuperscript{131} 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 84.
scale back some of the most disadvantageous provisions of the agreement. If once ACTA enters into force, it does impose obligations on non-parties or upset the balance between rights holders and rights users, there may be an opportunity for developing countries to challenge provisions of ACTA at the WTO.

Although patents have been excluded from the 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 of Part II of the TRIPS Agreement.” ACTA parties must also provide enforcement of measures related to geographical indications, protected by Article 22 of TRIPS, and protection of data from “unfair use” under Article 39(3) of TRIPS.

Civil trademark claims can implicate detainment of generic medicines, as occurred in a recent EU seizure case. ACTA requires countries to create procedures for customs officials to detain “suspect” goods; however, 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. Such detainment, particularly where in error, would certainly be considered a barrier to legitimate trade.

Heightened protections for test data under ACTA could also be a barrier to legitimate trade in generic medicines. While Article 39 of TRIPS does

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132 Anti-Counterfeiting Trade Agreement, supra note 7, art. 5(h).
133 Article 23 of TRIPS provides additional protections for wine and sprits, a category that countries are discussing expanding within TRIPS Council meetings based on the Doha mandate. Geographical Indications, World Trade Org., http://www.wto.org/english/tratop_e/trips_e/gi_e.htm (last visited June 7, 2010).
134 Grosse Ruse-Khan, supra note 84, at 24.
135 Anti-Counterfeiting Trade Agreement, supra note 7, art. 16(1).
136 Grosse Ruse-Khan, supra note 84, at 25; Maybarduk, supra note 125, at 8.
137 Maybarduk, supra note 125, at 8-9.
require that member countries protect test data from right holders “against unfair commercial use,” ACTA would oblige parties to have border enforcement measures for “goods which are suspected of infringing domestic test data protection system.”\footnote{Grosse Ruse-Khan, supra note 83, at 27.} If these border measures are also applied to in-transit goods, as ACTA allows,\footnote{Anti-Counterfeiting Trade Agreement, supra note 7, art. 16(2).} then the risks to legitimate trade in generics are even greater.

\textbf{D. 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.\footnote{Report of the Special Rapporteur, supra note 5, at 23.} Proliferation of Free Trade Agreements ("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,\footnote{Susy Frankel, Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes, 12 J. INT’L ECON. L. 1023, 1041 (2009).} although they are widely used and accepted.

\textbf{a. 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.”\footnote{TRIPS Agreement, supra note 33, art. 1.}

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 violated an additional article of TRIPS, or a different WTO text.

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\footnote{Grosse Ruse-Khan, supra note 83, at 27.}
\footnote{Anti-Counterfeiting Trade Agreement, supra note 7, art. 16(2).}
\footnote{Report of the Special Rapporteur, supra note 5, at 23.}
\footnote{Susy Frankel, Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes, 12 J. INT’L ECON. L. 1023, 1041 (2009).}
\footnote{TRIPS Agreement, supra note 33, art. 1.}
One proposed alternative that could provide a more successful dispute outcome for developing countries challenging TRIPS-plus measures would be a non-violation complaint.\textsuperscript{143} Because countries are often pressured to entering into standard FTAs that have provisions in IP protection, such as second use pharmaceutical patents that go against their own interests, they could likely show that they are not receiving a benefit that they the 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 United States to limit their ability to use TRIPS flexibilities.\textsuperscript{144} While developing countries’ fears may be well-founded, there is a compelling argument that now is the moment for developing countries to collectively use all dispute settlement options available to their advantage.

Since the TRIPS Agreement came into force, however, 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.\textsuperscript{145}

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.

\textsuperscript{143} Frankel, \textit{supra} note 141, at 1055.

\textsuperscript{144} Id. at 1043-44.

\textsuperscript{145} Id. at 1045-46.
E. Trans-Pacific Partnership Agreement

Another effort by the United States to enact trade agreements with TRIPS-plus IP protection is the Trans-Pacific Partnership (“TPP”), 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 and the IP chapter of the negotiating text was leaked in February 2011. 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.

a. 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. Moreover, a group of Senators sent the President a letter in May 2011 requesting inclusion of high IP standards, and application to all parties without exception. At this stage of the negotiations it is difficult to know that the TPP IP chapter will look like when finalized, and the possibility for dispute settlement is far off, however, if the final text of TPP’s IP chapter does include enforcement measures greater than those in ACTA, developing countries will be able to bring a claim.

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. People lack access to medicines and costs many times greater than the international reference price lead to millions of preventable illnesses and deaths each year.

One tool available to developing countries in the pursuit for 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 reinforcing the rights of developing countries to health and to use the TRIPS flexibilities to the 2003 Decision on parallel imports. However, as a result of developing countries’ increased power and capabilities within the WTO, developed countries are seeking to heighten IP protections and enforcement outside the multilateral forum.

It is this very endeavor that has given Brazil and India the ability to bring the first claim in the WTO alleging that a law with higher IP standards is in violation of the TRIPS agreement. EC 1383/2003’s border measures surpass those of TRIPS, but they do so in a way that creates barriers to trade and presents unnecessary restrictions, among other violations.

Developing countries must use their increased capacity and skills with dispute settlement to challenge unilateral, bilateral, and plurilateral measures that seek to limit developing countries right to use TRIPS flexibilities and expand access to medicines for their people and also those of other countries through parallel importation.