

Note

Call For Reform: Analyzing Trips Through European Seizure Of Generic Medication

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I. INTRODUCTION

The pharmaceutical industry has long been a subject of controversy in international patent law. In the past, medications were subject to strict patent protection from domestic laws but little international protection. However, the dramatic increase in prevalence of communicable diseases led to a sharp increase in demand from developing countries that had not developed their own pharmaceutical industries. Because of this demand, there was a substantial increase in the trade of pharmaceuticals. Such an increase led to the violation of domestic patents of many countries, which prompted the World Trade Organization (“WTO”) to implement international patent protection standards through the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). These standards, though, have been the subject of much criticism that has manifested itself through the drastic actions many countries are taking to protect their domestic industry. One such example is the seizing of ships with generic medications. Countries seizing the medication claim protection under international agreements. At the same time, countries whose domestically produced medication has been seized claim that such seizures are in violation of international agreements. This ambiguity is costly and requires resolution.

This note seeks to understand the conflict in TRIPS

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through recent European Union (E.U.) seizures of Brazilian and Indian medications. Part II describes the implementation of TRIPS and provides the factual background of the conflict over drug seizures. Part III analyzes the specific complaints made by Brazil and India to the WTO, and the resulting settlement between the E.U. and India. Then, the analysis looks to the resolution of the India and E.U. case to understand how TRIPS may be clarified in the future.

The purpose of this note will be two-fold. First, there will be an analysis of the cause of this conflict: the inherent flexibilities found within TRIPS. This will consist of a study of two primary parts of TRIPS: the extent countries can use TRIPS as the basis for production of generic medications in the violation of patents, and the measures countries can take to enforce their own domestic laws. The analysis of this second issue will specifically examine whether the E.U. had the authority to seize the generic medication under TRIPS. Such an analysis demonstrates the need for further clarification of the scope of this agreement.

The second part of this note will examine the Indian settlement to determine whether either of these issues has been solved. Such an analysis will demonstrate that the recent litigation has helped to clarify enforcement aspects of TRIPS while leaving production questions unanswered. This will set the stage for discussion about how the settlements' provisions will more broadly impact the rest of the international community.

II. BACKGROUND

A. THE DEVELOPMENT OF TRIPS

Adopted during the Uruguay Round, TRIPS was created in response to concerns over international patent protection and came into effect in 1995.¹ The growth of global trade led to concerns over inconsistencies in patent laws.² Loose patent protection created tensions in trade negotiations and in overall

1. See *Overview: The TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Feb. 12, 2012) [hereinafter *Overview*].

2. See *Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 12, 2012) [hereinafter *Intellectual property: protection and enforcement*] (emphasizing the various forms of intellectual property rights protections and enforcement measures enacted by WTO Members).

economic relationships.³ WTO Members negotiated TRIPS to facilitate innovation and ensure protection for domestic suppliers through establishing a minimum level of patent protection.⁴

TRIPS covers three basic areas.⁵ First, TRIPS required that Members adhere to substantive obligations of previously signed treaties, which had laid out international patent protection standards, and provided a minimum standard.⁶ Second, Members were required to develop domestic remedies and enforcement procedures that would allow a patent-holder to pursue a claim if necessary.⁷ Members were to develop criminal procedures and border protection remedies to prosecute those found in violation of patent agreements.⁸ Third, the agreement permitted utilization of the WTO's dispute settlement procedures within the Dispute Settlement Understanding.⁹

The adoption of TRIPS did not come without significant opposition, particularly from developing countries.¹⁰ Fewer than 20 developing countries were involved in the negotiations, a rather unrepresentative group, given that as of 2009 there were 106 developing countries bound by the treaty.¹¹ Indeed, many developing countries had a poor understanding of the scope and implications of signing on.¹² Furthermore, through

3. *See id.*

4. *See Overview, supra* note 1 (stating that TRIPS is a minimum standards agreement, meaning that Members are required to meet the standards of the agreement but are free to make provisions more extensive for increased intellectual property protection if they so desire).

5. *See id.*

6. *See id.* (noting that TRIPS required that Members comply, with minor exceptions, with the most recent versions of the Paris Convention for Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, and the World Intellectual Property Organization).

7. *See id.*

8. *See id.*

9. *See id.*; Understanding on Rules and Procedures Governing the Settlement of Disputes, App. 1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401.

10. *See* Carolyn Deere-Birkbeck, *Developing Countries in the Global IP System Before TRIPS: The Political Context for the TRIPS Negotiations*, in RESEARCH HANDBOOK ON THE PROTECTION OF INTELLECTUAL PROPERTY UNDER WTO RULES, INTELLECTUAL PROPERTY IN THE WTO VOLUME I, 22, 42–43 (Carlos M. Correa ed., 2010) (stating that many developing countries believed TRIPS was not an ideal agreement).

11. *Id.* at 46.

12. *Id.*

TRIPS, developing countries agreed to increased standards for IP protection, while receiving few or no concessions from developed countries to ensure the availability of necessary goods, such as essential medicines.¹³ Indeed, one commentator suggested that TRIPS will force developing countries to undertake significant legal and economic reforms consistent with free market principles,¹⁴ requiring developing countries to adopt policies that favored the interests of developed countries. Of much greater importance to developing countries was the need to develop domestic infrastructures in education, and other areas of society, which would assist in implementing and sustaining an intellectual property regime.¹⁵ Further, developing countries have unique cultural norms which would be “particularly vulnerable to infringement.”¹⁶ Despite these differences, developing countries signed on to TRIPS to ensure access to new technology and to take advantage of opportunity to design legislation in conjunction with their own interests.¹⁷

Thus, it came as no surprise that conflict quickly arose over the implementation of TRIPS. This conflict was particularly heated in the area of public health.¹⁸ The rise and spread of diseases such as AIDS, tuberculosis, and malaria caused many countries to look for a manner in which they could protect access to medications, whether through compulsory patent licenses, allowing the production of generic forms of medication, or by declaring a national health emergency.¹⁹ This led other countries, particularly those with developed pharmaceutical industries, to argue that TRIPS protected their

13. See CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 3 (2000). See also Ruth L. Gana, *Prospects For Developing Countries Under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 739–740 (1996) (arguing that the TRIPS Agreement put heavy IP protection burdens on developing countries, which were not as active in negotiations as developed countries, and provided them little benefit in return).

14. See Gana, *supra* note 13, at 735.

15. *Id.* at 744.

16. *Id.* at 767.

17. See CORREA, *supra* note 13, at 8 (stating that developing countries will be able to use the TRIPS obligations to design domestic laws focused on internal policies); Gana, *supra* note 13, at 373 (arguing that the TRIPS agreement would help developing countries to utilize international technology flows).

18. See *The Doha Declaration on the TRIPS Agreement and Public Health*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html (last visited Feb. 15, 2012) [hereinafter World Health].

19. See *id.*

own domestic patents.²⁰ Generic medication producers and suppliers in poor countries justified their production by arguing that TRIPS allows for justified infringement of patents for the purpose of protecting public health.²¹

The dispute over generic medication production grew to the point that most Members felt an international solution was needed.²² This solution came in 2001, at the WTO Ministerial Conference in Doha.²³ The WTO members adopted a ministerial declaration, known as the Doha Declaration, which stated that TRIPS should be interpreted “in a manner supportive of public health”²⁴ The Doha Declaration reaffirmed several terms of TRIPS as important measures in protecting public health. Chief among these was the ability to grant compulsory licenses, a substantial tool for generic pharmaceutical producers.²⁵ Compulsory licensing gives government bodies the broad authority to “license the use of a patented invention to a third party or government agency without the consent of the patent-holder.”²⁶ While there are some restrictions on compulsory licensing, these restrictions are fairly flexible and can be waived at the country’s choosing.²⁷ Additionally, the Doha Declaration reaffirmed a country’s freedom to designate which public health emergencies justified an infringement of the patent.²⁸

The Doha Declaration also provided a boost to least-

20. *Cf. Intellectual Property: Protection and Enforcement*, *supra* note 2.

21. Specifically, generic producing countries argued that TRIPS provided flexibility, pointing to provisions which allowed countries to grant licensing rights in order to better protect the general public, particularly during a public health crisis. The degree of flexibility within TRIPS remains unclear. *See id.*

22. *See generally* World Health, *supra* note 18 (“In 2001, WTO Members adopted a special Ministerial Declaration at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for governments to apply the principles of public health and the terms of [TRIPS].”).

23. *See id.*

24. World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746, 748 (2002), ¶ 17 [hereinafter Doha Declaration].

25. *See* World Health, *supra* note 18.

26. *Id.*

27. *See id.* Article 31 of TRIPS laid out several conditions that countries were required to fulfill before issuing a compulsory license, such as demonstrating unsuccessful negotiations with the patent owner and payment to the patent owner. The country could also waive these requirements by claiming a public health emergency. Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

28. *See* World Health, *supra* note 18.

developed countries (“LDC”) by extending the amount of time they had to implement domestic patent protections.²⁹ Initially, TRIPS called for each country to implement legislation that would ensure other country’s patents were protected by 2006.³⁰ The Doha Declaration extended this deadline for LDCs to 2016.³¹ This extension specifically targeted public health related patents, providing additional relief to LDCs that had not been able to enact the proper regulatory regimes.³² The adoption of the Doha Declaration gave generic medication producers additional flexibility to address public health concerns.

Perhaps more importantly, the Doha Declaration was enhanced by a General Council decision made in August 2003, which laid out a process to ensure the availability of medications to LDCs.³³ This decision created a process by which LDCs could import generic medications from other countries under TRIPS. The Doha Declaration recognized that some countries were unable to develop their own medications, and so it directed Members to find a solution to this problem.³⁴ The General Council decision solved this issue by holding that a country could use compulsory licensing solely for exporting to LDCs if it notified the WTO and the medications were produced for a country unable to produce them on their own.³⁵

Despite the clarity the Doha Declaration brought to TRIPS for issues of public health, many problems still remained. First, many countries claim TRIPS is still not an adequate solution to public health issues.³⁶ At the same time, many in the pharmaceutical industry argue that the Doha Declaration

29. *See id.* (recognizing that immediate adoption of TRIPS ran counter to the public health concerns of many LDCs).

30. *Cf.* World Health, *supra* note 18.

31. *See id.*

32. *See id.*

33. World Trade Organization, Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 43 I.L.M. 509 (2003), ¶ 6 [hereinafter General Council Decision]. Paragraph 6 of this decision instructed WTO Members to create a mechanism for LDCs to gain access to medications.

34. *Id.*

35. *Id.* ¶ 2.

36. *See*, Peter Hildpold, *WTO Laws and Human Rights: Bringing Together Two Autopoietic Orders*, 10 CHINESE J. INT’L L. 323, 361–62 (2011). The Doha Declaration was criticized for improving only the access to life-saving treatments and medications. Many felt such limited access excluded important health concerns. Furthermore, the requirement of payment to the patent holder was often times impossible as many countries simply did not have the money.

provided too much flexibility to generic manufacturers.³⁷ Such flexibility, they suggest, stifles innovation and creativity.³⁸ The pharmaceutical companies argue that many countries took advantage of the Doha Declaration, using the authority it granted individual countries to operate with only their own interests in mind,³⁹ and that many countries who claim public health as a rationale for compulsory licensing are actually able to afford medication.⁴⁰ As a result of these conflicts, Members are able, and have threatened, to bring legal action through WTO dispute resolution procedures.⁴¹

B. THE SEIZURE OF GENERIC MEDICATIONS AND SUBSEQUENT LITIGATION

Given the tension over TRIPS and the Doha Declaration, it was only a matter of time before conflicts elevated beyond diplomatic disagreements. Such was the case with the shipment of generic medications through the E.U. by India and Brazil. At least twenty times, medicines shipped from India and bound for Latin America were stopped and seized by the E.U.⁴² These seizures sparked complaints from many developing countries, who claimed that the drug seizures violated international law.⁴³

The tension over the seizure of generic medication finally reached a tipping point in May 2010. E.U. officials, operating through the Netherlands, stopped and seized a shipment of generic medication bound for Brazil (and eventually other Latin American countries).⁴⁴ These medications were produced

37. See, Alan O. Sykes, *TRIPS, Pharmaceuticals, and the Doha "Solution"*, 3 CHI. J. INT'L LAW 47, 66 (2002).

38. See *id.* (alluding to the fact that the Doha Declaration undermines the policy goals of TRIPS, as pharmaceutical companies argue that the ability to claim a "health emergency" with no penalty for false statements, forces additional costs to be borne by the original manufacturer).

39. *Id.*

40. See, *e.g., id.* at 66–67. The G-8 had committed new economic aid to help developing countries fight disease. Such aid, they argued, should be partially used to remunerate the pharmaceutical industry under Article 31 of the TRIPS agreement. Additionally, the pharmaceutical industry has argued the remuneration is only effective if research and development costs are taken into consideration.

41. See *generally Overview, supra* note 1 (outlining the use of the WTO's dispute resolution system in conflicts regarding TRIPS).

42. See John W. Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J., Aug. 6, 2009, <http://online.wsj.com/article/SB124949598103308449.html>

43. See *id.*

44. See *India, Brazil Raise Dispute over EU Drug Seizures*, THIRD WORLD

in India and were stopped in the Netherlands in transit when Dutch customs officials seized the cargo.⁴⁵

C. INDIA AND BRAZIL FILE SUIT IN THE WTO

Unlike previous seizures, India and Brazil moved quickly to file legal action, lodging a complaint with the WTO Dispute Settlement Body.⁴⁶ The WTO opened consultations, the first step in its dispute settlement process.⁴⁷ The Brazilian government asserted that the E.U. was in violation of international law.⁴⁸ India, while somewhat more measured in its public declarations, wanted assurance that its shipments would no longer be affected by E.U. customs officers.⁴⁹

Brazil was one of the leaders in the use of generic medications to combat health emergencies, and India was a major international player in the manufacture and export of generic drugs.⁵⁰ As such, both used TRIPS to great effect. Ironically, many Indian parliamentarians had raised concerns about TRIPS shortly after its adoption.⁵¹ Many Indian human rights activists believed that TRIPS, if implemented imprudently, would provide the pharmaceutical industry with too much protection.⁵² Without domestic safeguards they believed TRIPS could cause dramatic increases in the cost of medications.⁵³

NETWORK (May 17, 2010), <http://www.twinside.org.sg/title2/wto.info/2010/twninfo100509.htm>.

45. *See id.*

46. *See id.* Indian Ambassador Ujal Singh Bhatia noted the WTO complaint was filed over two primary concerns. First, he expressed that he believed the EU was acting at the request of their patent holders. Second, he articulated that the drugs were legally produced under WTO rules and that the EU had failed to respond to requests for information on the seizure.

47. *See id.*

48. *See id.* Ambassador Roberto Azevedo of Brazil said these seizures "are a clear violation of WTO disciplines on the freedom of transit, which is one of the cornerstones of the multilateral trading system. This is even clearer . . . when there is no doubt on the lack of patent protection for the goods either in the exporting country or in the importing country." *Id.*

49. *See India, Brazil Raise Dispute Over EU Drug Seizures, supra* note 44.

50. Mario Osava, *Brazil Imports Generic AIDS Drugs from India, China*, INTER PRESS SERVICE (Sept. 5, 2003), <http://www.ipsnews.net/news.asp?idnews=19997>.

51. Amy Kapczynski, *Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1587 (2009).

52. MSF, a humanitarian group, was concerned that TRIPS implementation would grant too much international protection to new uses for known substances. *Id.* at 1586–87.

53. Many humanitarian groups protested against an ordinance passed by

India sought to take advantage of the Doha Declaration, arguing that because its constitution guaranteed a right to health, it was required to interpret international agreements in a manner that favored supply of medication.⁵⁴ To do this, India implemented a domestic patent enforcement system which set very high standards for what could be considered patentable.⁵⁵ Such a patent system likely played a large role in allowing India to become an international leader in the development and exportation of generic medications because it led to increased competition in the pharmaceutical market. Brazil also took advantage of TRIPS and the Doha Declaration to develop a strong generic market. While Brazil did not have the constitutional requirement of health, it was the primary conduit for generic medications en route to most Latin American countries.⁵⁶ In order to meet these demands, Brazil took advantage of compulsory licensing, using it to respond to a variety of public health emergencies.⁵⁷ Furthermore, Brazil used the threat of compulsory licensing to negotiate favorable deals with the pharmaceutical industry, providing them access to patented medication at prices that were far below market value.⁵⁸

Litigation quickly proceeded against the E.U., with Brazil and India initiating a trade dispute in May of 2010. Brazil and India argued that the E.U.'s actions violated several Articles of both TRIPS and the General Agreement on Trade and Tariffs ("GATT").⁵⁹ First, India cited two different provisions of TRIPS.

the Indian parliament which brought it into compliance with TRIPS. They argued the ordinance should have included domestic limitations on India's obligations to respect patentability on known substances. *Id.* at 1586–87.

54. Timothy Bazzle, Note, *Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with the Right to Health: TRIPS, India's Patent System and Essential Medicines*, 42 GEO. J. INT'L L. 785, 799 (2011).

55. Kapczynski, *supra* note 51, at 1589. India created two requirements to determine whether a given item was deserving of a patent. First, the subject matter of the item had to be unique. This meant that if a medication was made of already known substances, it could not be patented unless it enhanced efficacy. *Id.* at 1590–1593. Second, India set an extremely high level for the "inventive step" requirement of patents. It required the inventive step to represent a technical advance or have economic significance; an "unusual, and perhaps unique" inventive step provision. *Id.* at 1594.

56. Osava, *supra* note 50.

57. *Id.*; Donald Harris, *TRIPS After Fifteen Years: Success or Failure, as Measured by Compulsory Licensing*, 18 J. INTELL. PROP. L. 367, 387–88 (2011). These public health emergencies were declared under Brazilian standards.

58. Harris, *supra* note 57, at 387–88.

59. See Request for Consultations by India, *European Union and a Member State—Seizure of Generic Drugs in Transit*, ¶¶ 1–5, WT/DS408/1 (May

It claimed authority to produce the medication under Article 4 of the Paris Convention and the General Council Decision of 2003 on the implementation of the Doha Declaration.⁶⁰ Second, India noted that the E.U.'s seizure was in violation of GATT Article V (it interfered with the free transit of goods) and Article X (it constituted non-uniform administration of trade practices and regulations).⁶¹ India also argued that the E.U. seizures were made in violations of Articles 7, 8, 28, 41, and 42 of TRIPS.⁶² Brazil, in turn, filed a more extensive complaint. In addition to the violations India cited, Brazil charged that the E.U. seizure was in violation of Article XVI of the GATT and Articles 49–55, 58, and 59 of TRIPS.⁶³

Brazil and India were primarily concerned with three issues arising from the seizures. First, Brazil and India argued that they had acted in full compliance with TRIPS, but that the E.U. measures were not administered in a uniform manner, despite the requirement contained in Article X of the GATT that measures be administered in a “uniform, impartial and reasonable manner.”⁶⁴ India argued that the E.U. measures were unreasonable because they involved enforcing strict patent control procedures without regard to the flexibilities TRIPS provided to generic producers.⁶⁵ Second, Brazil and India wanted to ensure protection of their thriving generic market.⁶⁶ Third, they claimed that the E.U. was disregarding

19, 2010); Request for Consultations by Brazil, *European Union and a Member State—Seizure of Generic Drugs in Transit*, at 4, WT/DS409/1 (May 19, 2010).

60. *Id.* ¶ 3. India argued that it was within its rights to produce and ship the drugs under the public health exceptions found in the TRIPS agreement.

61. *Id.* ¶¶ 1, 2. Article V allowed for the free transit of goods (subject to reasonable customs examinations), while Article X required member states to disclose customs regulations and restrictions on imports and exports. India charged that the EU failed to provide information about the rationale for the seizures. General Agreement on Tariffs and Trade, art. X, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

62. Request for Consultations by India, *supra* note 59, ¶¶ 1, 3–5.

63. Request for Consultations by Brazil, *supra* note 59. Brazil was much more aggressive than India, seeking to apply this ruling beyond generic medication. *C.f.* Bruce Lehr, *EU-India Settle WTO Drug Trade Dispute*, THE BIG RED BIOTECH BLOG (Dec. 13, 2010, 10:33 AM), <http://thebigredbiotechblog.typepad.com/the-big-red-biotech-blog/2010/12/eu-india-settle-wto-drug-trade-dispute.html/> (describing how quickly the EU-India dispute was resolved).

64. *See, e.g.*, Request for Consultations by India, *supra* note 59, ¶ 2.

65. *Id.* ¶¶ 1, 3.

66. *Id.* ¶ 5 (claiming Article 31 of TRIPS authorized the production of exportation of generic medications through compulsory licensing). The pharmaceutical industry in India was valued at over \$12 billion in 2009 and is projected to grow to \$55 billion by 2020, and generic pharmaceuticals

WTO regulations and acting only on behalf of patent holders.⁶⁷

While the E.U. never officially answered the Request for Consultations, Ambassador Eckart Guth had previously made statements to the WTO justifying the drug seizures. Ambassador Guth cited TRIPS Article 51, which gave it authority to suspend cargo shipments if they were in violation of international patent laws.⁶⁸ Ambassador Guth also emphasized that the drugs were returned to India after investigation, the seizure was temporary, and regardless of whether the cargo was produced properly, international law allowed for temporary seizures while customs officials checked the origin of the cargo.⁶⁹ E.U. officials argued that the cargo was only being checked to ensure that it would not be diverted and sold into E.U. ports in violation of domestic patent law.⁷⁰

With the case having been filed, parties began preparing for consultations. Five countries (Canada, China, Turkey, Japan, and Ecuador) joined the litigation, demonstrating the importance of the issue at hand: interpretation of the contentious TRIPS agreement and subsequent declarations.⁷¹

D. RESOLUTION WITH INDIA; CONTINUED LITIGATION IN BRAZIL

The E.U. was particularly interested in avoiding protracted litigation and therefore sought to settle the claims with each country. There was some speculation that the E.U.'s interest in settlement was in part motivated by a free trade agreement it was negotiating with India.⁷² Regardless, the E.U. quickly

produced by India constitute nearly twenty percent of global supplies. *Pharmaceuticals*, INDIA BRAND EQUITY FOUND., <http://www.ibef.org/industry/pharmaceuticals.aspx> (last updated Feb., 2012).

67. See *id.* ¶¶ 1-5 (discussing the list of GATT and TRIPS articles violated). See also *India, Brazil Raise Dispute over EU Drug Seizures*, *supra* note 44 (arguing the E.U. seized the medications under pressure from the pharmaceutical industry).

68. Eckart Guth, Ambassador of EU to WTO, *EC Intervention* (WTO General Council, (Feb. 2009) available at http://www.ip-watch.org/files/WTO_GENERAL_COUNCIL.doc

69. *Id.*

70. *Id.* See also *Brazil Slams EU for Seizure of Generic Drugs*, 13 INTELL. PROP. PROGRAMME 4 (Feb. 4, 2009), <http://ictsd.org/i/news/bridgesweekly/39772/>.

71. Prashant Reddy, *China, Canada, Japan, Turkey, Ecuador Seek to Join Consultations in the Indo-E.U. Trade Dispute over Seizure of 'In-transit' Generic Drugs*, SPICY IP (July 22, 2010, 3:58 PM), <http://spicyipindia.blogspot.com/2010/07/china-canada-japan-turkey-ecuador-seek.html>.

72. See e.g., Lehr, *supra* note 63. See also Matthias Williams, *India, EU Heal Drug Seizures Dispute with Interim Settlement*, REUTERS, JULY, 28, 2011,

entered into settlement talks with India.

These talks eventually bore fruit, and a settlement was reached in October 2010.⁷³ The E.U. agreed to undergo substantial reforms to its customs and patent enforcement procedures.⁷⁴ In return for these changes, India suspended its pursuit of the claim, though India retained the right to revive it should the E.U. fail to make satisfactory reforms to its customs regulations.⁷⁵ Despite the Indian settlement, there was no progress made in the Brazilian case. There has been little discussion about this, but the lack of a free trade agreement negotiation with Brazil likely put less pressure on the E.U. to reach an immediate settlement.⁷⁶

III. ANALYSIS

This analysis seeks to understand the ways in which TRIPS and the Doha Declaration are ambiguous and the ways in which the Indian settlement clarified this ambiguity. First, we turn to Article 1.1 of TRIPS, cited by Brazil in its request for consultations.⁷⁷ Article 1.1 states that countries may “determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”⁷⁸ The discretion allowed in Article 1.1 providing countries flexibility while implementing generic production resulted in considerable tension. Brazil used the flexibility to

available at <http://www.reuters.com/article/2011/07/28/india-eu-drugs-idUSL3E7IS4WW20110728> (discussing how generic medications have become a hot button issue between India and the E.U. as they conclude a free trade agreement); *EU, India Resolve Spat Over Generic Drug Settlements, But FTA to Wait Until 2011* INT'L CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, <http://ictsd.org/i/news/bridgesweekly/98989/htm> (last visited Apr. 9, 2012) (calling the drug seizure dispute “an irritant” in broader free trade negotiations).

73. George Mathew, *India, EU Settle Generic Drug Seizure Issue*, THE INDIAN EXPRESS (Oct. 8, 2010, 3:17 AM), <http://www.indianexpress.com/news/india-eu-settle-generic-drug-seizure-issue/694259/1>.

74. *Id.*

75. Press Release, Gov't of India, *India EU Reach an Understanding on Issue of Seizure of Indian Generic Drugs in Transit* (July 28, 2011), available at <http://pib.nic.in/newsite/erelease.aspx?relid=73554>.

76. However, Mercosur and the European Union have recently reentered negotiations over a free trade agreement. See *Mercosur*, EUROPEAN COMM. <http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/regions/mercosur/htm> (last visited Apr. 7, 2012). Brazil may have accepted the terms of India's settlement as adequate as well.

77. Request for Consultations by Brazil, *supra* note 59.

78. TRIPS, *supra* note 27.

aggressively implement compulsory licensing to bolster its generic pharmaceutical sector.⁷⁹ At the same time, the E.U. used this discretion to implement an aggressive customs system that led to extensive seizure of medications. The broad discretion allowed in Article 1.1 is essentially the root of the controversy, while the individualized implementations of TRIPS by each country amplify its ambiguity and demonstrate its inherent flaws.⁸⁰

A. DID INDIA AND BRAZIL HAVE THE RIGHT TO PRODUCE AND TRANSFER THE GOODS?

Likely a chief concern for the E.U. was that the aggressive generic production of India and Brazil went beyond the goals and purposes of TRIPS and that India used TRIPS to create a lucrative generic market. The dispute between the E.U. and India and Brazil thus embodied a more fundamental concern: the interpretation of TRIPS and the Doha Declaration. Do countries such as India and Brazil have the right to license, produce, and export generic medications under TRIPS? An analysis of the arguments presented demonstrates that TRIPS fails to definitively answer this question. Such ambiguity leads to enforcement problems.

India first claimed authority to produce the medication based on a reading of Article 28, in combination with Article 2, Article 4*bis* of the 1967 Paris Convention, and the Decision of the General Council of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration.⁸¹ Article 28, as discussed above, defines the rights provided to a patent holder and essentially gives the holder sole use of production.⁸² Article 2 reaffirms the commitments to previously negotiated agreements involving intellectual property.⁸³ These Articles provide an international standard for patent protection.⁸⁴

As described in India's request for consultations, India combines these TRIPS rights with the Paris Convention and Doha to assert a broad authority to produce generic medication.

79. Harris, *supra* note 57, at 387–88.

80. For reference, the other Articles used by India and Brazil were 2, 7, 8, 28, 31, 41, 42, 49, 50, 51, 52, 53, 54, 55, 58, and 59. Request for Consultations by India, *supra* note 59; Request for Consultations by Brazil, *supra* note 59.

81. Request for Consultations by India, *supra* note 59, ¶ 3.

82. TRIPS, *supra* note 27, at art. 28.

83. *Id.* at art. 2.

84. See *Overview*, *supra* note 1 (describing these articles as the standards of patent protection under TRIPS).

First, Article 4*bis* of the Paris Convention ensures the right of countries to independently grant their own patents.⁸⁵ Here, India uses the Article as a basis for India's own production of generic drugs, indicating that a drug manufacturer must have been granted a patent by India in order to receive protection from the Indian government, even if the medication produced violates other countries' patents.⁸⁶

India then uses the Doha Declaration to expand its authority to produce medication under the Paris Convention.⁸⁷ India does this by relying on Paragraph 6(i) of the Decision of the General Council of August 30, 2003 on the implementation of Paragraph 6 of the Doha Declaration.⁸⁸ Paragraph 6(i) provides a waiver under Article 31(f) of TRIPS, which had originally allowed countries to violate a patent only if the product produced was to be used for its domestic population.⁸⁹ Under Paragraph 6(i), countries can export pharmaceutical products to developing countries, provided that the importing country makes the exporting country aware of the need for such medication and demonstrates that it does not have the capacity to produce the drug on its own.⁹⁰

India combines these documents to broadly define its right to produce generic medication under TRIPS. Essentially, India argues that any pharmaceutical drug that originated from India could not be interfered with, provided it was manufactured and exported under the requirements of the Doha Declaration as interpreted in the General Council decision.⁹¹ India argues that "the rights conferred on the owner of a patent cannot be extended to interfere with the freedom of

85. Paris Convention for the Protection of Industrial Property art. 4*bis*, as last revised at the Stockholm Revision Conference, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 303 ("Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.").

86. See Request for Consultations by India, *supra* note 60, ¶ 3.

87. *Id.* Comparatively, the Paris Convention dealt more with the rights of countries to produce goods independent of other countries' laws.

88. *Id.* As discussed previously, this decision was meant to provide guidance on providing pharmaceutical products to developing countries which were unable to develop their own pharmaceutical industry.

89. See Decision of the General Council, *supra* note 33. Originally, India's actions would have violated Article 31 because most of its generic medications were exported. TRIPS, *supra* note 27, at art. 31.

90. Least developing countries do not need to demonstrate an inability to produce the medication. General Council Decision, *supra* note 33, ¶ 2.

91. Request for Consultations by India, *supra* note 59, ¶ 3.

transit of generic drugs lawfully manufactured within, and exported from, India.”⁹² The broad reach of India’s interpretation becomes even more evident when examining the nature of specific E.U. drug seizures. For example, one seizure targeted generic anti-hypertensive drugs.⁹³ Hypertension, more commonly known as high blood pressure, is a very common affliction.⁹⁴ The Doha Declaration was primarily implemented as a solution to high-profile public health emergencies, with the declaration specifically listing HIV/AIDS, tuberculosis, and malaria as examples.⁹⁵ India’s production of hypertension medication exceeds the intended limits of the Doha Declaration and TRIPS. Hypertension, while serious, has not risen to the level of a public health crisis on the scale of HIV/AIDS.⁹⁶ Thus, India’s production of hypertension medication demonstrates that India justifies the breaking of patents for many drugs far beyond the intended scope of the Doha Declaration, though, as will be discussed below, India can argue that the list of diseases in Doha is simply a non-exhaustive starting point. Essentially, India has ensured itself a lucrative generic industry, valid under TRIPS provided it serves developing countries.

This is not to say that India’s production of such medication is necessarily unjustified. Indeed, high blood pressure is a serious affliction that can lead to severe medical problems.⁹⁷ In fact, India may argue that the list of diseases in the Doha Declaration is not a closed list. Moreover, the Doha Declaration was implemented to confirm “that the [TRIPS] can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and,

92. *Id.*

93. Tim Stirrup & Katherine Hebditch, *EU dispute with India and Brazil up Stakes in Generics Saga*, BALDWIN INTELL. PROP. (July 21, 2010), <http://www.baldwins.com/eu-dispute-with-india-and-brazil-ups-stakes-in-generics-saga/>.

94. *High blood pressure (hypertension)*, MAYO CLINIC (Mar. 22, 2011) <http://www.mayoclinic.com/health/high-blood-pressure/DS00100>. 50 million people in the United States alone suffer from hypertension, which is nearly thirty percent of the population. Vincent R. Moloney, *High Blood Pressure: Can You Prevent It? Lower It?*, BLOODPRESSURE-DRS-PRACTICAL-GUIDE.COM, <http://www.bloodpressure-drs-practical-guide.com/highbloodpressure.html>.

95. Doha Declaration, *supra* note 24, ¶¶ 4–6; *See* World Health, *supra* note 18 (arguing that widespread epidemics were the driving force behind the Doha Declaration).

96. *C.f.* Junaid Subhan, *Scrutinized: The TRIPS Agreement and Public Health*, 9 MCGILL J. OF MED., 152, 156 (2006) (arguing that high cholesterol does not rise to the level of AIDS or other communicable diseases).

97. *See High blood pressure (hypertension)*, *supra* note 94.

in particular, to promote access to medicines for all.”⁹⁸ Such a broad statement lends considerable support to India’s claim.

First, public health can be defined very inclusively. Merriam Webster defines public health as “the art and science dealing with the protection and improvement of community health by organized community effort and including preventive medicine and sanitary and social science.”⁹⁹ Such a definition clearly is not limited to life-threatening illnesses. Certainly the treatment of hypertension can be included here, both in terms of community health and preventative medicine. Second, the last statement, “to promote access to medicines for all” is persuasive as well. Because India could argue that it was trying to provide medicine to developing countries, it can claim that it is doing nothing more than fulfilling the purpose of the Doha Declaration. It is ensuring that developing countries have access to a supply of medicine through generic production, a need recognized in paragraph 6i of the 2003 General Council decision.¹⁰⁰

Many countries, however, claim that the Doha Declaration was intended to promote access to *essential* medications.¹⁰¹ Essential medications, they argue, are those meant to treat diseases specifically listed in the Doha Declaration, those that were contagious and spreading.¹⁰² Were this definition adopted, many of the generic drugs produced by India would probably be produced in violation of TRIPS. Applying this definition specifically, there is a strong case to be made that hypertension is not the type of communicable disease that falls under Doha protection. Hypertension, while perhaps genetic, is not able to ravage a country in the way AIDS or malaria have.¹⁰³ This first subsection of India’s argument demonstrates a conflict over the scope and applicability of TRIPS to given medications. Without a resolution, further enforcement measures could be taken by patent holders, leading to more litigation.

India further reaffirms its claim to produce medication by citing Article 31, in conjunction with the General Council decision.¹⁰⁴ Here India argues that international exceptions to

98. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC2, 41 I.L.M. 755 (2001).

99. MERRIAM WEBSTER, <http://www.merriam-webster.com/medlineplus/public%20health> (June 11, 2010).

100. General Council Decision, *supra* note 33, ¶ 6.

101. Subhan, *supra* note 96.

102. *Id.*

103. *Id.*

104. Request for Consultations by India, *supra* note 60, ¶ 4.

TRIPS allow for the production of generic medication.¹⁰⁵ Article 31 provides several exceptions for when patents can be infringed upon.¹⁰⁶ Most prominent among these is the national emergency exception, which permits a country to produce generic medication in violation of TRIPS if such production is to deal with a public health emergency.¹⁰⁷ Each country is allowed to decide what determines such an emergency; there is no international standard.¹⁰⁸ India reinforces this with the General Council decision, declaring that it can use compulsory licensing to produce medications for developing countries that have an inability to produce such medication.¹⁰⁹ This essentially allows India to produce any medication without payment to the patent holder for any country that declares a public health emergency (under Article 31b) and claims a need for the medication. Such a conclusion greatly expands India's right of production under TRIPS and the Doha Declaration.

Some critics have argued that such a conclusion is against the collective interest of LDCs and alternative policies such as public funding of medical therapies, international aid, or price discrimination by patent holders should instead be considered.¹¹⁰ Furthermore, the E.U. may argue that the Doha Declaration does not waive these obligations; indeed, the General Council Decision specifically holds that only Article 31f is waived under Doha.¹¹¹ The E.U. could also argue that there is little penalty for countries declaring public health emergencies without good cause and that such conduct must be curtailed.¹¹²

However, the Doha Declaration makes compulsory licensing a much more feasible tool for developing nations, provided they possess the adequate manufacturing capacity.¹¹³

105. Additionally, India raised complaints over Articles 41 and 42. *Id.* ¶ 5.

106. *See* TRIPS, *supra* note 27, at art. 31(b).

107. *Id.* This Article holds that use without "reasonable commercial terms and conditions" with the right holder should be taken only in cases of "national emergency or other circumstances of extreme urgency."

108. *See id.* (allowing countries to use patents without authorization in cases of emergency, but providing no definition of when an emergency exists).

109. General Council Decision, *supra* note 33, ¶ 2.

110. *See* Sykes, *supra* note 37, at 66–67 (discussing alternatives to the current right of production predicated on national emergency).

111. General Council Decision, *supra* note 33, ¶ 2. As discussed earlier, Article 31f requires compulsory licensing for domestic use only.

112. For support of such an idea, see Sykes, *supra* note 37, at 66 (arguing that the costs of declaring public health emergencies are often externalized, so there is little incentive not to declare them).

113. *See id.* at 55 (arguing that Doha allows for compulsory licensing to be used more effectively for developing nations to achieve their goals, mainly

Combined with TRIPS, which, under Article 31, requires only payment of “adequate remuneration” for compulsory licensing if the importing country has declared a national emergency,¹¹⁴ the benefits of compulsory licensing far outweigh the consequences. Countries such as India would be able to benefit individually from such measures, while externalizing most of the costs of lost research incentives to the collective world.¹¹⁵

B. DO WTO PRECEDENTS CLARIFY THE AMBIGUITY OVER GENERIC MEDICATION PRODUCTION?

A look at WTO case law reaffirms this ambiguity over the manner in which generic medications are protected under TRIPS. Only one TRIPS case has ever reached the litigation stage, a case between China and the United States.¹¹⁶ In this dispute, the United States brought a complaint claiming that China had failed to create and enforce domestic measures to prevent counterfeiting (not of generic medications).¹¹⁷ The WTO panel was the first to address the enforcement obligations of TRIPS.¹¹⁸ The WTO panel, however, only reinforced the idea that TRIPS can and should be applied flexibly.¹¹⁹ The WTO panel found that TRIPS was meant to be applied differently depending on the industry being covered.¹²⁰ Scholars found that

lower prices).

114. Such remuneration may be minimal. *Id.* at 66.

115. The costs externalized to collective nations center primarily around the loss of valuable research incentives. Sykes, however, argues that because individual countries make up such a small fraction of the market, their decision to infringe on patents results in little loss of research incentive and thus an individual country will see no harm in engaging in compulsory licensing. However, if all developing countries behave this way there will be little incentive to research medications for diseases found in developing countries. This creates a collective action problem *Id.* at 65–66.

116. Patricia Judd, *Toward a TRIPS Truce*, 32 MICH. J. INT'L L. 613, 616 (2011). The United States argued that China had violated Article 61 of the TRIPS agreement.

117. *Id.* The case concerned the piracy of digital music files and other electronic media.

118. *Id.*

119. See Report of the Panel, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, ¶¶ 7.605, WT/DS362/R (Jan. 26, 2009) (citing Report of the Panel, *United States—Section 110(5) of the U.S. Copyright Act*, ¶¶ 6.113, 6.178, WT/DS160/R (June 15, 2000) (finding that the panel should consider market-specific conditions when determining whether a violation of TRIPS has occurred).

120. *Id.* See also Judd, *supra* note 116, at 617 (finding that the WTO “piracy” in China may affect the market differently than piracy in Germany and that one must assess piracy of books differently than peer-to-peer trading of digital music files.”)

the WTO panel only reinforces the fact that TRIPS should be applied differently based upon the product in question and which country is developing the product.¹²¹ This should be seen as a positive sign for generic medication producers because it could be seen as an indicator that the WTO's Dispute Settlement Mechanism will interpret TRIPS in a lenient manner in public health circumstances. Case law thus fails to provide an answer to what specific medications can be produced under the auspice of TRIPS. Indeed, if anything, the WTO panel decision only adds to the ambiguity and need for guidance. At the very least, the WTO's decision suggests a flexible approach, which greatly favors generic medication producers.

Thus, TRIPS and the Doha Declaration fail to definitively answer what generic medications may be produced in a manner that fulfills the goals of both TRIPS¹²² and the Doha Declaration.¹²³ While many scholars agree that TRIPS (and the Doha Declaration) should be interpreted in a flexible manner,¹²⁴ this case demonstrates that there is a need for clarification. Billions of dollars may be at stake in these seizures.¹²⁵ Frequently these seizures end with the confiscation of drugs, which prevents them from reaching their intended patients.¹²⁶ More importantly, there is a human element to consider. Drug seizures could delay the arrival of truly essential medicine to many developing countries. More guidance from the WTO would allow for the more efficient transportation of medicines,

121. *Id.*

122. *See Overview, supra* note 1 (discussing passage of TRIPS).

123. *See World Health, supra* note 18.

124. *See Judd, supra* note 116, at 617 (citing Rochelle Cooper Dreyfuss, TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis, in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* 51, 53 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1443248; Peter K. Yu, *The Objectives and Principles of the TRIPS Agreement*, 46 *HOUS. L. REV.* 979, 981 (2009)).

125. *See Nageshwar Patnaik, India Tops Exporting Generic Medications*, *THE ECONOMIC TIMES*, Mar. 7, 2010, http://articles.economictimes.indiatimes.com/2010-03-07/news/28443868_1_generic-medicines-india-tops-pharmaceutical-industry (finding that India exports over \$8 billion a year in generic medications).

126. *See Jennifer M. Freedman, India, Brazil Complain at WTO Over Generic Drug Seizures by European Union*, *BLOOMBERG*, MAY 12, 2010, <http://www.bloomberg.com/news/2010-05-12/india-brazil-complain-at-wto-over-generic-drug-seizures-by-european-union.html> ("EU permits customs authorities to confiscate goods in transshipment. . . .")

saving time and money.

C. THE INDIAN AND E.U. SETTLEMENT FAILS TO DETERMINE
WHAT GENERIC MEDICATIONS CAN BE PRODUCED.

Unfortunately, guidance regarding the production of generic medication did not come from resolution of this case. As was previously discussed, India and the E.U. were able to reach a settlement, in which the E.U. made several concessions regarding enforcement proceedings in exchange for suspension of India's claim in the WTO.¹²⁷ These concessions answer important questions regarding TRIPS and will be discussed later. What is also important, though, is what this settlement does not cover.

Specifically, the settlement does little to clarify what generic medications are protected under TRIPS.¹²⁸ There are two conclusions that can be drawn from this lack of clarification. First, one could infer that the E.U. did not challenge the production of any generic medication because such production is accepted, provided that it does not violate the patents of the producing country or destination country. Support for this claim is found within the statutory language of Doha, which allows countries the flexibility to determine what a public health emergency is, allowing them to take broad advantage of generic production.¹²⁹ Further support can be drawn from the fact that countries are free to implement their own procedures to gain access to generic medications. Indeed, because countries have this ability, through rights to implement compulsory licensing and other techniques,¹³⁰ a conclusion can then be drawn that the TRIPS exceptions provide countries the freedom to determine what medications are essential. As such, one could argue there is no need to determine what drugs are protected under the TRIPS exceptions.

Such an interpretation, though, assumes that TRIPS was created to promote access to *all* medicine. While such an aspiration may now be a goal of many,¹³¹ it clashes with a

127. Press Release, Gov't of India, *supra* note 75.

128. *See Id.* (showing no discussion about whether the drugs produced were legal under TRIPS and its exceptions).

129. *See* Doha Declaration, *supra* note 24, ¶¶ 4–6 (providing countries with flexibility to declare public health emergencies and to take appropriate measures to deal with such a crisis).

130. *Id.*

131. For support of such an interpretation, Bazzle, *supra* note 54, at 785 (arguing that a country's definition of public health could allow it to claim the

number of the ideas that drove the creation of TRIPS. At its inception, TRIPS only allowed patents to be violated to improve access to *life-saving* medications, suggesting that improved access to *all* medicines was not necessarily intended.¹³² Furthermore, the need to declare a public health emergency in order to invoke the TRIPS exceptions greatly limits its effectiveness, suggesting a similar conclusion.¹³³

However, the E.U. never raised the point that the drugs were produced in violation of TRIPS; instead, the E.U. focused solely on the issue of whether the drug seizures themselves were lawful.¹³⁴ Had the case proceeded to a WTO panel, the E.U. could have raised an interesting argument that would have allowed the WTO to better define the scope of TRIPS and the Doha Declaration. Unfortunately, because the settlement did not cover this issue, the ambiguity within TRIPS remains.¹³⁵

Despite this remaining ambiguity, there are solutions that could better define the scope of TRIPS protection(s) that should be considered. First, there could be a definitive listing of what pharmaceutical products are subject to compulsory licensing under TRIPS. Such a proposal was passed in Canada in 2004.¹³⁶ This list would provide clarity as to what drugs could be seized but would be difficult to implement. However, many Canadian observers raised the concern that such a list would greatly limit new drugs that could be subject to compulsory licensing.¹³⁷ Furthermore, an attempt to make an exhaustive list would be difficult, given there are constant innovations and developments in medications. Indeed, this list would require constant update and enforcement would be an issue.

authority to manufacture all forms of medication).

132. Hildpold, *supra* note 36, at 362. Many human rights activists made this criticism.

133. *Id.*

134. See Press Release, Gov't of India, *supra* note 75. The press release discussed the claims made by India and how they were being addressed. No mention was made of an EU claim regarding the right of India to produce the drug in question.

135. As discussed previously, the EU may have been quick to settle to protect its own lucrative interests in a free trade agreement. *EU-India Settle WTO Drug Trade Dispute*, *supra* note 63.

136. Richard Elliott, *Doha para 6 Implementation: EU proposal vs. Canadian legislation*, IP-HEALTH (Nov. 1, 2004, 1:30 PM), <http://lists.essential.org/pipermail/ip-health/2004-November/007091.html>.

137. *Id.* Many observers felt that the pharmaceutical industry would always lobby against the inclusion of more drugs to generic production. Such a limit would then run contrary to the goal of TRIPS, read together with Doha and the General Council decision.

Inconsistencies would lead back to the same issue currently facing countries. For example, the European Union could claim a drug for hypertension was subject to TRIPS protections. Canada, though, could decide that same drug was not subject to TRIPS protections. India could claim permission from Canada to manufacture the drug. But, if India ships the drug through E.U. waters, the drug could still be seized, despite India claiming the authority to manufacture the drug from Canada. As a result, such a list would have to come from the WTO or through multilateral negotiation between countries to ensure agreement on what drugs could be seized in transit. Such multilateral negotiations would undoubtedly be time-consuming. Overall, such a solution would be too cumbersome to properly address the rapidly evolving field.

A second potential solution, proposed in the E.U., would be to define what “essential medication” means under TRIPS.¹³⁸ This would categorize drugs into essential and non-essential. One expert has proposed that criteria for determining when a drug is essential include “availability of alternative treatment, severity of the disease the medication is aimed at treating, and the capacity of the patent-holder to adequately supply markets that demand the patented product.”¹³⁹ This distinction would allow different patent protection for essential and non-essential drugs.¹⁴⁰ Such a proposal would solidify TRIPS without sacrificing the flexibility needed to produce generic drugs to meet public health emergencies. Generic drug producers could meet the demand caused by such diseases as AIDS, malaria, and tuberculosis while still respecting most of the pharmaceutical industry’s patents. Such a proposal still has its flaws. After all, the criteria proposed above is still subject to interpretation and would limit availability of many medications to developing countries. In addition, this proposal gives more power to patent holders. If patent holders assert they can adequately supply the market, then it appears generic production may be outlawed. Such a meaning would clash with the idea behind the Doha Declaration, which sought to ensure a greater supply of medication to all countries.¹⁴¹

Nevertheless, this solution is still preferable, albeit with some minor tweaks; for instance, focusing more on the severity of the disease versus the capacity of the patent holder. Such a

138. Subhan, *supra* note 96, at 156.

139. *Id.*

140. *Id.*

141. World Health, *supra* note 18.

tweak ensures that if the disease is serious enough, generic production can take place without waiting for patent holders to decide if they can adequately meet demand. This criteria would then ensure that patent holders produce cheaply to meet demand for the severe disease or sacrifice the market to generic producers. Additionally, this solution better addresses the flexibility that comes with breakthroughs in medical research. Rather than amending a list every time a new drug is created, which could lead to domestic political battles over what drugs should be added, a new drug can be judged immediately by preset criteria. Such a definition could be proposed and implemented through a General Council decision, similar to the way in which generic exportation was permitted.

Thus, analysis of the first ambiguity shows that little has changed as a result of the recent drug seizure cases. Solutions are still required. There needs to be a firmer definition of what medications are covered and a stronger process for remuneration, when needed. Such a solution would solidify international patent protection, aiding manufacturers and developing countries alike. We now turn to the study of how the seizures impacted enforcement proceedings under TRIPS.

D. DOES THE TRIPS AGREEMENT PROVIDE FOR THE STOP AND SEIZURE OF GENERIC MEDICATIONS?

While the primary concern of the E.U. was the broad, aggressive interpretation of the TRIPS exceptions in producing generic medication, the principal concern of Brazil and India was the repeated seizures of generic medication. These seizures delayed shipments of medications for months at a time and, in some cases, resulted in the confiscation of the drugs.¹⁴² Again, an analysis of TRIPS provides little guidance as to whether the E.U. was acting within their legal authority in stopping and seizing medications. Nevertheless, such an analysis is important because it demonstrates how TRIPS was in part responsible for the ship seizure controversy.

There are two issues at play. First, did the E.U. adequately provide notice of their enforcement procedures as required by the GATT? Second, does the seizure of such generic medications violate the principles of free transit found within the GATT and TRIPS? The relevant articles in regards to enforcement regulations, as discussed previously, are the following: Article X of the GATT and Articles 50, 51, 52, 53, 54,

142. See Freedman, *supra* note 126.

55, 58, and 59 of TRIPS.¹⁴³

India and Brazil first claimed the E.U. failed to publish information regarding their trade practices, in violation of Article X of the GATT.¹⁴⁴ India argued that the E.U. violated Article X because it failed to provide specific information about the rationale of the seizures.¹⁴⁵ Article X provides that “[l]aws, regulations, judicial decisions and administrative rulings of general application . . . shall be published promptly in such a manner as to enable governments and traders to become acquainted with them.”¹⁴⁶ Here, India argued that even if the E.U. is able to justify its seizures, such seizures are *still* illegal because the E.U. failed to provide notice of such procedures to India, as required by Article X of the GATT.¹⁴⁷

The E.U., though, could make a fairly strong defense to this claim by arguing that European Commission regulations gave adequate notice as required under Article X of the GATT and TRIPS. The E.U. ambassador claimed that European Commission regulations created the right to regulate and inspect all shipments to ensure they complied with domestic patent regulations.¹⁴⁸ Such regulations, they could then argue, gave adequate notice to countries that shipments passing through E.U. territory were subject to regulations that may lead to temporary seizure. Specifically, the E.U. can point to Regulation 1383/2003,¹⁴⁹ which allows for patent holders to file complaints with customs authorities.¹⁵⁰ After such a complaint, E.U. officials may seize the product for three days to determine whether the product is in violation of E.U. law.¹⁵¹ Furthermore, 1383/2003 points to established E.U. regulations on the relevant customs process.¹⁵² Such detail should satisfy the requirement that such regulations be published for the benefit of other countries.¹⁵³

143. Request for Consultations by India, *supra* note 59, ¶ 5; Request for Consultations by Brazil, *supra* note 59.

144. Compare Request for Consultations by India, *supra* note 59, ¶ 2, and Request for Consultations by Brazil, *supra* note 59, at 4, with GATT, *supra* note 61, art. X ¶ 1.

145. Request for Consultations by India, *supra* note 59, ¶ 2.

146. GATT, *supra* note 61, art. X ¶ 1.

147. Compare Request for Consultations by India, *supra* note 59, ¶ 2, with GATT, *supra* note 61, art. X ¶ 2.

148. See *Brazil Slams EU for Seizure of Generic Drugs*, *supra* note 70.

149. Council Regulation 1383/2003, art. 4(1), 2003 O.J. (L 196) 7 (EC).

150. *Id.* art. 5(1).

151. *Id.* art. 4(1).

152. See *id.* art. 1.

153. See generally Commission Regulation 1891/2004, 2004 O.J. (L 328) 16

Brazil and India claimed that these regulations go beyond the authority prescribed for the E.U. in TRIPS and the Doha Declaration.¹⁵⁴ Specifically, Brazil and India argued that the E.U. actions were in violation of Articles V of the GATT, and 41 and 42 of TRIPS.¹⁵⁵ Additionally, Articles 50 through 55 are also cited by Brazil.¹⁵⁶ India and Brazil use these Articles to argue that the seizures were in violation of international law because they impaired the free transit of goods.¹⁵⁷

India and Brazil both based a strong part of this claim on Article V of the GATT.¹⁵⁸ India specifically alleged that the E.U. violated this Article because the goods were merely in transit.¹⁵⁹ The statutory language of Article V(1) defines goods in transit as:

Goods (including baggage), and also vessels and other means of transport, shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes.¹⁶⁰

The shipments of generic medication were never bound for the E.U. but for countries in Latin America and Africa.¹⁶¹ Given that the goods were never to stop in E.U. jurisdiction, Article V protections should apply, preventing outside countries from

(EC) (providing the provisions that allow for customs action to be taken against goods suspected to be in violation of domestic patent laws). These regulations are found on-line and easy to access.

154. *See generally* Request for Consultations by India, *supra* note 59, (arguing the these provisions were inconsistent with the GATT and TRIPS)

155. *Id.* ¶¶ 1,4; Request for Consultations by Brazil, *supra* note 59, at 4.

156. Request for Consultations by Brazil, *supra* note 59, at 4.

157. Request for Consultations by India, *supra* note 59, ¶ 5; Request for Consultations by Brazil, *supra* note 59, at 2.

158. Request for Consultations by India, *supra* note 59, ¶ 1; Request for Consultations by Brazil, *supra* note 59, at 4. Brazil also alleged the EU to be in violation of Article XVI of the WTO, which requires notification of contracting parties of any subsidies. *Id.* at 4; GATT, *supra* note 61, art. XVI. This Article was not the focal point of the litigation and will not be analyzed. *See* Swaraj Paul Barooah, *India, Brazil Start Dispute Proceedings Against EU*, SPICY IP (May 18, 2010, 2:50 PM), <http://spicyipindia.blogspot.com/2010/05/india-brazil-start-dispute-proceedings.html>. (claiming that the strongest arguments for India and Brazil came from within TRIPS and Article V of the GATT).

159. Request for Consultations by India, *supra* note 59, ¶ 1.

160. GATT, *supra* note 61, art. V ¶ 1.

161. *Brazil Slams EU for Seizure of Generic Drugs*, *supra* note 68.

interference.¹⁶² However, Subsection 3 may provide a basis for E.U. defense.¹⁶³ This section allows for reasonable delay so that goods may be entered and inspected to ensure compliance with domestic customs laws and procedures, provided that any delay is minimal.¹⁶⁴ E.U. officials argued that the cargo was only being checked to ensure that it was not to be diverted into E.U. ports.¹⁶⁵ However, given that no countries in the E.U. were a destination for the medication, such intrusive delay seems to go beyond the scope of ‘minimum delay.’ Rather, the E.U. should have limited its customs procedures to ensure the drugs stayed in transit, which would not require their seizure.

Brazil further argued that the E.U. did not meet the standard set forth in Article 52.¹⁶⁶ As one commentator points out,¹⁶⁷ Article 52 requires that in order for seizure to take place “under the laws of the country of importation, there is *prima facie* an infringement of the right holder’s intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities.”¹⁶⁸ Essentially, there must be a risk that the medicine being seized will be availed to the domestic market.¹⁶⁹ The problem is this standard was difficult to interpret and apply.

The first relevant article in applying this standard is Article 50. This article gives nations the authority to regulate and inspect all shipments under provisional measures to ensure they are in compliance with TRIPS and the Doha Declaration.¹⁷⁰ Such measures are intended to give Members of the WTO the ability to regulate patented goods.¹⁷¹ These provisional measures provide countries the authority to enforce their domestic laws, specifically “to prevent an infringement of any intellectual property right from occurring, and in

162. *Id.*

163. See GATT, *supra* note 61, art. V.

164. *Id.*

165. See *Brazil Slams EU for Seizure of Generic Drugs*, *supra* note 70.

166. Request for Consultations by Brazil, *supra* note 59, at 4.

167. Catherine Dounis, Note, *Enforcing Intellectual Property Rights via EU Border Regulations: Inhibiting Access to Medicine or Preventing Counterfeit Medicine*, 36 BROOK. J. INT’L L. 717, 748–49 (2011).

168. TRIPS, *supra* note 27, art. 52.

169. Dounis, *supra* note 167, at 748.

170. See generally TRIPS, *supra* note 27, art. 50. Here, Dutch customs officials, upon inspection, found a generic version of Cozaar, an anti-hypertensive drug produced by Merck. This discovery led to the subsequent seizure. See Stirrup & Hebditch, *supra* note 93.

171. *Overview*, *supra* note 1.

particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance” and to “to preserve relevant evidence in regard to the alleged infringement.”¹⁷²

The E.U. Ambassador Guth affirmed the E.U.’s right to seize the goods by citing Article 51,¹⁷³ which states:

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods.¹⁷⁴

Ambassador Guth argued that Article 51 gave it the authority to implement a customs system that allowed for temporary suspension of cargo.¹⁷⁵ In this instance, Ambassador Guth argued that the presence of generic medications in a Netherlands port was enough to justify a temporary seizure of cargo.¹⁷⁶ Specifically, Ambassador Guth argued that its seizure was necessary to ensure the drugs were not being brought into the Netherlands or other countries, undermining domestic patent protection.¹⁷⁷

One can again see the problems caused by the ambiguity found within these agreements. The E.U. can argue that seizing the cargo did not amount to a violation of the GATT, because the cargo was stopped only to ensure compliance with domestic customs procedures. At the same time, India and Brazil can make the argument that the drugs should not have been seized because they were never meant to end up in E.U. markets. The clash between these two arguments immediately raises questions over the Articles’ interpretation. The issue is whether European Commission regulations may apply to goods that merely pass through (Article V, goods-in-transit) or whether it may only apply to goods which are being exported to E.U. members.

Given these ambiguities, there was hope that settlement would provide greater guidance to this element of TRIPS.

172. TRIPS, *supra* note 27, art. 50(a)–50(b).

173. *See* Guth, *supra* note 68.

174. TRIPS, *supra* note 27, art. 51.

175. *See* Guth, *supra* note 68.

176. *See* Stirrup & Hebditch, *supra* note 93 (“ . . . Dutch officials deemed the “storage” of the patented drug on Dutch soil to be infringement of the Dutch patent.”). *See also* Guth, *supra* note 68 (“ . . . Duth authorities temporarily detained . . . a small shipment of drugs . . . in order to control it.”)

177. *See* Guth, *supra* note 68.

Again, we turn to the resolution reached between India and the E.U. to understand what lessons can be applied in further TRIPS interpretation.

E. THE INDIAN AND E.U. SETTLEMENT PROVIDES GUIDANCE AS TO WHAT CONSTITUTES ACCEPTABLE ENFORCEMENT.

Despite the lack of resolution on the issue of essential medications, the E.U.-India settlement made substantial progress in settling the issue of customs enforcement. India, as previously discussed, agreed to suspend its suit against the E.U. in exchange for amendments to E.U. customs regulations and seizure protocols. The specifics of the E.U. reforms are still in progress, but it seems that any potential reform will include the following proposals. First, the E.U. will no longer be able to seize medications on the basis of an E.U. patent alone.¹⁷⁸ Second, the European Commission will revise Regulation 1383/2003, which was the initial basis for the seizure.¹⁷⁹ The specifics to the overhaul of this regulation have not yet been made clear, but preliminary statements suggest the E.U. will be required to demonstrate that the seized drugs were intended to be sold within E.U. markets.¹⁸⁰ Finally, it will likely require that, upon seizure, some proof of evidence must be provided to the shipping company as to the rationale for the seizure of the drugs.¹⁸¹ The settlement terms greatly favor India and deal primarily with the customs procedures of E.U. territories. A comparison of the proposed reforms with the previous terms demonstrates several important changes made to the E.U.'s understanding of enforcement proceedings under TRIPS.

Under the new settlement terms, the E.U. will have a much higher standard to reach in order to justify the seizure of medications. Prior to this agreement, E.U. officials had seized many drugs on the basis that their sale within E.U. borders

178. Press Release, Gov't of India, *supra* note 75.

179. *Id.* The original regulation gave broad powers to customs officials in suspending the transit of goods, giving them the authority to suspend goods "for the period necessary to determine whether suspect goods are indeed counterfeit goods, pirated goods or goods infringing certain intellectual property rights." Council Regulation (EC) 1383/2003, ¶ 5, 2003 O.J. (L 196) 7.

180. Phil Taylor, *Dispute over EU Drug Seizure Nears Resolution*, SECURING PHARMA (Aug. 2, 2011), <http://www.securingspharma.com/dispute-over-eu-generic-drug-seizures-nears-resolution/s40/a1004/>.

181. *Id.* India had frequently complained that the EU would seize goods with no explanation, as was required under the TRIPS agreement. *India, Brazil raise dispute over EU drug seizures*, *supra* note 44.

would constitute a violation of E.U. laws.¹⁸² India always objected, claiming that such goods were merely in transit through E.U. ports and were intended to be sold in other countries, which would not be a violation of E.U. law.¹⁸³ Under the terms of the settlement, the E.U. has agreed to seize materials only in cases where “there is adequate evidence that satisfies the customs authorities that there is a substantial likelihood of diversion of such medicines on to the E.U. market.”¹⁸⁴ In doing so, the E.U. has increased its standard of seizure, having to provide substantial evidence that shows any shipment of generic medicine is meant to be sold within E.U. territory.¹⁸⁵

This heightened standard will be implemented through the proposed reforms to European Commission regulations.¹⁸⁶ The proposed reforms will provide important answers about the extent of which countries can take action to protect markets. Initially, European Regulation 1383/2003 was interpreted to allow the seizure of any drug that made its way through European territory.¹⁸⁷ As has been discussed before, India and Brazil had held that such interpretations violated the GATT Articles of free trade and transit.¹⁸⁸ The E.U.’s change of standard clarifies an important ambiguity of TRIPS enforcement. Patent protection enforcement must now be solely for the protection of domestic markets. No longer can seizures be made to effectively protect the violation of a domestic patent overseas. Such an interpretation is beneficial because it promotes free transit of goods. In addition, a pharmaceutical producer’s complaint can no longer be the basis for the seizure of medication. Such an interpretation would promote an important principle in international trade; countries should respect the flow of transit over the domestic protection of goods.

Such a solution appears to make sense. As one commentator points out, the previous E.U. interpretation of TRIPS made “goods illegal that were legitimate in their country of origin and destination country.”¹⁸⁹ This same commentator

182. See Taylor, *supra* note 180.

183. *India, Brazil raise dispute over EU drug seizures*, *supra* note 44.

184. Press Release, Gov’t of India, *supra* note 75.

185. See Taylor, *supra* note 180.

186. See Press Release, Gov’t of India, *supra* note 75.

187. See Taylor, *supra* note 180.

188. Request for Consultations by India, *supra* note 59, ¶ 5; Request for Consultations by Brazil, *supra* note 59.

189. Dounis, *supra* note, 167, at 748. Essentially, a good produced in India, bound for Brazil, legal in both countries, could be seized because a different

expressed concerns that previous interpretations of TRIPS would force countries to redirect trading routes in order to avoid countries with strict TRIPS enforcement protocol.¹⁹⁰ Such a process would have been greatly inconvenient and inefficient.¹⁹¹ The proposed reforms, as they stand, will ensure that such efficiency will not be sacrificed in the name of patent protection. Furthermore, it reinforces the independence that the TRIPS exceptions were created to protect.¹⁹² After all, TRIPS, when read together with the Doha Declaration and the General Council Decision, was designed to ensure that countries maintained their autonomy in developing their own patent protection and enforcement procedures.¹⁹³ By ensuring that goods are free to move, provided they are legal in both the host country and destination country, the reforms ensure that countries can set their own patent agendas without the fear of another country's agenda interfering. As a result, the proposed changes likely ensure that future seizures will be more carefully made, as countries will now be expected to immediately provide an explanation for their actions. Previous seizures required less evidence and made countries more apt to seize drugs.¹⁹⁴ Because of this change, countries will be more cautious in enforcement, as they will be expected to immediately turn evidence over. This raises the standard to seize generic medications (or any good produced under the auspice of TRIPS). And these heightened standards ensure that such drug seizures will decrease in frequency.¹⁹⁵

These settlement provisions, as discussed above, would

nation deemed it illegal.

190. *Id.*

191. *See id.*

192. *See Overview, supra* note 1.

193. Such autonomy would allow developing countries to maintain access to needed medications. *Id.*

194. *See Taylor, supra* note 180 (arguing that previous standards for seizure were so low they allowed for frequent search and seizure).

195. One interesting point remaining from the settlement is the lack of resolution between Brazil and the EU. *See EU-India Settle WTO Drug Trade Dispute, supra* note 63. Perhaps the most prominent reason for this is the fact that Brazil has been more aggressive in its use of compulsory licensing under the auspice of the TRIPS agreement. *See Cynthia M. Ho, Unveiling Competing Patent Perspectives*, 46 HOUS. L. REV. 1047, 1060 (2009); *see also Harris, supra* note 57, at 387 (discussing Brazil's use of compulsory licensing). Thus, Brazil may be looking to more strongly assert their rights to generic production. Additionally, Brazil, having pursued this more aggressively, without a free-trade agreement at stake, may be demanding some sort of reparation. This litigation will be interesting to follow, as it may answer more questions about the production of generic medications.

provide much-needed consistency to international patent enforcement regimes and should be adopted worldwide. While the India settlement deals only with E.U. provisions, the WTO should ensure other countries consider their adoption; alternatively, the WTO could consider amending TRIPS through a General Council decision to at least promote their serious consideration.

However, this type of WTO action would be contrary to a premise behind TRIPS, which was designed to allow nations to enact more stringent patent protections if they so chose.¹⁹⁶ Perhaps pressure from this suit will signal to other countries the standards needed to stop and seize drugs. However subsequent WTO panels will need to adopt standards similar to those conceded by the E.U. in its settlement. This will force countries to reevaluate their domestic procedures to meet the standards found in this settlement. This is a slow process and requires further suits to be filed against other offending countries, should seizures occur in the future. Short of outright renegotiation of TRIPS, this is the best way to ensure the settlement standards are applied worldwide.

IV. CONCLUSION

The recent drug seizures by the E.U. have been costly both in terms of money and health, and perhaps have reduced access to some medications. Such seizures have demonstrated the problematic ambiguities of TRIPS. Despite being created to enforce international patent laws while still protecting public health, the uncertainty of TRIPS has led to inconsistent interpretations, and costly domestic seizures of goods in transit. An analysis of the seizures shows that TRIPS is inherently uncertain about what type of medications can be produced and how countries may enforce domestic patent laws.

The recent settlement of the Request for Consultations Regarding Seizure of Generic Drugs in Transit helps to solve one ambiguity of TRIPS and its exceptions while leaving the other open. The settlement does little to answer the question of what medicines can be produced under TRIPS but demonstrates that free transit of goods should be of the utmost importance. Thus, going forward, E.U. seizures will likely cease, but there will still be important questions to answer regarding the scope of TRIPS in the production of generic medication. As discussed above, such questions can be

196. See *Overview*, *supra* note 1.

answered through the creation of a list of drugs that can be generically produced under TRIPS, or alternatively, through a more clear definition of the types of drugs TRIPS was meant to cover. The latter proposal is the best solution, as it allows TRIPS to stay relevant to new medications and can better be enforced through the WTO.

Nevertheless, this controversy helped to resolve one important ambiguity found within TRIPS. By ensuring stricter standards for the stop and seizure of medications, this settlement's emphasis on free transit ensures that countries can no longer seize drugs without credible evidence that their own domestic supply is being affected. If the WTO can adopt such standards in its subsequent decisions interpreting TRIPS, this settlement will have helped to ensure greater protection for the free transit of generic medications. Importantly, free transit will continue to ensure a steady flow of medications for lesser-developed countries in need.