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# ENFORCING INTELLECTUAL PROPERTY RIGHTS VIA EU BORDER REGULATIONS: INHIBITING ACCESS TO MEDICINE OR PREVENTING COUNTERFEIT MEDICINE?

## INTRODUCTION

On May 5, 2009, German customs officials detained a shipment on its way from India to the Republic of Vanuatu<sup>1</sup> containing over three million tablets of the essential medicine<sup>2</sup> amoxicillin,<sup>3</sup> a generic antibiotic.<sup>4</sup> The customs officials, acting under the authority of European Council (“EC”) Regulation No. 1383/2003 (“EC Regulation”), suspended the transit of the generic pharmaceutical on suspicion that it infringed the intellectual property rights<sup>5</sup> (“IPRs”) of the brand-name antibiotic,

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1. Vanuatu is a Least Developed Country (“LDC”) located in the South Pacific. *See Vanuatu*, UN OFFICE OF THE HIGH REPRESENTATIVE OF LEAST DEVELOPED COUNTRIES, LANDLOCKED DEVELOPING COUNTRIES, & SMALL ISLAND DEVELOPING STATES [UN-OHRLLS] (June 2008), <http://www.unohrlls.org/en/orphan/301/>. LDCs are the “poorest and weakest segments of the international community. Extreme poverty, the structural weaknesses of their economies and the lack of capacities related to growth, often compounded by structural handicaps, hamper efforts of these countries to improve the quality of life of their people.” *Least Developed Countries: About LDCs*, UN-OHRLLS, <http://www.unohrlls.org/en/ldc/25/> (last visited Feb. 15, 2011).

2. Essential medicines are defined as “those that satisfy the priority health needs of the population.” *WHO Essential Medicines*, WORLD HEALTH ORG., [http://www.who.int/medicines/services/essmedicines\\_def/en/index.html](http://www.who.int/medicines/services/essmedicines_def/en/index.html) (last visited Jan. 14, 2011); *see also* World Health Org., *WHO Model List of Essential Medicines List* (16th ed. Mar. 2010) [hereinafter *WHO Essential Medicines List*], available at [http://www.who.int/medicines/publications/essentialmedicines/Updated\\_sixteenth\\_adult\\_list\\_en.pdf](http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf).

3. Amoxicillin is an essential medicine used to treat a wide range of bacterial infections. *See WHO Essential Medicines List*, *supra* note 2, § 6.2.1; *see also* World Health Org., *WHO Model List of Essential Medicines for Children*, § 6.2.1 (2d ed. Mar. 2010), available at [http://www.who.int/medicines/publications/essentialmedicines/Updated\\_second\\_children\\_list\\_en.pdf](http://www.who.int/medicines/publications/essentialmedicines/Updated_second_children_list_en.pdf). The amoxicillin shipment was worth approximately 28,000 Euros and contained about 76,000 courses of treatment. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard*, ¶ 126, IP/C/M/60 (June 8–9, 2009) [hereinafter *June Minutes*].

4. *See* Kaitlin Mara, *Drug Seizures in Frankfurt Spark Fears of EU-Wide Pattern*, INTELLECTUAL PROPERTY WATCH (June 5, 2009), <http://www.ip-watch.org/weblog/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern> [hereinafter Mara, *Drug Seizures in Frankfurt*].

5. The May 5, 2009 seizure was based on the suspicion that the generic pharmaceutical infringed on the trademark rights of Amoxil; it did not involve any patent infringement. *Id.*; *see also June Minutes*, *supra* note 3, ¶ 141.

Amoxil, owned by GlaxoSmithKline (“GSK”).<sup>6</sup> The customs officials contacted GSK, as required by the EC Regulation and after GSK confirmed that the amoxicillin consignment did not violate its rights, the customs officials released the shipment to its final destination.<sup>7</sup>

The suspension, or seizure,<sup>8</sup> of the amoxicillin shipment is a recent action<sup>9</sup> taken by a regional customs authority within the European Union (“EU”), in an effort to prevent suspected counterfeit medicines from being sold illegally in the EU market and to protect the IPRs of European pharmaceutical companies.<sup>10</sup> On more than twenty occasions,<sup>11</sup> in the past few years, German and Dutch customs officials have seized generic pharmaceutical products in transit through their ports, alleging the goods violated domestic patent, copyright, and trademark laws, or domestic anti-piracy or counterfeit laws.<sup>12</sup> The majority of the seized goods were manufactured in and shipped from India, destined for developing nations, such as Peru, Colombia, Ecuador, Mexico, Portugal, Spain, Brazil, and Nigeria.<sup>13</sup> The duration of the detainment of the goods varied from a few weeks to over eight months.<sup>14</sup>

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6. See Mara, *Drug Seizures in Frankfurt*, *supra* note 4.

7. *Id.*

8. The word “seizure” is used by Indian and Brazilian representatives and other developing nations, when discussing the suspension or temporary detainment in transit by European Community customs authorities of the generic pharmaceuticals. See *June Minutes*, *supra* note 3, ¶¶ 116, 125, 136.

9. See Kaitlin Mara, *Generic Drug Delay Called “Systemic” Problem at TRIPS Council*, INTELLECTUAL PROPERTY WATCH (June 9, 2009), <http://www.ip-watch.org/weblog/2009/06/09/generic-drug-delay-called-%e2%80%9csystemic%e2%80%9d-problem-at-trips-council/> [hereinafter Mara, *Generic Drug Delay*].

10. *See id.*

11. John Miller & Geeta Anand, *India Prepares EU Trade Complaint*, WALL ST. J., Aug. 6, 2009, at B4.

12. For the year 2008, there were seventeen shipments detained under the authority of the EU Regulation. Of these, sixteen came from India and one came from China. The drugs were destined for Peru, Colombia, Ecuador, Mexico, Portugal, Spain, Brazil, and Nigeria. They contained the following types of goods: cardiologic medicines, lifestyle medicines, AIDS inhibitors, medicines against dementia, and medicines against schizophrenia. See Letter from J. van der Vlist, Mgmt. Team Member for the Tax & Customs Admin. on behalf of the State Sec’y for Fin. of The Hague, to Sophie Bloemen, Health Action Int’l Eur. (May 7, 2009), *available at* [http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20\(EN\).pdf](http://www.haiweb.org/19062009/7%20May%202009%20Dutch%20government%20response%20to%20Freedom%20of%20Information%20request%20(EN).pdf).

13. *See id.*

14. *See* Miller & Anand, *supra* note 11.

In response to the seizures of their shipments of generic pharmaceuticals, India, Brazil, and other developing nations<sup>15</sup> raised the issue at the World Trade Organization (“WTO”) Council on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) meeting on March 3, 2009,<sup>16</sup> and, again, at the June 8, 2009 meeting.<sup>17</sup> They contended the medicines seized were legitimate generic pharmaceuticals, since they were not under patent protection in the exporting and importing countries, and were not targeted for distribution in EU markets.<sup>18</sup> Furthermore, by suspending and detaining the shipments in transit they argued the EU not only prevented the ability of the exporting and importing countries to trade freely,<sup>19</sup> but they also prevented developing countries, even if only temporarily, from access to essential medicines,<sup>20</sup> which undermines the

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15. In addition to Brazil and India, the following nations expressed their concerns regarding the seizures of legitimate generic drugs by EU customs officials: Ecuador, Egypt (speaking on behalf of the African Group), Nigeria, China, Argentina, Cuba, Bolivia, Venezuela, Tanzania (speaking on behalf of the LDC Group), and Indonesia. *See* Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of Meeting Held in the Centre William Rappard*, ¶¶ 160–180, IP/C/M/59 (Mar. 3, 2009) [hereinafter *March Minutes*].

16. *Id.* ¶ 123. The specific seizure referred to at the March 3, 2009 WTO Council for TRIPS meeting regarded the December 4, 2008 seizure of 570 kilos of losartum potassium by Dutch customs officials, which was en route from India to Brazil. Losartum potassium is the “active pharmaceutical ingredient used in the production of medicines for arterial hypertension.” *Id.* ¶ 124. The shipment contained enough medicine to treat 300,000 Brazilian patients for a full month suffering from hypertension. *Id.* ¶ 126.

17. Mara, *Generic Drug Delay*, *supra* note 9. India, Brazil, and developing nations raised the issue about generic drug seizures again at this meeting because of the May 5, 2009 suspension of amoxicillin shipment by German customs officials. *Id.*

18. *March Minutes*, *supra* note 15, ¶¶ 131, 136.

19. India, Brazil, and the developing nations also argued that the suspensions violated Article V of the General Agreement on Tariffs and Trade (“GATT”). *Id.* Article V states, in relevant part: “2. There shall be freedom of transit through the territory of each contracting party . . . 3. Any contracting party may require that traffic in transit through its territory be entered at the proper custom house, but, except in cases of failure to comply with applicable customs laws and regulation, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions . . .” General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194, art. V(3).

20. In addition to the specific events mentioned, one of the most troubling suspensions of generic pharmaceuticals for developing countries took place on November 12, 2008. Dutch authorities seized a shipment of tablets of an anti-retroviral drug for HIV/AIDS treatment, destined for Nigeria. The tablets were suspected of violating the patent rights of GlaxoSmithKline and were deemed counterfeit. The drugs were supposedly paid for by the international governments supporting UNITAID and were to be distributed by the William J. Clinton Foundation. As a result of the suspension, it has been suggested that dozens of HIV patients have been placed at risk. *See* Kaitlin Mara

purpose of the public health dimension of the TRIPS Agreement<sup>21</sup> and goes against the spirit of commitments made at the last round of WTO meetings.<sup>22</sup>

At the WTO Council on TRIPS meetings, the EU reaffirmed its commitment to “ensuring access to affordable medicines in developing countries,” and stated that its actions “against counterfeit and dangerous medicines should not be at the expense of trade in genuine generic medicines” among developing countries.<sup>23</sup> The EU argued that the customs regulation protects developing countries by allowing for the control of counterfeit goods in transit and ensuring that measures are taken against global trade in products, such as fake medicines, that pose a dangerous threat to the public health of developing countries.<sup>24</sup> In addition, it contends the procedures used under the EU regulation are fully in accordance with the TRIPS Agreement,<sup>25</sup> which provides for temporary suspension of goods.<sup>26</sup>

The European Federation of Pharmaceutical Industries and Associations<sup>27</sup> (“EFPIA”) proffered support for the EU’s actions, stating that it

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&William New, *Concerns Continue Over Generic Drug Seizures as Legality Debates Begin*, INTELLECTUAL PROPERTY WATCH (Mar. 5, 2009), <http://www.ip-watch.org/weblog/2009/03/05/concerns-continue-over-generics-drug-seizures-as-legality-debates-begin/>; see also *March Minutes*, *supra* note 15, ¶ 129.

21. “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development . . .” Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 8(1), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]; see also *March Minutes*, *supra* note 15, ¶ 132.

22. The Doha Declaration on the TRIPS Agreement and Public Health provides: “[W]e affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

23. *June Minutes*, *supra* note 3, ¶¶ 137–138.

24. *Id.* ¶ 143. The EU provided a recent example where their efforts, under the EU customs regulation, led to the detainment of a consignment of 600,000 fake and sub-standard anti-malaria pills originating in India and destined for Togo. *Id.* ¶ 144.

25. Section 4 of the TRIPS Agreement is entitled “Special Requirement Related to Border Measures,” and provides requirements under which States are allowed to suspend the release of a shipment of goods, and establishes procedures for the temporary detainment and timely release of the goods. TRIPS Agreement, *supra* note 21, arts. 51–60.

26. *Id.*

27. “EFPIA represents the pharmaceutical industry operating in Europe . . . [It] is the voice on the EU scene of 2,200 companies committed to researching, developing and

“recognizes the right of Member States to stop products that they suspect may be counterfeit from entering the supply chain.”<sup>28</sup> However, the industry association also conveyed it was not the “policy nor practice of [the EFPIA] members to encourage Member States to use the power of detention available to them to prevent the flow of legitimate generic products.”<sup>29</sup> Rather, it reaffirmed its commitment to improving access to medicines in developing countries and ensured that delays or detentions would not be extended for any longer than necessary.<sup>30</sup>

Non-profit organizations, such as Health Action International Europe<sup>31</sup> (“HAI”), however, did not offer support for the EU.<sup>32</sup> Instead, they challenged the intentions of the Member States, as well as the pharmaceutical companies, stating that the “actions of overzealous customs authorities mainly intended to protect the private rights and profits of [IP] rights holders.”<sup>33</sup> Thereby siding with the developing nations, HAI and other non-profit organizations urged the EU and developed nations to modify regulations on border measures to ensure “developing countries are [not] being denied timely access to medicines.”<sup>34</sup>

This debate highlights the competing interests at stake: the right of access to medicine versus the right of preventing trade in counterfeit

bringing patients new medicines that will improve health and the quality of life around the world.” *About EFPIA: Who We Are*, EUR. FED’N OF PHARM. INDUS. & ASS’NS [EFPIA], <http://www.efpia.org/content/default.asp?PageID=319> (last visited Feb. 10, 2011).

28. *EFPIA Statement: Customs Seizures of In-Transit Medicines*, EFPIA (Mar. 13, 2009), <http://www.efpia.eu/content/default.asp?PageID=559&DocID=6574> [hereinafter *EFPIA Statement*].

29. *Id.*

30. EFPIA states that the pharmaceutical companies contribute to the goal of improving access to medicine in developing countries “through the supply of medicines and vaccines, via large-scale donation programs, preferential pricing and voluntary licensing, as well as through extensive participation in not-for-profit partnership activities.” *Id.*

31. “HAI works towards a world in which all people, especially the poor and marginalized, are able to exercise their human right to health. HAI’s contribution is through advocating for increased access to essential medicines and improved rational use of medicines. This is achieved through research excellence and the engagement of civil society in advocacy in the medicines policy debate.” *HAI Global Network*, HEALTH ACTION INT’L, [http://www.haiweb.org/01\\_about\\_a.htm/](http://www.haiweb.org/01_about_a.htm/) (last visited Feb. 18, 2011).

32. “Another seizure of generic medicines destined for a developing country, this time in Frankfurt,” Press Release, Health Action Int’l, *Another Seizure of Generic Medicines Destined for a Developing Country, This Time in Frankfurt* (June 5, 2009), *available at* <http://www.haiweb.org/19062009/5%20Jun%202009%20Press%20release%20Seizure%20of%20generic%20medicines%20in%20Frankfurt.pdf> [hereinafter HAI Press Release].

33. *Id.*

34. *Id.*

medicine. These conflicting interests aid in formulating the arguments for favoring or opposing the enforcement of the EC Regulation to seize suspected illegal goods in transit. On one side, developing nations fear that the EU will extend its power under the EC Regulation to thwart trade in legitimate generic pharmaceuticals, preventing access to medicine for those countries. The EU, on the other hand, does not view its actions as impeding legitimate trade or impacting access to medicine. Rather, it uses the EC Regulation to locate and destroy counterfeit medicine, even if in transit, not only to safeguard its own population's health, but also the populations of the destination country.

To reconcile these opposing interests and views, it must first be determined whether the EC Regulation comports with the existing international agreements and whether it may be applied to goods in transit that are not destined for the EU market. Even at the domestic level, within the EU, the answer to this question is ambiguous. Recently, the High Court of Justice Chancery Division in London stated that the EC Regulation did not apply to goods in transit,<sup>35</sup> while the District Court of The Hague, a year earlier, reached the opposite determination.<sup>36</sup> As a result of this uncertainty, India and other developing nations may initiate a formal complaint with the WTO, in order to have the WTO's dispute settlement body help mediate a resolution.<sup>37</sup>

This Note attempts to contribute to a resolution by assessing the interests of the EU and developing nations, as well as exploring both the international and domestic legal mechanisms regarding the suspension of goods in transit. Part I provides the necessary background by discussing the interests of pharmaceutical companies, developed and developing countries in protecting IPRs, increasing access to medicines, and preventing the distribution of counterfeit medicines. Part II, first, reviews the relevant overarching international agreements, EC laws, and juri-

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35. *Nokia Corp. v. Her Majesty's Comm'rs of Revenue & Customs*, [2009] EWHC (Ch) 1903.

36. See Frank Eijsvogels, *Sisvel v. Sosecal: Acting Against Transit Goods Still Possible Under the Anti-Piracy Regulation in the Netherlands*, LEGAL ISSUES IN INTELL. PROP. (2008), <http://ipintelligence.howrey.com/isisvel-v-sosecali-acting-against-transit-goods-still-possible-under-the-anti-piracy-regulation-in-the-netherlands-12-24-2008/> [hereinafter Eijsvogels, *Sisvel v. Sosecal*] (discussing the Court of The Hague decision in Rechtbank's Gravenhage [Court of The Hague], 18 juli 2008, IER 2008, 83 m.nt. J.G. Kuhlmann (Sosecal Inudstria E Comercio LTDA/ Societa Italiana Lo Sviluppo Dell'Eletronica) [Sosecal /Sisvel] (Neth.)). An unofficial version of the *Sisvel v. Sosecal* decision in English is available as a hyperlink from Geert Thuews, *ECJ to Decide on Manufacturing Fiction*, EPLAW PATENT BLOG (Dec. 20, 2009), <http://www.eplawpatentblog.com/eplaw/sisvel/>.

37. See Miller & Anand, *supra* note 11.

sprudence. It then analyzes whether the EC Regulation violates the TRIPS Agreement. Ultimately, this Note proposes that if the WTO must settle this dispute, it should render the EC Regulation in violation of the TRIPS Agreement only when customs authorities seize goods in transit, which do not have the potential of entering the market of the country of transit. Additionally, the Note recommends that the EU further clarify its regulation to ensure this result, and that the TRIPS Agreement should also be revised accordingly to help reduce any further uncertainties.

## I. BALANCING STATE INTERESTS

### A. *Protecting Intellectual Property Rights*

The overall purpose of intellectual property rights (specifically patents) is to encourage innovation and promote scientific development,<sup>38</sup> by granting inventors the exclusive right to prevent others from making, using, or selling their inventions for a limited period of time.<sup>39</sup> This right gives inventors a temporary monopoly on the inventions that qualify for a patent under a domestic intellectual property regime.<sup>40</sup> That is to say, in a country where a new product is protected by a patent, the consent of the inventor, or patentee, is required before another individual is legally allowed to manufacture, sell, or use the product within the country.<sup>41</sup>

The current international patent system, as outlined in the TRIPS Agreement, has applied this rule globally to all members of the WTO, requiring individuals within member countries to either acquire a license for a product from the patentee before the product can be made or used within a country, or purchase the product at a price determined by the patent holder.<sup>42</sup> For some WTO members, mostly least-developed coun-

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38. See U.S. CONST. art. 1, § 8 (authorizing Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

39. Article 28 of the TRIPS Agreement states in pertinent part: “A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product.” TRIPS Agreement, *supra* note 21, art. 28(1)(a); see also 35 U.S.C. § 271(a) (2007) (“Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent.”).

40. TRIPS Agreement, *supra* note 21, art. 28(1)(a).

41. *Id.*

42. P. Roffe et al., *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES* 9, 10 (Roffe et al. eds., 2006).



tries ("LDCs")<sup>43</sup> and developing countries, this requirement results in a reduced accessibility to essential medications, because those countries are unable to afford the fees associated with the license or purchase of the medications.<sup>44</sup> Pharmaceutical companies and developed nations, however, support a strong patent regime believing it necessary in order to recover research and development ("R&D") expenditures and to sustain the business of discovering and developing new drugs.<sup>45</sup> The TRIPS Agreement was an attempt, by the WTO, to balance the competing interests of developed and third world nations, by establishing a minimum set of standards to protect IPRs while allowing flexibilities for developing nations.<sup>46</sup>

Historically, competing economic interests and conflicts have surrounded the formation and enforcement of patent systems.<sup>47</sup> In Europe, during the nineteenth century, the presence of a major anti-patent sentiment, which opposed the use of patents for monopolies as a barrier to free trade, threatened the existence of the patent system in many European countries.<sup>48</sup> For example, the Prussian government sought to abolish all tariffs related to patent monopolies in order to promote free trade throughout the German territories.<sup>49</sup> Patents, at that time, were seen as preventing international free trade by directly restricting the activities and commercial interests of industrialists and inventors.<sup>50</sup> Advocates of patent systems,<sup>51</sup> however, prevailed because of the need for industrializ-

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43. See *Least Developed Countries: About LDCs*, *supra* note 1.

44. Karin Timmermans, *Ensuring Access to Medicine in 2005 and Beyond*, in *NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES* 41, 41 (Roffe et al. eds., 2006). "For developing countries, the TRIPS standards are usually higher than their previous standards . . . This will delay the marketing of generic versions of new drugs, and thus, the competition they entail. As a result, access to medicine is bound to become further compromised." *Id.*

45. Roffe et al., *supra* note 42, at 12.

46. HOLGER HESTERMEYER, *HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINE* 48 (2007).

47. TSHIMANGA KONGOLO, *UNSETTLED INTERNATIONAL INTELLECTUAL PROPERTY ISSUES* xxi (2008).

48. For example, in Switzerland, "the legislature in December 1863 renewed its opposition to the patent system with a reference to the fact that 'political economists of greatest competence' had declared that the principle of patent protection was 'pernicious and indefensible.'" Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 5 (1950).

49. *Id.* at 4.

50. *Id.*

51. Proponents of the patent system came from unlikely individuals, such as Adam Smith, who normally promoted free trade and "condemned 'exclusive privileges' as 'greatly prejudicial to society.'" ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY,

ing nations to encourage growth and stimulate their economies<sup>52</sup> in response to the decline in momentum of the free-trade movement during the late nineteenth century.<sup>53</sup> Protection of IPRs, therefore, was probably viewed as important to the development of an industrialized global economy.

At the same time, in 1883, the first multi-national intellectual property treaty, the Paris Convention for the Protection of Industrial Property (“Paris Convention”), was concluded.<sup>54</sup> The treaty created substantive intellectual property protections for inventors outside of their native countries.<sup>55</sup> It also provided flexibility for Member States in choosing the criteria for patentability, including the determination of which fields of industry should be subject to patent protection.<sup>56</sup> A “general trend” in most developed and developing countries at the time “was to extend protection to processes and not products,” excluding medical drug products.<sup>57</sup> To appease anti-patent supporters, the Paris Convention provided compulsory licenses,<sup>58</sup> allowing a government to grant a third party the right to use the patent without the consent of the true patent holder, in

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PATENT LAW AND POLICY: CASES AND MATERIALS 8 (4th ed. 2007); *see also* Machlup & Penrose, *supra* note 48, at 7. However, regarding awarding patents, Adam Smith “argued that a temporary monopoly granted to an inventor of a new machine could be justified as a means of rewarding risk and expense.” *Id.*

52. MERGES & DUFFY, *supra* note 51, at 6 (“Although the overall contribution of the patent system to the Industrial Revolution has been a matter of debate . . . , it seems no coincidence that the patent system matured alongside the early industrial technologies.”).

53. *See* WILLIAM CUNNINGHAM, THE RISE AND DECLINE OF THE FREE TRADE MOVEMENT 1, 164 (2d. ed. 1905).

54. *See* Roffe et al., *supra* note 42, at 9.

55. *See* MERGES & DUFFY, *supra* note 51, at 55. Article 2 of the Paris Convention provides: “Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.” Paris Convention for the Protection of Industrial Property art.2, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

56. *See* Roffe et al., *supra* note 42, at 9.

57. *Id.* at 11.

58. *See* Paris Convention, *supra* note 55, art. 5. “A compulsory license is an authorization given by the government for the use by a third party, without the consent of the right-owner of a patent or other intellectual property right.” Carlos M. Correa, *Pro-Competitive Measures Under TRIPS to Promote Technology Diffusion in Developing Countries*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 40, 48 (Drahos & Mayne eds., 2002).

order to prevent abuses that could result from the exercise of the exclusive rights of a patent holder.<sup>59</sup>

As a result of the increased interdependence on global trade in the twentieth century,<sup>60</sup> a need developed to create a stronger international intellectual property regime “to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.”<sup>61</sup> The TRIPS Agreement, signed in 1994, made drastic changes to the intellectual property systems of developing countries, but not to the systems of developed nations, like the United States.<sup>62</sup> The TRIPS Agreement established that patents “shall be available for any invention, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.”<sup>63</sup> Therefore, unlike the Paris Convention, the TRIPS Agreement extends patent protection to products, including pharmaceutical medicines.<sup>64</sup>

In addition to proscribing the scope of IPRs in the international realm, the TRIPS Agreement provides important flexibilities for developing nations in order to “to address some aspects of the controversies about the impact of IP rights on innovation and creativity, abuse of dominant power and restrictive business practices.”<sup>65</sup> The flexibilities included the freedom to define the scope of the patentability criteria, such as novelty

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59. See KONGOLO, *supra* note 47, at 6.

60. In the late twentieth century, “the international business community began to tackle the more ambitious project of harmonization, i.e., creating uniform substantive standards of intellectual property protection.” MERGES & DUFFY, *supra* note 51, at 57. “Moreover, world trade was becoming increasingly important to the economies of [the] United States and other industrialized nations. Markets in developing countries were no longer insignificant . . .” *Id.*

61. TRIPS Agreement, *supra* note 21, pmb1.

62. Under the TRIPS Agreement, all members of the WTO are obligated to include almost all important commercial fields within the scope of patentable subject matter—a major change for countries that had refused to enforce pharmaceutical patents on public health or access grounds; test patent applications for the presence of an “inventive step,” which is defined as synonymous with the US requirements of non-obviousness; include in the patentee’s rights the exclusive right to import the invention; and curtail the practice of granting compulsory licenses by requiring certain formal procedures. See TRIPS Agreement, *supra* note 21, arts. 21, 27.

63. *Id.* art. 27(1).

64. *Id.*

65. Ermias Tekeste Biadgleng, *The Development-Balance of the TRIPS Agreement and Enforcement of Intellectual Property Rights*, in INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR? 97, 109 (Malbon & Lawson eds., 2008).

or inventive step,<sup>66</sup> the possibility of establishing exceptions to exclusive rights,<sup>67</sup> and compulsory licensing.<sup>68</sup> The TRIPS flexibilities were meant to provide an advantage for developing nations so “that their level of development can benefit from the utilization of the flexibilities.”<sup>69</sup>

The conclusion of the TRIPS Agreement intended not only to establish a minimum set of standards of IPRs for the international community, but it also attempted to create a balanced system by which developed and developing countries could eventually improve their domestic technology base and economies.<sup>70</sup> For developed countries, TRIPS provides security for the global integrity of their domestic products by establishing procedures that ensure other countries will respect the IP protections surrounding those products and prevent unfair competition.<sup>71</sup> In theory, the flexibilities built into TRIPS allow developing countries to establish their own system for IPR protection as well as ensure access to products that benefit public health.<sup>72</sup> In practice, however, the flexibilities contained within the TRIPS Agreement are difficult to implement in developing nations.<sup>73</sup>

While developing nations can attempt to protect certain interests, such as public health, by excluding particular inventions from patentability, these actions are easily frustrated by other countries that do protect the offending invention.<sup>74</sup> As such, the flexibilities under the TRIPS Agreement are seriously affected by the nature of the IP laws in and the interests of the most industrious or innovative countries.<sup>75</sup> For example, developing nations may only utilize compulsory licenses in a national emergency, for a public non-commercial use, or as a remedy to anti-

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66. TRIPS Agreement, *supra* note 21, art. 27(1).

67. *Id.* arts. 27(2), 27(3), 30.

68. *Id.* art. 31.

69. Biadgleng, *supra* note 65, at 109.

70. See *Introduction*, in INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR? 1, 4 (Malbon & Lawson eds., 2008).

71. See TRIPS Agreement, *supra* note 21, art. 3 (“Each Member shall accord to the nationals of other Members treatment no less [favorable] than that it accords to its own nationals with regard to the protection of intellectual property . . .”).

72. The TRIPS agreement includes some provisions that attempt to “strike a balance between the implementation of TRIPS and the level of development” in developing countries. Biadgleng, *supra* note 65, at 108. First, TRIPS provides a transition period for the implementation of the agreement. *Id.* It also “targets the need for flexibility to create viable technologies” by “prompting and encouraging technology transfer” for LDCs. *Id.*

73. See *id.* at 110.

74. *Id.*

75. See Biadgleng, *supra* note 65, at 110. The purpose of the flexibilities “can be frustrated easily if another country decides to protect the offending invention.” *Id.*

competitive practices or a dependency on patents.<sup>76</sup> However, developing nations that lack the manufacturing capacity to produce the necessary products under these licenses are not able to benefit from this flexibility, frustrating its overall purpose.<sup>77</sup> Ultimately, these nations are forced “to acquire from the international market at higher prices the same . . . products they have excluded from patentability.”<sup>78</sup> The flexibility of compulsory licensing faces further problems regarding implementation in that generic manufacturers do not have effective incentives to “engage in production of pharmaceuticals for export to developing countries.”<sup>79</sup> Thus, the difficulties of implementing TRIPS flexibilities reveal the extent to which developing countries remain dependent on the cooperation of technologically developed countries.<sup>80</sup>

In the recent case of the temporarily seized shipment of amoxicillin, described at the beginning of this Note, developing countries argue that developed countries are not cooperative, but rather inhibiting legal exchanges of goods.<sup>81</sup> In this case, the shipment of amoxicillin did not violate any IPRs within the EU. Furthermore, under the TRIPS flexibilities, amoxicillin was not a protected product under the domestic IP systems of India or the Republic of Vanuatu; therefore, the countries were free to export and import this product.<sup>82</sup> While the goods were eventually released by the German customs officials, that action, as well as other like seizures, and the difficulties of implementing TRIPS flexibilities, nonetheless raises a genuine concern that technologically developed countries will attempt to enforce more restrictive, unyielding IPRs.<sup>83</sup>

Another recent cause for concern for developing countries is the use of free trade agreements by developed nations to negotiate and secure

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76. CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 314–15 (2007); see TRIPS Agreement, *supra* note 21, art. 31(b) (“[I]n the case of national emergency or other circumstances of extreme urgency or in cases of extreme urgency or in cases of public non-commercial use” a Member can waive the requirement of obtaining “authorization from the right holder.”).

77. Biadgleng, *supra* note 65, at 110.

78. *Id.*

79. *Id.*

80. *Id.*

81. *June Minutes*, *supra* note 3, ¶¶ 118–121.

82. Martin Khor, *Row Over European Seizures of Low Cost Drugs*, THIRD WORLD NETWORK (Aug. 10, 2009), <http://www.twinside.org.sg/title2/gtrends/gtrends262.htm>; see also HAI Press Release, *supra* note 32 (“There is no valid reason for detaining these medicines especially since the name ‘Amoxicillin’ is an international non-proprietary name.”).

83. See Mara, *Generic Drug Delay*, *supra* note 9.

stronger IP protections than established under the TRIPS Agreement.<sup>84</sup> These additional efforts by developed countries to protect their rights in intellectual property, in conjunction with the dependence of developing countries on others' technologies and products, are underlying reasons why developing countries must advocate for their right of access to medicine.

### *B. Ensuring Access to Medicine*

"The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being."<sup>85</sup> It is argued that the right to health, which is a right enshrined in many international treaties and documents,<sup>86</sup> includes a right of access to essential medicines.<sup>87</sup> Even though the health of all populations is an important international goal, the "availability of affordable essential medicines is still far from adequate."<sup>88</sup> Currently, governments in developing nations are only able to meet one third of their population's medical needs via government sponsored initiatives.<sup>89</sup> In addition, prices of medicines vary widely and

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84. See Graham Dutfield, *Knowledge Diplomacy and the New Intellectual Property Fundamentalism*, in INTERPRETING AND IMPLEMENTING THE TRIPS AGREEMENT: IS IT FAIR? 31, 31 (Malbon & Lawson eds., 2008). One of the most effective strategies being employed is that of so-called free-trade agreements containing highly constraining and protectionist 'TRIPS Plus' IP provisions that seem to be aimed to serve the interests of the developed world corporations. *Id.* "The FTA negotiations and FTAs themselves seem to be neither wholly free, since the IP Provisions in them are inherently protectionist, nor fair to the weaker negotiating parties. . . . They are popular with the United States government and the European Commission . . . because [they] . . . are the major producers and exporters of patent, copyright and trademark-protected goods and services, and therefore have much to gain from them. *Id.*

85. Constitution of the World Health Organization pmbl., July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185 [hereinafter WHO Constitution].

86. The right to health has been asserted not only in the WHO Constitution, but also in the International Covenant on Economic, Social and Cultural Rights, and in the Universal Declaration of Human Rights. See International Covenant on Economic, Social and Cultural Rights art. 12(1), Dec. 16, 1966, 993 U.N.T.S. 3; Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/Res/217(III), art. 25(1) (Dec. 10, 1948).

87. *Access to Medicines—A Fundamental Element of the Right to Health*, U.N. HUMAN RIGHTS OFFICE OF THE HIGH COMM'R FOR HUMAN RIGHTS, <http://www.ohchr.org/EN/Issues/Development/Pages/AccessToMedicines.aspx> (last visited Feb. 22, 2011); see also G.A. Res. 12/24, ¶ 1, U.N. Doc. A/HRC/RES/12/24 (Oct. 12, 2009).

88. Press Release, MDG Gap Task Force, UN Report: Significant Progress in Debt Relief for Poorest Countries but Trade and Aid Still Major Barriers to Achieving Anti-Poverty Goals, U.N. Press Release DPI/2517 C (Sept. 2008).

89. *Id.*

are higher than the suggested international reference prices, making it difficult for individuals in poorer nations to obtain essential medications.<sup>90</sup>

The HIV/AIDS epidemic, in particular, brought to light the need for the international community to reassess the existing legal framework and priorities regarding access to essential medicines for developing nations.<sup>91</sup> When the compound *azidothymidine* (“AZT”) and subsequent method of treating HIV were discovered, the pharmaceutical company responsible for the discovery sought and received a patent.<sup>92</sup> As a result, the company was able to “set the price for a drug that promised to be the only available life-saving therapy” for affected individuals.<sup>93</sup> The price was set so high that HIV activists and developing nations used this decision to illustrate that “pharmaceutical patents result in higher prices thus reducing the accessibility of drugs.”<sup>94</sup> Activists, non-governmental organizations, and even Congress challenged the pharmaceutical company and lobbied for a price reduction.<sup>95</sup> For the remainder of the patent’s life, which eventually expired in 2005, litigation continued over its validity.<sup>96</sup>

HIV/AIDS is only one of many ailments that dramatically affect the health of the populations of developing nations.<sup>97</sup> Chronic diseases, cardiovascular diseases, diabetes, and asthma are other ailments that afflict poorer populations, who not only have limited access to medicines due to cost, but also have inadequate health care systems to provide treatment and deliver medication.<sup>98</sup> With the enactment of the TRIPS Agreement and the resulting “imposition of . . . minimum standards for patent protection,” public health advocates raised concerns that the TRIPS requirements were not flexible enough to allow developing countries to access affordable medicines and technologies to meet their population’s

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90. *Id.* In order to purchase the “lowest-priced generic combination treatment regimen” for diabetes, in Ghana, a person would have to spend eight day’s worth of wages. MDG Gap Task Force, *MDG Task Force Report 2009: Strengthening Global Partnership for Development in a Time of Crisis*, 53, U.N. Sales No. E.09.I.8 (2009) [hereinafter *MDG Report*], available at [http://www.un.org/millenniumgoals/pdf/MDG\\_Gap\\_%20Task\\_Force\\_%20Report\\_2009.pdf](http://www.un.org/millenniumgoals/pdf/MDG_Gap_%20Task_Force_%20Report_2009.pdf).

91. See HESTERMEYER, *supra* note 46, at 1–15; see also Daniel J. Gervais, *Intellectual Property and Human Rights: Learning to Live Together*, in *INTELLECTUAL PROPERTY AND HUMAN RIGHTS* 3, 20 (Torremans ed., 2008).

92. HESTERMEYER, *supra* note 46, at 4.

93. *Id.* at 5.

94. *Id.*

95. *Id.*

96. *Id.* at 6.

97. See *MDG Report*, *supra* note 90, at 53–55.

98. *Id.*

health needs.<sup>99</sup> The flexibilities, in particular compulsory licensing, did not provide enough aid to developing nations that did not have the manufacturing capability to produce the medicines needed.<sup>100</sup> In addition, developed nations along with pharmaceutical companies were not particularly willing to implement these “flexibilities.”<sup>101</sup> As a result, the global community decided to discuss and try to resolve the public health concerns raised by the TRIPS Agreement.<sup>102</sup>

On November 14, 2001, the World Trade Organization adopted the Declaration on the TRIPS Agreement and Public Health, also known as the “Doha Declaration.”<sup>103</sup> The declaration attempts to have all parties “recognize the gravity of the public health problems afflicting many developing and least-developed countries,”<sup>104</sup> and commit to implement the TRIPS Agreement in light of protecting public health and the promotion of access to medicines.<sup>105</sup> In addition, it acknowledges that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could not make effective use of compulsory licenses, and that an “expeditious solution” was needed.<sup>106</sup> The solution was slated to be completed by 2002; however, as a result of differences between the U.S. and the other WTO Member States, a solution was not finished until 2003, and the TRIPS Agreement was not amended until 2005.<sup>107</sup>

The solution includes a waiver of the limitation on exports imposed by the TRIPS Agreement, which “waives the obligation to grant a compulsory license . . . insofar as necessary for the production of a pharmaceutical product” as long as it is exported to an eligible importing Member State.<sup>108</sup> To obtain this waiver, an LDC or developing nation must dem-

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99. HESTERMEYER, *supra* note 46, at 76; *see also* Kumariah Balasubramaniam, *Access to Medicines: Patents, Prices and Public Policy—Consumer Perspectives*, in GLOBAL INTELLECTUAL PROPERTY RIGHTS: KNOWLEDGE, ACCESS AND DEVELOPMENT 90, 90 (2002).

100. Roffe et al., *supra* note 42, at 18.

101. *Id.* at 16–17. In 1997, South Africa introduced an Act that “permitt[ed] parallel imports and compulsory licensing of pharmaceuticals. The US Government denounced the measures as an infringement of patent rights and the . . . [USTR] designated South Africa as a Special 301 ‘watch list’ country—a status that could lead to trade sanctions.” *Id.* Furthermore, even after the U.S. and South Africa resolved their dispute, thirty-nine international companies filed a suit against the South African department of health and Nelson Mandela. *Id.*

102. *Id.*

103. *See* Doha Declaration, *supra* note 22.

104. *Id.* ¶ 1.

105. *See id.* ¶ 4.

106. *Id.* ¶ 6.

107. HESTERMEYER, *supra* note 46, at 263–64.

108. *Id.* at 266.



onstrate to the Council for TRIPS that it does not have the capability to manufacture medicines.<sup>109</sup> Once approved, patented pharmaceuticals may be imported into the country's domestic market without a compulsory license.<sup>110</sup> The nation exporting the goods, however, must obtain a compulsory license, in order to manufacture and sell the product to the authorized importing Member State.<sup>111</sup>

The waiver received mixed reviews as a solution for increasing access to medicines.<sup>112</sup> Some viewed the compromise, between developed and developing nations, as a success, proclaiming that the waiver "proves once and for all that the [WTO] can handle humanitarian as well as trade concerns."<sup>113</sup> Others, however, cautioned that the new framework needs to be used effectively and support must be given to developing nations to use the mechanisms available to fulfill their health needs.<sup>114</sup> Furthermore, many activists contend that the solution is not sufficient because private parties can still block the export and import of pharmaceutical goods under their national laws.<sup>115</sup>

These concerns are reflective of developing nations' reservations regarding the recent seizures of pharmaceutical goods in transit. The developing nations argue that the seizures go against the object and purpose of the Doha Declaration,<sup>116</sup> which is to implement the TRIPS Agreement to promote public health, not to impede it.<sup>117</sup> The EU, however, states that it is committed to promoting public health, and that the seizures were not done to prevent access to medicine but to ensure protection from counterfeit medicines in its domestic market as well as globally.<sup>118</sup>

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109. *Id.* at 267.

110. *Id.*

111. *Id.*

112. See Roffe et al., *supra* note 42, at 22–24. Some view the decision regarding the waiver as "an appropriate and balanced solution, responding to the concerns of both developing and developed nations." *Id.* Other groups, however, have criticized the decision because of the procedural requirements, and the doubts they have regarding its economic viability and sustainability. *Id.* at 23.

113. *Id.* at 22–23. The proclamation was made by the WTO Director General. *Id.* at 22.

114. *Id.* at 23. Then Secretary General of the United Nations, Kofi Annan, stated that "we must now ensure that developing countries are given the support they need to make use of the mechanisms that have been agreed, so that drugs reach the millions who are suffering and dying. This is a moral imperative." *Id.*

115. *Id.*

116. *June Minutes, supra* note 3, ¶¶ 131, 134.

117. See Doha Declaration, *supra* note 22, ¶ 4.

118. See *June Minutes, supra* note 3, ¶¶ 143–145.

### C. Fighting Counterfeit Medicines

A counterfeit medicine is one which is deliberately and fraudulently mislabeled [sic] with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of) active ingredient(s) or with fake packaging.<sup>119</sup>

Counterfeit medicines pose a significant public health risk because the content of the drugs may lack necessary ingredients,<sup>120</sup> or may contain insufficient quantities, or toxic substances.<sup>121</sup> As a result, these products have the potential to be fatal, lead to drug-resistant pathogens, and place a significant economic burden on developing nations.<sup>122</sup> Further, the risk of receiving undetected counterfeit medicines is greatest in those regions that lack efficient regulatory and enforcement systems.<sup>123</sup>

In an effort to combat trade in counterfeit medicines, international organizations have formed task forces, and countries have passed legislation and negotiated multi-national treaties. In 2006, the World Health Organization (“WHO”) launched the International Medical Products Anti-Counterfeiting Taskforce (“IMPACT”), whose goal is to coordinate “across and between countries, in order to halt production, trading and selling of fake medicines . . . .”<sup>124</sup> A recent example of IMPACT’s efforts took place on May 29, 2009, when IMPACT, Egyptian police, customs, and private sector investigators worked together to seize “[ten] containers each holding hundreds of thousands of counterfeit medicines”

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119. *What Are Counterfeiting Medicines?*, WORLD HEALTH ORG., <http://www.who.int/medicines/services/counterfeit/faqs/03/en/index.html> (last visited Feb. 10, 2011).

120. See *WHO Fact Sheet: Counterfeit Medicines*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs275/en/index.html> (last visited Feb. 18, 2011) [hereinafter *WHO Fact Sheet*] for an example from 2007, in which the product Xenical, an anti-obesity drug, sold via the Internet and imported into the United States, contained no active ingredient.

121. The WHO Fact Sheet for Counterfeit medicines lists a recent example of the impact of a counterfeit medicine containing a toxic amount of an ingredient. See *id.* In 2009, a counterfeit anti-diabetic traditional medicine, in China, was found to contain six times the normal does of the compound glibenclamide (which is used to lower blood sugar). *Id.* As a result, two people died and nine people were hospitalized. *Id.*

122. *Id.*

123. “Trade in counterfeit medicines is widespread and affects both developed and developing countries but is more prevalent in countries facing a variety of problems such as: weak drug regulatory control and enforcement . . . .” *IMPACT Activities*, WORLD HEALTH ORG., <http://www.who.int/impact/activities/en/> (last visited Feb. 10, 2011).

124. *About Us*, WORLD HEALTH ORG. INT’L MED. PROD. ANTI-COUNTERFEITING TASK FORCE (IMPACT), <http://www.who.int/impact/about/en/> (last visited Feb. 18, 2011).

destined for the Middle East.<sup>125</sup> The counterfeit medicine included lifestyle products, and medications for organ-transplant patients, as well as patients with cancer, diabetes, heart disease, epilepsy and schizophrenia.<sup>126</sup> Critics of IMPACT, however, are concerned that the underlying public health purpose will be “counterproductive and will create barriers to trade in and access to legitimate medicines.”<sup>127</sup> They fear that IMPACT may misuse its enforcement power to further the developed nations’ intellectual property agenda.<sup>128</sup>

Another international effort underway to fight counterfeit products is the Anti-Counterfeiting Trade Agreement (“ACTA”), for which negotiations among several nations<sup>129</sup> are still ongoing. The goal of the agreement is to “establish international standards for enforcing [IPRs] in order to fight more efficiently the growing problem of counterfeiting and piracy.”<sup>130</sup> The agreement outlines a legal framework for the enforcement of IPRs, including a section pertaining to “Border Measures,” which authorizes customs officials to suspend the “entry of goods suspected to in-

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125. “Arrests and major seizure of counterfeit medicines across Egypt follow international cooperation with INTERPOL and IMPACT stake-holders.” *Arrests and Major Seizures of Counterfeit Medicines Across Egypt Follow International Co-Operation with INTERPOL and IMPACT Stake-Holders*, INT’L CRIMINAL POLICE ORG. (May 29, 2009), <http://www.interpol.int/Public/news/2009/CounterfeitMedecine20090529.asp>.

126. *Id.*

127. WHO Drops Counterfeit Drug Resolution Targeting Generic Products, ACTION FOR GLOBAL HEALTH (Feb. 2, 2009), [http://old.actionforglobalhealth.eu/news/who\\_drops\\_counterfeit\\_drug\\_resolution\\_targeting\\_generic\\_producers](http://old.actionforglobalhealth.eu/news/who_drops_counterfeit_drug_resolution_targeting_generic_producers). IMPACT had proposed a draft counterfeit resolution that revised the definition of “counterfeit,” and opponents argued that the new definition would allow IMPACT and other organizations to seize goods suspected of trademark infringement as counterfeit. *Id.* The new definition would have expanded the definition of counterfeit to include trademark violations as well. *Id.* Thus, IMPACT would be used as a venue of enforcing certain IP rights, rather than inhibiting counterfeits. In the end, however, as a result of the critic’s concerns, the WHO did not pursue adopting the resolution. *Id.*

128. *Id.* Critics argue that the measures taken by IMPACT would result in entities refusing to conduct business with generic manufacturers, ultimately impacting access to medicine and the growing generic pharmaceutical industries negatively. *Id.*

129. The States involved in negotiations are the United States, Australia, Canada, the European Union (including its twenty-seven member states), Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, and Switzerland. *Anti-Counterfeiting Trade Agreement (ACTA)*, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/acta> (last visited Feb. 18, 2011).

130. ACTA—Summary of Key Elements Under Discussion, OFFICE OF THE U.S. TRADE REPRESENTATIVE, <http://www.ustr.gov/about-us/press-office/factsheets/2009/november/acta-summary-key-elements-under-discussion> (last visited Feb. 22, 2011).

fringe on [IPRs] at the border.”<sup>131</sup> The scope of this section has not yet been determined, but it may apply to both goods being imported or exported from states and to goods in transit.<sup>132</sup>

On a more domestic scale, the EU implemented and executed a program called MEDI-FAKE, “which targeted customs control on illegal medicines entering the EU.”<sup>133</sup> Customs officials seized more than 34 million illegal medicines, including fake antibiotics, anti-cancer, and anti-malaria pills, in a period of two months.<sup>134</sup>

International organizations and national governments have invested their time in developing programs and negotiating treaties because counterfeit medicines have a significant impact on a population’s health.<sup>135</sup> According to the WHO, “the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries, to over 10 percent in developing countries. . . .”<sup>136</sup> The complex trade routes of fake medicines, moving through several territories before reaching their final destination, increase the need for the EU and other nations, at both a local and global scale, to take on measures to prevent these products from illegally re-entering their territories.<sup>137</sup>

The outcomes of measures like IMPACT and MEDI-FAKE, in seizing large quantities of counterfeit medicines, may bolster, or even fully justify, the developed nations’ argument for the need to control medicines in transit. Despite the opposing arguments that these measures go beyond the standards allowed by TRIPS or the Doha Declaration, the WTO, in light of the severity and prevalence of counterfeit medicines throughout the world’s trade routes, may decide that the action of customs officials in seizing goods, either *ex officio* or by request of a rights holder, is permissible within the existing international legal framework.

## II. ENFORCING STATE INTERESTS

In response to the seizures of generic medicines and in order to protect their state interests in ensuring fair trade, developing nations, specifically

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131. *Id.*

132. *Id.*

133. Press Release, Eur. Comm’n, Customs: Millions of Illegal Medicines Stopped by MEDI-FAKE Action, (Dec. 16, 2008) (Press Release No. IP/08/1980).

134. *Id.*

135. See *WHO Fact Sheet*, *supra* note 120.

136. *Counterfeit Medicines: An Update on Estimates*, WORLD HEALTH ORG. INT’L MED. PROD. ANTI-COUNTERFEITING TASK FORCE (IMPACT) (Nov. 15, 2006), <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>.

137. *June Minutes*, *supra* note 3, ¶ 144.

India, may decide to file a trade complaint with the WTO against the EU,<sup>138</sup> invoking the WTO's dispute settlement process.<sup>139</sup> The complaint will probably allege that "the European Union allowed big pharmaceutical companies to use the bloc's tough patent laws to have national customs agencies [via the EC Regulation] detain generic drugs in transit to developing countries."<sup>140</sup> Most likely, India will focus on the potential violation of the TRIPS Agreement and the Doha Declaration by the developed nations in restricting free trade and access to medicines.<sup>141</sup> To bolster the strength of its complaint, India may look to recent decisions by the European Court of Justice ("ECJ") and EU national courts,<sup>142</sup> which addressed the application of the EC Regulation on goods in transit. The EU and developed nations, on the other hand, will try to support their actions with their legitimate state interests in protecting IPRs as well as preventing the distribution of counterfeit medicine. The remainder of this section reviews the importance of the TRIPS Agreement and Doha Declaration and will examine the scope of the EC Regulation regarding the seizure of goods in transit.

#### *A. Relevance of the TRIPS Agreement & Doha Declaration*

By their very nature, intellectual property rights are restrictive on trade.<sup>143</sup> Therefore, while an objective of the TRIPS Agreement is to "ensure that measures and procedures to enforce intellectual property

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138. See Miller & Anand, *supra* note 11.

139. *Understanding the WTO: Settling Disputes*, WORLD TRADE ORG., [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/disp1\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm) (last visited Feb. 18, 2011). The WTO's procedure for resolving trade disputes is essential for enforcing rules and ensuring the free flow of trade between countries. *Id.* A dispute typically arises "when one country adopts a trade policy measure or takes some action that one or more fellow-WTO members considers to breaking the WTO agreement." *Id.* The first stage of the dispute settlement is consultation, which requires the disputing countries to try to come to an agreement between themselves. The second stage involves the appointment of a panel, which will help to make rulings or recommendations to help solve the dispute. *Id.*

140. See Miller & Anand, *supra* note 11.

141. As previously mentioned, India and developing nations took issue with the seizures of generic medicine because they felt that the seizures compromised the spirit of the Doha Declaration, which was developed to promote access to medicine, as well as the TRIPS Agreement, which allows developing nations to establish their own IP laws. See *March Minutes*, *supra* note 15, ¶¶ 160–180.

142. See Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36; see also *Nokia Corp. v. Her Majesty's Comm'rs of Revenue & Customs*, [2009] EWHC (Ch) 1903.

143. IPRs are intended to grant the inventor a monopoly over his invention, therefore preventing others from manufacturing and selling that invention without the inventor's consent, thus reducing trade. See TRIPS Agreement, *supra* note 21, art. 28(1)(a).

rights do not themselves become barriers to legitimate trade,”<sup>144</sup> in practice, this assurance is difficult to achieve. The tension between free trade and IPRs is also recognized in Article 8 of TRIPS, which recommends that Members States “adopt measures necessary to protect public health and nutrition,”<sup>145</sup> and to “prevent practices which unreasonably restrain trade or adversely affect the international transfer of technology,”<sup>146</sup> while deciding on an intellectual property regime for their nation. The acknowledgment of the importance of maintaining free trade, especially in light of public health concerns, may support the more liberal interpretation of the TRIPS Agreement advocated by developing nations. However, the overarching goal of the international agreement is to protect intellectual property rights and enforce those legitimate interests globally.<sup>147</sup>

The TRIPS Agreement attempts, in its provisions regarding both enforcement measures<sup>148</sup> and border control measures,<sup>149</sup> to include notions of free trade in order to mitigate the potential restrictions on trade inherent in enforcing IPRs internationally.<sup>150</sup> For example, in its section on enforcement of IPRs, Article 41 requires that any enforcement measures adopted by Member States “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”<sup>151</sup> This part of the agreement establishes the general obligations of Member States in enforcing IPRs.<sup>152</sup> This mandatory language further demonstrates the significance placed on protecting against abuse by right-holders and the importance of protecting trade while enforcing IPRs. This provision helps developing countries speak out against the excessive actions of the EU, in light of the principles of fair trade embodied throughout the agreement. Also, since the agreement focuses on “legitimate trade,” India and other developing nations can further argue that the EC Regulation was overly restrictive regarding the seizure of goods in transit because the goods were “legitimate” in both the importing and exporting nations.

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144. *Id.* pmbl.

145. *Id.* art. 8(1).

146. *Id.* art. 8(2).

147. The Preamble to the TRIPS Agreement states that the agreement “takes into account the need to promote effective and adequate protection of intellectual property rights.” *Id.* pmbl.

148. *Id.* art. 41.

149. *Id.* arts. 51–52.

150. *See id.* art. 41.

151. *Id.*

152. Article 41 is included in Part III: Enforcement of Intellectual Property Rights; Section 1: General Obligations. *Id.*

The TRIPS Agreement, within its section on enforcement, also outlines specific requirements on border measures that both protect IPRs and guarantee freedom of trade. Article 51 establishes the obligation to allow an application to be lodged for suspension of the release into free circulation of infringing goods by “a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place.”<sup>153</sup> This provision establishes minimally that customs authorities may seize goods, if directed by a right-holder, which are being imported into the country.<sup>154</sup> Further, a footnote to the provision provides that a State is not under an obligation to apply these procedures to goods in transit.<sup>155</sup> Consequently, it is unclear whether a violation of the TRIPS Agreement results when a Member State stops allegedly infringing goods in transit. In addition, the provision seems to be limited only to copyright and trademark goods. A reason for this limitation may be that it is easier for customs authorities to discern “visibly infringing” goods than to determine whether a good violates a particular patent claim.<sup>156</sup> As a result, since TRIPS only establishes minimum requirements, border measures are optional when applied to other intellectual property rights, such as patents.<sup>157</sup> Therefore, the EC Regulation, since it allows for border measures to apply to patents as well,<sup>158</sup> has expanded upon the minimal requirements of TRIPS.<sup>159</sup>

Under Article 52, customs authorities will seize goods if (1) there is a “prima facie infringement of an intellectual property right ‘under the laws of the country of importation,’” and (2) the right-holder provided a sufficient “detailed description of the goods” to enable authorities to identify the goods in question.<sup>160</sup> An argument against the European seizures and the EC Regulation can be found within this provision, since the

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153. *Id.* art. 51.

154. *Id.*

155. *Id.* art. 51 n.13.

156. DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 220–21 (1998).

157. *Id.* at 221. “WTO Members may apply border measures to any intellectual property right [] and also to goods destined for exportation.” *Id.*

158. Council Regulation 1383/2003, Concerning Customs Action Against Goods Suspected of Infringing Certain Intellectual Property Rights and the Measures to be Taken Against Goods that have Infringed Such Rights, art. 2(1)(c)(i), 2003 O.J. (L 196) 7 [hereinafter EC Regulation]; *see also infra* Section II B.

159. Article 1 of TRIPS allows Member States to “implement in their law more extensive protection than is required by this Agreement.” TRIPS Agreement, *supra* note 21, art. 1. Thus, in including patent infringement in the EC Regulation, the EC did not violate the TRIPS Agreement.

160. *Id.* art. 52.; *see also* GERVAIS, *supra* note 156, at 222.

agreement requires that the infringement occur “under the laws of the country of importation,” and does not specify that this includes the country of transit. Therefore, developing nations contend that goods in transit, even if they infringe under the laws of the country of transit, cannot be seized because the goods are legitimate and non-infringing under the laws of the destination country (or the importing country).<sup>161</sup> If this argument is accepted by the WTO, then the action of EU customs authorities in many cases will constitute a violation of Article 52 of the TRIPS Agreement.

Developed nations, however, and in particular The Netherlands, have utilized a legal fiction of manufacturing in order to defeat this argument.<sup>162</sup> Under this rationale, in order to establish infringement, goods in transit are regarded in the same manner as goods that have been produced in that country.<sup>163</sup> Further, for states within the EU, the EC Regulation applies to exported goods (i.e. goods made within the country) as well as to imported goods.<sup>164</sup> As a result, if the goods in transit were evaluated as if made in the country of transit, and under those laws they infringed on a domestic product, then customs authorities would have a legitimate reason to seize those goods. If the WTO were to interpret the TRIPS Agreement as including this legal fiction, then the strength of the arguments for developing countries would significantly deteriorate.

Finally, developing nations may be able to persuade the WTO that the EC Regulation, utilized by the EU to seize goods, directly conflicts with the purpose of the Doha Declaration. The ministerial declaration states:

[W]hile reiterating our commitment to the TRIPS Agreement, we reaffirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.<sup>165</sup>

One of the goals of the declaration is to garner international support for the needs of developing nations, in particular for access to medicine, and

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161. See *March Minutes*, *supra* note 15, ¶¶ 131, 136.

162. The Netherlands applied this legal fiction in the *Sosecal v. Sisvel* case. Jens van der Brink, *Comeback for the Legal Fiction of the Anti Piracy Regulation?*, KENNEDY VAN DER LAAN (Aug. 2008), [http://www.kvd.nl/KVdL/en\\_GB/\\_main/News/Newsletter/Newsletter+August+2008/Anti+Piracy+Regulation\\_IP/default.htm](http://www.kvd.nl/KVdL/en_GB/_main/News/Newsletter/Newsletter+August+2008/Anti+Piracy+Regulation_IP/default.htm).

163. *Id.*

164. See EC Regulation, *supra* note 158, pmb1. The EC Regulation “lay[s] down measures to prohibit the release for free circulation, export, re-export or entry for suspensive procedures of counterfeit and pirated goods.” *Id.*

165. Doha Declaration, *supra* note 22, ¶ 4.



to have Member States work together to find a solution to this problem.<sup>166</sup> While the declaration may be more of an expression of international commitment than the creation of binding international law,<sup>167</sup> developing nations may be able to argue that they rely on this commitment in order to improve the quality of life for their own citizens. Further, since they are politically and economically weaker than other Member States, international commitments should be interpreted in a manner that ensures the welfare of developing nations.<sup>168</sup>

*B. Goods in Transit: Scope of EU Customs Regulation 1383/2003*

The regulation at issue in the dispute over the seizure of generic medicines is the EC Customs Regulation 1383/2003.<sup>169</sup> This regulation allows customs authorities, either on their own initiative (*ex officio*) or at the request of the right-holder, to detain goods suspected of infringing “certain intellectual property rights,” in order to enable the right-holders to initiate proceedings against these goods.<sup>170</sup> With each revision to the regulation, the scope of the border control measures has gradually expanded from “counterfeit goods, to pirated goods and . . . to goods suspected of infringing certain [IPRs].”<sup>171</sup>

The first regulation on border controls, Council Regulation 3842/86, enacted in January 1988, permitted trademark owners to request “the suspension of the release for free circulation of goods suspected of infringing trademark rights.”<sup>172</sup> The next revision, Council Regulation 3295/94, enlarged the scope of protection to include copyrights, it introduced the *ex officio* procedure, and mandated the detention of counterfeit and pirated goods, in cases where the goods were imported, ex-

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166. WTO Members had come to realize that a “compromise with developing country Members [was needed] to start a new negotiation round.” HESTERMEYER, *supra* note 46, at 256.

167. *Id.* at 279–80 (arguing that the Doha Declaration is considered a binding agreement).

168. *See* Doha Declaration, *supra* note 22, ¶ 4.

169. *See* William New, *Alarm Escalates Over Delayed Generic Drug Shipments as Action Sought*, INTELLECTUAL PROPERTY WATCH (Mar. 6, 2009), <http://www.ip-watch.org/weblog/2009/03/06/alarm-escalates-over-delayed-generic-drug-shipments-as-action-sought/>.

170. *See* EC Regulation, *supra* note 158.

171. Stephanie McAviney, *Ever Broader Border Controls?*, 4J. INTELL. PROP. L. & PRAC. 455, 455 (2009).

172. *Id.*; *see also* Council Regulation 3842/86, Laying Down Measures to Prohibit the Release for Free Circulation of Counterfeit Goods, 1986 O.J. (L 357) 1.

ported, re-exported, or entered for a suspensive procedure.<sup>173</sup> Then, Council Regulation 3295/94, in 1999, amended the border control measures to include infringement of patents.<sup>174</sup> Finally, in 2004, the EC implemented Council Regulation 1383/2003, which “add[ed] plant variety rights, geographical indications, and designations of origin within the ambit of” certain intellectual property.”<sup>175</sup> The evolution of the EC Regulation has had the ultimate effect of strengthening right-holders’ interests by broadening the IPR categories covered, facilitating the destruction of alleged infringing goods, and extending the scope for *ex officio* action by customs authorities.

The recent seizures of generic pharmaceuticals have been executed under the authority of Council Regulation 1383/2003 by regional customs officials, invoking Article 1<sup>176</sup> of the regulation to justify seizing goods in transit, or by IP right-holders via customs officials, invoking Article 2<sup>177</sup> to validate the seizures by alleging patent or trademark infringement

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173. McAviney, *supra* note 171, at 455; *see also* Council Regulation 3295/94, Laying Down Measures to Prohibit the Release for Free Circulation, Export, Re-Export, or Entry for a Suspensive Procedure of Counterfeit and Pirated Goods, 1994 O.J. (L 341) 18.

174. McAviney, *supra* note 171, at 455.

175. *Id.*

176. EC Regulation, *supra* note 158, art. 1. Article 1 states:

1. This Regulation sets out the conditions for action by the customs authorities when goods are suspected of infringing an intellectual property right in the following situations:

(a) when they are entered for release for free circulation, export or re-export in accordance with Article 61 of Council Regulation (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (3);

(b) when they are found during checks on goods entering or leaving the Community customs territory in accordance with Articles 37 and 183 of Regulation (EEC) No 2913/92, placed under a suspensive procedure within the meaning of Article 84(1)(a) of that Regulation, in the process of being re-exported subject to notification under Article 182(2) of that Regulation or placed in a free zone or free warehouse within the meaning of Article 166 of that Regulation.

2. This Regulation also fixes the measures to be taken by the competent authorities when the goods referred to in paragraph 1 are found to infringe intellectual property rights.

*Id.*

177. *Id.* art. 2. The relevant provision of Article 2 of the EC Regulation 1383/2003 states:

within the Member State. Article 1 of the Council Regulation sets out the conditions for action by customs authorities when goods are suspected of infringing intellectual property rights.<sup>178</sup> There are four conditions under which customs authorities may suspend or seize goods: (1) goods entering for free circulation<sup>179</sup>—goods imported into the State for sale on the market, (2) goods being exported<sup>180</sup> and re-exported<sup>181</sup>, (3) goods found during check on goods entering or leaving the Community customs terri-

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1. For the purposes of this Regulation, “goods infringing an intellectual property right” means:

(a) “counterfeit goods,” namely:

(i) goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder’s rights under Community law, as provided for by Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trademark(5) or the law of the Member State in which the application for action by the customs authorities is made;

(ii) any trademark symbol (including a logo, label, sticker, brochure, instructions for use or guarantee document bearing such a symbol), even if presented separately, on the same conditions as the goods referred to in point (i);

(iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i);

(b) “pirated goods,” namely goods which are or contain copies made without the consent of the holder of a copyright or related right or design right, regardless of whether it is registered in national law, or of a person authorized by the right-holder in the country of production in cases where the making of those copies would constitute an infringement of that right under Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs(6) or the law of the Member State in which the application for customs action is made;

(c) goods which, in the Member State in which the application for customs action is made, infringe:

(i) a patent under that Member State’s law.

178. *Id.* art. 1.

179. *Id.* art. 1.1(a).

180. *Id.*

181. Re-exportation refers to the departure from the EC of non-Community goods introduced into the European territory without having been released for free circulation at any time. *Id.*

tory,<sup>182</sup> and (4) goods found during checks on goods placed under a suspensive procedure.<sup>183</sup> For the seizure of generic pharmaceuticals, only the last category applies, since the goods were either under the “external transit” suspensive procedure<sup>184</sup> or they were being transshipped—goods arrive in the EC with the sole purpose of changing means of transport—at the time of seizure.

Article 2 of the Council Regulation fixes the measures to be taken by the competent authorities when the goods are found to infringe intellectual property rights.<sup>185</sup> It establishes the meaning of “goods infringing an intellectual property right,” which includes goods infringing on patent and trademark rights under the laws of the Member State of transit.<sup>186</sup> As a result, in deciding whether to seize goods in transit, customs authorities must confirm that the goods will infringe IPRs under the national law.<sup>187</sup> It is unclear, however, whether goods in transit, not destined for sale in the EU markets, can even infringe on IPRs within Member States of transit, since those rights are territorial. If not, then customs authorities will not be able to use IPR infringement, as stated in the EC Regulation, as a reason to seize goods in transit. In addition, developing nations will have a stronger argument against the seizure of generic pharmaceuticals that are being transported through the Member States of the EU prior to reaching the final destination. If the opposite determination is reached, however, then the Member States of the EU will have a legitimate basis, at least under their Community laws, to seize goods in transit.

The ECJ and national courts within the EU recently addressed the issue of the legitimacy of seizing goods in transit.<sup>188</sup> Specifically, the courts have examined (1) whether those goods are able to infringe IPRs in the Member State of transit, if the seized goods were not targeted for sale in the State, and (2) whether EC Regulation 1383/2003 applies to goods in transit.<sup>189</sup> Unfortunately, the decisions of the courts conflict with one

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182. *Id.* art. 1.1(b).

183. *Id.*

184. External transit allows non-Community goods to move from one point to another within the EC customs, without such goods being subject to import duties or other charges. Council Regulation 2913/92, Establishing the Community Customs Code, art. 91(1)(a), 1992 O.J. (L 302) 37.

185. EC Regulation, *supra* note 158, art. 2.

186. *Id.*

187. *Id.* art. 2(1)(c)(i).

188. See Case C-281/05, *Montex Holdings Ltd v. Diesel SpA*, 2006 E.C.R. I-10881 [hereinafter *Montex*]; see also *Eijsvogels, Sisvel v. Sosecal*, *supra* note 36; *Nokia Corp. v. Her Majesty's Comm'rs of Revenue & Customs*, [2009] EWHC (Ch) 1903.

189. See *Montex*, 2006 E.C.R. I-10881, ¶¶ 1, 9–11; see also *Nokia*, [2009] EWHC (Ch) 1903, [1]; *Eijsvogels, Sisvel v. Sosecal*, *supra* note 36.

another and do not provide a cohesive resolution to this problem. The following three cases highlight and provide insight into the important legal considerations surrounding this issue that the WTO could take into consideration when evaluating a potential trade complaint against the EU.

### 1. Montex Holdings Ltd. v. Diesel SpA

In *Montex Holdings Ltd. v. Diesel SpA*, on November 9, 2006, the ECJ reaffirmed and concluded that a trademark holder, under the Trademark Directive, can only prohibit the transit of goods through a Member State in which the trademark is protected if it can demonstrate that the goods in question are actually at risk of being on the market in that Member State of transit.<sup>190</sup> On December 31, 2000, German customs officials seized a delivery of over five thousand pairs of pants bearing the “Diesel” mark on its way from Poland, where they were manufactured, to Ireland.<sup>191</sup> Diesel argued that the garments infringed its trademark rights because of the danger that the goods could find their way onto the German market.<sup>192</sup> Montex, on the other hand, contended that the mere transit of the goods through Germany did not infringe any trademark rights.<sup>193</sup>

The ECJ stated that the entitlements provided to proprietors by the Trademark Directive did not apply to goods in transit, but only to goods either being imported or exported from a Member State.<sup>194</sup> The court further considered whether the transit of the goods was likely to damage the particular interests of Diesel as proprietor of the trademark in Germany, regarding the essential function of the mark in guaranteeing to customers the origin of the goods.<sup>195</sup> It determined that only acts of marketing the goods are likely to infringe the proprietor’s rights in the State of transit.<sup>196</sup> Therefore, in the absence of such acts, an infringement of the rights of the trademark holder could not be established.<sup>197</sup> Further, “the mere risk that the goods could . . . theoretically be marketed fraudulently in Germany [did] not by itself” prove that the essential functions of the trademark had been infringed.<sup>198</sup> As a result, the ECJ concluded that

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190. *Montex*, 2006 E.C.R. I-10881, ¶ 46.

191. *Id.* ¶ 4.

192. *Id.* ¶ 5.

193. *Id.*

194. *Id.* ¶ 46.

195. *Id.* ¶ 24.

196. *Id.* ¶ 25.

197. *Id.* ¶ 25–28.

198. *Id.* ¶ 24.

Montex did not infringe Diesel's trademarks, under the Trademark Directive, since the goods were in transit through and not in free circulation in Germany.<sup>199</sup>

The decision in *Montex* lends support to the interests of developing nations who argue that their goods are merely in transit and therefore do not violate the intellectual property rights protected within the transit State. In light of this decision, the recent seizures of generic medications in transit by EU customs authorities may be violating the EC Regulation, as long as there is no evidence that those goods would be sold in the transit state. However, the following decision by the district court in the Netherlands may cast some doubt on this conclusion.

## 2. Sisvel v. Sosecal

On July 18, 2008, the President of the District Court of The Hague ruled in *Sisvel v. Sosecal* that the EC Regulation 1383/2003, which entitles IP holders to request customs authorities to detain infringing products that enter the European Union from outside of the EU, can be applied to goods in transit.<sup>200</sup> The dispute between the parties arose when Dutch customs detained a shipment of MP4 players, acting on behalf of Koninklijke Philips Electronics, for the benefit of Sisvel, because the goods infringed upon the rights of the patent owner.<sup>201</sup> The MP4 players were being transported from China to South America.<sup>202</sup> In *Sisvel*, the opposition to the detainment argued that since the MP4 players were only in transit in The Netherlands and not destined for use in its market, customs officials could not intervene, in accordance with the decision in *Montex*.<sup>203</sup>

The court, however, distinguished *Montex* by limiting that ruling, exclusively, to the interpretation of the Trademark Directive, and chose not to expand the decision to goods detained in transit according to the EC Regulation's patent infringement provisions.<sup>204</sup> The court, in this case, applied the legal fiction of manufacturing, which assumes that the seized goods were manufactured in the Member State of transit and so have been released into free circulation and are thus on the market in that

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199. *Id.* ¶ 46.

200. Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36; Maria Pereira & Eva den Ouden, *IP Enforcement and Goods in Transit: Recent Developments*, EXECUTIVE VIEW (Mar. 18, 2010), [http://www.executiveview.com/knowledge\\_centre.php?id=11309](http://www.executiveview.com/knowledge_centre.php?id=11309).

201. Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36.

202. *Id.*

203. *Id.*; *see also* Pereira & den Ouden, *supra* note 200.

204. Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36; Pereira & den Ouden, *supra* note 200.

Member State.<sup>205</sup> As a result, the goods in question infringed upon the patent rights of the proprietor in that Member State, since the goods were illegally competing in the market with the right holder's product.<sup>206</sup> Therefore, under the EC Regulation, the goods were considered to be in violation of the regulation and subject to seizure.<sup>207</sup> Furthermore, in reaching this decision, the court reasoned that it cannot be concluded that the ECJ wished to go back on its decision in *Polo/Lauren*, in which it ruled that the EC Regulation is to be interpreted as being applicable to goods in transit.<sup>208</sup>

Thus, the decision in *Sisvel* suggests that in cases arising under the EC Regulation, at least in the Netherlands, courts will apply the legal manufacturing fiction, which in effect allows customs authorities to seize goods in transit as long as they infringe on an intellectual property right protected within the Member State. This result, however, was not adopted in a similar case recently decided in the United Kingdom.

### 3. *Nokia v. Her Majesty's Commissioners of Revenue & Customs (HMCRC)*

In July 2009, the United Kingdom High Court followed the decision of the *Montex* court and determined, in *Nokia v. HMCRC*, that goods in transit are not subject to the suspension procedures of the EC Regulation and do not infringe trademark rights, unless the goods are placed on the market.<sup>209</sup> In July 2008, HMCRC stopped and inspected a consignment of goods being shipped from Hong Kong to Colombia.<sup>210</sup> It consisted of approximately four hundred mobile telephone accessories, which were designated by the "NOKIA" trademark.<sup>211</sup> HMCRC sent samples of the goods to Nokia.<sup>212</sup> After investigating the samples, Nokia identified the goods as counterfeit<sup>213</sup> and infringing under the Trademark Directive and requested that HMCRC seize the goods according to the EC Regulation.<sup>214</sup> HMCRC, after receiving legal advice, however, did not seize the goods, contending the goods could not be counterfeit within the meaning

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205. Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36; Pereira & den Ouden, *supra* note 200.

206. Eijsvogels, *Sisvel v. Sosecal*, *supra* note 36.

207. *Id.* at 10–11.

208. van der Brink, *supra* note 162.

209. *Nokia Corp. v. Her Majesty's Comm'rs of Revenue & Customs*, [2009] EWHC (Ch) 1903, [77]–[80].

210. *Id.* ¶ 4.

211. *Id.*

212. *Id.* ¶ 5.

213. *Id.* ¶ 11.

214. *Id.* ¶ 5.

of the EC Regulation unless there was evidence that the goods would be diverted onto the EU market.<sup>215</sup> Nokia argued that HMCRC adopted an “unduly restrictive interpretation” of the EC Regulation, stating that it does apply to goods in transit.<sup>216</sup> Also, Nokia argued that, in applying the EC Regulation, the legal fiction of manufacturing should be adopted.<sup>217</sup>

The High Court did not adopt Nokia’s arguments, finding that infringement of a registered trademark required goods to be placed on the market, and goods in transit and subject to suspension, do not, without more, satisfy this requirement.<sup>218</sup> Further, the court distinguished the ECJ’s *Polo/Lauren* decision by contending that the court, in that case, only addressed the general question of whether the EC Regulation applied to goods in transit, and that it did not consider the more specific question, posed in the *Nokia* case, as to whether the definition of counterfeit goods encompasses goods in transit when there is no threat of them being placed on the market in a Member State.<sup>219</sup> Accordingly, the court reaffirmed *Montex* by concluding that the mere risk of goods being diverted into the market is not sufficient to justify a conclusion that the goods are in free circulation in the State of transit, and thus, infringing or counterfeit and subject to the suspension procedures of the EC Regulation.<sup>220</sup>

### C. Analysis

The WTO dispute settlement body, upon review of the cases, would have to decide on several issues. First, it would need to decide if the legal fiction of manufacturing should be applied to goods seized in transit. Then, it would need to determine whether the seizures of in-transit generic medicines, via the EC Regulation, are permissible under the current international law regime.

For the first issue, the court in *Nokia* directly dismissed the idea of applying the legal fiction of manufacturing to goods in transit.<sup>221</sup> The judge stated, in the context of trademarks, “it is not uncommon for the same mark to be owned and used quite legitimately by different proprietors in different territories in respect of the same goods.”<sup>222</sup> He further stated that applying the legal fiction would produce a result that was “most un-

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215. *Id.* ¶ 6.

216. *Id.* ¶ 38.

217. *Id.*

218. *See id.* ¶¶ 49–51.

219. *See id.* ¶ 67.

220. *See id.* ¶¶ 77–80.

221. *See id.* ¶¶ 73–76.

222. *Id.* ¶ 76.



likely” intended by EC Regulation—the seizure of “goods lawfully made in one territory and intended for lawful use in another but transhipped through a Member State in which the mark was registered.”<sup>223</sup> The WTO may be persuaded by this opinion, especially in light of Article 52 of the TRIPS Agreement. In that section of the agreement, a limitation is placed on the “suspension of goods,” so that goods may be seized if they are infringing under the “laws of the country of importation.”<sup>224</sup> Developed nations, and the court in *Sisvel*, would try to persuade the WTO to interpret “country of importation” as including the country of transit under the legal fiction theory. However, the plain meaning of the provision does not indicate that the country of transit is included within the meaning of country of importation. As a result, the WTO should not interpret the phrase as including the country of transit.

Furthermore, an interpretation that applies the legal manufacturing fiction to the TRIPS Agreement would go against the purpose of the TRIPS Agreement, itself, the Doha Declaration, and the principles of fair trade. The purpose of these constructs of international law is to not only ensure protection of IPRs, but to facilitate legitimate trade among nations. The legal fiction, while protecting IPRs in a way, actually inhibits and places obstacles in the pathway of trade in the international arena. For one, the legal fiction will render goods illegal that were legitimate in their country of origin and destination country.<sup>225</sup> It will also force developing nations, and perhaps some developed nations, to redirect their trading routes, so as not to transship goods through countries that apply the legal fiction to goods in transit—thereby decreasing trade relations between countries. Furthermore, in light of the Doha Declaration, the TRIPS Agreement is supposed to be interpreted so as to protect the public health and ensure access to medicine.<sup>226</sup> If this recommendation is adhered to, then Article 52 should be read to not allow the country of transit to suspend goods by applying the legal fiction.

If the WTO determines that the TRIPS Agreement does not include the country of transit in Article 52, it must then determine whether the EC Regulation complies with the TRIPS Agreement. In both *Nokia* and *Montex* the courts decided that goods in transit could not be seized unless there was a significant risk of the goods entering the European market.<sup>227</sup>

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223. *Id.*

224. TRIPS Agreement, *supra* note 21, art. 52.

225. *See* Nokia Corp. v. Her Majesty's Comm'rs of Revenue & Customs, [2009] EWHC (Ch.) 1903, [76].

226. *See* Doha Declaration, *supra* note 22, ¶ 4.

227. *See* Case C-281/05, *Montex Holdings Ltd v. Diesel SpA*, 2006 E.C.R. I-10881, ¶ 29; *Nokia*, [2009] EWHC (Ch.) 1903, [77]–[78].

The mere threat of a risk was not sufficient in the courts' view to allow for the seizure of goods in transit.<sup>228</sup> The rationale behind these decisions should be adopted by the WTO as well, since it follows the reasoning and purpose behind enforcing IPRs. IPRs were developed, in part, to give inventors a monopoly over their idea, invention, or brand for a limited period of time.<sup>229</sup> The goal, therefore, was to prevent unfair competition within certain protected markets. If goods in transit do not have the potential to enter a protected market, then unfair competition in that market can never result and infringement of the patent, trademark, or copyright at issue cannot occur in that country. By adopting this reasoning, the WTO would acknowledge that the EC Regulation should only be applied to goods in transit that have the potential for seeping into the European marketplace. For actions taken by the EU, where there is little to no evidence that goods will be placed on the market in the country of transit, and thus, not infringe on the IPRs under national law, the WTO should categorize those actions as violating the TRIPS Agreement.

#### CONCLUSION

Despite efforts made over the past few years to improve access to essential medicines, developing nations are still far from meeting the medical needs of their populations. The recent drug seizures are an illustration of one of the many reasons for the deficiency in public health in those countries, including inadequate domestic health care networks and poverty. Measures such as the Doha Declaration and the TRIPS Agreement are a necessary start to the continuing dialogue concerning access to medicine and public health in developing nations.

Regardless of the accusations made, the EU and EFPIA have stated that they support access to medicine for developing nations, and they are committed to the object and purpose of the Doha Declaration and the TRIPS Agreement.<sup>230</sup> The seizures, on their part, were not executed to prevent access, but rather to protect against counterfeit medicine, which is also a significant problem for developing nations.<sup>231</sup> In light of the decisions of the ECJ, the EU does not seem to have the authority to stop goods in transit even if those goods are counterfeit and harmful to public health. As a result, there is a need to balance these two concerns—access

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228. See sources cited *supra* note 227.

229. See HESTERMEYER, *supra* note 46, at 29–33.

230. See *June Minutes*, *supra* note 3, ¶ 137; *EFPIA Statement*, *supra* note 28.

231. Philip Stevens & Julian Harris, *International Policy Network: Fake Scare About Fake Drugs*, INTELLECTUAL PROPERTY WATCH (Dec. 15, 2009), <http://www.ip-watch.org/weblog/2009/12/15/international-policy-network-fake-scare-about-fake-drugs/>.

and counterfeit medicines—in order for developing nations to achieve a higher level of health.

One attempt at a balance may be to revise the EC Regulation to affirm that it does not impede legitimate drugs transiting through European customs. It needs to ensure that the domestic laws of the country in transit do not apply to those goods, when raising IPR violations. If goods are counterfeit, then the goods should not be seized as violations of patent rights or trademark rights, but under another standard that does not prohibit legitimate trade and requires customs authorities to provide evidence of the goods being counterfeit. Another attempt to reach a balance may be to broaden the permissions of compulsory licenses to health needs that are significant, but may not meet the emergency standard under the current TRIPS Agreement.

Regardless of how international laws are modified, the populations of these countries are looking to the international community for some type of solution, to work together and compromise for the benefit of global health. In this instance, oral and written commitments are not sufficient, and the international community should demand change via State's actions.

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