

# Improper Seizures by Sovereigns at Customs—Limiting EC 1383/2003 through the Effects Principle

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## I. INTRODUCTION

Recently, European Community (“EC”) customs officials, on several occasions have seized generic pharmaceuticals at Community ports as non-EC manufacturers sought to transship these goods to non-EC markets.<sup>1</sup> In securing the release of these drugs, the manufacturers have had to recall the shipments rather than sending them forward to the destination countries.<sup>2</sup> These European nations would seem to be within their rights to hinder the free passage of these goods. After all, vessels entering a port typically succumb to the jurisdiction of the sovereign.<sup>3</sup> However, by detaining these legitimate goods, these nations are applying their domestic patent laws in a manner that is *effectively* extraterritorial. By using their customs facilities and ports in a manner that may be contrary to international norms and agreements, although their actions are territorial, these European nations are effectively expanding their patent laws, which are understood to be limited nationally, to have significant extraterritorial effects.

Jurisdictional issues, at their core, implicate limits on the rights of sovereigns to exert influence, in particular the ability to affect legal interests. Although municipal law is the *primary* means of regulation within national boundaries, international law restricts a nation’s jurisdiction in applying its municipal law extraterritorially.<sup>4</sup> Therefore, while municipal laws dominate national conduct, they are correspondingly limited internationally.<sup>5</sup> The modern view,

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<sup>1</sup> Martin Khor, *Row over seizure of low-cost drugs*, THE STAR ONLINE, Aug. 10, 2009, <http://thestar.com.my/columnists/story.asp?file=/2009/8/10/columnists/globaltrends/4487956&secc=Global%20Trends>. These generic medicines, although patented in these European nations, are unprotected both where they are manufactured and in the markets to which they are destined. *Id.*

<sup>2</sup> *Id.*

<sup>3</sup> LORI F. DAMROSCH, ET. AL., INTERNATIONAL LAW CASES AND MATERIALS 1123 (4th ed. 2001).

<sup>4</sup> *Id.* at 1089.

<sup>5</sup> *Id.*

then, is that states, when exercising extraterritorial jurisdiction, must give an appropriate basis.<sup>6</sup> For example, the Third Restatement supports jurisdiction over foreign conduct that is “directed against ... a limited class” of national interests.<sup>7</sup> At the same time, the Third Restatement limits this power by a reasonableness test to analyze the validity of the exercise of extraterritorial jurisdiction.<sup>8</sup> Thus, while jurisdiction is generally unbounded nationally—within the restrictions of local law—international law limits its exercise extraterritorially, and as a result, nations need to justify affirmatively such exercise of power.

International treaties and customary law can also impinge on domestic law and circumscribe domestic jurisdiction.<sup>9</sup> For example, in the United States, international agreements ratified by the legislature *typically* have domestic effect.<sup>10</sup> For example, “public international law recognizes that limits must be placed on territorial jurisdiction in order to extend diplomatic courtesy and ... [facilitate] reciprocal rights in other nations.”<sup>11</sup> Thus, there are even limits in applying domestic law nationally.

This paper considers the limits on the application of domestic customs law to transshipped goods at local ports. I argue that while it is internationally accepted that port states have jurisdiction over vessels that enter their port, the exercise of local customs laws to seize goods in transshipment should be limited to those cases where there is an appropriate nexus

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<sup>6</sup> *Id.* at 1090.

<sup>7</sup> Restatement (Third) of Foreign Relations Law of the U.S.: Bases of Jurisdiction to Prescribe § 402.

<sup>8</sup> *Id.* at Limitations on the Jurisdiction to Prescribe § 403.

<sup>9</sup> Patricia Ann Long, *The North Atlantic Treaty Organization: The Legal Status of an Allied Headquarters to Import and Resell Duty-Free Merchandise within the Conflicts of Law Hierarchy*, 34 GEO. WASH. INT’L L. REV. 287, 287 (2002).

<sup>10</sup> See *Medellin v. Texas*, 552 U.S. 491, 505 (2008) (finding that a treaty may be an international commitment but needs to be either self-executing or ratified by Congress to be effective domestically).

<sup>11</sup> Long, *supra* note 9 at 287.

between the supposed violations of domestic law and the interests of the port nation. As will be shown, even within the EC, the seizure of goods purely in transit, such as generic pharmaceuticals as issue here, is controversial. For example the United Kingdom (“U.K.”) has limited the application of EC Regulation No. 1383/2003 (“EC 1383”) to seize only goods that could enter and effect its markets, while Netherlands officials promote a broader reading of the statute, allowing seizure of goods without regard to direct effects on its market.<sup>12</sup> This paper in particular contends that the broad application of EC 1383 by European nations’ customs officials to seize generic pharmaceutical transshipped from India to Latin American nations, improperly extends the reach of local patent laws extraterritorially and hinders trade, and in order to determine when such application is appropriate, the EC should promote the use of the effects principle.

#### **A. EC Customs Officials’ Seizures of Generic Pharmaceuticals in Transshipment**

During the past two years, EC member nations, at the behest of multi-national pharmaceutical corporations (“MNCs”), have intercepted and prevented the onward shipment of generic medicines en route to developing Latin American countries—such as Columbia, Peru, and Brazil—apparently for intellectual property (“IP”) violations.<sup>13</sup> EC member nations seized these goods despite the absence of patent protection for the pharmaceutical, in either the manufacturing country or the Latin American destination country, and despite the fact that the drugs do not infringe copyright or trademark protection in either the manufacturing or the

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<sup>12</sup> See *Nokia Corp. v. Revenue & Customs Commissioners*, [2009] E.T.M.R. 59 ¶ 79-80 (Ch.); *Sosecal Industria e Comercio Ltda v. Societa Italiana Lo Sviluppo Dell’ Elettronica* – Case No. 311378 (Court of the Hague 2008).

<sup>13</sup> These countries include Germany and the Netherlands. Khor, *supra* note 1. These medicines include clopidrogel, a blood thinner; rivastigmine for Alzheimer’s disease; olanzapine, an anti-psychotic; and losartan, for high blood pressure. *Id.*

destination country.<sup>14</sup> World organizations monitoring the access to drugs are concerned that these seizures are not incidental, but are instead a tactic of MNCs to increase the market for their patented, brand-name drugs by persuading intermediary port nations to disrupt the legitimate global trade in generics.<sup>15</sup>

Developing nations to where these goods were destined have especially criticized the December 2008 seizure of Losartan, a generic version of the brand name drug, Cozarr.<sup>16</sup> Rotterdam customs officials seized this shipment en route to Brazil at the prompting of Merck Inc., which holds the Dutch patents on Cozarr.<sup>17</sup> Customs officials, relying on their *national* interpretation of EC 1383, a Community regulation meant to restrict goods violating IP rights, confiscated these drugs at the request of Merck representatives, ostensibly for patent violation and arguably to prevent the proliferation substandard medications.<sup>18</sup>

It is indeed true that the quality of medicines can be a genuine concern since counterfeit medicines have caused health issues throughout the world, and because counterfeiting also affects generics, there is a legitimate concern over the authenticity of drugs reaching Latin

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<sup>14</sup> *Id.* Compulsory licensing enables a government to allow the production of medicine without the patent owner's permission. WTO, Trips and Health: Frequently asked questions, Compulsory licensing of pharmaceuticals and TRIPS (September 2006), [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm).

<sup>15</sup> See Peter Maybarduk, *Stop Fakes, Not Generics*, Letter to the Editor, ACCESS TO MEDICINES PROJECT, May 13, 2009 (stating pharmaceutical companies deliberately confuse patent rights and trademark counterfeiting issues and put forward public safety concerns to protect their monopolies).

<sup>16</sup> See Goran Danilovic, Recent Dutch seizures of generic drugs add fire to the WTO dispute regarding seizure of goods in transit, Bird & Bird (March 23, 2009), [http://www.twobirds.com/English/NEWS/ARTICLES/Pages/Recent\\_Dutch\\_seizures\\_drugs\\_WTO\\_dispute\\_230309.aspx](http://www.twobirds.com/English/NEWS/ARTICLES/Pages/Recent_Dutch_seizures_drugs_WTO_dispute_230309.aspx).

<sup>17</sup> See *id.*

<sup>18</sup> Reasons given for the seizure "include cracking down of counterfeit drugs and substandard potentially hazardous products, and preventing patent violation." ECONOMIC JUSTICE NETWORK, 18 August 2009, <http://www.ejn.org.za/index.php/component/content/article/60/210-seizure-of-medicines-a-blow-to-developing-countries->.

America.<sup>19</sup> However, the goods that the Rotterdam customs officials seized were *not* counterfeit versions of Cozarr and no evidence indicates there was any suggestion to that effect.<sup>20</sup> In fact, the manufacturers intentionally and accurately designated these medicines as the generic drug—Losartan.<sup>21</sup>

Moreover, even if there are legitimate concerns as to the *authenticity* of the *generic* drug, these apprehensions do not implicate the trademark rights of manufacturers of *brand name* drugs or anti-counterfeit laws of European countries to which these generics had no relation but as goods in transit.<sup>22</sup> These drugs, properly created and properly labeled, were not made for EC national markets but for Latin American destination countries. As a result, this *effectively* extraterritorial application of IP laws does not comply with the Agreement on the Trade Related Aspects of Intellectual Property Rights (“TRIPS”).<sup>23</sup> By applying EC 1383 broadly under the guise of IP violations by goods that are *not* to be imported and do not have any credible way of entering the EC marketplace, these customs officials are inadvertently encumbering the free

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<sup>19</sup> Wyatt Yankus, *Counterfeit Drugs: Coming to a Pharmacy Near You (Condensed Version)*, American Council on Science and Health, August 24, 2006, available at [http://www.acsh.org/publications/pubid.1384/pub\\_detail.asp](http://www.acsh.org/publications/pubid.1384/pub_detail.asp). The World Health Organization (“WHO”) has defined counterfeit drugs as medicines that are “deliberately and fraudulently mislabeled ... [as to] identity, composition, and/or source.” *Id.* In 2006, the American Council on Science and Health Law estimated that about ten percent of the world’s drug supply is counterfeit. *Id.* The WHO has estimated that the amount counterfeit drugs in less developed countries reaches up to twenty-five percent. Julian Morris & Philip Stevens, *Counterfeit medicines in less developed countries: Problems and solutions*, INTERNATIONAL POLICY NETWORK (London 2006), 3; Counterfeit Drugs Kill!, World Health Organization, 2 (18 Feb. 2006), available at <http://www.gphf.org/images/downloads/impactbrochure.pdf>.

<sup>20</sup> Khor, *supra* note 1.

<sup>21</sup> *Id.*

<sup>22</sup> Morris, *supra* note 19, at 4.

<sup>23</sup> See Jennifer Giordano-Coltart, *Walking the Line: Why the Presumption Against Extraterritorial Application of U.S. Patent Law should Limit the Reach of 35 U.S.C. § 271(F)*, 2007 DUKE L. & TECH. REV. 4, 24.

trade of legitimate pharmaceuticals. This consequently affects the health and economy of Latin American nations and effectively applies local patent laws internationally.

## **B. International Agreements Governing Shipment in Trade**

Shortly following World War II, at an international conference held in Havana, Cuba, nations set up a charter for an International Trade Organization (“ITO”) to “apply uniform principles of fair dealing with regards to trade.”<sup>24</sup> The ITO eventually failed to come into force but led to the development of the General Agreement on Trade and Tariff (“GATT”) protocol.<sup>25</sup> After several rounds of negotiations and modifications, in 1994, under the then relevant version of GATT, members formed the World Trade Organization (“WTO”) as a permanent trade body.<sup>26</sup> Most nations are now part of this multilateral organization created to reduce trade barriers and promote tariff-free trade.<sup>27</sup> As part of the WTO, members are obliged to follow GATT protocols.<sup>28</sup> Moreover, the WTO has also set up a forum for dispute resolution where nations can bring issues such as the compliance of local law with GATT requirements.<sup>29</sup>

GATT Article V discusses the agreement between nations concerning the transit of goods.<sup>30</sup> GATT dictates that goods—and vessels transporting these goods—are in transit through a WTO member’s territory when “the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier” of the member’s territory.<sup>31</sup>

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<sup>24</sup> DAMROSCH, *supra* note 3, at 1576.

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> WTO, The World Trade Organization ..., *available at* [http://www.wto.org/english/res\\_e/doload\\_e/inbr\\_e.pdf](http://www.wto.org/english/res_e/doload_e/inbr_e.pdf).

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> General Agreement on Tarriffs and Trade (1947), Art V.

<sup>31</sup> *Id.* at Art V, par 1.

GATT requires that member nations allow goods to move “via the routes most convenient for international transit.”<sup>32</sup> Nations have the option of requiring these goods to enter into customs houses for routing and traffic control but should not otherwise unnecessarily delay or restrict the transshipment of goods through their port.<sup>33</sup> These provisions also apply to goods transported by way of aircraft.<sup>34</sup> Members of the WTO, such as these EC nations, have agreed to comply with these regulations primarily because it reduces the restrictions their goods face in potential markets by lowering trade barriers.<sup>35</sup>

In addition to GATT, these EC nations are also subject to other international obligations. For example, they have agreed to the United Nations Convention on the Law of the Sea (“UNCLOS”), a generally accepted body of principles ratified by many nations.<sup>36</sup> Apart from one provision regarding seabed mining, “nearly all the substantive provision in the Convention reflect existing customary international law, which is binding even on those states that have not become members of the Convention.”<sup>37</sup> Thus, UNCLOS serves as a body of international law to which all nations should adhere.

Concerning the transit of goods, UNCLOS requires port states to open their ports to facilitate trade with land locked states.<sup>38</sup> In particular, port states must take all measures “to

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<sup>32</sup> *Id.* at Art V, par 2.

<sup>33</sup> *Id.* at Art V, par 3.

<sup>34</sup> *Id.* at Art V, par 7.

<sup>35</sup> Both the Netherlands and Germany, as part of the European Union (“EU”), have been members of the WTO since its inception in January 1, 1995.

<sup>36</sup> One major exception is the United States, which has not agreed to be bound by its terms.

<sup>37</sup> Richard J. McLaughlin, *UNCLOS and the Demise of the United States’ Use of Trade Sanctions To Protect Dolphins, Sea Turtles, Whales, and Other International Marine Living Resources*, 21 *ECOLOGICAL L.Q.* 1, 4 (1994).

<sup>38</sup> UN, Preamble to the United Nations Convention on the Law of the Sea, Part X: Right of Access of Land-Locked States to and from the Sea and Freedom of Transit, Art 124.



avoid delays or other difficulties of a technical nature in traffic and in transit.”<sup>39</sup> Therefore, while it is true that ports and customs are under the sovereignty of the territorial authority, the local authority must also take into account international obligations that limit how they apply its laws nationally.

### C. TRIPS and the Territoriality of Patent Rights

The WTO’s Trade Related Aspects of Intellectual Property Rights Agreement (“TRIPS”) was signed at the Marrakesh ministerial meeting in April 1994 and sets the *minimum standard* that WTO member nations must meet for the protection of intellectual property.<sup>40</sup> This modern agreement is successful and almost universally accepted; however, its principles are based upon the Paris Convention of 1884, which historians characterize as the “first true international legislation of patent law.”<sup>41</sup> Prior to the Paris Convention, nations held patents as “dependant,” such that if an inventor obtained patents in two nations and let the patent lapse in one, the second nation could hold the patent lapsed as well.<sup>42</sup> The second state could claim that the patent rights lapsed in their nation as soon as the inventor let it lapse in the first nation and in this way relate the application of the patent law in one country to the validity of the patent in another.<sup>43</sup> Thus, prior to the Paris Convention, local application of patent laws had extraterritorial implications.

The Paris Convention explicitly promoted the principle of *independence*.<sup>44</sup> Independence originated with the notion of a state’s sovereignty and the view that national patents are property

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<sup>39</sup> *Id.* at Art. 130.

<sup>40</sup> WTO, A Summary of the Final Act of the Uruguay Round, [http://www.wto.org/english/docs\\_e/legal\\_e/ursum\\_e.htm](http://www.wto.org/english/docs_e/legal_e/ursum_e.htm) (last visited March 21, 2010).

<sup>41</sup> ROBERT P. MERGES, ET. AL., *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGY AGE* 344 (4th ed. 2007).

<sup>42</sup> Jacob A. Schroeder, *So Long As You Live Under My Roof, You’ll Live By ... Whose Rules?: Ending The Extraterritorial Application of Patent Law*, 18 TEX. INTELL. PROP. L.J. 55, 68 (2010).

<sup>43</sup> *Id.*

<sup>44</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 (as last revised at Stockholm, July 14, 1967), art. 4bis(1) (patents).

rights granted by the sovereign.<sup>45</sup> Independence limited the extraterritorial application of local patent law, but other problems remained. Because states implemented patent protections independently, there were huge disparities in the protections available in different nations.<sup>46</sup> For example, because of variations in the law, although some technologies could be patented in one nation, they were not afforded protections in another.<sup>47</sup> In India, protections for pharmaceuticals were not present until 2005, allowing a huge generics industry to form that capitalized upon copying drugs invented in countries where patent protection was available.<sup>48</sup> In addition to a lack of patents for some goods, nations also gave stronger protection to nationals than to citizens of foreign countries.<sup>49</sup> Because of these global inconsistencies in protection, when patents became national in scope, trade barriers arose.<sup>50</sup>

As a result of these disparities, developed nations promoted TRIPS as a WTO obligation in order to set a minimum level of protection for inventions and to promote national treatment for all WTO member states.<sup>51</sup> Although TRIPS seeks to set a uniform minimum level of protection, because it adopted Article 4bis of the Paris Convention, TRIPS maintained the independence of national patent system.<sup>52</sup> As TRIPS is a non-self executing agreement, each member nation must implement their own patent system.<sup>53</sup> Then as nations offer greater protections than those

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<sup>45</sup> Schroeder, *supra* note 42, at 65.

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> Amy Kapczynski, *Harmonization and its Discontent: A Case Study of Trips Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1576-80 (2009).

<sup>49</sup> Schroeder, *supra* note 42, at 65.

<sup>50</sup> Kapczynski, *supra* note 48, at 1579.

<sup>51</sup> *Id.*

<sup>52</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 319, 33 I.L.M. 1125, 1197 (1994) [hereinafter TRIPS Agreement], Art 2.

<sup>53</sup> Schroeder, *supra* note 42, at 66.

required by TRIPS, variations between IP laws result.<sup>54</sup> Consequently, signatories of TRIPS, like EC nations, are required to recognize the sovereignty of other states and apply their patent laws territorially.

A fundamental basis for jurisdiction is territoriality; the sovereign has supreme authority over its lands.<sup>55</sup> Nations can voluntarily circumscribe these territorial rights when they enter into an international treaty such as GATT and UNCLOS and through membership in international organizations such as the WTO. At the same time, there is a presumption that the laws of the sovereign are confined to his territory; in the strict territorial view, “every state enjoy[s] broad exclusive jurisdiction over person and activities within its territory, but no state [can] assert its jurisdiction extraterritorially.”<sup>56</sup> Thus, patent law through the Paris Convention and by its subsequent adoption into TRIPS is based on the independence doctrine, and each nation is limited to applying their patent system nationally.

## **II. FLAG STATE V. PORT STATE JURISDICTION: RIGHTS OF THE SOVEREIGN AT PORT**

Both GATT and TRIPS recognize the importance of trade to limit the jurisdiction of sovereigns. It is for trade purposes that international law “presumes that ports of every state should be open to all commercial vessels.”<sup>57</sup> These commercial vessels are treated as having the nationality of the flags they fly, *i.e.*, flag-state jurisdiction, as long as there is a true association between the vessel and the nation whose flag is flown.<sup>58</sup> In international waters, the jurisdiction

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<sup>54</sup> *Id.*

<sup>55</sup> DAMROSCH, *supra* note 3, at 1093.

<sup>56</sup> Gary B. Born, *A Reappraisal of the Extraterritorial reach of U.S. Law*, 24 LAW & POL’Y INT’L BUS. 1, 8, 14-17 (1992)

<sup>57</sup> John T. Oliver, *The Ins and Outs of the Modern Port: Where Do We Go From Here*, 5 S.C.J. INT’L L. & BUS. 209, 210 (2009).

<sup>58</sup> DAMROSCH, *supra* note 3, at 1123-24; Aircraft are treated as the nationality of the state in which they are registered. *See id.* at 1123.

of the flag state traditionally dominates.<sup>59</sup> On the other hand, when a flag-state vessel enters port, at least when that entry is voluntary and barring other international agreements, the vessel succumbs to the jurisdiction of the port state.<sup>60</sup> However, in some instances it is possible for port states to exercise authority over actions that take place in international waters as well as over those actions in ports where international agreements generally limit sovereign authority. This expansion of jurisdiction is based upon the effects principle, under which extraterritorial conduct having domestic consequences can be regulated.<sup>61</sup>

### **A. Port States and Transshipments**

In the area of transshipment, international agreements have circumscribed some of the substantial jurisdiction that port states typically wield. This section considers the actions of port states as it relates to the transshipment of cargo, first, in the early twentieth century case of transport of alcohol through U.S. ports when the Eighteenth Amendment was in effect; and second, the more recent case of Chilean ports and the transshipment of swordfish caught by European fishermen. In both cases, transshipment had sufficient effect on the port state that it justified the hindrance of the international norms for the facilitation of trade.

#### ***i. Transshipments of Liquor at U.S. Ports under Volstead Act vs. the Modern View of Extraterritoriality***

The United States adopted a national prohibition of alcohol with the passage of the Eighteenth Amendment.<sup>62</sup> In particular, the Eighteenth Amendment provided that “the

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<sup>59</sup> Suzanne Bostrom, *Halting the Hitchhikers: Challenges and Opportunities for Controlling Ballast Water Discharges and Aquatic Invasive Species*, 29 ENVTL. L. 867, 890 (2009).

<sup>60</sup> *Id.* at 1123.

<sup>61</sup> *See U.S. v. Aluminum Co. of America*, 148 F.2d 416, 443 (1945).

<sup>62</sup> Thomas H. Walters, *Michigan's New Brewpub License: Regulation of Zymurgy for the Twenty-First Century*, 71 U. DET. MERCY L. REV. 621, 630-35 (1994). The national prohibition bill passed through Congress and was sent to the states in 1917 and ratified in 1919. *Id.* at 635.

manufacture, sale, or transportation of intoxicating liquors within, the importation thereof into, or the exportation thereof from the United States and all territory subject to the jurisdiction thereof for beverage purpose is hereby prohibited.”<sup>63</sup> The Volstead Act, passed subsequently, enforced the Eighteenth Amendment, stating that “no persons shall ... manufacture, sell, barter, *transport*, import, export, deliver, furnish, or possess any intoxicating liquor” unless explicitly exempted by the act.<sup>64</sup> It is important to note that this act is strictly territorial and should apply only domestically.

However, United States customs officials applied the Volstead Act to have extraterritorial effects by restricting the transport of liquors between foreign nations through U.S. ports. One instance involved a Canadian corporation that sought to ship liquor to Latin American countries through Detroit, Michigan.<sup>65</sup> In this case, the Eastern District of Michigan granted an injunction to prevent the transport.<sup>66</sup> A second instance involved a British ship transporting liquor to Canada by way of New York in which the Southern District of New York refused to apply an injunction under the Volstead Act.<sup>67</sup>

The Supreme Court joined and decided both cases.<sup>68</sup> The Court analyzed a treaty with England that should have allowed passage through U.S. ports when items were brought to port strictly for transshipment to British possessions.<sup>69</sup> The appellants argued that according to the treaty and by a strict reading of the Volstead Act, transshipment should be allowed since the liquor was not intended for beverage purpose in the United States—the Volstead Act was

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<sup>63</sup> U.S. CONST., EIGHTEENTH AMENDMENT (enacted in 1920).

<sup>64</sup> CAPPER-VOLSTEAD ACT, 7 U.S.C. §§ 291 et seq. (2006) (emphasis added).

<sup>65</sup> *Grogan v. Hiram Walker & Sons*, 259 U.S. 80, 87 (1922).

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* Also, note that this was prior to GATT.

concerned with domestic consumption and did not explicitly restrict the transshipment at U.S. ports.<sup>70</sup> The majority however, found this unpersuasive and stated that although Congress had not strictly prohibited transshipment, such was its intent because it had explicitly forbidden all *other* customs actions and explicitly allowed transshipments through the Panama Canal.<sup>71</sup> In considering whether the Act covered transshipments, the majority also explained that the Volstead Act took into consideration that liquor *could* be diverted for local use.<sup>72</sup> The dissent expounded that it is possible that a quantity of the liquor entering for transshipment could find its way into the domestic marketplace.<sup>73</sup> As a result, it was possible that a large quantity was indeed entering the United States “for beverage purposes,” and the transshipment *in effect* resulted in a violation of the Volstead Act.<sup>74</sup>

However, the dissent argued the Volstead Act only prohibited the type of transportation that was “within the United States *for* beverage purposes.”<sup>75</sup> The dissent contended that the transshipped liquor did not fall under the ambit of the Volstead Act and therefore should be transshipped per the treaty with England.<sup>76</sup> Furthermore, the dissent argued that such an application of national law resulted in “directing the practices of the world” by effectively applying the local law extraterritorially.<sup>77</sup> By setting up barriers to free trade in liquor, the U.S. was indirectly hindered the extraterritorial consumption of alcohol.<sup>78</sup> Moreover, the dissent argued that, when considering the extraterritorial effects, even if there is some diversion of the

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<sup>70</sup> *Id.*

<sup>71</sup> *Id.* at 90.

<sup>72</sup> *Grogan*, 259 U.S. at 89-90.

<sup>73</sup> *Id.* at 98.

<sup>74</sup> *Bars Foreign Rum From U.S. Ports – Court Decides Law Prohibits Transshipment of Liquors Through This Country*, N.Y. TIMES (October 21, 1921).

<sup>75</sup> *Grogan*, 259 U.S. at 94 (emphasis added).

<sup>76</sup> *Id.*

<sup>77</sup> *Id.* at 95.

<sup>78</sup> *See Id.*

liquor into domestic markets, the quantity must be significant before it could be used as a reason to prevent transshipment per the Volstead Act.<sup>79</sup>

Unfortunately, rather than resorting to something akin to the effects principle, the majority relied primarily upon sovereignty and the understanding that Congress had authorized the customs actions, its analysis showing little concern for international duty.<sup>80</sup> Although, the majority did attempt to bolster its analysis with some inquiry of the effect of the transshipped liquor, it was primarily the dissent that considered the significant effects on domestic markets as a reason to justify limiting transshipments. As shown below, post-1940s, the United States has made greater use of the effects principle.<sup>81</sup> Although there is debate as to whether courts should apply the effects principle as broadly as they currently do, it is clear that with greater international obligations and commensurate potential for subsequent international response, modern U.S. courts, as shown below, take greater efforts to associate the exercise of jurisdiction with the prevention of domestic harm through the effects principle.<sup>82</sup>

## *ii. The Chilean Swordfish Dispute: Modern View on Extraterritorial Application*

More recently, in a dispute involving a port nation preventing transshipment, Chile acted to restrict Spanish deep-sea fishers carrying swordfish destined for the United States access to their local ports. Chile applied its local Fisheries Law which “prevents any vessel from transshipping or landing vessels in Chilean ports” when its catches do not comply with Chilean

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<sup>79</sup> *Id.* at 96.

<sup>80</sup> *Does the Eighteenth Amendment Violate International Law*, 33 YALE L.J. 72, 77-78 (1923).

<sup>81</sup> See Austen Parrish, *The Effects Test: Extraterritoriality's Fifth Business*, 61 VANDER. L. REV. 1455, 1471-72 (2008). “In 1965, the Second Restatement of Foreign Relations Law stated that federal statutes apply to ‘conduct occurring within, or having an effect within, the territory of the United States.’” *Id.* at 1472-73; See Born, *supra* note 56, at 22, 26, 30-32 (showing the increased importance of the effects principle in international law).

<sup>82</sup> See generally *id.*

law.<sup>83</sup> Chile found that swordfish were an over exploited species and contended that the Spanish fisheries' methods directly outside of Chile's 200-mile exclusive economic zone ("EEZ") resulted in depletion that had devastating effects upon Chile's own industries.<sup>84</sup> Chile also formed local alliances with Ecuador and Peru to prevent cargo containing migratory deep-water fish from utilizing any Pacific ports in South America.<sup>85</sup> As a result, ANAPA, the Spanish National Association of deep-sea long liners, brought a complaint in the European Union ("EU") that Chile was creating unnecessary obstacles to trade.<sup>86</sup> According to the ANAPA, the Chilean practices prevented "community vessels ... [from expanding] their fishing capacity within the South Pacific fishing area ... [so as to make] it unprofitable to invest in the exploitation of the fishing resources in this area."<sup>87</sup> Based upon these complaints, the EU conducted an examination and subsequently brought action against Chile in the WTO.<sup>88</sup> In response, Chile brought a claim against the EU in the International Tribunal for the Law of the Sea ("ITLOS").<sup>89</sup>

In the WTO, the EU based its action upon Article V of GATT, which specifies "freedom of transit for goods through the territory of each contracting party."<sup>90</sup> In defense, Chile claimed that its actions were neither discriminatory nor a "disguised restriction on international trade," but were "necessary to protect human, animal, or plant life or health" as allowed per Article

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<sup>83</sup> John Shamsey, *ITLOS vs. Goliath: The International Tribunal for the Law of the Sea Stands Tall with the Appellate Body in the Chilean-EU Swordfish Dispute*, 12 *TRANSNAT'L L. & CONTEMP. PROBS.* 513, 518 (2002).

<sup>84</sup> *Id.* at 519.

<sup>85</sup> *Id.*

<sup>86</sup> Notice of Initiation of an Examination Procedure Concerning an Obstacle to Trade, within the Meaning of Council Regulation (EC) No 3286/94, Consisting of Trade Practices Maintained by Chile in Relation to the Transit and Transshipment of Swordfish in Chilean Ports, 98/C 215/02, 1998 O.J. (C 215) 3 (EC).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*; Shamsey, *supra* note 83, at 520.

<sup>89</sup> Shamsey, *supra* note 83, at 520.

<sup>90</sup> *Id.* at 521.



XX(b) of GATT.<sup>91</sup> At the same time, in the ITLOS action, Chile explained the steps that it had taken to establish restrictions and controls for its own fishing vessels with its EEZ.<sup>92</sup>

Furthermore, they explained that the Spanish vessels had not provided the documentation required to show their compliance with these requirements.<sup>93</sup> Moreover, Chile stated that because these fish were a migratory species, unrestricted fishing directly outside of its EEZ has a direct impact upon Chile's economic interests.<sup>94</sup> Chile contended that its "good-faith non discriminatory, domestic environmental regulation that reach activities beyond its sovereign jurisdiction can stand up to international free trade concerns."<sup>95</sup>

In the end, the EU and Chile came to an agreement allowing a limited number of Chilean ships to land at its ports.<sup>96</sup> However, Chile made a strong case for its stance by linking the extraterritorial activity to a direct local detriment. In this way, again, the effects principle played a significant role in justifying its effectively extraterritorial action.

## **B. The Effects Principle**

Jurisdiction in a port is typically based upon the territoriality principle such that when a ship enters a port it cedes jurisdiction to that sovereign.<sup>97</sup> Thus, the port-state would have jurisdiction over violations of domestic law committed by the foreign-flag vessel at port. However, violations committed out of the territory of the sovereign would presumably not be

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<sup>91</sup> *Id.* at 521-22.

<sup>92</sup> *Id.* at 523

<sup>93</sup> *Id.* at 524.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 526.

<sup>96</sup> *Id.* at 538. In a prior WTO dispute, Tuna/Dolphin I, the WTO panel held that a state could not undertake an environmental measure that has "the effect of regulating cargo caught outside its jurisdiction." *Id.* at 531. However, ITLOS may have allowed broader protection for the environment at the detriment of trade. *Id.* at 536.

<sup>97</sup> Oliver, *supra* note 57, at 219.

subject to its jurisdiction.<sup>98</sup> Often to apply domestic law extraterritorially, courts consider whether the legislature *intended* the law to apply extraterritorially and whether such application would comply with international law.<sup>99</sup> Under this principle, application of domestic law at port to conduct outside the port is possible only if it has been authorized and the application complies with the strictures of international law.

The Permanent Court of Justice, with the *S.S. Lotus* case, recognized the effects principle, also known as the objective territoriality principle, in the international context.<sup>100</sup> With the effects principle, it is not necessary that there is a territorial violation of all elements of the State's law; it is enough that the violation lead to effects in the state.<sup>101</sup> In the United States, the principle found voice in the *Alcoa* case where the Second Circuit stated that "it is settled law ... that any state may impose liabilities even upon persons not within its allegiance, for conduct outside its borders that has *consequence within* its borders that the state reprehends."<sup>102</sup>

With the increasingly international scope of trade and the rise in international interaction, cooperation, and conflict, resulting from lowered barriers to the mobility of humans, capital, and information, the effects principle provides a method to regulate extraterritorial conduct.<sup>103</sup> The effects test, however, suffers from several problems. The test is difficult to apply first, in

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<sup>98</sup> *Id.* at 220.

<sup>99</sup> *Id.*

<sup>100</sup> "In the *S.S. Lotus* case, the court [in 1927] found that Turkey had jurisdiction to prosecute French citizens for injuries sustained by Turkish citizens after a collision [on the high sea] between a French steamer and a Turkish boat." Julie L. Henn, *Targeting Transnational Internet Content Regulation*, 21 BOSTON UNIV. INT'L L. J. 157, 161 (2003).

<sup>101</sup> David J. Gerber, *Prescriptive Authority: Global Markets as a Challenge to National Regulatory Systems*, 26 HOUS. J. INT'L L. 287, 294 (2004)

<sup>102</sup> *Id.* (quoting *United States v. Aluminum Co. of America*, 148 F.2d 416 (2d Cir. 1945)) (emphasis added).

<sup>103</sup> See Austen Parrish, *supra* note 81, at 1456-60.

determining what an “effect” is and second, when it is sufficient to warrant action.<sup>104</sup> However, although scrutiny is less mechanical than with the territorial jurisdiction principle, the effects principle does allow straightforward analysis in many instances.<sup>105</sup> For example, economic effects are relatively easy to recognize, as evidenced through the acceptance of the extraterritorial application of federal securities law and anti-trust actions.<sup>106</sup> Thus, when applied to economic effects, the primary concern is determining whether the effect is sufficient to warrant action.

Read broadly, the effects principle could result in universal application of domestic law since any act could have *some* effect, however tenuous, upon the interests of a state. Therefore, most jurisdictions recognize some limitations of the principle; *e.g.*, the United States applies a “reasonableness requirement as a threshold for applying national law to extraterritorial activities.”<sup>107</sup> Another limitation incorporated by the United States into the effects principle is that extraterritorial application is only available when the effects are “direct, substantial, and reasonably foreseeable.”<sup>108</sup> For example, the Foreign Trade Anti-trust Improvements Act of 1982 (“FTAIA”) limits the Sherman Act to domestic application except where foreign conduct “significantly harms imports, domestic commerce, or American exporters.”<sup>109</sup> In particular, the FTAIA states that the effect must be “direct, substantial, and reasonably foreseeable,” codifying common law limitations on the effects test.<sup>110</sup> In *Empagram*, the court considered price fixing

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<sup>104</sup> *Id.* at 1481-82.

<sup>105</sup> *See* Born, *supra* note 56, at 29.

<sup>106</sup> *Id.* at 45-48.

<sup>107</sup> Yulia A Timofeeva, *Worldwide Prescriptive Jurisdiction in Internet Content Controversies: A Comparative Analysis*, 20 CONN. J. INT’L L. 199, 205 (2005).

<sup>108</sup> Gerber, *supra* note 101, at 295 (in context of extraterritorial application of the Sherman Act).

<sup>109</sup> *F. Hoffman – La Roche LTD v. Empagram S.A.*, 542 U.S. 155, 155 (2004).

<sup>110</sup> *Id.* at 161.

by vitamin manufacturers outside the United States and concluded that the FTAIA can apply to only the effects within U.S. territory of the foreign action and not to independent foreign adverse effects.<sup>111</sup> The court espoused a territorial limit to the effects of harmful foreign action when applying the Sherman Act, and found the domestic economic effects to be significant enough to bring a claim.<sup>112</sup> Generalizing this notion, the effects principle must be limited to direct, substantial, and reasonable foreseeable actions that have domestic effects, when applied to economic effects, the principle should serve as a viable method to judge whether the application of domestic laws that have significant extraterritorial effects are warranted.

### **C. UNCLOS and Environmental Harm from Actions in International Waters**

Environmental harms quite often are an archetypical occurrence of the tragedy of the commons, where the producer of harm is not naturally subject to the cost of the harm and therefore does not have sufficient incentive to desist from acting in a destructive manner.<sup>113</sup> In the context of maritime law and commercial shipping, this may occur from substandard vessels, which pollute the environment or poor shipping practices such as high speeds, or improper routes that harm ocean life.<sup>114</sup> Because these harms affect port nations, *e.g.*, harming wildlife may affect the nation's tourism industry or environmental pollution in international waters may affect a nation's resources, customary laws and treaties have extended port state jurisdiction to vessels in international waters.<sup>115</sup>

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<sup>111</sup> *Id.* at 164.

<sup>112</sup> *Id.* at 173.

<sup>113</sup> Barton H. Thomson, *What Good is Economics?*, 37 U.C. DAVIS L. REV. 175, 187 (2003).

<sup>114</sup> Vincent J. Foley and Christopher R. Nolan, *The Erika Judgment – Environmental Liability and Places of Refuge: A Sea Change in Civil and Criminal Responsibility that the Maritime Community Must Heed*, 33 TUL. MAR. L.J. 42, 58-59(2008).

<sup>115</sup> Oystein Jensen, COSTAL STATE JURISDICTION AND VESSEL SOURCE POLLUTION, THE INTERNATIONAL LAW OF THE SEA FRAMEWORK FOR NORWEGIAN LEGISLATION, FNI REPORT 3/2006, 5 (The Fridtjof Nansen Institute 2006).

UNCLOS is an agreement ratified by a majority of nations that has been generally accepted as customary international law.<sup>116</sup> General obligations under Article 192 of Part XII of UNCLOS mandate that “[s]tates have an obligation to protect and preserve the marine environment.”<sup>117</sup> Moreover, while Article 193 recognizes state sovereignty to dispose of resources freely, Article 192 limits its application based upon the impact to the environment.<sup>118</sup> In addition, Article 194(2) requires states to take measures necessary to control their pollution such that it does not cause damage to “other states and their environment.”<sup>119</sup> These articles set customary environmental requirements for vessels operating on the open seas.

However, Article 218 of UNCLOS goes beyond traditional port-state jurisdiction that only allows port states to exercise authority over foreign flag vessels for actions in their territorial waters or ports. Article 218 allows states to exercise enforcement jurisdiction over vessels in their territory for acts that have occurred in either international waters or the waters of another state, albeit at the request of that state.<sup>120</sup> Thus, Article 218 of UNCLOS provides a mechanism for a claimant of damage to restrict such harmful action outside its normal jurisdiction. Hence, the purpose of these regulations is to prevent a situation where one state’s ships can take the most expedient course while harming unassociated states.

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<sup>116</sup> Signed by 159 nations, “UNCLOS created an international legal regime to govern the use of the high seas.” Nicholas H. Berg, *Bringing it All Back Home: The Fifth and Second Circuits Allowed Domestic Prosecution for Oil Record Book Violation on Foreign-Flagged Vessels*, 34 *TU. MAR. L.* 253, 258 (2009). Although the U.S. is a signatory to UNCLOS, they have not ratified the convention. Oliver, *supra* note 57, at 213. “UNCLOS is considered customary international law to which the United States adheres.” Foley, *supra* note 114, at 58-59.

<sup>117</sup> United Nations Convention on the Law of the Sea, art. 192, Dec. 10, 1982, 1833 U.N.T.S. 397 [hereinafter UNCLOS].

<sup>118</sup> *See id.* at art. 193.

<sup>119</sup> *Id.* at art. 194(2).

<sup>120</sup> Ho-Sam Bang, *Port State Jurisdiction and Article 218 of the UN Convention on the Law of the Sea*, 40 *J. MAR. L. & COM.* 291, 296 (2009). Note, however, that by taking action themselves, flag-states may preempt such action by a foreign state for unlawful discharges or other environmental harm. *Id.*

Although UNCLOS extends port state jurisdiction, there must be a relationship of the harm suffered to the state exercising jurisdiction. The port state must show that it has suffered a cognizable harm. “[T]he port state may institute legal proceedings against offenders” if a violation occurred in another state’s maritime zone and “the violation has caused or is likely to cause pollution in its own maritime zones.”<sup>121</sup> Thus, “the powers enjoyed by the port state authority under Article 218(2) are in essence those under the *effects principle*” where the action must have a recognizable effect on the state.<sup>122</sup>

#### **D. Weapons of Mass Destruction and Port States**

Another instance in which port states may extend their traditional jurisdiction to restrict vessels of another flag is under the concern of terrorism. In the United States, following the attacks on September 11, 2001, the government has extended efforts to contain weapons of mass destruction (“WMDs”).<sup>123</sup> The United States has fortified diplomatic efforts such as the Treaty on the Non-Proliferation of Nuclear Weapons (“NPT”), the Chemical Weapons Convention, and the Biological Weapons Conventions.<sup>124</sup> In addition, the United States has undertaken new initiatives such as the Proliferation Security Initiative (“PSI”), in which a loose alliance of countries focuses on restricting the movement of WMDs through shipping routes.<sup>125</sup> The PSI has been especially contentious because it envisions using combined intelligence from member

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<sup>121</sup> *Id.* at 297.

<sup>122</sup> *Id.*

<sup>123</sup> Daniel H. Joyner, *Jus Ad Bellum in the Age of WMD Proliferation*, 40 GEO. WASH. INT’L L. REV. 233, 236 (2008).

<sup>124</sup> Samuel E. Logan, *The Proliferation Security Initiative: Navigating the Legal Challenges*, 14 J. TRANSNAT’L L & POL. 254, 254 (2005).

<sup>125</sup> *Id.* at 255. The United States has also made advances to restrict the transshipment of illegal WMDs. See Bureau of Industry and Security, U.S. Dept. of Commerce, Statement of Principles at Global Transshipment Control Enforcement Conference (Sydney, Australia, July 15-18, 2003), available at [http://www.bis.doc.gov/complianceandenforcement/tecisydney7\\_03principles.htm..](http://www.bis.doc.gov/complianceandenforcement/tecisydney7_03principles.htm..)

nations to hinder ships on the open sea, which is beyond the traditional jurisdiction allowed by customary international law or UNCLOS.<sup>126</sup>

Without a doubt, one of the primary international norms is the right of innocent passage, which UNCLOS Article 19 defines to require states to permit the passage of ships unless the passage is “prejudicial to peace, good order, or security of the coastal state.”<sup>127</sup> For a state to have jurisdiction to hinder a vessel under UNCLOS, it would have to show that the transport of WMD results in a threat against it by force, threatens its “sovereignty, territorial or political independence, or violates some other principle of international law,” *and not in the future* but contemporaneously with the passage.<sup>128</sup> Thus, it is the transport of the WMD that must pose a threat and not the possible future use of the WMD.<sup>129</sup>

Under Article 25 of UNCLOS, a nondiscriminatory stoppage of all vessels is possible to conduct routine searches for *temporary* bans in *specified areas of territorial waters*—an area extending 12 miles beyond the coastal territory.<sup>130</sup> Beyond these routine searches though, there must be credible evidence that the passage is not innocent—presumably through solid intelligence.<sup>131</sup> This demonstrates that for states to act to circumscribe a traditionally held international norm there should be a significant *nexus with the territory*. However, in the internal water of a state and at its ports, that state has more freedom; subject to the international

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<sup>126</sup> Michael A. Becker, *The Shifting Public Order of the Oceans: Freedom of Navigation and the Interdiction of Ships at Sea*, 46 HARV. INT’L L.J. 131, 134 (2005).

<sup>127</sup> UNCLOS, art. 19, ¶ 1 at 404.

<sup>128</sup> Logan, *supra* note 124 at 259

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 261

<sup>131</sup> *Id.* at 261-62. However, it is likely that the world may accept some collateral damage in the hindrance of innocent passage to accomplish such an important goal. *Id.*

principles discussed earlier, they will have the freedom to inspect the contents of a foreign vessel at its port and seize its *illegal* cargo.<sup>132</sup>

In the examples of actions given above, where a state has applied its national laws on non-national property, either to vessels of transport or to goods in transit, it has done so because of a justifiable domestic effect. In the case of environmental pollution from substandard vessels, it is the direct harm to an associate state's resources or harm to its own resources that justifies extraterritorial jurisdiction. In the case of shipments of WMDs, the direct threat from terroristic activities upon its state presents the harmful effect.<sup>133</sup> In the case of liquor, it is the direct harm from the illegal entry of regulated substance into the domestic market. Finally, in the case of Chilean swordfish, it is the substantially direct depletion of its resources from its waters, which it relies upon economically, that, gives Chilean authorities the ability to restrict transshipments and subsequently apply its domestic laws having extraterritorial effects. In the same way, as discussed below, in order to seize legitimate pharmaceuticals, EU nations must also show a direct, substantial, and reasonably foreseeable effect upon its state by the transshipment of these goods through their ports.

### **III. GENERIC PHARMACEUTICALS AS A LEGITIMATE GOODS IN INTERNATIONAL TRADE**

The present state of Latin American health care has resulted from the conversion of public health institutions to privately managed companies, a result of policies promoted by

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<sup>132</sup> *Id.* at 265.

<sup>133</sup> However, some U.S. Courts state that these actions may be justified by the protective principle, recognized under international law to apply in a strict sense to dangers of security. Oliver, *supra* note 57, at 224. On the other hand, federal courts have required an "adequate nexus between the activity and the United States," demonstrating a limitation of the protective principle ultimately by some requisite effect. *Id.*



global lending agencies following governmental bankruptcies in the early 1990's.<sup>134</sup> By the late 1990's, with health delegated to the private sector, "access ... for the poor was shrinking," resulting in significant health crises in Latin America.<sup>135</sup> With the encouragement of international organizations, local governments increased access to life preserving medicines, in particular by using TRIPS flexibilities for less developed nations.<sup>136</sup> This enabled Latin American countries, whose poverty rates are generally between twenty to sixty percent, to obtain generic medicines.<sup>137</sup> Such intervention continues to be necessary since economic development is intimately tied to the health of their population—as health worsens, the country's economic output also decreases.<sup>138</sup> In this situation, the government has an obligation to intervene by supporting the availability of medicines.

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<sup>134</sup> Celia Iriart, Howard Waitzkin, & Emerson Merhy, *HMOs abroad: Managed Care in Latin America*, in *SICKNESS AND WEALTH* 69, 70-71 (Meredith P. Fort, Mary Ann Mercer, & Oscar Gish eds., 2004).

<sup>135</sup> *Id.* at 71, 73, 76.

<sup>136</sup> Press Release, Medecins Sans Frontieres, MSF Calls Upon Latin American governments to Guarantee Access to Medicines (November 13, 2003), <http://doctorswithoutborders.org/press/release.cfm?id=491&cat=press-release&ref=tag-index>; Servaas van Thiel, Public health versus intellectual property or how members of the World Trade Organization (WTO) without pharmaceutical production capacity could have access to affordable medicines in public health emergencies by using compulsory licenses, 5-8 (July 2003), <http://www.cid.harvard.edu/cidtrade/Papers/vanthiel.pdf>.

<sup>137</sup> See generally U.N. ECONOMIC COMMISSION FOR LATIN AMERICA AND THE CARIBBEAN [ECLAC], *The reactions of Latin American and Caribbean governments to the international crisis: an overview of policy measures up to 30 January 2009*, U.N. Doc. LC/L 3000, 37-69 (30 January 2009). Analysts expect these 2007 values to worsen with the global recession as Latin American countries have been hurt by the global economic recession of 2008-2009. See *id.* at 3. The availability of flexibilities is based upon the country's stage of development and its manufacturing capabilities. See generally World Trade Organization, Declaration on the TRIPS Agreement and Public Health of 9-14 Nov. 2001, WT/MIN(01)/DEC/2, available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.pdf](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf).

<sup>138</sup> C. James Attridge & Alexander S. Preker, *Improving Access to Medicines in Developing Countries, Application of New Institutional Economics to the Analysis of Manufacturing and Distribution Issues 1* (The World Bank's Human Development Network, Health Nutrition, and Population Discussion Paper, March 2005), available at

The present controversy involves generic pharmaceuticals that Indian companies have manufactured and subsequently shipped to Latin America. The WTO TRIPS Preamble requires that members should “ensure that measures and procedures [they undertake] to enforce intellectual property rights do not themselves become barrier to *legitimate* trade.”<sup>139</sup> In this section, we show that generic drugs that Rotterdam customs official seized and sent back to India were indeed legitimate goods that are entitled to be shipped under the provisions of GATT, UNCLOS, and TRIPS so that actions taken by EC nations require justification by the effects principle.

#### **A. TRIPS and Latin American Governments’ Importation of Generics**

MNCs support governmental intervention using government resources to provide direct financial aid to improve access to medicines.<sup>140</sup> However, international agreements allow other forms of governmental involvement.<sup>141</sup> Latin American governments, for example, can use compulsory licenses as allowed by TRIPS.<sup>142</sup>

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<http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/AttridgeImprovingAccessFinal.pdf>.

<sup>139</sup> TRIPS, Preamble (emphasis added).

<sup>140</sup> See GlaxoSmithKline Inc., Corporate Responsibility Report 2008: The role of others, available at <http://www.gsk.com/responsibility/role-of-others.htm> (last visited Apr. 4, 2010); Novartis, Inc., Access to medicines, available at <http://www.corporatecitizenship.novartis.com/patients/access-medicines.shtml> (last visited Apr. 4, 2010).

<sup>141</sup> See generally Laurinda L Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U. J. INT’L & POL’Y 769, 812-13 (1997). International IP protection, which developed under the Paris Convention for the Protection of Intellectual Property in 1883 to “eliminate discrimination ... [at] the national level,” allowed foreigners rights in IP but also granted compulsory licenses. *Id.* at 778-79.

<sup>142</sup> *Id.*

With TRIPS the WTO established a modern framework for IP protection “grounded in the principles of national and most favored nation treatment.”<sup>143</sup> At the same time, TRIPS incorporated limitations on patents, for national emergency and *public health*, by allowing governments the flexibility to apply compulsory licenses, where the government can force a patent holder to license its technology at a fair rate.<sup>144</sup> TRIPS flexibilities also enable least developed countries (“LDCs”) to forgo patent protection for pharmaceuticals until 2016.<sup>145</sup> In this way, while supporting and promoting patent protections through TRIPS, the WTO—and the World Health Organization (“WHO”)—understanding the potentially detrimental impact of IP protection on the access to medicines in developing nations, envisioned the use of generics to meet pharmaceutical needs.<sup>146</sup>

However, until the TRIPS Council Agreement resulting from the 2001 WTO meeting in Doha, Qatar, which issued the Doha Declaration, compulsory licensing limited generic medicines to *domestic* use.<sup>147</sup> With the Doha Declaration, explicitly recognizing a government’s power to issue compulsory licenses and granting qualified waivers of the export limitation, via TRIPS 31(f), countries that produce generic medicines could export them to developing nations

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<sup>143</sup> *Id.* at 784.

<sup>144</sup> *Id.* at 788. TRIPS effectively allows compulsory licenses to make the patent protected material without the authorization of the rights holder under limited circumstances. Subhasis Saha, *Patent Law and TRIPS: Compulsory Licensing of Patents and Pharmaceuticals*, 91 J. PAT. & TRADEMARK OFF. SOC’Y 364, 364-65 (2009)

<sup>145</sup> The countries are required to apply to the Trips Council. World Health Organization, *Medicines: WTO and the TRIPS Agreement*, [http://www.who.int/medicines/areas/policy/wto\\_trips/en/index.html](http://www.who.int/medicines/areas/policy/wto_trips/en/index.html) (last visited Apr. 3, 2010).

<sup>146</sup> *Id.*

<sup>147</sup> Article 31, which “implicitly provides for compulsory licensing,” and article 27(2), which recognizes the conflict of public health and IP protection, were used by South Africa to support compulsory licensing. Jessica J. Fayerman, *The Spirit of TRIPS and the Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 NW. J. INT’L L. & BUS. 257, 260-61 (2004).

lacking manufacturing capabilities.<sup>148</sup> Using 31(f), “a country that needs to import a drug ... [may] ask the government of a country that produces a generic version of the drug to authorize one of its manufacturers to export it, without the consent of the patent holder.”<sup>149</sup> Therefore, with use of compulsory licensing, the adoption of a 31(f) waiver of the limitations in exporting, and the use of a waiver for patent requirements for LDCs, Latin American nations that provide generic medicines to combat their national health crises are TRIPS compliant.

## **B. International Organizations’ Support of Latin American Use of Generics**

Non-governmental organizations (“NGOs”) have encouraged Latin American countries to promote access to medicines using compulsory licensing and have pushed Latin American countries to limit restricting the flexibilities allowed by TRIPS when negotiating continental free-trade agreements.<sup>150</sup> As necessitated by developmental goal and humanitarian concerns, and supported by these requests, Latin American governments have increased their reliance on generic medicines.<sup>151</sup> Latin American countries, such as Brazil, have promoted accessibility and ensured quality by taking steps such as demonstrating equivalence of the drugs, implementing

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<sup>148</sup> The Commission on Intellectual Property proposed a waiver to allow export of items created under compulsory license by article 31(f) of the TRIPS agreement. Roberta Parrish, *Does Waiver of Patent Restriction Clear Way for Generics in Poor Countries*, 16 HEALTH LAW 12, 14 (2004). This waiver was accepted by the WTO. *Id.* TRIPS required that exporters differentiate the goods to avoid confusion in the marketplace and avoid re-exportation. Fayerman, *supra* note 147, at 263-64.

<sup>149</sup> Roberta Parrish, *supra* note 148, at 15. “The requests have to be made in good faith and for no commercial gain.” *Id.*

<sup>150</sup> Medecins Sans Frontieres, Campaign for the Access to Medicines, Meet the Activist: Leena Menghaney, <http://www.msaccess.org/main/access-patents/meet-the-activist-leena-menghaney/> (last visited Apr. 8, 2010).

<sup>151</sup> Between 2004 to 2005 the generic sector in Latin America had increased by 26.9%. The Latin American Market for Generic Drugs – A Comparative Study of 7 Key Markets, ESPICOM Business Intelligence, *available at* [https://www.espicom.com/ProdCat.nsf/Product\\_ID\\_Lookup/00001287?OpenDocument](https://www.espicom.com/ProdCat.nsf/Product_ID_Lookup/00001287?OpenDocument).

good manufacturing practices, and applying post-approval procedures.<sup>152</sup> Thus, the generics market and its resulting cost savings improves the accessibility of the local population to quality pharmaceuticals primarily devoted to combating chronic disease in Latin American countries.<sup>153</sup>

Furthermore, multi-lateral trade agreements such as the South-South Cooperation (“SSC”) agreement also support Latin American access to generics through the TRIPS 31(f) waiver.<sup>154</sup> The United Nations recognizes SSC as a useful tool to implement the Millennium Development Goals (“MDG”), encouraging “a better quality of life for the world’s poor” by improving health.<sup>155</sup> Recent meetings amongst Brazil, India, and South Africa have concentrated upon the pharmaceutical sector as an area to increase SSC activities.<sup>156</sup>

While compulsory licensing, lack of patenting, the use of TRIPS 31(f), and multi-lateral trade agreements involving generic pharmaceuticals may result in revenue pressures for MNCs,

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<sup>152</sup> *Id.* at 31-33

<sup>153</sup> *Id.* at 33-34. While Brazil’s results are atypical, the results support the view that accessibility of generics can follow hand-in hand with quality medicines. *See id.* at 36. However, in response, MNCs have argued that these generic policies fail to deliver *quality* medicines, which is a legitimate concern because when governments are focusing on affordability, quality may degrade. Vera Valente, *Generics in Latin American: An analysis of Brazilian experience*, 4 JOURNAL OF GENERIC MEDICINES 30, 30-31 (October 2006).

<sup>154</sup> SSC was undertaken by “industrialized southern countries and lesser developed nations of the southern hemisphere” for mutual benefit through technical and monetary cooperation. Gary Corbin, *South-South Cooperation Defies the North*, MercyCorps (December 6, 2006), available at <http://www.globalenvision.org/library/3/1371>.

<sup>155</sup> Anwarul K. Chowdhury, Under-Secretary-General and High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, *Celebrating the Global South: Diversity and Creativity*, Statement for the United Nations Day for South-South Cooperation at Trusteeship Council at United Nations Headquarters, NY (19 December 2005), available at <http://www.un.org/special-rep/ohrlls/Statements/19%20Dec%2005%20-%20South-South%20Cooperation.pdf>.

<sup>156</sup> Indranil Banerjee, *Development: Turning South-South Rhetoric into Action*, INTERPRESS SERVICE NEWS AGENCY, October 15, 2008, available at <http://ipsnews.net/news.asp?idnews=44265>. These meetings follow free trade agreement between Mercosur – “an integration of the economies of Argentina, Brazil, Uruguay, and Paraguay” – and India. Ranja Sengupta, *Free Trade Between Mercosur and India*, GLOBAL POLICY FORUM, July 18, 2003, available at <http://www.globalpolicy.org/component/content/article/162/27877.html>.

their use is supported by NGOs, the UN, and by global trade agreements to alleviate the Latin American health crises and complies with international agreements.<sup>157</sup> Thus, the importation of generic medicines by Latin American countries is *legitimate trade* protected by TRIPS and championed by international organizations.

#### **IV. EC MEMBER NATIONS' SEIZURE OF GENERIC PHARMACEUTICALS AS GOODS IN TRANSIT: USE OF THE EFFECTS PRINCIPLE**

MNCs are increasing the cost of generic drugs shipped to Latin American countries by improperly using EC regulations to hinder the transfer of goods from manufacturers to purchasers.<sup>158</sup> By allowing MNCs to use EC 1383 to impound medicines intended for developing Latin American countries, some EC member nations are improperly administering IP protection, intended for national use, extraterritorially.<sup>159</sup> Such an application of EC 1383, using the manufacturing fiction doctrine, discussed below, oversteps the maximum TRIPS IP protection available to WTO member nations.<sup>160</sup> Moreover, it is inconsistent with international agreements such as GATT and UNCLOS. Rather than using the manufacturing fiction doctrine to support the seizure of legitimate goods, member nations should analyze their exercise of EC 1383 under the effects principle.

##### **A. Need to Regulate Counterfeit Pharmaceuticals**

Counterfeit medicines—those that are deliberately and fraudulently labeled to mislead the consumer and those that have improper active ingredients—are an issue for both the brand name

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<sup>157</sup> P.B. Jayakumar, *MNC Drug Makers Eye Generics in India, Other Emerging Countries*, BUSINESS STANDARD, April 3, 2009, available at <http://www.business-standard.com/india/news/mnc-drug-makers-eye-generics-in-india-other-emerging-countries/353814/>.

<sup>158</sup> Medecins Sans Frontieres, *supra* note 136.

<sup>159</sup> See Giordano-Coltart, *supra* note 23, at \*24.

<sup>160</sup> Shashank Kumar, *Kumar: Freedom of Transit and Trade in Generic Pharmaceuticals*, INT'L LAW REPORTER, May 9, 2009, [http://ilreports.blogspot.com/2009\\_05\\_03\\_archive.html](http://ilreports.blogspot.com/2009_05_03_archive.html).

and generic medicine marketplace.<sup>161</sup> For obvious reasons they pose a health risk causing drug resistance, therapeutic failure, and possibly even death.<sup>162</sup> This is a problem for both developed and developing nations: in one instance, counterfeit drugs have been introduced to the United States market through free-trade zones, areas where goods can be transshipped without entering customs, in Dubai;<sup>163</sup> in another, when customs officials intercepted drugs at Heathrow Airport in London, the mislabeled pharmaceuticals—counterfeits of Merck, Novartis, AstraZeneca, Pfizer, and Proctor & Gamble—were being transshipped to the Bahamas.<sup>164</sup> However, counterfeiting is especially serious in developing countries, where “supply shortages, lax regulations and oversight, and corruption allow the trade to thrive.”<sup>165</sup>

Recognizing problems created by counterfeits, not just for pharmaceuticals but also for a wide range of goods, TRIPS obligated member states to implement laws to enable trademark and copyright owners a means to prevent counterfeit trademark and pirated copyright goods from entering their markets.<sup>166</sup> In particular, rights holders having “valid grounds” may file an application with the government to have customs authorities detain suspect goods.<sup>167</sup> However, TRIPS requirements and GATT provisions requiring members to prevent hindrances of trade, as

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<sup>161</sup> Counterfeit Drugs Kill!, World Health Organization, 2 (18 Feb. 2006), *available at* <http://www.gphf.org/images/downloads/impactbrochure.pdf>.

<sup>162</sup> *Id.*

<sup>163</sup> Walt Bogdanich, *Free Trade Zones Ease Passage of Counterfeit Drugs to U.S.*, NEW YORK TIMES (Dec. 17, 2007).

<sup>164</sup> These free trade zones, where customs official do not sufficiently regulate conduct, result in areas where illegal actions can risk international health. Brendan P. Geary, *Counterfeiting in the Global Drug Trade Poses International Health Risks*, GEORGETOWN UNIV. BLOG, posted Dec. 18, 2007, *available at* <http://blogs.georgetown.edu/?id=30035>.

<sup>165</sup> Wyatt Yankus, *Counterfeit Drugs: Coming to a Pharmacy Near You (Condensed Version)*, American Council on Science and Health, August 24, 2006, *available at* [http://www.acsh.org/publications/pubid.1384/pub\\_detail.asp](http://www.acsh.org/publications/pubid.1384/pub_detail.asp).

<sup>166</sup> TRIPS, Art. 51. TRIPS sets only minimum requirements, allowing states to go beyond these stipulations, and specifies that states have a right to apply these required provisions to other intellectual property, such as patents.

<sup>167</sup> TRIPS, Art. 51.

discussed above, place limits on how states can apply their anti-counterfeit laws to prevent the entry of illegal goods into their markets.<sup>168</sup> Accordingly, TRIPS recognizes the problems associated with counterfeit trade and requires member nations to implement national laws to give rights holders recourse. It is with the TRIPS requirements in mind that EC nations modified their border protections and implemented EC 1383.

## **B. Improperly Broad Application of EC 1383/2003 to Seize Transshipped Goods**

European Community nations have implemented EC 1383 as the latest in a series of measures undertaken to limit IP infringement within their member states. First, in 1986, the Community enacted Council Regulation EEC No. 3842/86, prohibiting the circulation of goods that infringed trademark rights, and then in 1994, EC nations expanded protection through EC regulation No. 3295/94 to prohibit the circulation, exportation, and importation of counterfeit goods and goods violating copyright protection, *i.e.*, pirated goods.<sup>169</sup> Later, in 1999, the Community added enforcement for patent violations.<sup>170</sup> The latest regulation, EC 1383, expanded the power of customs officials and made it easier for rights holders to request action to impound goods violating IP rights.<sup>171</sup>

EC 1383 grants member nations' customs authorities the right to take action against goods suspected of infringing their national IP rights, stating in particular that

[i]n cases where ... goods infringing on *intellectual property rights* originate in or come from *third countries*, their introduction into the community customs

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<sup>168</sup> Note that TRIPS explicitly makes clear that members have no obligation to apply such seizures to transshipped goods. TRIPS, Art. 51, Footnote 13.

<sup>169</sup> Council Regulation (EC) No 3295/94 of 22 December 1994, 1994 O.J. (L341) 8 [hereinafter "EC No 3295/94"].

<sup>170</sup> Council Regulation (EC) No 241/1999 of 25 January 1999, 1999 O.J. (L027) 02/02/1999 [hereinafter "EC No 241/1999"].

<sup>171</sup> See Council Regulation (EC) No 1383/2003 of 22 July 2003 [hereinafter "EC 1383"], art. 5, 2003 O.J. (L 196) 7.



territory, including their *transshipment*, ... shall be prohibited and a procedure set up to enable the customs authorities to enforce this prohibition as effectively as possible.<sup>172</sup>

Thus, EC 1383, read broadly, *could* provide for the seizure of infringing, imported goods as well as infringing goods that are *not destined* for countries within the Community, i.e., goods in transshipment that have not attempted to clear customs.<sup>173</sup> In fact, this particular issue has been considered by the Dutch Group of AIPPI, a NGO that formulates local IP policy.<sup>174</sup> Supporting the seizures by customs officials, they have stated that Article 16 of EC 1383 *prohibits any further trade* in goods that “infringe an IP right,” including goods in transit that have entered community customs territory.<sup>175</sup> However, there must be a basis to argue that goods are infringing EC member states’ IP rights when the only contact that these goods have with these states is during the transshipment.

For this reason, Dutch courts permitting these seizures employ the manufacturing fiction doctrine, also known as the production fiction doctrine, under which courts treat goods in transit as manufactured in the state where the customs action is brought.<sup>176</sup> Application of this doctrine causes goods in transit to infringe an exclusive right of the patent holder to “make, use, put on

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<sup>172</sup> *Id.* ¶ 3 (emphasis added).

<sup>173</sup> *Id.*

<sup>174</sup> Gertjan Kuipers (chairman), Manon rieger-Jansen, Bas Pinckaers, Faisal Van Vesel, Jef Vandeckerckhove, Border Measures and other means of custom Intervention against Infringers, In the name of the Dutch Group of the AIPPI by 2009, Netherlands, Report Q208 (2009), available at <http://www.aippi.nl/uploads///Q208%20NL%201.PDF>.

<sup>175</sup> *Id.*

<sup>176</sup> Paul Maeyaert, Grey and counterfeit goods in transit: trademark law in no-man’s land, IAM Magazine 12, 14 (June 8, 2009), available at <http://www.iam-magazine.com/issues/Article.ashx?g=e5225bb7-e7ac-4231-853e-6415dae67879>. Per EC 1383/2003, the manufacturing fiction doctrine stems from Recital 8, which states that “[p]roceedings initiated to determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods *produced in that Member State* infringe intellectual property rights.” Council Regulation 1383/2003, 2003 O.J. (L 196) 8 (EC) (emphasis added).

the market or resell, hire out or deliver the patented invention, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes,” because the goods are assumed to be made in the EC nation where such manufacture would be illegal.<sup>177</sup>

The manufacturing fiction doctrine was applied under EC 3295/94 in the European Court of Justice (“ECJ”) case *Polo Lauren v. Dwidua*.<sup>178</sup> In this case, a U.S. trademark owner brought an action against an Indonesian consignee shipping goods through Austrian customs.<sup>179</sup> The ECJ held that because the goods would have been illegal *if manufactured in Austria*, the trademark owners could prohibit their transit.<sup>180</sup> Netherlands has applied the manufacturing fiction doctrine to patent infringement since 2004, where its Supreme Court held that a consignment of CD-R disks from Taiwan violated Philips, Inc.’s patent rights, without requiring the rights holder to show that the goods would enter the European market.<sup>181</sup> Thus, the Netherlands customs authorities’ seizure of Losartan is consistent with their previous application of domestic law to

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<sup>177</sup> LUCIE GUIBAULT OT VAN DAALEN, UNRAVELLING THE MYTH AROUND OPEN SOURCE LICENCES – AN ANALYSIS FROM A DUTCH AND EUROPEAN LAW PERSPECTIVE 91 (TMC Asser Press, The Hague, 2005), draft available at [http://www.ivir.nl/publications/guibault/unravelling\\_the\\_myth\\_around\\_open\\_source\\_licences.pdf](http://www.ivir.nl/publications/guibault/unravelling_the_myth_around_open_source_licences.pdf). The European Patent Convention (“EPC”) which grants patents is entirely separate from the European Community, however, these patents form a “‘bundle’ of national patents which have to be validated, maintained and litigated separately in each Member State.” *Id.* In the Netherlands, an inventor may choose to obtain a strictly national patent per the Dutch Patent Act or an EPC Patent with a Netherlands designation. *Id.* at 92. Pharmaceutical MNCs almost universally choose the latter.

<sup>178</sup> Case C-383/98, *Polo/Lauren Co. v Dwidua LP Int’l Freight Forwarders*, 2000 E.C.R. 1-02519, ECJ.

<sup>179</sup> *Id.*

<sup>180</sup> A56: Jens van den Brink, *Comeback for the Legal Fiction of the Anti Piracy Regulation?* Kennedy Van der Lann Newsletter (Aug. 2008), *available at* [http://www.kennedyvanderlaan.nl/KVdL/en-GB/\\_main/News/Newsletter/Newsletter+August+2008/Anti+Piracy+Regulation\\_IP/default.htm](http://www.kennedyvanderlaan.nl/KVdL/en-GB/_main/News/Newsletter/Newsletter+August+2008/Anti+Piracy+Regulation_IP/default.htm).

<sup>181</sup> Geert Theuws, Howrey, LLP, *ECJ to Decide on ‘Manufacturing Fiction’ under Counterfeit Goods Regulation*, EPLAW Patent Blog, posted on Dec. 20, 2009, *available at* <http://www.eplawpatentblog.com/eplaw/sisvel>.

prevent the transshipment of goods that violate local patents using the manufacturing fiction doctrine.

However, recent ECJ decisions may render the application of this doctrine to EC 1383 questionable.<sup>182</sup> For example, in *Class International* the ECJ held that trademark owners attempting to prevent infringement under the Trademark Directive 89/104 (“89/104”) should not obstruct the movement of goods-in-transit without showing that items *will* be released into the member nation’s market.<sup>183</sup> The court further limited importation to mean goods *to be placed* in the Community market—not simply entering the member nation for external transit or transshipment.<sup>184</sup> Then, in *Montex*, while analyzing a lower court question as to whether 89/104 allowed a trademark owner the right to prohibit transit of goods, the ECJ followed *Class International*, allowing the free external transit of fake Diesel jeans to countries that did not protect the trademark.<sup>185</sup> The court also held that infringement must be judged by considering the status of the mark in the *destination* country.<sup>186</sup> The court further held that to prohibit transit the trademark owner must establish, “either the existence of a release for free circulation of the non-Community goods bearing his mark in a Member State in which the mark is protected, or of another act necessarily entailing their being put on the market in such a Member state.”<sup>187</sup>

Thus, there is currently debate, fueled in part by the *Montex* decision, as to whether the manufacturing fiction doctrine applies to 1383 in general and patents in particular. Opponents of the doctrine hold that *Montex* essentially did away with the doctrine while proponents argue that

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<sup>182</sup> *Id.*

<sup>183</sup> Case C-405/03, *Class International BV v. Colgate-Palmolive Company and Others*, 2006 1 C.M.L.R. 14 at 325.

<sup>184</sup> *Id.* at 324-25.

<sup>185</sup> Case C-281/05, *Montex Holdings Ltd v. Diesel SpA*, 2006 E.C.R. I-10881, Ruling ¶ 1.

<sup>186</sup> *Id.*

<sup>187</sup> *Id.* at ¶ 26.

*Montex* was not analyzing 1383 but rather the Trademark Directive 89/104, *i.e.*, that the court did not speak to viability of the doctrine applying to 1383.<sup>188</sup> Recently, in a July 2008 case, *Sosecal v. Sisvel*, the District Court for The Hague, which decides Dutch patent cases, held that the latter interpretation of *Montex* was correct and the manufacturing fiction is applicable—at least in its jurisdiction.<sup>189</sup> The ECJ still has to speak on the issue. By interpreting EC 1383 to apply to goods *purely* in transit, the legality of shipped pharmaceutical is dependent on the IP rights of the Community port where it makes an incidental stop to its Latin American destination.<sup>190</sup> In this way, although the ECJ has prohibited seizing goods that will not enter the member nation’s protected market, the practice continues in some European Community member nations, *e.g.*, the Netherlands, where customs officials seized Losartan.

### **C. Need for EC Member Nations to Comply with EC Laws and International Trade Agreements in Applying EC 1383/2003**

EC member nations generally have an obligation to interpret national laws to comply with Community regulations.<sup>191</sup> Following this principle, the High Court of Justice, Chancery Division, in the U.K. used *Montex* to support Her Majesty’s Commissioners of Revenue and Customs’ refusal to detain fake cell phones in transit through the EU under EC 1383.<sup>192</sup> Nokia, Inc., sought the seizure of cell phones manufactured in Asia and transported to third nations

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<sup>188</sup> Theuws, *supra* note 181.

<sup>189</sup> *Sosecal Industria e Comercio Ltda v. Societa Italiana Lo Sviluppo Dell’ Elettronica* – Case No. 311378 (Court of the Hague 2008).

<sup>190</sup> EC 1383 defines infringing items as “goods which in the member state in which the application for customs action is made, infringe ... *under that member state’s law.*” EC No 1383/2003 art. 2. In *Rolux*, the ECJ found EC 3294/94 – and therefore EC 1383 – applies to goods in transit *between two non-member nations*. Case C-60/02, Criminal Proceedings against X, 2004 E.C.R. I-651 Ruling ¶ 1.

<sup>191</sup> Case C-12/08, *Mono Car Styling SA, in liquidation v Dervis Odemis and Others* Reference, 2009 WL 2143654 at ¶ 61 (ECJ July 16, 2009).

<sup>192</sup> *Nokia Corp. v. Revenue & Customs Commissioners*, [2009] E.T.M.R. 59 ¶ 79-80 (Ch.).

through the U.K.<sup>193</sup> The Court held that these items were not counterfeit because *as goods in transit*, they were *never to be placed on the U.K. market* to infringe the trademark.<sup>194</sup> The Court also refused to espouse the manufacturing fiction doctrine, establishing that it is contrary to *Montex*.<sup>195</sup> Most importantly, the Court specifically stated that it is unlikely that EC 1383 authorizes “goods *lawfully made in one territory* and intended for *lawful use in another* but transshipped through a Member state in which the mark is registered ... [to] be ... seiz[ed].”<sup>196</sup> Unfortunately, this is exactly what occurred when member nations, such as the Netherlands, who are under the same obligation as the United Kingdom to apply ECJ holdings, seized generic pharmaceuticals in transit to Latin America. Rather than relying upon the manufacturing fiction doctrine, EC nations who wish to seize drugs in transit should link the effects of the transport of these drugs through their ports to a significant effect on their market.

In addition, member nations of the WTO are obligated to implement TRIPS.<sup>197</sup> TRIPS requires member countries to establish IP laws that enforce IP rights only “in such a manner [so as] to avoid the creation of barriers to *legitimate trade*.”<sup>198</sup> The agreement defines legitimate trade as that which is “justifiable ... by relevant public policies,”<sup>199</sup> and takes into account public

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<sup>193</sup> *See id.* ¶ 6.

<sup>194</sup> *See id.* ¶ 49.

<sup>195</sup> *Id.* at ¶ 76.

<sup>196</sup> *Id.* (emphasis added).

<sup>197</sup> *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 319, 33 I.L.M. 1125, 1197 (1994) [hereinafter “TRIPS”], art. 8.

<sup>198</sup> TRIPS, art. 41 (emphasis added).

<sup>199</sup> Xavier Seuba, *Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit* 9 (INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT, Working Paper for Programme on IPRs and Sustainable Development, June 2009), available at [http://ictsd.net/downloads/2009/08/border-measures-concerning-goods-allegedly-infringing-intellectual-property-rights\\_the-seizures-of-generic-medicines-in-transit.pdf](http://ictsd.net/downloads/2009/08/border-measures-concerning-goods-allegedly-infringing-intellectual-property-rights_the-seizures-of-generic-medicines-in-transit.pdf); TRIPS, art. 41.

interest. Previous sections have shown that the international community recognizes generic pharmaceuticals as legitimate goods. While the general view of TRIPS is that it sets only minimum requirements, allowing member nations to expand IP protections, TRIPS also sets mandates on the application of IP law to goods in transit by requiring that the rights in the *country of importation* should determine the infringement status of goods.<sup>200</sup> In this manner, TRIPS requires that EC member nations evaluate goods in transit according to the IP laws in the goods' *destination* countries.<sup>201</sup> Therefore, while Dutch officials attempt to interpret EC 1383 through the manufacturing fiction doctrine to justify their actions in seizing legal pharmaceuticals, ECJ holdings, other member nations' execution of EC 1383, and requirements for compliance with TRIPS, indicate that EC 1383 may not support the seizures of these pharmaceuticals in transit through this doctrine.<sup>202</sup>

#### **D. The Effects Principle Applied to Analyze Seizures under 1383/2003**

In applying EC 1383 to goods in transit, the ECJ should explicitly endorse the effects principle. As shown above, the United States and other nations have used the effects principle to justify the regulation of foreign conduct. In the economic context, this typically involves the action of the foreign government where the corporation or person violating a local policy is located. For example, in the U.S. anti-trust context, enforcement mechanisms typically flow through multinational agreement with the local governments of the violating corporation.<sup>203</sup> Thus, the action by a nation to apply its laws would be *directly* extraterritorial in nature. In the

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<sup>200</sup> WTO, Intellectual Property (TRIPS): Negotiation, Implementation, and TRIPS Council Work, [http://www.wto.org/english/thewto\\_e/minist\\_e/min99\\_e/english/about\\_e/10trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/10trips_e.htm); TRIPS, art. 52.

<sup>201</sup> *Id.*

<sup>202</sup> Kuipers, *supra* note 174.

<sup>203</sup> See Jordan A. Dresnick, et. al., *The United States as Global Cop: Defining the Substantial Effects Test in U.S. Anti-trust Enforcement in the Americas and Abroad*, 40 U. MIAMI INTER-AM. L. REV. 453, 489-90 (2009).

situation of EC official acting in their home port, however, these EC nations should use the effects test to justify the territorial action EC nations take, which have *indirect* extraterritorial consequences. Thus, this application of the effects principle is slightly different from the traditional approach but nonetheless applicable.

As discussed above, it is important to justify these seizures from an international perspective because of agreements that EC nations have entered into that constrains their action at port and the resultant effective expansion of the reach of their national patent laws. In some ways this is a balancing test, considering whether the national effects from continued transshipment of the pharmaceuticals outweighs the international effects from seizure. In order for EC nations to seize and prevent the onward transport of these drugs, the transshipment through their ports must have a direct, substantial, and reasonably foreseeable effect on their domestic market that significantly outweighs foreign detriment from restrictions in transshipment.

Arguments against the effects principle center upon the claim that it gives too much discretion to the judiciary, which in turn can lead to universal application of domestic laws.<sup>204</sup> However, this is not the case when only direct, substantial, and reasonably foreseeable effects are able to compel seizures. In this context, if the pharmaceuticals in transit were being imported, they could be regulated without relying upon the manufacturing fiction doctrine, and there is not a question of effectively extraterritorial application of domestic law. On the other hand, the effects principle analysis is necessary in pure transshipment and applicable if the goods could credibly find their way into community markets. If domestic leakage occurs in substantial number to have a reasonably foreseeable effect on the market, the state would then have a

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<sup>204</sup> Austen Parrish, *supra* note 81 at 1478-82.

legitimate right to enforce its local patent laws to transshipped goods. The goods in transshipment could be confiscated and seized on the basis that they were contributing to this leakage. Thus, in this case, when the measure of effect is economic harm, as in the anti-trust and securities context, the result of damage from leaked goods into the market should be evident from the use of the pharmaceuticals in the market and the subsequent financial losses to the brand name drugs.

As in the case of environmental law under UNCLOS, if the acts that are outside of a state's borders, i.e., the manufacture and the sale of "infringing" goods involving only non-EC nations, would lead to a cognizable harm to the state itself, the state should have a right to seize these goods. Such enforcement has already occurred, as evidenced through the application of the Volstead Act and debated in the Chilean swordfish dispute where extraterritorial actions, which were significant, direct, and reasonably anticipated to affect national interests, were curtailed. However, unlike the transshipment of liquor, a modern view should be espoused which attempts to appropriately justify the seizure of goods that pose a substantial economic threat to domestic markets. In the case of the seizure of Losartan by Dutch authorities, without presenting credible evidence of leakage into protected markets, which has a significant economic effect, the action of seizing the goods and diverting them back to the source country are likely not justified under the effects principle.

However, the lack of justification in this case should not be the determining factor in applying this test. Rather, the EC should consider the increasingly interconnected nature of trade and the possible retaliatory effects from unjustifiably restricting the trade of legitimate goods. These considerations underlie the increasing use of the effects principle to justify extraterritorial actions. And although the action by EC customs officials are in the strictest sense territorial,



they have significant extraterritorial effects such that EC customs officials must justify their action in an international context using the effects principle.

## **V. CONCLUSION**

EC customs officials have applied EC 1383/2003 to seize transshipped generic pharmaceuticals under the theory that local intellectual property laws apply per the manufacturing fiction doctrine to pharmaceutical manufactured in and destined for foreign nations. These actions result in raising barriers to legitimate trade and are contrary to EC nations' international obligations. These actions also result in local patent laws, which are territorially restricted, having extraterritorial implications. Rather than rely upon a legal fiction, these EC states should use an effects principle analysis to determine whether the impact of these goods upon local markets justifies restricting their transshipment through seizures. The effects in this circumstance are sufficiently measurable and the effects principle can be sufficiently constrained to provide a reasonable basis to analyze the appropriateness of these seizures.