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

Soji John[*]

Introduction

On several recent occasions, European Union ("EU") (formerly the European Community ("EC"))[1] customs officials seized generic pharmaceuticals at Union ports that non-EU manufacturers sought to transship to non-EU markets.[2] In order to secure the release of these drugs, the manufacturers have had to recall the shipments rather than sending them forward to the destination countries.[3] These European nations seem to be within their rights to hinder the free passage of these goods. After all, vessels entering a port are typically subject to the jurisdiction of the sovereign state.[4] However, by detaining legitimate goods, these nations are applying their domestic patent laws in a manner that is *effectively* extraterritorial. Although their actions are territorial, by using their customs facilities and ports in a manner that may be contrary to international norms and agreements, these European nations are essentially expanding their

∗ The author thanks Professor Anthony Colangelo of The Southern Methodist University Dedman School of Law for his help with this article. His comments and guidance were invaluable in its preparation. Any errors are attributable solely to the author.

1 Coming into force on December 1, 2009, the Treaty of Lisbon resulted in amendment of the Treaty on European Union. Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, Dec. 13, 2007, 2007 O.J. (C306) 1. This caused the European Union ("EU") to "replace and succeed" the European Community ("EC"). *Id.* art. 1(2)(b).

2 Martin Khor, *Row over Seizure of Low-Cost Drugs*, STAR ONLINE (Aug. 10, 2009) (citing John W. Miller and Geeta Anand, *Corporate News: India to Fight EU Drug Delays in WTO Complaint*, WALL ST. J., Aug. 6, 2009, at B4), http://thestar.com.my/columnists/story.asp?file=/2009/8/10/columnists/globaltrends/4487956&sec=Global%20Trends (last visited Oct. 16, 2011). 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. *See id.*

3 *See id.* (reporting that a shipment of Losartan was returned to India after being held by Dutch customs).

4 RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 512 n.5 (1987).

patent laws, which are understood to be bounded nationally, to have significant extraterritorial effects.

Jurisdictional issues implicate limits on the rights of sovereigns to exert influence over other states, 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.[5] Therefore, while municipal laws dominate national conduct, they are correspondingly limited internationally.[6]

The modern view is that states must give an appropriate basis for exercising extraterritorial jurisdiction.[7] For example, the Third Restatement of Foreign Relations Law supports jurisdiction over foreign conduct that is "directed against . . . a limited class" of national interests.[8] At the same time, the Third Restatement limits this power, utilizing a reasonableness test to analyze the validity of the exercise of extraterritorial jurisdiction.[9] Thus, while local law restricts jurisdiction nationally, additional international principles generally limit extraterritorial jurisdiction. As a result, nations need affirmatively to justify this extraterritorial exercise of power.

This paper considers the limits on the application of domestic customs law to transshipped goods at local ports. It proposes that the exercise of local customs laws to seize goods in transshipment should be restricted to those cases where there is an appropriate nexus between the supposed violations of domestic law and the interests of the port nation, even though it is internationally accepted that port states have jurisdiction over vessels that enter their port. In particular this paper contends that the broad application of EC Regulation No. 1383/2003[10] ("EC 1383") by

5 LORI F. DAMROSCH ET AL., INTERNATIONAL LAW CASES AND MATERIALS 757-58 (5th ed. 2009).

6 *Id.*

7 *See id.* at 758.

8 RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 402 (1987).

9 *Id.* § 403.

10 Council Regulation 1383/2003, Concerning Customs Action Against Goods Suspected of Infringing Certain Intellectual Property Rights and the Measures to be Taken Against

European nations' customs officials to seize generic pharmaceuticals transshipped from India to Latin American nations improperly extends the reach of local patent laws extraterritorially and hinders trade. Further it asserts that in order to determine when applying domestic law to transshipped goods is appropriate, the EU should promote the use of the effects principle.

Part I of this paper explains that the seizure of goods purely in transit, such as generic pharmaceuticals, is controversial, even within the EU. Part II addresses the evolution of extraterritorial application of domestic customs regulations, including the use of the effects principle. Part III posits that the EU's pharmaceutical transshipment intervention is illegitimate under the effects principle and international law. Finally, part IV advocates for using the effects principle to guide extraterritorial application of EC 1383 customs regulations.

I. EU and International Customs Regulations of Transshipped Goods

The seizure of goods that are solely transiting through a port state by customs officials is a highly controversial issue. International treaties have attempted to balance the competing interests of efficient trade and intellectual property ("IP") protection by focusing on facilitating trade to the greatest extent possible within the parameters of minimum requirements of participating states to protect patent rights. Nonetheless, the conflict between safeguarding patent rights and promoting the free flow of goods remains apparent with the seizure of transshipped goods such as pharmaceuticals, even within the EU. For example, the United Kingdom ("U.K.") has limited the application of EC 1383 to seize only goods that could enter and affect its markets, while Netherlands officials promote a broader reading of the statute, allowing seizure of goods without regard to direct effects on its market.[11] This section will analyze the controversy surrounding the confiscation of pharmaceuticals transiting through the EU, within the context of international law.

Goods Found to Have Infringed Such Rights, art. 5, 2003 O.J. (L 196) 7, 9-10 (EC) [hereinafter EC 1383].

11 *See* Rb. Gravenhage 18 juli 2008, rolnr. 311378 / KG ZA 08-617 (Sosecal Industria e Comercio Ltda/Societa Italiana Lo Syiluppo Dell' Elettronica) (Neth.), *available at* http://www.eplawpatentblog.com/PDF_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf; Nokia Corp. v. Her Majesty's Comm'r of Revenue & Customs, [2009] EWHC (Ch) 1903, [79]-[80].

A. EU Customs Officials' Controversial Seizures of Generic Pharmaceuticals in Transshipment

During the past two years, EU member nations have intercepted and prevented the onward shipment of generic medicines en route to developing Latin American countries for IP violations.[12] Largely at the behest of multi-national pharmaceutical corporations ("MNCs"), EU member nations seized these goods despite the absence of patent protection or trademark infringement in the manufacturing or destination country.[13] World organizations monitoring access to drugs are concerned that these seizures are not incidental, but rather 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.[14]

For example, developing nations which were denied transshipments of these pharmaceuticals were especially critical of a December 2008 seizure of Losartan, a generic version of the brand name drug, Cozarr.[15] Customs officials in Rotterdam, Netherlands seized this shipment en route to Brazil at the prompting of Merck Inc., which holds the Dutch patents on Cozarr.[16] These officials relied on their *national* interpretation of EC 1383, designed to restrict goods violating IP rights, and confiscated these drugs

12 Khor, *supra* note 2. Germany and the Netherlands have intercepted the following medicines: Clopidrogel, a blood thinner; Rivastigmine for Alzheimer's disease; Olanzapine, an anti-psychotic; and Losartan, for high blood pressure. *Id.*

13 *Id.* Compulsory licensing enables a government to allow the production of medicine without the patent owner's permission. *Compulsory Licensing of Pharmaceuticals and TRIPS*, WORLD TRADE ORG. (Sept. 2006), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited Oct. 16, 2011).

14 *See* Peter Maybarduk, *Stop Fakes, Not Generics*, ACCESS TO MED. PROJECT (May 13, 2009), http://www.essentialaction.org/access/index.php?/archives/181-Stop-Fakes,-Not-Generics.html#extended (stating that pharmaceutical companies deliberately confuse patent rights and trademark counterfeiting issues and exploit public safety concerns to protect their monopolies).

15 *See* Goran Danilovic, *Recent Dutch Seizures of Generic Drugs Add Fire to the WTO Dispute Regarding Seizure of Goods in Transit*, LEXOLOGY (March 23, 2009), http://www.lexology.com/library/detail.aspx?g=06012359-6993-4ee8-a8e5-e3a93ef4c245.

16 *See id.*

ostensibly for patent violations and to prevent the proliferation of substandard medications.[17]

The quality of medicines can be a genuine concern since counterfeit medicines have caused health issues throughout the world. Because counterfeiting occurs for generics as well as brand-name medicines, there is a legitimate concern over the authenticity of generic drugs, in this case, Losartan, entering Latin America.[18] However, the goods that the Rotterdam customs officials seized were *not* counterfeit versions of Cozarr or Losartan, and no evidence indicates there was any suggestion to that effect.[19] Rather, the manufacturers accurately designated these medicines as the generic drug Losartan.[20]

Moreover, even if there are legitimate concerns as to the *authenticity* of the *generic* drug,[21] these apprehensions do not trigger the trademark rights of manufacturers of *brand name* drugs or the anti-counterfeit laws of

17 *See Seizure of Medicines a Blow to Developing States*, ECON. JUST. NETWORK (Aug. 18, 2009), http://www.ejn.org.za/index.php/ejn-on-the-move/ejn-on-the-move-news/211-seizure-of-medicines-a-blow-to-developing-states. Reasons given for the seizure "include cracking down of counterfeit drugs and substandard potentially hazardous products, and preventing patent violation." *Id.* Nonetheless, the generic was manufactured in a country where Dutch patents do not apply and was en route to a country where Dutch patents do not apply. Thus, the seizure appears to be a power play to sell more brand-name drugs. *See id*.

18 *See* INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, WORLD HEALTH ORG., COUNTERFEIT DRUGS KILL! 2 (2008), *available at* http://www.who.int/impact/FinalBrochureWHA2008a.pdf; WYATT YANKUS PHARMACY NEAR YOU 1-2 (Am. Council on Sci. & Health ed., 2009), *available at* http://www.acsh.org/docLib/20090202_counterfeitdrug09.pdf . The World Health Organization ("WHO") has defined counterfeit drugs as medicines that are "deliberately and fraudulently mislabeled with respect to identity, composition, and/or source." Yankus, *supra*, at 1, anization estimated that about ten percent of the world's drug supply is counterfeit. Yankus, *supra*, at 1, 3 n.4. The WHO has estimated that the amount of 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 3 (Int'l Policy Network ed., 2006), *available at* http://www.policynetwork.net/sites/default/files/IPN_Counterfeits.pdf.

19 Danilovic, *supra* note 15; Khor, *supra* note 2.

20 Khor, *supra* note 2.

21 INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, *supra* note 18, at 4; Morris & Stevens, *supra* note 18, at 3.

European countries through which these generics merely transit. These drugs, properly manufactured and labeled, were not made for EU national markets, but for Latin American 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").[22] By applying EC 1383 broadly under the guise of IP violations to goods that are *not* to be imported and do not have any credible way of entering the EU marketplace these customs officials are inadvertently encumbering the free trade of legitimate pharmaceuticals. This consequently affects the health and economy of Latin American nations and essentially applies local patent laws internationally.

B. International Agreements Governing Shipment in Trade

Despite these situations of EU nations extending the extraterritorial reach of domestic patent regulations, these countries are subject to international law, including their obligations to international organizations such as the World Trade Organization ("WTO"). Shortly following World War II, nations set up a charter for an International Trade Organization ("ITO") to "apply uniform principles of fair dealing with regards to trade."[23] The ITO eventually failed to come into force but led to the development[24] of the General Agreement on Trade and Tariff ("GATT") protocol.[25] After several rounds of negotiations and modifications, the "WTO" was formed in 1994 as a permanent trade body under the GATT.[26]

---

22 Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Apr. 15, 1994, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]; *see* Jennifer Giordano-Coltart, Comment, *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.

23 LORI F. DAMROSCH, ET AL., INTERNATIONAL LAW CASES AND MATERIALS 1575-76 (4th ed. 2001).

24 *Id.* at 1576.

25 General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. pt. 5, 55 U.N.T.S. 194 [hereinafter GATT].

26 DAMROSCH, *supra* note 23 at 1577.

Most nations are now part of this multilateral organization created to reduce trade barriers and promote tariff-free trade.[27]

As part of the WTO, members are obliged to follow GATT protocols.[28] In particular, GATT Article V discusses the agreement between nations concerning the *transit* of goods.[29] 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.[30] GATT requires that member nations allow goods to move "via the routes most convenient for international transit."[31] Nations may require 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.[32]

In addition to GATT, EU nations are also subject to other international obligations on their ports and customs. For example, EU member states have agreed to the United Nations Convention on the Law of the Sea ("UNCLOS"), a generally accepted body of principles ratified by many nations.[33] In fact, "nearly all of the substantive provisions in the Convention reflect existing customary international law, which is binding

27 WORLD TRADE ORG., THE WORLD TRADE ORGANIZATION (2009), *available at* http://www.wto.org/english/res_e/doload_e/inbr_e.pdf.

28 *Id.*

29 GATT, *supra* note 25, art. V.

30 *Id.* ¶ 1.

31 *Id.* ¶ 2.

32 *Id.* ¶ 3.

33 United Nations Convention on the Law of the Sea art. 192, Dec. 10, 1982, 1833 U.N.T.S. 397 [hereinafter UNCLOS]. One major exception is the United States, which has not agreed to be bound by its terms. *Chronological Lists of Ratifications of, Accessions and Successions to the Convention and the Related Agreements as at 03 June 2011*, UNITED NATIONS, http://www.un.org/Depts/los/reference_files/chronological_lists_of_ratifications.htm (last updated June 3, 2011) (indicating that the United States has not agreed to be bound by UNCLOS).

even on those states that do not become members to the Convention."[34] Thus, UNCLOS, serving as a body of international law to which all nations should adhere, applies to the transit of goods.

UNCLOS requires port nations to open their ports to facilitate trade with landlocked states.[35] In particular, port states must take all measures "to avoid delays or other difficulties of a technical nature in traffic and in transit."[36] Therefore, while it is true that ports and customs are under the sovereignty of the territorial authority, this local authority must also take into account international obligations that limit how they apply national laws.

C. TRIPS and the Territoriality of Patent Rights

In addition to international obligations such as GATT and UNCLOS, the WTO set up the TRIPS Agreement in April 1994 to establish the *minimum standard* that WTO member nations must meet for the protection of intellectual property.[37] This modern agreement is successful and almost universally accepted. Its principles are based upon the Paris Convention of 1884, which historians characterize as the first true international legislation of patent law.[38] Prior to the Paris Convention, nations held patents as "dependant," so 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.[39] In this way, the application of the patent law in one

34 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 ECOLOGY L.Q. 1, 4 (1994).

35 UNCLOS, *supra* note 33, art. 124.

36 *Id*. art. 130.

37 *See A Summary of the Final Act of the Uruguay Round*, WORLD TRADE ORG., http://www.wto.org/english/docs_e/legal_e/ursum_e.htm (last visited Oct. 6, 2011).

38 ROBERT P. MERGES, ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGY AGE 331-32 (4th ed. 2007) ("The Paris Convention was . . . a product of the first true "internationalization" wave in the field of patent law.").

39 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, 64 (2010).

country was linked to the validity of the patent in another.[40] Therefore, local application of patent laws had extraterritorial implications prior to the Paris Convention.

Conversely, the Paris Convention explicitly promoted the principle of *independence*.[41] Independence originated with the notion of state sovereignty and the view that national patents are property rights granted by the sovereign.[42] Although independence limited the extraterritorial application of local patent law, other problems remained. Because states implemented patent protections independently, there were huge disparities in the protections available in different nations.[43] Though some technologies could be patented in one nation, they were not afforded protections in another because of variations in the law.[44] For example, in India, protections for pharmaceuticals were not present until 2005, allowing a large generics industry to develop that capitalized on copying drugs that were invented in countries with patent protection.[45] In addition to inequality resulting from protection for some technologies, nations also gave stronger protection to nationals than to citizens of foreign countries.[46] As a result, when patents became national in scope and states acted independently, trade barriers resulted from these global inconsistencies in protection.[47]

To reduce these disparities, developed nations promoted TRIPS as a WTO obligation, setting a minimum level of protection for inventions and encouraging national implementation of IP laws by all WTO member

40 *Id.*

41 Paris Convention for the Protection of Industrial Property art. 4bis(1), July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305.

42 *See* Schroeder, *supra* note 39, at 65.

43 *See id.*

44 *Id.*

45 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).

46 Schroeder, *supra* note 40, at 65.

47 *See id.* at 65-66.

states.[48] While TRIPS seeks to establish a uniform level of protection, it maintains the independence of national patent systems.[49] Furthermore, since TRIPS is a non-self executing agreement, each member nation must implement its requirements within their own patent system.[50] Accordingly, when nations offer greater protections than the minimum required by TRIPS,[51] variations between IP laws inevitably result. Consequently, signatories of TRIPS, like EU nations, are required to recognize the sovereignty of other states and apply their patent laws only territorially.

A fundamental basis for jurisdiction is territoriality: the sovereign has supreme authority over its land.[52] Nations can voluntarily limit these territorial rights when they enter into international treaties such as GATT and UNCLOS or join 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.[53] Thus, from a strictly territorial view, "every state enjoy[s] broad exclusive jurisdiction over person[s] and activities within its territory, but no state [can] assert its jurisdiction extraterritorially."[54] This applies to patent law, based on the independence doctrine under TRIPS, such that each nation is limited to applying its patent system nationally.

II. Flag State v. Port State Jurisdiction: Rights of the Sovereign at Port

As discussed above, both GATT and TRIPS recognize the importance of limiting the jurisdiction of sovereigns for efficient trade. Also to promote trade, international law "presumes that ports of every state

48 Kapczynski, *supra* note 45, at 1579; Schroeder, *supra* note 39, at 65-66.

49 TRIPS Agreement, *supra* note 22, art. 2.

50 Schroeder, *supra* note 39, at 66.

51 *Id.* at 66.

52 DAMROSCH, *supra* note 5, at 768.

53 Gary B. Born, *A Reappraisal of the Extraterritorial Reach of U.S. Law*, 24 L. & POL'Y INT'L BUS. 1, 8 (1992).

54 *Id.* at 8 n.28.

should be open to all commercial vessels."[55] These commercial vessels are treated as having the nationality of the flags they fly, known as flag-state jurisdiction, as long as there is a "genuine link" between the vessel and the nation whose flag is flown.[56] In international waters, the jurisdiction of the flag state traditionally dominates.[57] Generally it is only when a flag-state vessel enters port voluntarily that the vessel is subject to the jurisdiction of the port state.[58] In some instances, though, it is possible for port states to exercise authority over actions that take place in international waters or in ports where international agreements generally limit sovereign authority. This extension of jurisdiction is based upon the effects principle, under which extraterritorial conduct having domestic consequences can be regulated by the impacted state.[59]

A. Port States and Transshipments

Although the extraterritorial expansion of sovereign jurisdiction under the effects principle has important implications for transshipment, international agreements have, at the same time, circumscribed some of the jurisdiction that port states typically wield in their own territory. This section considers the evolution of the jurisdiction and actions of port states concerning the transshipment of cargo. First, an early twentieth century case regarding alcohol transshipment through United States ports during Prohibition is examined. Second, a more recent case of Chilean transshipment of swordfish caught by European fishermen is considered. In

55 John T. Oliver, *Legal and Policy Factors Governing the Imposition of Conditions on Access to and Jurisdiction over Foreign-Flag Vessels in U.S. Ports*, 5 S.C. J. INT'L L. & BUS. 209, 210 (2009).

56 UNCLOS, *supra* note 33, art. 91, para. 1; DAMROSCH, *supra* note 23, at 1466-67. Aircraft are treated as having the nationality of the state in which they are registered. Convention on International Civil Aviation art. 17, Dec. 7, 1944, 61 Stat. 1180, 15 U.N.T.S. 295.

57 *See* Suzanne Bostrom, Comment, *Halting the Hitchhikers: Challenges and Opportunities for Controlling Ballast Water Discharges and Aquatic Invasive Species*, 29 ENVTL. L. 867, 890 (2009) ("As exemplified by the International Convention for the Prevention of Pollution from Ships (MARPOL) and UNCLOS, international law tends to favor flag state enforcement over port state powers.").

58 RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 512, reporters' nn.5-6 (1987).

59 *See* United States v. Aluminum Co. of Am., 148 F.2d 416, 443 (2d Cir. 1945).

both cases, the transshipment had sufficient effect on the port state that it justified the expansion of sovereign jurisdiction hindering international norms set up to facilitate trade.

i. Transshipments of Liquor at United States Ports under the Volstead Act

This case study examines United States port jurisdiction over the transshipment of liquor. The United States adopted a national prohibition of alcohol with the passage of the Eighteenth Amendment.[60] In particular, the Eighteenth Amendment provided that "the 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."[61] The Volstead Act 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.[62] This act, like most United States statutes, should be strictly territorial and should apply only domestically.[63]

However, United States customs officials applied the Volstead Act to have extraterritorial effect by restricting the transport of liquors between foreign nations through United States ports. In one case in the Eastern District of Michigan, the United States collector of customs and other officials attempted to prevent the shipments of liquor to foreign countries through the United States.[64] However, the district court issued an

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

61 U.S. CONST. amend. XVII, *repealed by* U.S. CONST. amend. XXI.

62 National Prohibition (Volstead) Act, ch. 85, 41 Stat. 305 (1919) *invalidated by* U.S. CONST. amend. XXI (emphasis added).

63 Grogan v. Hiram Walker & Sons, Ltd., 259 U.S. 80, 93 (1922) (McKenna, J., dissenting) ("It is certainly the first sense of every law that its field of operation is the country of its enactment."); *see also* Am. Banana Co. v. United Fruit Co., 213 U.S. 347, 357 (1909) (stating that "a construction of any statute [is] intended to be confined in its operation and effect to the territorial limits over which the lawmaker has general and legitimate power").

64 Hiram Walker & Sons, Ltd. v. Lawson, 275 F. 373, 373 (E.D. Mich. 1921).

injunction to prohibit the United States officers from interfering with the transshipment of the liquors.[65] In contrast, a second case in the Southern District of New York denied the plaintiff's motion to enjoin officials from stopping transshipments of liquor to foreign countries on the basis that transshipment violated the Volstead Act.[66]

The Supreme Court joined and decided both cases.[67] The Court analyzed a treaty with England that allowed passage through United States ports when items were brought to port strictly for transshipment to British territories.[68] The transshipment companies argued that this treaty and a strict reading of the Volstead Act permitted transshipment because the liquor was not intended for consumption in the United States.[69] The Volstead Act was concerned with domestic consumption and did not explicitly restrict transshipment at United States ports.[70] The majority, however, found that although Congress had not strictly prohibited transshipment, such was its intent because it had explicitly forbidden all *other* customs actions while expressly allowing transshipments through the Panama Canal.[71] 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.[72] Since it was possible for a quantity of the liquor entering for transshipment to be diverted to the domestic marketplace,[73] the alcohol was indeed entering the United States

65 *Id.* at 379.

66 Anchor Line (Henderson Bros.) v. Aldridge, 280 F. 870, 871-72, 876 (S.D.N.Y. 1921).

67 *Grogan*, 259 U.S. at 87.

68 *Id.* Also, note that this case was decided in 1922, prior to GATT.

69 *Id*. at 89.

70 *Id*.

71 *Id.* at 90.

72 *Id.* at 89-90.

73 *Id*. at 89. In fact, liquor was known to be stolen from the Port of New York. In 1921, it was documented that approximately 100,000 bottles of liquor were stolen from docks, lighters, and trucks in two years. *Bars Foreign Rum from U.S. Ports – Court Decides Law Prohibits Transshipment of Liquors Through this Country*, N.Y. TIMES, Oct. 21, 1921 (reporting the decision of Anchor Line (Henderson Bros.) v. Aldridge, 280 F. 870 (S.D.N.Y. 1921)).

"for beverage purposes."[74] Thus, the transshipment directly resulted in a violation of the Volstead Act.[75]

However, the dissent argued that the Volstead Act only prohibited the type of transportation that was "within . . . the United States and '*for* beverage purposes.'"[76] 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.[77] The dissent also argued that the majority's application of national law resulted in "direct[ing] the practices of the world" by essentially applying the local law extraterritorially.[78] That is, by setting up barriers to free trade in liquor, the United States was indirectly hindering the extraterritorial consumption of alcohol.[79] Moreover, the dissent noted that even if there is some diversion of the liquor into domestic markets, the quantity must be significant before that diversion justified the prevention of transshipment per the Volstead Act.[80]

Unfortunately, rather than resorting to an analysis akin to the effects principle, the majority relied primarily upon the notion of sovereignty and its interpretation of Congressional intent authorizing the customs actions, showing little concern for international duty.[81] Although the majority did attempt to bolster its analysis with some inquiry into the effect of the transshipped liquor, it was primarily the dissent that considered whether there could be a significant impact on domestic markets that justified limiting transshipments. Today, United States courts make greater efforts to associate the exercise of jurisdiction with the prevention of domestic

74 *Grogan*, 259 U.S. at 88-89.

75 *Id.* at 90.

76 *Id.* at 94 (McKenna, J., dissenting) (emphasis added).

77 *Id.*

78 *Id.* at 95.

79 *See id.* at 89 (majority opinion).

80 *Id.* at 96-97 (McKenna, J., dissenting).

81 Comment, *Does the Eighteenth Amendment Violate International Law?*, 33 YALE L.J. 72, 77-78 (1923) ("[I]t must be conceded, perhaps, that the United States is under an international duty not to prevent the enjoyment of [a state's privilege to transport liquor on the seas] under international law by any act proximately causing the inhibition.").

harm through the effects principle due to greater international obligations and the potential for subsequent international response.[82]

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

The shift in modern extraterritorial application is further illustrated through the modern case study of Chile's refusal to permit transshipment of Chilean fish. Chile restricted access to its ports by Spanish deep-sea fishers carrying swordfish destined for the United States. In doing so, Chile applied its local Fisheries Law, which has been described as preventing "any vessels from transshipping or landing vessels in Chilean ports when its catches do not comply with Chilean law."[83] Chile found that swordfish were an over-exploited species and contended that the Spanish fishing just outside of Chile's 200-mile exclusive economic zone ("EEZ") resulted in depletion that had devastating effects upon Chile's own industries.[84] As a result of Chile's action, ANAPA, the Spanish National Association of deep-sea long liners, brought a complaint in the EC that Chile was creating unnecessary obstacles to trade.[85] According to ANAPA, the Chilean practices prevented "[c]ommunity 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."[86]

Based upon these complaints, the EC conducted an examination and brought action against Chile in the WTO.[87] The EC based its action upon Article V of the GATT, which requires "freedom of transit for goods

---

82 *See* Born, *supra* note 53, at 22, 26, 30-32; Austen Parrish, *The Effects Test: Extraterritoriality's Fifth Business*, 61 VAND. L. REV. 1455, 1471-72 (2008).

83 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).

84 *Id.* at 519.

85 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 Transhipment of Swordfish in Chilean Ports, §§ 1, 3,1998 O.J. (C 215) 2.

86 *Id.*

87 *Id.*; Shamsey, *supra* note 83, at 520.

through the territory of each contracting party."[88] 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 XX(b) of the GATT.[89]

In response to the WTO action, Chile brought a claim against the EC in the International Tribunal for the Law of the Sea ("ITLOS").[90] Chile explained the steps it took to establish restrictions and controls for its own fishing vessels within its EEZ[91] and stated that the Spanish vessels had not provided the necessary documentation to show their compliance with these requirements.[92] Moreover, Chile stated that because these fish are a migratory species, unrestricted fishing directly outside of its EEZ has a direct impact upon Chile's economic interests.[93] Chile contended that its "good-faith non discriminatory, domestic environmental regulations that reach[ed] activities beyond its sovereign jurisdiction can stand up to international free trade concerns."[94]

In the end, the EC and Chile came to an agreement allowing a limited number of EC ships to call at Chile's ports.[95] However, Chile made a strong case by linking its extraterritorial activity to a direct domestic detriment. In this way, the effects principle played a significant role in justifying Chile's effectively extraterritorial action.

---

88 Shamsey, *supra* note 83, at 520-21 (quoting GATT, *supra* note 25, art. V, ¶ 2).

89 *Id.* at 521-22 (quoting GATT, *supra* note 25, art. XX(b)).

90 *Id.* at 523.

91 *Id.* at 523-24.

92 *Id.* at 524.

93 *See id.* at 525 (detailing Chile's assertion that "a state's support of its nationals' right to fish should end when those fishing practices contravene Articles 63, paragraph 2, and 64-67, which provide that states shall work to protect highly migratory species occurring within and *outside* of the coastal state's EEZ").

94 *Id.* at 526.

95 *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 of* a nation's jurisdiction." *Id.* at 531. However, ITLOS may have allowed broader protection for the environment at the detriment of trade. *Id.* at 536.

B. The Effects Principle

Given the trend in justifying extraterritorial jurisdiction based on negative domestic impact, it is essential to outline the emergence and limitations of the effects principle. Jurisdiction in a port is typically based upon the territoriality principle: when a ship enters a port it submits to the jurisdiction of that sovereign.[96] Thus, the port state would have jurisdiction over violations of domestic law committed by the foreign-flag vessel at port.[97] Violations committed out of the territory of the sovereign, however, would not be subject to its jurisdiction.[98] In addition, when considering the application of domestic law extraterritorially, courts often consider whether the legislature *intended* the domestic law to apply extraterritorially and whether such application would comply with international law.[99] Under this analysis, application of domestic law to conduct outside sovereign ports is possible only if it has been authorized and the application complies with international law.

In this context, several courts began to hold that the effects principle permitted the regulation of extraterritorial conduct that impacted the state. For instance, the Permanent Court of Justice recognized the effects principle in the *S.S. Lotus* case.[100] Under the effects principle, a violation of a state's law need not occur in the state's territory for the state to have jurisdiction; it is enough that the violation leads to effects in the state.[101] Furthermore, the effects principle was acknowledged in the *United States v. Aluminum Company of America*[102] case, where the Second Circuit stated, "it is settled

96 Oliver, *supra* note 55, at 219.

97 *Id.* at 231.

98 *Id.* at 233.

99 *Id.* at 233-34.

100 Julie L. Henn, Note, *Targeting Transnational Internet Content Regulation*, 21 B.U. INT'L L.J. 157, 161 (2003) (citing Case of the S.S. Lotus (Fr. v. Turk.), Judgment, 1927 P.C.I.J. (ser. A) No. 10 (Sept. 7)) ("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.").

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

102 148 F.2d 416 (2d Cir. 1945).

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 which the state reprehends."[103]

Indeed, with the increase in international trade and cooperation resulting from lowered barriers to human and capital mobility and to information exchange, the effects principle provides a method to regulate extraterritorial conduct.[104] At the same time, the effects test has flaws. For example, the test is difficult to apply in determining what an "effect" is and when an effect is sufficient to warrant action.[105] Nonetheless, even though scrutiny is less mechanical than with the territorial jurisdiction principle, the effects principle provides a straightforward analysis in many instances.[106] 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.[107] Thus, when applying the effects test, the primary issue is determining whether the effect is sufficient to warrant action.

When 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. For instance, the United States applies a "'reasonableness' requirement as a threshold for applying national law to extraterritorial activities."[108]

As another constraint in administering the effects principle in the United States, extraterritorial application is only available when the

---

103 *Id.* at 443 (emphasis added); Gerber, *supra* note 101, at 294.

104 *See* Parrish, *supra* note 82, at 1456-60.

105 *Id.* at 1480-82.

106 *See* Born, *supra* note 53, at 29.

107 *Id.* at 33-34, 45-48.

108 Yulia A Timofeeva, *Worldwide Prescriptive Jurisdiction in Internet Content Controversies: A Comparative Analysis*, 20 CONN. J. INT'L L. 199, 205 (2005) (citing RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 403(1) (1987)).

domestic effects are "direct, substantial, and reasonably foreseeable."[109] For example, the Foreign Trade Antitrust Improvements Act of 1982 ("FTAIA") limits the Sherman Act to domestic application except where foreign conduct "significantly harms imports, domestic commerce, or American exporters."[110] In particular, the FTAIA states that the effect must be "direct, substantial, and reasonably foreseeable,"[111] codifying common law limitations on the effects test.

The FTAIA limits on the effects principle are clearly illustrated in the *F. Hoffman – La Roche Ltd. v. Empagram S.A.*[112] case. In *Empagram*, the Court considered price fixing by vitamin manufacturers outside the United States and concluded that the FTAIA can only apply to significant adverse effects within United States territory from a foreign action and not to foreign adverse effects independent of any adverse domestic effect.[113] The Court imposed a territorial limit to the effects of harmful foreign action when applying the Sherman Act although it ultimately found the domestic economic effects to be significant enough to bring a claim.[114] Generalizing this notion, the effects principle must be limited to direct, substantial, and reasonably foreseeable actions that have domestic impact. When applied to economic effects, the principle serves as a viable method to determine whether the application of domestic laws resulting in significant extraterritorial effects is warranted.

C. UNCLOS and Environmental Harm from Actions in International Waters

Similar to jurisdictional limitations in the United States extraterritorial application of domestic anti-trust law, the effects principle also plays a significant role in the application of port state jurisdiction to

109 Foreign Trade Antitrust Improvements Act of 1982, 15 U.S.C. § 6a (2006); Gerber, *supra* note 101, at 295 (describing the 15 U.S.C. § 6a rule in the context of extraterritorial application of the Sherman Act).

110 F. Hoffman –La Roche Ltd. v. Empagran S.A., 542 U.S. 155, 158 (2004).

111 15 U.S.C. § 6a (2006).

112 *Empagran*, 542 U.S. 155 (2004).

113 *Id.* at 164.

114 *Id.* at 173.

international issues, such as environmental pollution. Environmental harms are the result of the tragedy of the commons, where the producer of a harm is not naturally subject to its cost and, therefore, does not have sufficient incentive to desist from acting in a destructive manner.[115] In the context of maritime law and commercial shipping, this may occur from substandard vessels that pollute the environment or from poor shipping practices, like high speeds or improper routes that harm ocean life.[116] Because these harms affect port nations, potentially damaging the nation's tourism industry or polluting the nation's hydrological resources, customary laws and treaties have extended port state jurisdiction to vessels in international waters.[117]

For example, UNCLOS was designed to control several laws-of-the-sea issues, including pollution, and it has largely been accepted as customary international law.[118] General obligations under Article 192 of Part XII of UNCLOS mandate that "[s]tates have the obligation to protect and preserve the marine environment."[119] This limits the state's right to dispose of resources freely, recognized by Article 193, based upon the impact to the environment.[120] In addition, Article 194(2) requires states to

115 Barton H. Thomson, *What Good is Economics?*, 37 U.C. DAVIS L. REV. 175, 187 (2003).

116 Vincent J. Foley & 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. 41, 58 (2008).

117 ØYSTEIN JENSEN, COASTAL STATE JURISDICTION AND VESSEL SOURCE POLLUTION, THE INTERNATIONAL LAW OF THE SEA FRAMEWORK FOR NORWEGIAN LEGISLATION 5-6 (The Fridtjof Nansen Inst. ed., 2006).

118 *See generally* Nicholas H. Berg, *Bringing It All Back Home: The Fifth and Second Circuits Allow Domestic Prosecutions for Oil Record Book Violations on Foreign-Flagged Vessels*, 34 TUL. MAR. L.J. 253, 258 (2009) (explaining that "UNCLOS created an international legal regime to govern the use of the high seas" and was signed by 159 nations); Foley & Nolan, *supra* note 116, at 58 ("UNCLOS is considered customary international law to which the United States adheres."); John T. Oliver, *Legal and Policy Factors Governing the Imposition of Conditions on Access to and Jurisdiction Over Foreign-Flag Vessels in U.S. Ports*, 5 S.C.J. INT'L L. & BUS. 209, 213 (2009) (stating that although the U.S. is a signatory to UNCLOS, the U.S. Senate has not yet ratified the convention).

119 UNCLOS, *supra* note 33, art. 192.

120 *See id.* art. 193.

take necessary measures to control their pollution so it does not damage "other [s]tates and their environment."[121] These articles set customary environmental requirements for vessels operating on the open seas.

In addition, Article 218 of UNCLOS goes beyond traditional port state jurisdiction, which 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 at the request of that state.[122] Thus, Article 218 of UNCLOS provides a mechanism to restrict harmful actions outside of a state's normal jurisdiction. The purpose of this regulation is to prevent one state's ships from using the most expedient course of travel when it harms unassociated states.

As shown above, UNCLOS extends port state jurisdiction, however, there must be a relationship similar to the effects principle, between the harm suffered and 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.[123] 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.[124]

D. Weapons of Mass Destruction and Port States

Combating terrorism is another instance in which port states may extend their traditional jurisdiction through the effects principle to restrict vessels of another flag. Following the attacks on September 11, 2001, the

121 *Id.* art. 194(2).

122 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.*

123 UNCLOS, *supra* note 33, art. 218; Bang, *supra* note 122, at 297.

124 Bang, *supra* note 122, at 297 (emphasis added).

United States government extended efforts to contain weapons of mass destruction ("WMDs").[125] The United States strengthened diplomatic efforts such as the Treaty on the Non-Proliferation of Nuclear Weapons and the Chemical and Biological Weapons Conventions.[126] In addition, the United States undertook new initiatives like the Proliferation Security Initiative ("PSI"), in which a loose alliance of countries focuses on restricting the movement of WMDs through shipping routes.[127] The PSI has been especially contentious because it envisions using combined intelligence from member nations to hinder ships on the open seas, extending beyond the traditional jurisdiction allowed by customary international law or UNCLOS.[128]

This controversy stems from the widely accepted international norm of the right of innocent passage. UNCLOS Article 19 requires states to permit the passage of ships unless the passage is "prejudicial to the peace, good order, or security of the coastal state."[129] For a state to have jurisdiction to hinder a vessel under UNCLOS, it would have to show that the transport of WMDs results in a threat by force that endangers its "sovereignty, territorial integrity, or political independence"[130] or that violates some other principle of international law *contemporaneously* with

125 Daniel H. Joyner, *Jus Ad Bellum in the Age of WMD Proliferation*, 40 GEO. WASH. INT'L L. REV. 233, 236 (2008).

126 Samuel E. Logan, *The Proliferation Security Initiative: Navigating the Legal Challenges*, 14 J. TRANSNAT'L L & POL'Y 253, 254 (2005).

127 *Id*. at 255. The United States has also made advances to restrict the transshipment of illegal WMDs. *See Global Transshipment Control Enforcement Conference: Statement of Principles*, BUREAU OF INDUS. AND SEC., U.S. DEP'T OF COMMERCE, (July 2003), http://web.archive.org/web/20080819190211/http://www.bis.doc.gov/complianceandenforcement/tecisydney7_03principles.htm (accessed by searching for http://www.bis.doc.gov/complianceandenforcement/tecisydney7_03principles.htm in the Internet Archive index) (last visited Oct. 16, 2011).

128 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).

129 UNCLOS, *supra* note 33, art. 19, ¶ 1.

130 *Id.* art. 19, ¶ 2(a).

the transshipment.[131] Thus, it is the transport of the WMD that must pose a threat and not the possible future use of the WMD.[132]

Under Article 25 of UNCLOS, a nondiscriminatory stoppage of all vessels is allowed for conducting routine searches for *temporary* bans within 12 nautical miles of the state's coastal territory.[133] Beyond these routine searches, there must be credible evidence that the passage is not innocent.[134] Thus, for states to circumscribe a traditional international norm there should be a *significant nexus between the harm and the territory in question*, a direct application of the effects principle.[135]

As the above examples clearly illustrate, a state must justify the application of its national laws extraterritorially to transport vessels or to transshipped goods based on substantial domestic effect.[136] In the older case of liquor transshipment, the direct harm from the potential illegal entry of a regulated substance into the domestic market met the effects test.[137] More recently, the transshipment of Chilean swordfish demonstrated that significant, direct depletion of natural resources upon which a state relies economically may be sufficient to grant authority to restrict transshipments

131 *See* Logan, *supra* note 126, at 259.

132 *Id.* at 259.

133 *Id.* at 261. Regarding the 12 nautical miles, the suspension of right of innocent passage must, among other requirements, "only cover specified areas of the territorial sea," wherein "territorial sea" is a limit not exceeding 12 nautical miles. UNCLOS, *supra* note 33, arts. 3, 25.

134 Logan, *supra* note 126, 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.*

135 However, in the internal water of a State and at its ports, that State has more freedom; subject to the international principles discussed earlier, it will have the freedom to inspect the contents of a foreign vessel at its port and seize its illegal cargo. *Id.* at 265.

136 However, some United States Courts hold 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 55, at 234-35, 239-40. On the other hand, federal courts have required what has been described as an "adequate nexus between the prohibited activity and the United States," demonstrating a limitation of the protective principle by some requisite effect. *Id.* (citing United States v. Perlaza, 439 F.3d 1149, 1162 (9th Cir. 2006)).

137 *See* Grogan v. Hiram Walker & Sons, 259 U.S. 80, 90 (1922).

and apply domestic laws having extraterritorial effects.[138] In addition, regulation of environmental pollution issues resulting from substandard vessels establishes that direct harm to a state's resources may justify extraterritorial jurisdiction.[139] Finally, a direct threat resulting from the actual transshipment of WMDs may represent sufficient harmful effect to warrant extraterritorial jurisdiction.[140]

III. Generic Pharmaceuticals as Legitimate Goods in International Trade

Similar to the diverse transshipment and foreign vessel issues governed by the effects principle above, EU nations must also show a direct, substantial, and reasonably foreseeable effect upon their states by the transshipment of drugs through their ports in order to seize legitimate pharmaceuticals. In this sense, considerations beyond the protection of MNCs and their patented brand name drugs must be taken into account. Latin American countries, for example, converted their healthcare from public institutions to privately managed companies, resulting in significant health crises throughout Latin America due to dwindling healthcare access for the poor.[141] International organizations encouraged and assisted less developed countries in increasing access to life preserving medicines, in particular by using TRIPS flexibilities.[142] This enabled Latin American

138 *See supra* Part II.A.ii.; *see also* 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 Transhipment of Swordfish in Chilean Ports, 1998 O.J. (C 215) 3.

139 *See* Bang, *supra* note 122, at 291.

140 *See* Logan, *supra* note 126, at 269-70.

141 Celia Iriart et al., *HMOs Abroad: Managed Care in Latin America*, *in* SICKNESS AND WEALTH 69-71, 73-76 (Meredith P. Fort et al. eds., 2004).

142 *See* 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 (Center for Int'l Dev. ed., 2003), http://www.cid.harvard.edu/cidtrade/Papers/vanthiel.pdf (reporting the assistance of the World Intellectual Property Organisation and WTO in implementing the TRIPS Agreement on intellectual property); Press Release, Doctors Without Borders, MSF Calls Upon Latin American Governments to Guarantee Access to Medicines (Nov. 13, 2003), http://doctorswithoutborders.org/press/release.cfm?id=491&cat=press-release&ref=tag-index (last visited Oct. 16, 2011) (reporting that "MSF urges countries in the Americas to

countries, whose poverty rates are generally between twenty to sixty percent,[143] to more easily obtain generic medicines. Such assistance is necessary because economic development and output are intimately tied to a healthy population.[144] Thus if EU nations are to infringe upon Latin American countries' need for generic medicines, they must present a justifiable effect upon their interests.

The present controversy involves generic pharmaceuticals that Indian companies have manufactured and 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 barriers to *legitimate* trade."[145] Therefore, the legitimate generic drugs that Rotterdam customs officials seized and sent back to India are entitled to be shipped under the provisions of TRIPS, as well as GATT and UNCLOS. Thus, intervening actions by EU nations require justification based on substantial and foreseeable harm under the effects principle to warrant pharmaceutical seizures in contravention of international law.

---

make full use of the flexibilities in the TRIPS agreement, . . . particularly those that refer to the production or importation of generic medicines . . .").

143 *See generally* U.N. Econ. Comm'n for Latin Am. and the Caribbean, *The Reactions of Latin American and Caribbean Governments to the International Crisis: an Overview of Policy Measures up to 30 January 2009*, 37-69, U.N. Doc. LC/L 3000 (Jan. 30, 2009) (reporting poverty rates of Latin American countries, such as 21% for Argentina in 2006, 54% for Bolivia in 2007, and 30% for Brazil in 2007). Analysts expect the 2007 values to worsen with the global recession as Latin American countries have been hurt by the global economic recession of 2008 and 2009. *See id.* at 3. The availability of flexibilities, such as compulsory licensing under the TRIPS Agreement, is based upon the country's stage of development and its manufacturing capabilities. *See generally* World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (2011), *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf.

144 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, Health Nutrition, and Population Discussion Paper, 2005), *available at* http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/AttridgeImprovingAccessFinal.pdf.

145 TRIPS Agreement, *supra* note 22, Preamble (emphasis added).

A. TRIPS and Latin American Importation of Generics

In this context, it is important to examine international provisions that support the transshipment of generic drugs through EU nations. In particular, TRIPS allows Latin American governments to use compulsory licenses to acquire medicine.[146] Although TRIPS establishes a modern framework for IP protection "grounded" in the principles of national and most favored nation treatment,[147] it also incorporates limitations on patents for national emergency and *public health*, allowing compulsory licenses to force a patent holder to license its technology at a fair rate.[148] TRIPS also enables least developed countries ("LDCs") to forgo patent protection for pharmaceuticals until 2016.[149] In this way, TRIPS supports patent protections while balancing the potentially detrimental impact of IP protection on access to medicine in developing nations by promoting the use of generics to meet pharmaceutical needs.[150]

However, until the 2003 TRIPS Council Agreement following the 2001 Doha Declaration, compulsory licensing limited generic medicines to *domestic* use.[151] While the Doha Declaration explicitly recognized a government's power to issue compulsory licenses, the Council Agreement waives the provisions of Article 31(f) that prohibit exporting compulsory

146 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, 788 (1997).

147 *Id.* at 784.

148 *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, 366-67 (2009).

149 *Medicines: WTO and the TRIPS Agreement*, WORLD HEALTH ORG., http://www.who.int/medicines/areas/policy/wto_trips/en/index.html (last visited Apr. 3, 2010) (discussing the impact of the implementation of TRIPS).

150 *Id.*

151 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, 262-63 (2004). 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. *See id.* at 260.

licensed products.[152] Using the Council Agreement's waiver, a country in need of a drug may ask the government of another 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."[153] Therefore, Latin American nations that provide generic medicines to combat national health crises are TRIPS compliant when using compulsory licensing, the waiver of Article 31(f)'s limitations in exporting, or the waiver for patent requirements for LDCs. As a result, TRIPS supports transshipment of generic pharmaceuticals through EU nations.

B. International Organizations' Support of Latin American Use of Generics

Importantly, the use of TRIPS' compulsory licensing to obtain necessary medicines in Latin American is strongly encouraged. For example, non-governmental organizations ("NGOs") have encouraged Latin American countries to retain as much flexibility as possible under TRIPS[154] to maximize access to generic drugs for developmental and humanitarian reasons.[155] Furthermore, multilateral trade agreements such as the South-South Cooperation ("SSC") agreement support Latin American access to generics.[156] The United Nations recognizes the SSC as a useful tool to encourage "a better quality of life for the world's poor" by improving

152 *Id.* at 260-64 (proposing 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) (requiring that exporters differentiate the goods to avoid confusion in the marketplace and avoid re-exportation).

153 Parrish, *supra* note 153, at 15 ("The requests have to be made in good faith and for no commercial gain.").

154 *See* Doctors Without Borders, *supra* note 142.

155 ESPICOM, THE LATIN AMERICAN MARKET FOR GENERIC DRUGS – A COMPARATIVE STUDY OF 7 KEY MARKETS (2006) (documenting an increase between 2004 and 2005 in the generic sector in Latin America, which increased by 26.9% from $1.3 to $1.7 billion (USD)).

156 Gary Corbin, *South-South Cooperation Defies the North*, MERCYCORPS (Dec. 6, 2006), http://www.globalenvision.org/library/3/1371 (last visited Oct. 16, 2011).

health,[157] and Brazil, India, and South Africa are concentrating on the pharmaceutical sector as an area to increase SSC activities.[158]

Although compulsory licensing, waivers for patent requirements and for export limitations, and multilateral trade agreements promoting access to generic pharmaceuticals may result in revenue pressures for MNCs,[159] these tools fully comply with international agreements. Thus, the importation of generic medicines by Latin American countries is *legitimate trade* protected by TRIPS and championed by international organizations.

IV. EU 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 advocating for the use of EU regulations to hinder the transfer of goods from manufacturers to purchasers.[160] By using EC 1383 to impound medicines intended for developing Latin American countries, some EU member nations are improperly administering national IP protections extraterritorially.[161] Such an application of EC 1383, using the manufacturing fiction doctrine discussed below, oversteps TRIPS IP protections available to WTO member

157 Anwarul K. Chowdhury, U.N. 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 (Dec. 19, 2005), *available at* http://www.un.org/special-rep/ohrlls/Statements/19%20Dec%2005%20-%20South-South%20Cooperation.pdf.

158 Indranil Banerjee, *Development: Turning South-South Rhetoric into Action*, INTERPRESS SERV. NEWS AGENCY (Oct. 15, 2008), *available at* http://ipsnews.net/news.asp?idnews=44265; Ranja Sengupta, *Free Trade Between Mercosur and India*, GLOBAL POLICY FORUM (July 18, 2003), http://www.globalpolicy.org/component/content/article/162/27877.html (last visited Oct. 16, 2011).

159 P.B. Jayakumar, *MNC Drug Makers Eye Generics in India, Other Emerging Countries*, BUS. STANDARD (Apr. 3, 2009), *available at* http://www.business-standard.com/india/news/mnc-drug-makers-eye-generics-in-india-other-emerging-countries/353814.

160 *See* Martin Khor, *supra* note 2.

161 *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 ("[T]he territorial nature of intellectual property law is implicit in the principles of comity and national treatment.").

nations.[162] 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, EU nations should apply EC 1383 under the effects principle.

A. Need to Regulate Counterfeit Pharmaceuticals

There is a clear need to balance the importance of IP protection with the danger of counterfeit drugs. Counterfeit medicines that are deliberately and fraudulently labeled to mislead the consumer or that have improper active ingredients are an issue for both the brand name and generic medicine marketplace.[163] They pose a health risk, causing drug resistance, therapeutic failure, and possibly even death.[164] This is a problem for both developed and developing nations, but counterfeiting is especially serious in developing countries, where "supply shortages, lax regulations and oversight, and corruption allow the trade to thrive."[165]

Recognizing problems created by counterfeits, TRIPS obligated member states to implement national laws to prevent goods with counterfeit trademarks and pirated copyrights from entering their markets.[166] In particular, rights holders having "valid grounds" may file an application with the government to have customs authorities detain suspect goods.[167] At the same time, TRIPS requirements and GATT provisions requiring members to prevent hindrances of trade, as discussed above, limit how states can apply their anti-counterfeit laws to prevent the entry of illegal

162 Shashank P. Kumar, *Border Enforcement of IP Rights Against in Transit Generic Pharmaceuticals: An Analysis of Character and Consistency*, EUR. INTELL. PROP. REV., (forthcoming 2010), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1383067 (last visited on Oct. 16, 2011).

163 INT'L MED. PRODS. ANTI-COUNTERFEITING TASKFORCE, *supra* note 18, at 2.

164 *Id.*

165 Yankus, *supra* note 18, at 2.

166 TRIPS Agreement, *supra* note 22, art. 51.

167 *Id.*

goods into their markets.[168] Aware of these limitations, EU nations modified their border protections and implemented EC 1383.

B. Improperly Broad Application of EC 1383 to Seize Transshipped Goods

In order to understand the application of EC 1383 to the seizure of legitimate pharmaceuticals in transshipment, a brief overview of EU efforts to protect IP is essential. EC nations implemented EC 1383 as the latest in a series of measures undertaken to limit IP infringement within their member states. First, in 1986, the EC enacted Council Regulation EEC No. 3842/86, prohibiting the circulation of goods that infringed trademark rights.[169] Then, in 1994, the EC expanded protection through EC Regulation No. 3295/94 ("EC 3295/94") to prohibit the circulation, exportation, and importation of counterfeit goods and goods violating copyright protection.[170] The EC added enforcement for patent violations in 1999.[171] Finally, 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.[172]

EC 1383 grants member nations' customs authorities the right to take action against goods suspected of infringing an intellectual property right, stating in particular that

> [i]n cases where . . . goods infringing an *intellectual property right* originate in or come from *third countries*, their introduction into the Community customs territory, including their *transshipment*, . . . should be prohibited and a procedure set up to enable the customs authorities to enforce this prohibition as effectively as possible.[173]

168 *Id.* (clarifying that members have no obligation to apply such seizures to transshipped goods).

169 Council Regulation 3842/86, 1986 O.J. (L 357) 1 (EEC).

170 Council Regulation 3295/94, 1994 O.J. (L 341) 8 (EC).

171 Council Regulation 241/1999, 1999 O.J. (L 027) 1 (EC).

172 *See* EC 1383, art. 5, 2003 O.J. (L 196) 9-10.

173 *Id.* ¶ 3, at 7.

Therefore, EC 1383 *could* provide for the seizure of both infringing imported goods and infringing goods that are *not destined* for countries within the EU but are merely being transshipped.[174] In fact, this particular issue has been considered by the Dutch Group AIPPI, an NGO that formulates local IP policy.[175] 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 the EU customs territory.[176] The important element, however, is that the goods must infringe an intellectual property right, even if they are only being transshipped through the EU.

For this reason, Dutch courts permitting seizures of transshipped goods employ the manufacturing fiction doctrine under which courts treat goods in transit as manufactured in the state where the customs action is brought.[177] Application of this doctrine causes goods in transit to infringe an exclusive right of the patent holder to "make, use, put on the market or resell, hire out or deliver the patented invention, or otherwise deal in it commercially, or to offer, import or stock it for any of those purposes," because the goods are assumed to be made in the EU nation where such manufacture would be illegal.[178]

---

174 *See id*.

175 *See* GERTJAN KUIPERS ET AL., BORDER MEASURES AND OTHER MEANS OF CUSTOM INTERVENTION AGAINST INFRINGERS 16 (AIPPI ed., 2009), *available at* http://www.aippi.nl/uploads///Q208%20NL%201.PDF (Neth.).

176 *Id.* at 12.

177 Paul Maeyaert, *Grey and Counterfeit Goods in Transit: Trademark Law in No-man's Land*, IAM MAGAZINE, June 8, 2009, at 12, 14, *available at* http://www.iammgazine.com/issues/Article.ashx?g=e5225bb7-e7ac-4231-853e-6415dae67879; *see also* Kuipers, *supra* note 175, at 12 (explaining that the manufacturing doctrine that the Netherlands employs is based on language in EC 1383 that has been removed).

178 LUCIE GUIBAULT & O. VAN DAALEN, UNRAVELLING THE MYTH AROUND OPEN SOURCE LICENSES 91 (TMC Asser Press, 2005). 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.

The manufacturing fiction doctrine was applied under EC 3295/94 in the European Court of Justice ("ECJ") case *Polo Lauren v. Dwidua*.[179] In this case, a United States trademark owner brought an action against an Indonesian consignee shipping goods through Austrian customs.[180] The ECJ held that because the goods would have been illegal *if manufactured in Austria*, the trademark owners could prohibit their transit.[181] In fact, the Netherlands has applied the manufacturing fiction doctrine to patent infringement since 2004, when 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.[182] Thus, the Netherlands customs authorities' seizure of Losartan is consistent with their previous application of domestic law to prevent the transshipment of goods that violate local patents using the manufacturing fiction doctrine.

However, recent ECJ decisions bring the application of this doctrine to EC 1383 into question.[183] For example, in *Class International BV v. Colgate-Palmolive Company*[184] the ECJ held that trademark owners attempting to prevent infringement under the Trademark Directive 89/104 ("89/104")[185] must show that items *will* be released into the member nation's market before obstructing the movement of goods in transit.[186] The

179 Case C-383/98, Polo/Lauren Co., L.P. v. PT. Dwidua Langgeng Pratama Int'l Freight Forwarders, 2000 E.C.R. I-2531, ¶ 29, at I-2544, ¶ 34, at I-2545.

180 *Id.* ¶ 2, at I-2534.

181 *Id.* ¶ 1, at I-2546; *see also* Jens van den Brink, *Comeback for the Legal Fiction of the Anti Piracy Regulation?*, KENNEDY VAN DER LANN NEWSL. (Aug. 2008), http://www.kennedyvanderlaan.nl/KVdL/en-GB/_main/News/Newsletter/Newsletter+August+2008/Anti+Piracy+Regulation_IP/default.htm (last visited Oct. 16, 2011).

182 HR 19 maart 2004, NJ 2004, 110 m.nt. JMH (Koninklijke Philips Electronics N.V./Postech Corp.)(Neth.); *see also* Geert Theuws, *ECJ to Decide on Manufacturing Fiction*, EPLAW PATENT BLOG (Dec. 20, 2009), http://www.eplawpatentblog.com/eplaw/sisvel.

183 *See* Theuws, *supra* note 182.

184 Case C-405/03, Class Int'l BV v. Colgate-Palmolive Co., 2005 E.C.R. I-8735.

185 First Council Directive 89/104/EEC, 1989 O.J. (L 040) 1 (EC).

186 *Class Int'l*, 2005 E.C.R. ¶ 34, at I-8775, ¶ 48, at I-8779.

court further limited importation to mean goods *to be placed* in the EU market, not simply entering the member nation for external transit or transshipment.[187]

Furthermore, in *Montex Holdings Ltd. v. Diesel SpA,*[188] the ECJ analyzed whether 89/104 allowed a trademark owner the right to prohibit transit of goods. The court followed its previous *Class International* decision that allowed unencumbered external transit of fake Diesel jeans to countries that did not protect the trademark.[189] The ECJ also held that infringement must be determined by the legal status of the mark in the *destination* country.[190] Finally, the court found that 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" to prohibit transit.[191]

Nevertheless, the *Montex* decision fueled debate about whether the manufacturing fiction doctrine applies to EC 1383 in general, and to patents in particular. Opponents of the doctrine hold that *Montex* essentially did away with the doctrine while proponents argue that *Montex* was not analyzing EC 1383 but rather 89/104, so the court did not speak to the viability of the doctrine applying to EC 1383.[192] In the 2008 *Sosecal v. Sisvel*[193] case, the District Court for The Hague, which decides Dutch patent cases, held that the latter interpretation of *Montex* was correct and that the manufacturing fiction is applicable in its jurisdiction.[194]

---

187 *Id.* ¶ 34, at I-8775, ¶ 2, at I-8788.

188 Case C-281/05, Montex Holdings Ltd. v. Diesel SpA, 2006 E.C.R. I-10897.

189 *Id.* ¶¶ 20-23, at I-10907 to -10908, ¶ 27, at I-10909, ¶ 1, at I-10913.

190 *Id.* ¶ 1, at I-10913.

191 *Id.* ¶ 26, at I-10909.

192 Theuws, *supra* note 182.

193 Rb. Gravenhage The Hague 18 juli 2008, rolnr. 311378 KG ZA 08-617 (Sosecal Industria e Comercio Ltda/Societa Italiana Lo Syiluppo Dell' Elettronica) (Neth.), *available at* http://www.eplawpatentblog.com/PDF_December09/The%20Hague%20DC%20Sisvel%20v%20Sosecal%20EN.pdf.

194 *Id.* ¶ 4.14.

The ECJ still has to speak on the issue. By interpreting EC 1383 to apply to goods *purely* in transit, the legality of shipped pharmaceuticals is dependent on the IP rights in the EU port where it makes an incidental stop.[195] As a result, although the ECJ prohibited seizing goods that will not enter the member nation's protected market, the practice continues in some EU member nations like the Netherlands, where customs officials seized Losartan.[196]

C. Need for EU Member Nations to Comply with EU Laws and International Trade Agreements in Applying EC 1383

When determining how to apply EC 1383 to the transshipment of generic pharmaceuticals, EU nations should consider both EU law and international agreements. EU member nations generally have an obligation to interpret national laws to comply with EU regulations.[197] Following this principle, the United Kingdom's High Court of Justice's Chancery Division 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.[198] Nokia, Inc., sought the seizure of cell phones manufactured in Asia and transported to third nations through the U.K.[199] 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.[200] The Court also refused to espouse the manufacturing fiction doctrine, stating

195 EC 1383, art. 2, 2003 O.J. (L 196) 7 (defining infringing items based on the law of the Community port, such as "goods which, in the Member State in which the application for customs action is made, infringe . . . a patent *under that Member State's law*") (emphasis added). The ECJ found in *Rolex* that EC 3295/94 enumerated measures regarding the entry, export, and re-export in and out of the Community of goods that infringe certain intellectual property rights, 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-665, ¶ 1, at I-688 (emphasis added).

196 *See supra*, Part I.A.

197 Case C-12/08, Mono Car Styling SA v. Odemis, 2009 E.C.R. I-06653, ¶ 61.

198 Nokia Corp. v. Her Majesty's Comm'r of Revenue & Customs, [2009] EWHC (Ch) 1903, [79]-[80].

199 *Id.* [3]-[13], at 1094-95.

200 *Id.* [49], at 1107.

that it was contrary to *Montex*.[201] Most importantly, the Court specified 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]."[202] Unfortunately, this is exactly what occurs when member nations like the Netherlands, who are under the same obligation as the United Kingdom to apply ECJ holdings, seize generic pharmaceuticals in transit to Latin America. Rather than relying upon the manufacturing fiction doctrine, EU 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 under the effects principle.

In addition to applying EU law, EU nations that are members of the WTO are obligated to implement TRIPS.[203] 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*."[204] The agreement defines legitimate trade as being "justifiable . . . by relevant public policies,"[205] which take into account public interest.[206] As shown above, the international community recognizes generic pharmaceuticals as legitimate goods in which there is a strong public health interest.[207] Although TRIPS only sets minimum requirements to allow 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.[208] TRIPS

201 *Id.* [76], at 1112.

202 *Id.* (emphasis added).

203 *See* TRIPS Agreement, *supra* note 22, art. 8.

204 *Id.* art. 41 (emphasis added).

205 *Id.*

206 Xavier Seuba, Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit (June 2009) (unpublished Working Paper, on file with the International Center for Trade and Sustainable Development), http://ictsd.net/downloads/2009/08/border-measures-concerning-goods-allegedly-infringing-intellectual-property-rights_the-seizures-of-generic-medicines-in-transit.pdf (last visited Oct. 16, 2011).

207 *See TRIPS: Negotiation, Implementation, and TRIPS Council Work*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/10trips_e.htm (last visited Oct. 16, 2011); *see also supra* Part III.

208 TRIPS Agreement, *supra* note 22, art. 52.

requires that EU member nations evaluate goods in transit according to the IP laws in the goods' *destination* countries.[209] Therefore, while Dutch officials interpret EC 1383 through the manufacturing fiction doctrine to justify seizing legal pharmaceuticals,[210] ECJ holdings, other EU nations' execution of EC 1383, and TRIPS requirements indicate that EC 1383 may not support the seizure of legitimate pharmaceuticals in transit under the manufacturing fiction doctrine.

D. The Effects Principle Applied to Analyze Seizures under EC 1383

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. For example, in the United States anti-trust context, enforcement mechanisms for businesses or persons in foreign countries that violate United States domestic law are typically applied through multinational agreements with the local governments of the violating entity.[211] In this instance, application of a nation's laws abroad would be *directly* extraterritorial in nature and must be justified by substantial negative domestic effects.

Also, EU officials acting in their homeport should use the effects test to justify territorial actions that have *indirect* extraterritorial consequences, such as seizures of transshipped goods. It is important to justify these seizures because EU nations have entered into international agreements that constrain their actions at their ports and the resultant extraterritorial expansion of their national patent laws. 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 EU 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.

---

209 *Id.* art. 51.

210 *See, e.g.*, Kuipers, *supra* note 175.

211 *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).

Detractors of the effects principle claim the principle gives too much discretion to the judiciary, which could lead to universal application of domestic laws.[212] However, this is not the case when only direct, substantial, and reasonably foreseeable effects compel seizures. This effects test only applies in pure transshipment cases where goods could credibly find their way into EU markets. If domestic leakage is substantial enough to have a reasonably foreseeable effect on the market, the state would then have a 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, when the measure of effect is economic harm, as in the anti-trust and securities context,[213] 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 drug manufacturers.

As in the case of environmental law under UNCLOS, if the acts that are outside of a state's borders, such as the manufacture and sale of "infringing" goods involving only non-EU 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 through the application of the Volstead Act,[214] and it has been further debated in the Chilean swordfish dispute, where extraterritorial action significantly, directly, and reasonably foreseeably affected national interests.[215] However, unlike the transshipment of liquor under the Volstead Act, a modern view should be espoused that 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, justification of the seizure to divert the goods back to the source country would require credible evidence of both a leakage into protected markets and a significant economic effect of that leakage on domestic markets.

In addition to substantial justification underlying the seizure of Losartan by the Netherlands, other economic factors should be considered

212 Parrish, *supra* note 82, at 1478-82.

213 Born, *supra* note 53, at 45-48.

214 *See id.* at 33-34, 45-48.

215 *See* 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 Transhipment of Swordfish in Chilean Ports, 1998 O.J. (C 215) 2.

when applying the effects principle to extraterritorial actions. The EU should consider the increasingly interconnected nature of trade and the possible retaliatory action resulting from unjustifiably restricting the trade of legitimate goods. Although EU customs officials' actions are in the strictest sense territorial, they have significant extraterritorial effects, and EU customs officials must justify their conduct in an international context using the effects principle.

Conclusion

EU customs officials have applied EC 1383 to seize transshipped generic pharmaceuticals under the manufacturing fiction theory that local intellectual property laws apply to pharmaceuticals manufactured in and destined for foreign nations. These actions result in raising barriers to legitimate trade and are contrary to EU 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 EU states should use an effects principle analysis to determine whether the impact of these goods upon local markets justifies restricting their transshipment through seizures. This impact is objectively measurable, and the effects principle can be adequately constrained to provide a reasonable basis to analyze the appropriateness of these seizures.