EU Customs Blockade of India’s Generic Medicines

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EU CUSTOMS BLOCKADE OF INDIA’S GENERIC MEDICINES:
CLAIMS OF COUNTERFEITING TAKE ADVANTAGE OF A LOOPTHOLE IN TRIPS

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ABSTRACT

On over twenty occasions between 2008 and 2010, customs authorities in the Netherlands have detained consignments of Indian-manufactured generic medicines that were in transit to developing countries. Each time the containers reached Dutch ports, the medicines were apprehended based on claims that the goods were counterfeit. While India has yet to file a complaint with the World Trade Organization (“WTO”), many have accused the European Union (“EU”) of impeding legitimate trade in affordable medicines and putting patients in low-income countries at risk. In its defense, the EU maintains that it has legal authority under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) to apply its own anti-counterfeiting regulation, EC Regulation 1383/2003, to detain in-transit consignments suspected of trademark violation. This Comment examines whether the Dutch seizures, as well as EC Regulation 1383/2003, violate the international trade rules of the General Agreement on Tariffs and Trade (“GATT”) and TRIPS. This Comment also highlights the potential hazards that are created by seizing in-transit generic medicines under the suspicion of counterfeiting, rather than on violation of patent rights, and why both international trade agreements and policy regulations that control the policing of counterfeit medicines need to be changed.
INTRODUCTION

On December 4, 2008, a 570 kilo consignment of Indian-manufactured generic medicines en route to Brazil was detained by Netherlands customs officials in port. The medicine detained was losartan potassium, a product that is not patented in either the country of origin or in the country of destination, and was not meant for domestic use within the European Union (“EU”).

Again, on March 4, 2009, a forty-nine kilo shipment of generic abacavir sulfate, a second-line HIV/AIDS medication, en route from India to Nigeria was detained by Dutch customs authorities under the claim that it contained counterfeit goods. The shipment was not counterfeit and did not infringe intellectual property rights (“IPRs”). Shippers, recipients, NGOs, and developing countries alike are concerned that these actions by Dutch customs authorities towards Indian-produced generic medications are putting poor patients in the developing world at risk. Due to the high cost of brand pharmaceuticals and the lack of manufacturing capacities, low-income countries rely heavily on the availability of generic versions of medicines essential for treating the illnesses from which their populations suffer.

The EU defended the Netherlands' actions. In light of the millions of counterfeit pills that the EU caught in 2007 and the fact that one-third came from India, the EU claims that the Dutch seizures were in line with international trade rules and were consistent with the Dutch government's responsibility to provide for the general benefit of public health by halting trade of poor quality medicines. The EU further asserts that their anti-counterfeiting regulation, EC Regulation 1383/2003, permits EU customs authorities to directly take action against counterfeit goods by intercepting foreign goods in transit. Within the past two years and under the mantle of anti-counterfeiting, the EU detained generic medications originating from India nearly twenty times. The obvious question arises as to whether the EU has discovered a loophole with respect to counterfeiting in two of the main international trade agreements—the General Agreement on Tariffs and Trade (“GATT”) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”). If so, whether this loophole permits EU customs authorities to actively target and detain in-transit medicines produced by a select foreign competitor, such as India, in order to protect the economic interests of European pharmaceutical companies.

Historically, one of the main reasons why the European community, along with other developed countries, made the long, nearly ten-year push for the TRIPS Agreement was to impede the production of cheap, patent-free generic pharmaceuticals. The battle between generic and brand-name medicines began in 1970, when India, after struggling to provide affordable medicines to its public, enacted its Patent Act, 1970, which deliberately denied patent protection to all pharmaceutical inventions. The result was India’s flourishing generics manufacturing industry. In the 1980s, generic medicines were introduced onto the
In the 1980s, generic medicines were introduced onto the world market, and since then, generics have not only been a low-cost alternative to brand-name pharmaceuticals, but have also forced European pharmaceutical giants, such as Roche\textsuperscript{16} and Bayer AG\textsuperscript{17} to reduce their patented drug prices substantially in order to remain competitive.\textsuperscript{18} In 2005, when the international community forced India to recognize pharmaceutical patent rights under its TRIPS Agreement obligations,\textsuperscript{19} India was the fourteenth largest exporter of drugs in the world, exporting $3.2 billion worth of medicines to more than 65 countries.\textsuperscript{20} Thus, the recent Dutch seizures may readily be seen as a retaliatory effort by the EU. To date, India is the only country to have its medicines blocked in transit.\textsuperscript{21} A closer look at the situation, however, gives two causes for alarm. First, while it is important to question whether the Netherlands violated international trade agreements, an equal, if not more important issue arises from the particular IPR violation on which the EU bases its reasoning. The EU claims that the seizures of India’s generic medicines were legal, not because of patent right violations, but because the medicines were counterfeit.\textsuperscript{22} By claiming that goods are counterfeit, the Dutch and the EU transformed nature of IPR infringement claim from patent infringement to trademark infringement. The consequences are profound. Patent rights are exclusionary rights granted for a defined period, and will expire.\textsuperscript{23} Trademark rights, on the other hand, can last indefinitely, as long as the rights are renewed.\textsuperscript{24} In changing the IPR violation from patent right infringement to trademark infringement, the EU appears to have created a means under which seizure of generic medicines potentially never expires. As long as the trademark for a medication is in good standing, the EU can find shipments of generic versions to infringe on trademark rights, and be seized as counterfeit goods.

Second, for the past ten years, the EU has aggressively campaigned against counterfeiting. From 2001 to 2005, EU countries experienced a 900% growth in the number of seized counterfeits cases, and the EU claims that this is just the tip of the iceberg.\textsuperscript{25} During this time the EU placed its customs authorities at the forefront of this battle in order to protect the economy, the health, and the security of citizens worldwide.\textsuperscript{26} Europe, however, is not alone in its obsession with stamping out counterfeiting. Since October 2007, developed nations\textsuperscript{27} have renewed their focus on counterfeits. The United States, the European Community, Switzerland, and Japan (all developed countries) have actively negotiated the newly created Anti-Counterfeiting Trade Agreement Act (“ACTA”).\textsuperscript{28} This Agreement provides a framework of “improved international standards” for intellectual property rights enforcement, with the goal of preventing large-scale IPR infringements. The cornerstone provision states that “Each Party shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting . . . on a commercial scale . . . [which] include[s] at least those carried out as commercial activities for direct or indirect economic or commercial advantage.”\textsuperscript{29} Apparently the negotiations failed to address the current need for developing countries to be ensured their ability to trade in and have access to legitimate generic medicines. Instead, ACTA serves to further strengthen the
Dutch approach of blockading generic medicines manufactured by foreign competitors under the guise of protecting the world from harmful counterfeits—an approach, as noted above, that gives customs authorities a never-expiring ability to target and seize any and all generic medicine consignments in transit. This Comment provides an in-depth analysis of the recent Dutch customs authorities’ in-transit seizures of India’s generic medications in order to reveal whether these current threats to international trade are a legitimate legal maneuver by the EU in their efforts to take an increasingly aggressive stance against counterfeiting. This discussion proceeds in five parts and begins in Part I with a critical examination of whether the Netherlands’ seizures are in compliance with international trade agreements—GATT and TRIPS. The validity of each side’s legal arguments are analyzed, and an opinion is proffered as to whether goods in transit may be detained by third parties over concerns of trademark violation and whether a WTO Member State can apply its own nation’s anti-counterfeit laws to goods in transit between two other nations. In this Part, a brief look is made to a 2009 British court ruling on whether EU customs authorities are bound by the European anti-counterfeiting regulation, EC Reg. 1383/2003, to detain counterfeit goods in transit. Here, a distinction is made between the option and the obligation to detain in-transit goods, and the proposition is proffered that the level of the custom authorities’ duties may depend on whether consignments of medicines are involved.

The next two Parts of this Comment are devoted to analysis of whether the European anti-counterfeiting regulation, EC Reg. 1383/2003, on which the EU relies in its defense of blockading goods in transit, violates the TRIPS Agreement. Part II examines the legal history behind the Regulation in order to discern whether the EU intended for customs officials to protect European economic interests by targeting foreign trade in generic medicines. Part III compares EC Reg. 1383/2003 to the relevant TRIPS Agreement provisions that set forth required, minimum guidelines which Members must adhere to when drafting anti-counterfeiting border-control measures. The discovery is made that while past EU border-control legislation has been approved by the TRIPS Council, EC Reg. 1383/2003 has not. Although the EU anti-counterfeiting regulation is on most accounts “in conformity” with TRIPS, Council action is still required for several reasons.

Part IV reviews recent international border-control measures initiated by the EU and other developed countries. Such measures increase the powers given to customs authorities and place this agency at the forefront of the battle to stop trade in counterfeit medicines. Part V explores why customs officials are not sufficiently equipped to detain medicines in-transit, and suggests alternatives to placing customs authorities in sole control over IPR infringement actions. If customs authorities are not better supervised, the danger remains that legitimate generic medicines in transit will continue to be detained at a third-party ports for nationalistic reasons under the guise of counterfeit violations. It is urged that developed countries do not adopt the new plurilateral Anti-Counterfeiting Trade Agreement because it fails to incorporate lessons from the Dutch customs authorities’ actions and only promulgates the risks that exist when customs authorities are placed in positions of unchecked control over the flow of goods merely passing through their ports.
I. INTERNATIONAL TRADE AGREEMENTS: THE RULES ON IN-TRANSIT SEIZURES

Two key international trade agreements govern the question of whether the seizures by Dutch customs authorities of Indian generic drugs in transit to South America are legal: (1) the General Agreement on Tariffs and Trade, and (2) the Agreement on Trade-Related Aspects of Intellectual Property Rights. Both agreements establish provisions regulating international trade, yet each regulates a different aspect of trade practices. GATT primarily addresses tariffs and non-tariff barriers surrounding legitimate trade, while the TRIPS Agreement protects an extensive array of intellectual property rights associated with traded goods.

From the outset, India and Brazil claimed that the Indian consignments seized by Dutch customs authorities contained legal goods. Aside from this issue, India and Brazil further argue that Dutch customs authorities did not detain the Indian consignments temporarily, as would be permissible by international trade rules. Instead, the Dutch not only held India’s shipments for months, but also initiated procedures to destroy the medicines. India and Brazil maintain that such actions constitute a confiscation of goods and run counter to the spirit of both GATT and TRIPS. They claim that an in-transit seizure of goods violates the “freedom of transit” provision of GATT Article V, and is inconsistent with the mandate of the TRIPS Agreement that all enforcement procedures against goods involving IPRs should neither bar legitimate trade nor be used abusively.

The EU, though, claims that Dutch customs authorities detained India’s consignment of losartan potassium in conformity with EU regulations and international trade rules. In defense of the Netherlands, the EU states that the Dutch actions comply with both Article V of GATT, which permits customs authorities to suspend the release of goods, and Article 51 of the TRIPS Agreement, which allows customs authorities to temporarily detain any good suspected of infringing an intellectual property right. The EU maintains that it has “no intention to hamper any legitimate trade in generic medicines or create legal barriers to prevent movement of drugs to developing countries.”

The analysis presented below investigates each party’s claims and examines whether the Dutch seizures were legitimate under the international trade rules of GATT and TRIPS. Since India has yet to formally request a consultation at the WTO, it is uncertain how a Panel report might actually rule on the legal issues inherent in this dispute. However, the following analysis is helpful in understanding the claims of each party and whether a clear violation of international trade rules exists.

A. GATT: A Balance Between India’s Right to “Freedom of Transit” and the EU’s Right to Apply Its Customs Rules to In-Transit Goods

1. Interpreting GATT from the Standpoint of Trading Partners: India and Brazil
Under Brazil’s interpretation of GATT, the Netherlands’ blockade of Indian consignments while the goods were in transit, violates Article V, “Freedom of Transit.” Concerning the transport of international goods, Article V:2 states:

> There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties. No distinction shall be made which is based on . . . the place of origin . . . or destination, or on any circumstances relating to the ownership of goods.

This provision applies to the passage of all types of commodities. Furthermore, the principle of reciprocity dictates that all parties to GATT enjoy the freedom of transport of their goods through each other’s territories.

Dutch customs authorities appear to have violated Article V:2 in two ways. First, uncertain transit conditions in Europe have made trade for India a much greater challenge due to the lack of “freedom of transit” for their goods. For India, the transit route through Europe and the Netherlands is much less expensive (i.e. the “most convenient”) than through non-EU routes. Even though Indian generic pharmaceutical manufacturers incurred substantial monetary and reputational losses due to repeated seizure of their goods, Indian companies are unwilling to ship through non-EU ports due to the higher costs. Distraught by these economic repercussions, the Indian government offered to reimburse Indian generic pharmaceutical manufacturers for the additional expense of shipping through non-EU ports, however, this is not an acceptable long-term solution for India.

Second, according to Article V:2: “[n]o distinction shall be made . . . based on . . . the place of origin.” In other words, detaining in-transit goods based solely on where the goods originate violates GATT. Thus, the EU’s defense—that Dutch actions are justified because India was the source of thirty percent of counterfeit medicines caught in 2007—is not a valid argument. Dutch customs authorities cannot target shipments from India and block all in-transit consignments of Indian generic medications. The EU’s actions not only violate Article V:2, but also violate the spirit of GATT, which is to eliminate discriminatory treatment in international commerce.

GATT Article V:4 further provides that “[a]ll charges and regulations imposed by contracting parties on traffic in transit to or from the territories of other contracting parties shall be reasonable, having regard to the conditions of the traffic.” The term “reasonable” is not defined by GATT; however, both India and Brazil stress that preventing the transport of life-saving medicines is not reasonable. The 570 kilogram shipment of losartan potassium was enough to treat 300,000 people who suffer from hypertension, a disease that can be deadly if not treated properly.

Under typical canons of construction, the term “reasonable” must be consistent with the provisions of GATT. GATT’s hallmark against
discriminatory trade practices is its overarching Most-Favored-Nation ("MFN") principle,\textsuperscript{58} which states that the best treatment made available to any country in the agreement, must be made available to all countries.\textsuperscript{59} On its face, India and Brazil’s link of “reasonable” with the transport of life-saving treatments may appear to stretch the term beyond its intended description of trade practices to an emphasis on the trade goods themselves. Nonetheless, it is clear that no nation other than India has had its generic pharmaceutical shipments repeatedly detained by EU customs authorities. On over twenty occasions, Indian consignments of generic medications have been singled-out at European ports\textsuperscript{60} and the goods detained for months—a much longer time than expected by WTO Member States.\textsuperscript{61} Even the EU admits that the Dutch customs authorities’ behavior towards India has been unusual.\textsuperscript{62} After being detained, the consignment of losartan potassium was returned back to India—normally counterfeits are destroyed, not returned.\textsuperscript{63}

2. Interpreting GATT from the Standpoint of the In-Transit Port: The EU

In opposition, the EU claims that its customs authorities’ actions are compatible with WTO rules.\textsuperscript{64} It argues that under GATT Article V.3, Europe can apply its specialized customs laws to goods in transit.\textsuperscript{65} Article V.3 provides:

Any contracting party may require that traffic in transit through its territory be entered at the proper custom house, but except in cases of failure to comply with applicable customs laws and regulations, such traffic coming from or going to the territory of other contracting parties shall not be subject to any unnecessary delays or restrictions.\textsuperscript{66}

Within the EU, EC Reg. 1383/2003 is the controlling customs law for Member States.\textsuperscript{67} This border control regulation permits customs authorities to “take action against counterfeit goods, pirated goods and goods infringing certain intellectual property rights which are in the process of being exported, re-exported or leaving the Community customs territory.”\textsuperscript{68} It also provides that goods can be held as long as necessary in order to determine whether the merchandise is in fact counterfeit, pirated, or infringes intellectual property rights.\textsuperscript{69} Thus, it appears that the detention of Indian drug shipments for periods longer than one month by Dutch customs officials, under suspicion of being counterfeit,\textsuperscript{70} may not violate GATT. Yet, India and Brazil’s complaint against the length of detention of its goods by Dutch customs authorities may still hold if they can establish that the detentions of the consignments were “unnecessary delays or restrictions.”\textsuperscript{71} Since GATT Article V.3 allows goods in transit to be inspected at a contracting party’s custom house under that party’s laws, EU customs authorities are permitted to apply EC Reg. 1383/2003 to goods in transit through Europe. Furthermore, Article 10 of EC Reg. 1383/2003 provides that “the law in force in the Member State within
the territory of which the goods are placed [] shall apply when deciding whether an intellectual property right has been infringed under national law." Application of EU trademark law means that an "unnecessary delay" occurs if India's goods were not counterfeit. But, as mentioned in the Introduction, the careful choice by the EU to detain India's generic medicines on trademark grounds, rather than the alternate intellectual property violation of patent rights, greatly benefits the EU's claim that its customs authorities' seizures were legitimate.

A jurisdictional paradox occurs under GATT Article V.3 if the medicines were detained for violation of patent rights. Patent rights are territorial by nature; they can only be exercised in the jurisdiction in which they have been granted. However, under EC Reg. 1383/2003, if the State through which goods are being transported has stricter IP laws than either the origination or destination States, the goods can be confiscated for patent infringement. Consequently, any non-EU country that transports its goods through the EU assumes the risk of abiding by EU intellectual property law. This striking result is also possible under the TRIPS Agreement—a point that will be discussed in the next subpart.

GATT Article XX must also be considered in relation to the EU’s assertions that its customs authorities’ actions comply with international trade rules. Article XX provides tariff-based trade rules for protecting against trademark and other intellectual property infringement:

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries . . . or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures . . . (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including . . . the protection of patents, trade marks [sic] and copyrights and the prevention of deceptive practices.

Under Article XX, the argument for or against violations by Dutch customs authorities depends on whether the actions were either unjustifiably discriminatory or were necessary to secure compliance with EU intellectual property laws. The EU may argue that since developing countries circumvented paying medical patent right holders in the past, the recent detention and inspection of Indian shipments by EU customs authorities is warranted to “prevent[] deceptive practices.” For example, Brazil, which is India's trading partner in the losartan potassium seizure, has decisively ignored patent rights when acquiring medicines for its country. In 2007, Brazilian President Luiz Inácio Lula da Silva broke the patent on Efavirenz, a principal component in a seventeen-drug cocktail to treat AIDS, even after Merck offered to cut prices to satisfy demands from the Brazilian health ministry. President da Silva further signed a law that allowed the government to purchase a generic version until Merck’s price was
satisfactory. Such practices do not represent good-faith trade and directly violate EU intellectual property laws. Thus, the EU may succeed on the contention that Indian shipments in transit to Brazil require heightened inspection. While the above analysis focuses primarily on specific provisions of GATT, the general spirit of the agreement is also an important factor in party negotiations and in WTO dispute settlements. In addition to GATT’s MFN principle, a second principle exists, which maintains that Member States’ tariffs should not create discriminatory barriers to trade. Based on recent events between the Netherlands and India, EU customs regulation, EC Reg. 1383/2003, has the potential to be regarded as a “non-tariff” barrier. The Regulation made it difficult, and in some cases impossible, for Indian generic medications to reach South America and Western Africa. Moreover, the continuous seizures by EU customs authorities of in-transit Indian generic pharmaceuticals are damaging India’s credibility as a reliable supplier of affordable medicines—Indian suppliers defaulted on their contracts more than twenty times because of EU detentions.

The EU, though, argues that EC Reg. 1383/2003 is not an “arbitrary or unjustifiable discrimination between countries,” but rather a protectionist measure designed to ensure against the spread of counterfeit medicines, which can pose serious safety issues and harm public health. Since international law has not designated which parties—exporting countries, importing countries, or in-transit port countries—are responsible for policing counterfeits, the EU can claim that its customs authorities have an obligation to ensure that medicines in transit are not fakes.

As discussed above, each side has potentially legitimate arguments with respect to the international trade rules provided by GATT, and unfortunately, no provision is determinative. Although GATT declares that goods shall be given freedom of transit through the territory of a WTO Member State, a Member State is allowed to proactively take measures that protect its patents and trademarks, and prevent deceptive practices. However, these protective actions should be “reasonable” and should not be disguises that cause unnecessary delays or restrictions, unjustifiable discrimination between countries, or restrictions to international trade. Disputing parties often find the provisions of GATT to be too general and thus interpretation of agreement rules is typically resolved by the WTO dispute settlement system. India has yet to seek resolution regarding the legitimacy of the EU customs authorities’ trade practices, but nonetheless, a basic principle of GATT should be applied in this EU-India trade dispute. Member countries are expected to act based in the principle of reciprocity: “[C]ontracting parties shall co-operate with each other . . . .”

B. TRIPS: Supports India’s Right to Trade Generic Medicine, But It Also Provides the Loophole Under Which the EU Can Apply Its Rules to Goods In-Transit
While GATT rules authorize the freedom of transit for trade in legitimate goods, the TRIPS Agreement builds in the minimum level of intellectual property protections that all WTO Member must recognize and comply with regarding goods sold by fellow Members. Specifically, the preamble of the TRIPS Agreement reflects two fundamental objectives:

Reduce distortions and impediments to international trade, and . . . to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.  

It follows that measures used by WTO Members to protect their intellectual property rights should not bar legitimate trade.  

1. Interpreting TRIPS from the Standpoint of Trading Partners: India and Brazil

The Counselor at the Permanent Mission of Brazil described the Dutch customs authorities’ seizures as “an attempt at extraterritorial enforcement of [intellectual property] rights.”  

In particular, Brazil advocates that the Dutch actions do not comply with the TRIPS Agreement on two grounds.  

First, Dutch actions violate TRIPS Article 7, which requires that the enforcement of intellectual property rights is executed “in a manner conducive to social and economic welfare.”  

Second, the actions violate TRIPS Article 8, which gives a Member State government the right to “adopt measures necessary to protect public health . . . [which] may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade.”

Historically, in spite of Articles 7 and 8, the early effects of the TRIPS Agreement were an increase in the price of pharmaceutical products, and in turn, an obstruction in developing countries’ ability to access affordable medicines.  

Developing countries attempted to remedy this discriminatory effect by arguing that TRIPS Articles 7 and 8 were not general exceptions clauses to the Agreement, but rather each provision of the TRIPS Agreement should be read in light of Article 7 and 8 principles and objectives.  

Not all WTO members agreed.  Rather, to address the issue and to improve access to essential medicines, the WTO adopted the 2001 Declaration on TRIPS and Public Health (“Doha Declaration on TRIPS and Public Health”).  This declaration creates specific categories of “flexibilities” within the TRIPS Agreement’s mandatory recognition of intellectual property rights. In instances of national emergency, situations of public health crisis, or through compulsory licensing, the TRIPS Agreement provisions can be bypassed in accordance with the new rules of the Doha Declaration, and medicines are available to all.  

It stands to reason, that in the case presented here, Brazil and India do not have a strong argument that the Dutch customs authorities’ detention of in-transit medicines is a violation of the TRIPS Agreement.
provisions on public health and welfare. The WTO has clearly resisted acceptance of the notion that Articles 7 and 8 should override the IPR protections accorded to pharmaceutical products.\textsuperscript{108} While India claims that the EU seizures “undermine[] the public health dimension of [the] TRIPS Agreement,”\textsuperscript{109} this statement is also weak. There is no indication that any of India’s consignments were shipped in accordance with one of the flexibilities under the Doha Declaration. None of the shipments were in response to a Member’s compulsory license or a declaration of national emergency. Therefore, India’s consignments remain subject to the IPR protection regime of the TRIPS Agreement.

2. Interpreting TRIPS from the Standpoint of the In-Transit Port: The EU

The EU claims that the Dutch detention of in-transit shipments containing possible IPR-infringing goods is consistent with TRIPS Article 51.\textsuperscript{110} This claim is surprising because the detention and inspection of goods merely passing through a territory en route to a completely different destination, is atypical.\textsuperscript{111} Ordinarily, customs authorities inspect goods being imported into or exported from their own territory. In fact the text of Article 51 describes the procedures that Member States are to take with respect to the suspension of imported and exported goods suspected of trademark and other IPR infringement. However, a footnote to Article 51 states, “It is understood that there shall be no obligation to apply such procedures . . . to goods in transit.”\textsuperscript{112} While there is no obligation for WTO Members to detain goods in transit, such action is permitted. Thus, footnote thirteen creates a “loophole” through which the EU can detain in-transit consignments that violate EU IPRs, regardless of whether the goods (medicines) are legal in both the country of origin and of destination. Furthermore, TRIPS Article 51 grants customs authorities specific powers: “Members shall . . . adopt procedures to enable . . . counterfeit trademark [] goods . . . [be] suspend[ed] by the customs authorities of the release into free circulation of such goods.”\textsuperscript{113} Thus, at face value, the conclusion can be drawn that the EU customs authorities’ suspensions of Indian goods in transit based on suspected IPR violations conform to TRIPS provisions. It should be noted, however, that significant differences exist between EC Reg. 1383/2003, which dictates EU customs authorities’ power over counterfeit goods, and the TRIPS IPR concessions instituted to provide access to medicines.\textsuperscript{114} This disparity is discussed infra.\textsuperscript{115} Despite the EU’s assertions of propriety, Brazil challenged that EU customs authorities acted beyond the scope of the TRIPS Agreement when they sent India’s consignment of losartan potassium back to India.\textsuperscript{116} Brazil claimed that returning the goods back to the country of origin is an act of defiance, and thus, the Netherlands’ actions are sanctioned under international trade rules.\textsuperscript{117} According to TRIPS Article 46, an “effective deterrent to infringement” is to dispose infringing goods “outside the channels of commerce, in such a manner as to avoid any harm caused to the right holder” or have
the goods destroyed.\textsuperscript{118} This holds for any category of IPR violation. Since the TRIPS Agreement does not enumerate what actions constitute a disposal “outside the channels of commerce” or what specific measures Members are to implement, shipment of consignments back to the country of origin meets the TRIPS requirement of removing the infringing goods from the system of trade. Article 46 also states that “the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.”\textsuperscript{119} Furthermore, under Article 59, “authorities shall not allow the re-exportation of the [counterfeit] infringing goods in an unaltered state.”\textsuperscript{120} Since the Netherlands’ custom officials’ actions comply with both of the provisions, the return of allegedly counterfeit goods back to India does not violate the TRIPS Agreement.

India also challenged the EU’s assertions of propriety and stated, “This is not a case of ‘temporary detention’ since some consignments continue to be held for over months.”\textsuperscript{121} TRIPS Article 55 addresses how Member States are expected to behave with respect to the duration of detention of goods. Once the rights holder’s application for suspecting infringement is approved, goods are to be suspended for a maximum of four weeks after the rights holder is served notice of suspension.\textsuperscript{122} Failure by a party other than the defendant to subsequently initiate a proceeding that leads to a decision on the merits of the case, results in release of the consignments.\textsuperscript{123} The provisions under Article 58 also allow ex officio suspension by competent authorities, acting upon their own initiative.\textsuperscript{124} However, if competent authorities suspend goods ex officio, Article 58 sets no time limit for detention.\textsuperscript{125} In the case of Dutch customs authorities’ suspension of India’s consignments, it is not certain whether a rights holder lodged an application or the action was taken ex officio.\textsuperscript{126} Thus, the detainment by the Netherlands of India’s losartan potassium consignment for longer than one month\textsuperscript{127} might comply with the TRIPS Agreement, and thus the EU customs agents may have acted with propriety.

Yet, the EU failed to communicate with India that its customs agents had detained India’s medicines consignments.\textsuperscript{128} This behavior conflicts with the spirit of TRIPS (and its roots in GATT) and its prohibition of protective measures that become barriers to legitimate trade. India and Brazil’s accusations that the EU is creating a trade barrier under the guise of counterfeit medicines seem to have some weight.

As this examination of international trade rules demonstrates, the rules set forth in GATT and TRIPS both have wide margins for interpretation. While not predictive, this analysis demonstrates that the argument for or against Dutch customs authorities’ violation of GATT is closely balanced between whether EU actions were unjustifiably discriminatory due to repeated interference by the Netherlands’ with the free transit of Indian goods’ through the most convenient international trade routes, and whether the actions were a permitted application of EU law against in-transit trade in counterfeits goods. GATT’s overriding principles of reciprocity and of MFN treatment appear to favor India’s claims—any actions that create a trading environment that is objectionable to one party would most likely be
environment that is objectionable to one party would most likely be unfavorable to other parties, if applied equally.\textsuperscript{129}

Under the TRIPS Agreement, the EU’s arguments dominate. Although the TRIPS Agreement bends some of its protections in cases of public welfare,\textsuperscript{130} the WTO has yet to accept that this is a principle that supersedes all intellectual property right protections for pharmaceutical products being delivered between developing countries.\textsuperscript{131}

Both GATT and TRIPS permit the EU to detain goods in transit through its territory on grounds of suspected IPR infringement. The EU can also apply its intellectual property laws and regulations to determine whether the goods comply with such rules.\textsuperscript{132} However, according to a recent British court ruling, there is a nuance to consider with respect to this ability to detain in-transit goods.

### C. The Distinction Between the Option and the Obligation to Stop Goods in Transit

In the July 27, 2009 case of Nokia Corp. v. Her Majesty’s Commissioners of Revenue & Customs (HMRC), the British High Court gave its ruling on whether—within the framework of GATT and TRIPS—the local EU anti-counterfeiting policy EC Reg. 1383/2003 should be applied to goods in transit.\textsuperscript{133} The case involved counterfeit cell phones en route from Hong Kong to Columbia via London Heathrow.\textsuperscript{134} Even though the rights holder, Nokia, verified that the goods were fakes,\textsuperscript{135} the HMRC declined to seize the goods.\textsuperscript{136} They claimed they did not have the legal authority to do so without evidence that the goods would be released into the EU market.\textsuperscript{137}

The British High Court sided with its customs officials and ruled that in order to qualify as counterfeit, the goods must be on the doorstep of the destination country and not in transit.\textsuperscript{138} Since the phones were destined for Columbia, Nokia had no right to expect the fake versions of its phones would be seized in transit by customs authorities.\textsuperscript{139} This ruling is in stark contrast to the Netherlands’ position with respect to the seizures of Indian goods in transit.\textsuperscript{140} It is also a much narrower view of the application of EC Reg. 1383/2003 within international trade rules than the stance currently taken by the EU.\textsuperscript{141} However, it draws attention to an interesting subtlety articulated by the “in transit” provisions of GATT and TRIPS.

Both of these international trade agreements make the clear distinction between the ability of a Member to apply its laws to goods in transit, and the necessity to do so. GATT Article V:3 states contracting parties “may require,”\textsuperscript{142} and TRIPS Article 51 footnote 13 states that Members have “no obligation”\textsuperscript{143} to detain goods in transit in order to determine whether they comply with local counterfeit or other laws.

By its ruling, the British High Court held that at least within its territory, British customs authorities are not obligated to apply its laws to in-transit consignments.\textsuperscript{144} Since in Nokia the trade was in cell phones, the nuance between “may” and “must” does not affect public health or welfare. However, when dealing with counterfeit medicines, the nuance between “may” and “must” has life-threatening implications.
The nuance between “may” and “must” has life-threatening consequences. Thus, if the Indian seizure cases were before the British High Court, the Court might be persuaded by the EU’s assertions that the EU is responsible for protecting public health by halting trade in counterfeit medicines. Accordingly, the High Court might reinterpret its country’s trade obligations, and hold that customs authorities must apply EU law to consignments of in-transit medicines. Since this potential reversal of precedent, as well as the GATT and TRIPS analyses discussed above, rest on the EU’s application of anti-counterfeiting regulation EC Reg. 1383/2003 to goods in transit, the next Part examines the history behind the current EU border control regulation to determine whether it was truly designed to protect the public from hazardous counterfeits or was it created to bar legitimate trade.

II. EU ANTI-COUNTERFEITING REGULATIONS WERE NOT DESIGNED TO BLOCK TRADE IN GENERIC MEDICINES

The EU asserts that its anti-counterfeiting regulation, EC Reg. 1383/2003, gives its customs authorities the legal authority to detain India’s generic medicines consignments in transit on suspicion of trademark infringement. The EU claims that the Netherlands customs authorities are mandated by the EU to protect the public from trade in counterfeit medicines. This Part examines the legislative intent behind EC Reg. 1383/2003 to determine whether European Member States tailored this directive so that it could be used to address economic threats from foreign generic medicine manufacturers or whether it was meant as a legitimate means to regulate trade in unsafe counterfeit goods.

The international concern with combating trade in counterfeits predates the TRIPS Agreement. As early as the 1970’s, multinational corporations no longer viewed counterfeiting as an “acceptable obstacle” to free trade. Initial proposals of anti-counterfeiting measures were submitted as part of the 1978 Tokyo Round of the GATT trade negotiations. Yet, despite fervent efforts, the United States, the European communities, Canada, Japan, and Switzerland failed to attract the broad international support necessary to adopt a multilateral anti-counterfeiting code.

Developing countries, led by India and Brazil, strongly opposed the insertion of anti-counterfeiting measures. They claimed that GATT had no jurisdiction over trademark counterfeiting and that the World Intellectual Property Organization (“WIPO”) was a more appropriate forum for addressing counterfeiting issues. Against this backdrop of international disagreement, the European Economic Council (“EEC”) adopted its first domestic counterfeiting regulations in 1986. EEC Regulation 3842/86, “On the Free Circulation of Counterfeit Goods,” laid down measures that mandated all Member States actively halt the release of counterfeit goods within the European community. Customs authorities received full power “to act to ensure that such a prohibition is observed under optimum conditions.” In addition, trademark holders could now file an application to limit the free circulation of counterfeit goods. By the early 1990’s, however, the EU no longer felt that this regulation...
By the early 1990's, however, the EU no longer felt that this regulation was strong enough. In 1994, EC Regulation 3295/94, “A Suspensive Procedure of Counterfeit and Pirated Goods,” extended the scope of IPR enforcement in two ways. First, the new provisions enabled swifter action by custom authorities in the seizure of infringing goods. Second, IPR protections were extended beyond trademarks (counterfeit goods) to include copyright and design rights (pirated goods).

In 2000, the European Commission once again strengthened its approach to counterfeiting and piracy. The Annual Statistical Report of 2001 showed an alarming nine-fold increase in the number of fraudulent items intercepted at European borders from 1998–2001. In 2001 alone, approximately 100 million articles were intercepted with an estimated value of nearly €2 billion. Furthermore, the face of counterfeiting was changing. Previously, only luxury goods were counterfeited, but today all areas of economic activity are affected:

[H]undreds of kilos of medicines, thousands of spare parts for cars, washing powder, shampoo, skin creams, stamps, thousands of packets of condoms, toothpaste, insect sprays, kitchen whiteware, and wooden palettes were all the subject of customs proceedings for counterfeiting and piracy. CDs (audio, games, software), DVDs and cassettes were the second largest—and very fast-growing.

The Commission announced that “vigorous measures should be taken at EU level to step up and improve the fight against counterfeiting and piracy in the single market.” Regulatory change was again proposed, which resulted in promulgation of the border control regulation that the EU uses today, EC Reg. 1383/2003, “On Goods Suspected of Infringing Certain Intellectual Property Rights.” The EC Reg. 1383/2003 broadened customs authorities’ powers, enabling them to protect every IPR category—trademark, copyright, patent, plant variety, supplementary protection certificate, protected designation of origin, and protected geographical indication. The Regulation also greatly extended customs officials’ authority—the most notable is the expansion of customs’ “ex officio” capacity so that it can act without a prior application for action. The ramifications of these new ex officio powers directly impact the recent Dutch seizures and are discussed in greater detail in Part III.

The legislative history thus reveals that the EU did not design EC Reg. 1383/2003 as a nationalistic endeavor for targeting and economically crippling foreign generic pharmaceutical corporations such as those in India. Rather, the EU measures respond to a serious problem involving a wide range of goods, not just medicines. Furthermore, the intention of the anti-counterfeiting regulation was to “offer a powerful new legal arsenal against the growing problem of counterfeiting and piracy.” Although EC Reg. 1383/2003 is the latest revision to EU anti-counterfeiting regulations, it is not the last time that the European Commission bolstered EU customs authorities’ powers. The EU appears to be obsessed with making its customs authorities “front-line warriors in the battle against counterfeiting.” In 2007, after the EU and the United States confiscated over 360,000 counterfeit integrated circuits in
their first joint-customs operation (Operation INFRASTRUCTURE), the EU vowed to “continue to build upon this operation [] a growing cooperation with our U.S. colleagues to combat the global trade in fake goods.”

Today, Europe is in relentless pursuit of stamping out all counterfeits of all types of goods. EC Reg. 1383/2003 is only one part of a two-prong approach to combat counterfeiting and piracy. While EC Reg. 1383/2003 strengthens and broadens trade control at EU borders, the Commission also sought to increase the EU’s punitive strength against IPR infringers as its second goal. The purpose of the 2004 EU IPR Enforcement Directive was to “make it dramatically easier to enforce copyrights, patents, and trademarks in Europe, and punish people who tamper with technical mechanisms designed to prevent copying or counterfeiting.” In spite of strong resistance from many EU Members, the Directive is now firmly in place. Consequently, all legislation on civil and administrative proceedings within the EU have been harmonized, and uniform minimum thresholds of sanctions with respect to the enforcement of intellectual property rights has been instituted. This means that goods crossing through any one of the EU’s twenty-seven member states or arrival at any one of the 600 international trading ports is more readily detained by customs authorities under EC Reg. 1383/2003 and subject to stronger and swifter penalties through Directive 2004/48/EC.

Although the EU considers its measures successful, there is cause for concern that ever-stronger EU IPR enforcement measures are becoming a barrier to international trade. Since enactment of this recent legislation, Indian shipments of generic medicines have been detained in a multitude of ports throughout Europe, including the Netherlands, France, Germany, and the United Kingdom.

While the EU desires stronger anti-counterfeiting rules to protect their economy and public welfare, its regulations and directives should not conflict with its trade commitments to the international community. Ideally, there should be no uncertainties between EU customs regulations and the TRIPS Agreement. The next part of this Comment explores whether the EU legislative actions targeting trade in counterfeits remain within the minimum guidelines put forth in the TRIPS Agreement. Article 51 of TRIPS explicitly states that Members are free to adopt their own procedures for suspending suspected infringing goods at customs; however, any newly-drafted provisions must conform with TRIPS Agreement provisions.

III. EC ANTI-COUNTERFEITING REGULATION 1383/2003 DOES NOT CONFORM TO TRIPS PROVISIONS ON ACCESS TO MEDICINES

Section 4 of the TRIPS Agreement instructs Members on how to regulate counterfeiting and other intellectual property right violations at their borders. Two different methods for suspending suspected infringing goods are prescribed. The first method—a right holder initiated suspension—is mandated. The second method—an ex officio
The second method—an ex officio interception by competent authorities—is optional. The EU anti-counterfeiting regulation, EC Reg. 1383/2003, implements both methods. It is unknown, though, which method was used in the EU customs authorities seizures of India’s generic medicines. To date, no party has come forward to claim responsibility; the EU has side-stepped the issue with its silence; and the European Pharmaceutical Manufacturing Association (“EFIPA”) emphatically denies any industry involvement. For these reasons, the Netherlands’ seizures of India’s medicines appear to be ex officio actions.

According to TRIPS, ex officio actions allow competent authorities to act on their own initiative in an ex officio (automatic) manner to suspend the release of goods. Prima facie evidence that an IPR is infringed must first be obtained, and both the importer and right holder promptly notified. There are no pre-suspension oversight mechanisms—only remedial measures for liability exist. The apparent danger is that ex officio border control opens the door for potential nationalistic seizures of goods and interference with free trade. However, it has been argued that ex officio actions are an essential protection mechanism that protects the right holder who is unaware that her rights are being infringed, and protects the public in the event that enforcement against counterfeiting by the right holder has not taken place.

In the spirit of transparency, the TRIPS Agreement requires that while Members are to enact their own legislation, the TRIPS Council must be notified of Members’ new rules or amendments involving TRIPS provisions so that the Council can review and approve the legislation. In 1998, the precursor to EC Reg. 1383/2003—EC Reg. 3295/94—underwent such review. The Council approved the EU customs authorities’ ability to act ex officio in seizing goods, but stipulated that the right holder had to be notified within three working days in order to enable an application for action to be filed. The current European border control measure, EC Reg. 1383/2003 also places customs authorities in ex officio capacity; however, this Regulation has not been approved by the TRIPS Council. To determine whether the Regulation is still in compliance with the TRIPS Agreement, the three main amendments to EC Reg. 3295/94 that are codified in EC Reg. 1383/2003 are compared to the TRIPS minimum guidelines as follows.

The first amendment broadens the eligible goods infringements in EC Reg. 1383/2003 to all IPRs. This measure is in accordance with TRIPS Article 51, so would likely pass WTO review. The second amendment reduces the level of suspicion required in ex officio suspensions of goods from “evident” to “sufficient,” thereby lowering the standard of liability for customs authorities. According to the prior EU Regulation, the goods must have been clearly and unmistakably counterfeit. Today, officials only need adequate suspicion that the goods are infringing in order to detain a consignment. The minimum standard set by the TRIPS Agreement is “prima facie” evidence of an IPR infringement before goods can be
Prima facie evidence of an IPR infringement before goods can be suspended ex officio. Supra note 202

Thus, this amendment to EC Reg. 1383/2003 appears to comply with the TRIPS Agreement as well. The third amendment changes customs authorities’ ex officio liability exemptions. The TRIPS Agreement contemplates that “Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.” Supra note 204 However, EC Reg. 1383/2003 indemnifies customs authorities from liability “for damages suffered [] as a result of the authority’s intervention, except where provided for by the law of the Member State.” Supra note 205 This completely changes the grounds under which customs authorities can be found liable. The TRIPS Agreement excuses only good faith mistakes, whereas the EC Reg. 1383/2003 excuses all customs authorities’ actions that are not otherwise expressly prohibited under Member State law. While good faith is an abstract and subjective standard, it can at least be argued on a case-by-case basis. EC Reg. 1383/2003, however, provides a more concrete, objective standard that potentially provides blanket immunity for any EU customs authorities’ actions. Not only would the TRIPS Council need to approve this radical shift in liability under EC Reg. 1383/2003, but the broadened customs authorities’ immunity is partly the reason for current EU-India tensions. The EU customs authorities detained India’s consignments of generic medicines for more than one month without notifying India of the detention. Supra note 206 Under TRIPS, such customs authorities’ actions are beyond “good faith” mistakes, however under EU Reg. 1383/2003, such failure to communicate was not expressly prohibited by Netherlands law, so the customs authorities’ actions did not give rise to liability. There is another important issue at stake in the current Netherlands-India dispute—the WTO now requires that Members give special consideration to trade in medicines. In the ten years between the WTO Council review of EC Reg. 3925/94 and the enactment of EC Reg. 1383/2003, the WTO’s position towards trade in medicines has changed. Supra note 207 At the 2001 WTO Ministerial Conference in Doha, Qatar, the Ministers recognized that TRIPS obligations were raising prices and blocking access to affordable medicines for developing and least-developed countries. Supra note 208 By enacting the 2001 Doha Declaration on TRIPS and Public Health, Member States laid down new TRIPS guidelines with respect to IPR enforcement and medicines—affirming that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” Supra note 209 Consequently, the ex officio border control provisions of EC Reg. 1383/2003 need to include two new customs procedures for handling medical consignments: (1) when a Member uses the Doha “flexibilities” (i.e. compulsory licenses, national emergencies, and other circumstances of extreme urgency), Supra note 210 and (2) when medicine are shipped to least-developed country Members, which are not obliged to implement or enforce pharmaceutical products patent rights until January 1, 2016. Supra note 211 The first new provision relates to situations when the medicines (usually generic) are shipped to (or through) a country in which the patent rights have not expired—thus, the shipment infringes prima facie. Yet, because the medicines are shipped in
response to a TRIPS-sanctioned emergency, the shipment is not illegal. To prevent these shipments from being seized based on suspicion of counterfeiting or other IPR infringement, EC Reg. 1383/2003 needs to contain a new provision that ensures that these medicines are clearly marked as Doha flexibilities consignments and that customs authorities do not detain these shipments. The new provision might provide a simple electronic labeling and notification system used by all TRIPS Agreement Members. Such system could alert customs authorities at in-transit ports when consignments are being transported due to a Doha flexibility. The system would involve a WTO Member database that lists country activities for customs authorities’ to access and confirm authenticity, but would be secured by the latest encryption methods so that rogue consignments of true counterfeit medicines are not passed-off and potentially endanger thousands of lives.

The second new border control provision involves a key patent rights issue that is imperative for the TRIPS Council to address in light of the Netherlands’ use of TRIPS Article 51 footnote 13 (“the loophole”) to seize India’s in-transit goods. Customs authorities’ detention of in-transit goods under EC Reg. 1383/2003 for patent infringement has the potential to violate the TRIPS Agreement “Transitional Arrangements” provisions. According to transitional arrangement provisions, Members that are developing countries and least-developed countries have a grace period before they must comply with the TRIPS Agreement. Developing countries had five years, in addition to the general transition period, to recognized and enforce patent protection on products that were unprotected as of the general date of application. This transition period allowed patent-infringing generic pharmaceutical products to be produced by India, Argentina, and Brazil until 2005. The Netherlands, however, was obligated to recognized pharmaceutical patents as of January 1, 1996. Thus, if generic medicines were sent from India to Brazil and were stopped in transit in the Netherlands before 2005, and the Netherlands applied its patent laws as to the in-transit consignments—as instructed by TRIPS Article 51 footnote 13—the goods could have been seized by customs authorities for patent infringement under EC Reg. 1383/2003. Today, similar improper detention by Member’s customs authorities could occur for Indian generic medicines in transit to least-developed countries, such as Cambodia, Niger, or Bangladesh, where pharmaceutical compounds are not required to be under patent protection until 2016.

Another critical area for Council review is the EU’s use of the TRIPS loophole that permits detention of not only imports and exports, but also goods in transit. Based on the Netherlands use of the loophole to repetitively target and detain India’s goods in transit, the Council may see in-transit seizures as a barrier to legitimate trade. As part of the “in-transit” analysis, it will be vital for the Council to address the issue of trade in counterfeit medicines—an issue that was not significant enough to appear on the statistics previously provided to the Council in 1998. Today stopping trade in counterfeit medicines is the focus of several major initiatives that extend beyond just the borders of the EU. The next Part examines the measures that the EU, along with
other developed countries, are taking to stop counterfeiting—measures that appear to be building new walls to trade in medicines based on trademark violation.

IV. BEYOND TRIPS: NEW BARRIERS TO TRADE IN MEDICINES

In addition to implementing more rigorous domestic legislation, the EU and other developed countries continue to pursue levels of anti-counterfeiting enforcement above that agreed upon in the multilateral TRIPS Agreement. Although EC Reg. 1383/2003 was not drafted to specifically increase protective measures against generic medicines or pharmaceuticals in general, the issue of counterfeit medicines has not escaped the attention of the European Commission. In 2005, the European Commission seized more than half a million fake drugs. That same year, the EU customs code was amended to introduce a new community-wide, computerized framework that enabled customs offices in all twenty-seven member states to quickly share more extensive risk information about consignments traveling throughout Europe. Armed with new tools to “tackle the growing threat to security and safety posed by dangerous goods,” EU customs officials in conjunction with the European Commission and “pharmaceutical specialists” launched the MEDI-FAKE initiative in 2008, and confiscated over thirty-four million fake drug items in just two months. The primary sources of the illegal pills were China, Pakistan, and India.

Encouraged by the success of MEDI-FAKE, the Council of Europe proposed a new directive against counterfeit medicines aimed at protecting public health, which was open for signature as of 2010. This edict proscribes the manufacturing of counterfeit medicinal products and demands that each party take “necessary legislative measures.” Additionally, the 2009–2012 EU Customs Action Plan continues to expand customs administrations’ policing efforts in the EU to include the sale of counterfeits over the internet. Both measures highlight the increasing use of customs authorities in international cooperation and coordination protection efforts. In concert with the changes in customs authorities’ power under EC Reg. 1383/2003, the European Commission clearly has placed customs authorities in a position of administrative authority.

Two hazards emerge from granting customs authorities a nearly autonomous role in border control. The first is a moral hazard. In response to the European Commission’s grant of ex officio control along with increased powers to its customs authorities, EU customs officials may be inclined to over-reach their legitimate control. The growing number of EU fake drug seizures may be a “chicken or the egg” scenario: Did EC Reg. 1383/2003 facilitate capture of existing pharmaceutical counterfeits, or did it enable unauthorized seizures of a large number of legal drugs that were falsely claimed to be counterfeit? This question does not imply that the dangers of counterfeit medicines are not real. The issue of counterfeit medicines is real and is not confined to Europe. Harmful fakes are reaching developing nations at an alarming rate. In 2009, Kenya adopted a new anti-counterfeiting law.
after its Pharmacy and Poisons Board found that thirty percent of drugs in Kenya are counterfeit—“some consisting of no more than chalk or water.”  

In June 2009, Nigeria received a large consignment of fake anti-malarial drugs labeled “Made in India;” however, the fakes were produced in China. Trade in medical products must be carefully regulated in order to protect the health and safety of both developed and developing countries’ populations. The purpose of this question is to realize that the existence of actual fake medicines is not the only plausible reason to explain the large number of counterfeit drugs seized by the EU.

The second hazard of near autonomous custom authority power has been brought to light by the repeated EU customs authorities’ seizures of Indian consignments. As explained above, the EU seized India’s generic medications, which is a patent right distinction, and based the confiscations and detainments on claims of counterfeits, a much different intellectual property right that can be used to detain consignments of otherwise legal generic pharmaceuticals. With no oversight and complete autonomy, customs authorities can potentially engage in protectionist strategies that bar shipment of legal goods. After all, India has reported nearly twenty separate incidents in which its drug firms’ exports were seized in transit in Europe for shipments meant for other markets. Autonomous customs control may be to blame for the 2009 Netherlands’ confiscations of India’s generic losartan potassium. But independent customs authorities’ actions were clearly at play in the 2008 abacavir sulfate shipment detained en route from an Indian drug manufacturer to Nigeria. GlaxoSmithKline, which holds the patent for abacavir, sent a waiver to Dutch customs authorities after detention of an abacavir tablet consignment meant to treat 166 Nigerians suffering from HIV/AIDS for three months. The Dutch customs authorities did not readily release the drugs. Instead, the European Commission declined comment on the specific seizure, and stated that that under EU legislation, customs authorities are expected to detain good suspected of IPR infringements.

It is imperative that these hazards stemming from the EU’s grant of autonomous power to its customs authorities are addressed by the WTO Council. Not only does the international community need certainty for the availability of generic pharmaceuticals manufactured in India and other developing countries, but developed nations continue to negotiate trade agreements related to intellectual property rights that extend beyond the enforcement measures permitted in TRIPS. For example, the Anti-Counterfeiting Trade Agreement (“ACTA”), which creates a more efficient system of protection of intellectual property rights, was finalized in December 2010 as a plurilateral agreement among parties only in the developed world. ACTA has been highly criticized because many developing and least-developed countries were excluded and all negotiations were conducted in secret. In addition, the primary negotiating countries—the United States, the European Community, Switzerland, and Japan—all are rigid supporters of intellectual property enforcement and were the primary movers behind the 1994 TRIPS negotiations. The danger of the ACTA agreement is that it gives continued support of
The danger of the ACTA agreement is that it gives continued support of unilateral customs authorities’ power and condones actions which interrupt legitimate trade such as those recently taken by the Netherlands against India. Without input and agreement from non-developed nations, industrialized nations continue to “improve the international legal framework for IP protection” to the detriment of developing and least-developed countries. Border protection measures are becoming stronger, and no resolutions are sought to ensure that the Netherlands’ seizures do not recur. Discussions also fail to address how to prevent improper detainment of developing country goods received at developed country ports. Instead of helping developing countries become part of international trade, it appears that developed countries continue to build an ever taller trade wall.

V. WHO IS BEST TO POLICE COUNTERFEIT MEDICINES: ISSUES OF COMPLEXITY AND NATIONALISM

Asking who is best to police counterfeit medicines is a particularly important question in light of the “zero-tolerance” campaign against counterfeit goods launched by the European Commission. It is also an important question in light of the new intellectual property regulations secretly negotiated by developed countries under ACTA. Clearly, international trade rules place customs agencies in the position of power when it comes to regulating trade entering, exiting, and passing through Member states. The WTO, through the TRIPS Agreement, bestows on customs authorities the power to suspend goods suspected of IPR infringement for goods being imported, exported, and in transit through their country. Additionally, the EU has long viewed customs as the “first line of defense when protecting our borders.” However, this Comment questions whether customs officials are the right hands in which to place authority over goods being traded.

Since no person or party has claimed responsibility for ordering the multi-national seizures of India’s generic medicine consignments, it is logical to assume that the repeated Indian generic drug seizures are a result of the independent, nearly autonomous authority given to customs authorities under EC Reg. 1383/2003. If EU customs authorities are to be the “first line of defense” and solely responsible for detecting IPR violations, they must be well-prepared to deal with the fundamental complexities associated with policing medicines so that the health and safety of consumers is ensured and life-saving medicines are delivered. The minimal requirements of an effective border enforcement policy requires knowledge of: (1) the multitude of different names given to the same medicinal compound; (2) the territories in which the compound has been granted IPR protections; (3) the date on which the IPR protections expire in both the sending and receiving countries; and (4) whether the consignment has been compulsory licensed under Doha flexibilities. All of this information needs to be collected in a database and updated on a daily basis. Without a thorough and accurate database, the ability for customs authorities to determine whether a medication is counterfeit based on the name of the product is not a simple matter. For example, under current pharmaceutical sales practices a single drug can be given a
range of different names depending on whether it is sold under a brand or a generic name. The diabetes medication known by its generic name metformin, is also known by brand names, Glucophage, Glucophage XR, Glumetza, Fortamet, Riomet. Imagine these six different names for one medicinal compound multiplied by the tens of thousands of medicines sold on the worldwide market. A WTO Members system such as the U.S. Food and Drug Administration’s “Electronic Orange Book,” can greatly simplify drug identification and patent rights can be readily determined. However, without such a database, consignments entering foreign borders have the potential to be unnecessarily detained by customs authorities due to nationalistic preferences against goods, legal or illegal, that may pose an economic threat to European industry. Actions such as the Netherlands customs authorities’ seizure of the Indian generic pharmaceuticals have the potential to continue. A second consideration to the question of ‘who is best to police counterfeit medicines’ is whether one party should have total enforcement control over IPR violations. While the TRIPS Agreement allows ex officio action by customs authorities, the consequence is that the same agency that controls the daily flow of goods into, out of, and through a Member’s borders is the same agency that has the complete, unchecked authority to destroy or dispose of infringing goods. In non-ex officio actions, the TRIPS Agreement contemplates a duality of authority. Competent judicial or administrative authorities are responsible for determining whether a right holder’s application for customs authorities to intercept counterfeit goods is actionable and the judicial or administrative authorities are held responsible for the improper destruction or disposal of goods. While omission of the judicial or administrative authority in ex officio actions enables customs authorities to intercede when the right holder either is unaware or has failed to file a claim, there is no reason why the system of checks and balances for customs authority power is obviated. Approval of customs authorities’ actions by judicial or administrative authorities is still possible. In light of dominant European Commission’s and developed nations’ trade policies that encourage strong protection and enforcement of intellectual property rights, the checks and balances envisioned under the TRIPS Agreement non-ex officio actions would be a suitable deterrent to over-reaching protectionism that currently frustrates the principles of legitimate trade.

CONCLUSION

The recent in-transit seizures by the Netherlands of Indian generic pharmaceuticals brought international attention to the consequences of new multilateral anti-counterfeiting measures being created by developed nations. As the volume of counterfeit goods, including medicines, continues to grow, WTO Members undoubtedly need to strengthen their enforcement measures in order to protect the health, safety, and welfare of their populations. However, the crux of the Netherlands’ seizures is in customs authorities’ near-autonomous border-control powers that permit seizures of goods merely traveling...
An analysis of the underlying international trade agreements reveals that while both GATT and TRIPS permit Members to apply their border control measures to goods in transit, this provision is optional under both agreements—in-transit goods are not required to be detained and inspected. Additionally, while the TRIPS Council approves of customs authorities’ acting independently in ex officio actions, the Council has yet to approve the EU anti-counterfeiting regulation, EC Reg. 1383/2003, which merges both factors—(1) customs authorities’ ex officio control (2) over in-transit goods. This unapproved combination that has the danger of becoming a nationalistic measure to impede legal trade, and is the basis for over twenty separate seizures of India’s generic medicine consignments at EU ports. In addition, EC Reg. 1383/2003 lacks the required border control measures that recognize and incorporate the 2001 Doha Declaration provisions that balance access to medicines and intellectual property rights. The hazard is that future situations will arise in which medicines shipped under the Doha “flexibilities” in response to a national emergency are unnecessarily detained in transit at an EU port under counterfeiting suspicions, causing delays in the delivery of urgent medicines such as HIV/AIDS medications, which, if failed to be timely delivered, can cause setbacks in a patient recovery and health.

In order to avoid an international policy stand-off between developed and developing nations, the solution to eradicating trade in counterfeits may be as simple as instituting a system of information sharing. A secure, WTO-instituted database could send timely information about IPR approvals and Member’s medical shipments to all Members’ custom authorities. It also might be best for Members to implement the TRIPS Agreement’s non-ex officio system of border control measures, which inherently contains a system of check and balances to seizure actions. These solutions may provide a better solution to both protecting the public against the life-threatening dangers of fake medicines and enabling access to life-saving medicines, than the developed countries’ one-sided goals under new plurilateral trade agreements.

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