


# Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare

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The European Union amended its border control regulations in 2003 in a way that allegedly signalled permission to EU patent holders to demand seizure of goods in transit through EU ports and airports.<sup>1</sup> The precise intention of the EU IP Border Regulation has been the subject of some controversy among European courts.<sup>2</sup> What

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<sup>1</sup> Council Regulation 1383/2003 concerning customs actions against goods suspected of infringing certain intellectual property rights (EC IP Border Regulation).

<sup>2</sup> See *Montex Holdings v Diesel* (C-281/05) [2006] E.C.R. I-10881; [2007] E.T.M.R. 13 (interpreting 1994 predecessor to 2003 IP Border Directive, and holding that customs may not suspend transit of goods in commerce based on EU trade mark absent direct evidence of third party activity to place goods on market within Member State, even if goods were produced in contravention of trade mark holder rights in a non-EU state); *Nokia v UK Customs* [2009] EWHC 1903 (Ch), (holding that UK customs did not have authority under 2003 EU IP Border Regulation to detain fake goods in transit based on UK trade mark holder claim where no direct evidence of third party intention to place on market within EU, and rejecting Court of Hague analysis in Case 311378 *Sisvel v Sosecal* of July 18, 2008 based on manufacturing fiction); compare Court of Hague, Case 311378 *Sisvel v Sosecal* of July 18, 2008 (holding that Netherlands customs authorities may suspend goods in transit based on allegation of infringement of Dutch patent based on “manufacturing fiction” derived from recital of 2003 IP border regulation). See also Barbara Kuchar, “Comparative Presentation of Recent National Court Decisions in Transit Cases”, *INTA International Forum on Anticounterfeiting*, Paris, December 4, 2008; Jens van den Brink, “Comeback for the Legal Fiction of the Anti Piracy Regulation?” in *Kennedy Van der Laan Newsletter*, August 2008 (translating *Sisvel* decision to English).

has generated intense controversy, however, is the use of the regulation as the basis for seizure of pharmaceutical products alleged to be infringing “local” patents on their way through European airports.<sup>3</sup> Although the next steps at the inter-governmental level remain to be determined, the fundamental IP related issues raised by the seizures are worthy of attention because of their long-term implications for the international economic system, economic development and public welfare.

Implementation of the EU IP Border Regulation represents a challenge to fundamental ideas about the way the international intellectual property system operates. The Paris Convention on the Protection of Industrial Property incorporates “independence” of patents as a core principle.<sup>4</sup> The principle is framed in terms of protecting national institutions and decision-making against intrusive determinations by foreign authorities. The principle of independence of patents preserves the sovereign authority of states to adopt and implement patent protections as they consider appropriate, within the framework of a general set of rules. Each member of the Paris Convention decides whether to grant or deny patent protection, and that determination is not dependent on decisions of foreign courts or administrative bodies. The principle of “independence” is corollary to the “act of state doctrine” in international law pursuant to which the courts in one country do not sit in judgment on the acts of foreign governments taken within their own territory based on considerations of comity and restraint.<sup>5</sup>

The principle of independence is sometimes equated with a “territorial” nature of the international patent system. The Paris Convention does not prescribe the jurisdictional scope of patents, nor does it prescribe or define “territoriality”. The scope, extension or limitation of patent jurisdiction is determined by national legislatures and courts within boundaries prescribed by public international law. Traditionally, national legislatures and courts have approached potential extraterritorial application of patent law with considerable caution, recognising the problems that would arise in attempting to extend local control to economic activity taking place (and fundamentally regulated by) foreign legislatures and courts. (A territorial nature of the international patent system is recognised in the WTO Decision of August 30, 2003, at para.6(i), and in the corresponding TRIPS Agreement Amendment, at art.31bis.3, each expressly referring to the “territorial nature of [ . . . ] patent rights”.)

In recent years, some national courts have begun to move away from a rigid understanding of the “territoriality” of patent law. In the *Blackberry* case,<sup>6</sup> the United States Court of Appeals for the Federal Circuit recognised that advances in technology may create situations in which an invention operates through actions carried out in more than one country, and that the issue of infringement within a country may not

<sup>3</sup> See, e.g. “Access to Medicines Back on Centre Stage at the WTO”, (2009) 13(1) *ICTSD Bridges Monthly* 12, and joint letter from public health NGOs to Pascal Lamy, WTO Director General, February 18, 2009.

<sup>4</sup> Paris Convention for the Protection of Industrial Property (1883, as amended), art.4bis (Patents: Independence of Patents Obtained for the Same Invention in Different Countries), 828 U.N.T.S. 305. See Frederick M. Abbott, Thomas Cottier & Francis Gurry, *International Intellectual Property in an Integrated World Economy* (New York: Aspen 2007), pp.65–70.

<sup>5</sup> See *Banco Nacional de Cuba v Sabbatino* 376 U.S. 398 (1964).

<sup>6</sup> *NTP v Research in Motion* 418 F 3d 1282 (Fed. Cir. 2005).

always be assessed only by examination of actions within that single national territory. A modest extension into extraterritorial application of patent law in the *Blackberry* case was grounded in traditional international law concepts of jurisdiction whereby an act undertaken outside the territorial limits of a state that has a direct and substantial effect within that state may lead its courts to take cognisance of those acts. In cases such as *Blackberry*, the infringement affects most directly and substantially the country where the allegedly infringed patent is held. Following the US Supreme Court decision in *Microsoft v AT&T*,<sup>7</sup> which stressed limitation of patent infringement to the national territory (and cautioned against extraterritorial extension), the Federal Circuit acknowledged a strong presumption against extraterritorial effect in excluding process patents from the scope of a US statutory prohibition on exporting infringement-capable components.<sup>8</sup>

It is an axiom of public international law that sovereign nations exercise exclusive control over activities taking place within their own territory (although international human rights law challenges certain aspects of that axiom).<sup>9</sup> The European Union bases its exercise of jurisdiction over pharmaceutical products moving in transit through EU airports on its right as sovereign to control activity taking place within EU (and Member State) territory. This extension of jurisdiction is said to be codified in EU customs regulations.<sup>10</sup>

Yet a corollary of the axiom of sovereign control over activities within the national territory is that states have the right to cede elements of exclusive control through international agreement and custom.<sup>11</sup> Thus, through a long history of international agreements and custom, states of the international community have adopted exceptions from exercise of jurisdiction in favor of immunity for diplomats, for naval vessels from *in rem* admiralty actions and for activities taking place on foreign operated military bases established under basing agreements.

Since 1947, Member States of the European Union have been members of the GATT, now the World Trade Organization (WTO). The EU is a Member of the WTO. The WTO provides the legal framework under which international trade is conducted. From its inception, the GATT/WTO has recognised in GATT art.V the principle of “freedom of transit” for goods moving through ports and airports in international trade. This fundamental principle has been so widely and consistently implemented that there has been virtually no controversy about it in the history of the GATT/WTO, despite the fact that goods are constantly moving in transit through its Members.<sup>12</sup> It is simply a “given” in international trade law that the customs authorities of a country

<sup>7</sup> *Microsoft v AT&T* 550 U.S. 437 (2007).

<sup>8</sup> *Cardiac Pacemakers v St. Jude Medical*, 576 F. 3d 1348 (Fed. Cir. 2009).

<sup>9</sup> Cf. United Nations Charter, art.2.

<sup>10</sup> See, e.g. art.3 of the 1992 Community Customs Code defining the “customs territory” of the Community as the territory of its Member States (Council Regulation (EEC) No.2913/92 of October 12, 1992 establishing the Community Customs Code).

<sup>11</sup> See, e.g. *The Case of the S.S. “Lotus”*, PCIJ, Judgment No.9, PCIJ, Ser. A., No.10, 1927.

<sup>12</sup> See, e.g. Note by WTO Secretariat, Article V of GATT 1994—Scope and Application, TN/TF/W/2, January 12, 2005 (updating G/C/W/408, September 10, 2002). There is a recent WTO panel report, “Colombia—Indicative Prices and Restrictions on Ports of Entry”, Report of the Panel, April 27, 2009, WT/DS366/R. That report addresses an issue unrelated to the subject of this essay, i.e. the point at which transit within a country removes goods from the protection of art.V.

do not seize or detain goods passing through their ports and airports *en route* to foreign destinations without a good reason. GATT art.V prohibits Members from imposing unreasonable regulatory requirements on goods in transit.<sup>13</sup>

The WTO TRIPS Agreement did not purport to modify the three core principles of the Paris Convention: national treatment, independence and right of priority.<sup>14</sup> The TRIPS Agreement obligates WTO Members to extend patent subject matter coverage to all fields of technology.<sup>15</sup> But the authority to grant or deny patent protection remains with national patent offices of Members based on relevant national legislation.<sup>16</sup>

An inventor may lack patent protection in a WTO Member for a number of reasons, including: (1) no patent was ever sought; (2) a patent has expired; (3) a patent application was rejected because the claimed invention was deemed not to meet the criteria of patentability; (4) the claimed invention did not constitute patentable subject matter under the law of the particular Member (e.g. computer software as such in Europe). India, as a case in point, was not required by the TRIPS Agreement to provide pharmaceutical product patent protection until January 1, 2005, and many pharmaceutical products patented in Europe are not patented in India.

Article 51 of the TRIPS Agreement obligates WTO Members to adopt procedures allowing trade mark and copyright owners to prevent counterfeit trade mark and pirated copyright goods from entering national markets through detention at the border and notification by customs authorities. The TRIPS Agreement also allows members to adopt measures to prevent importation of goods “infringing” other forms of intellectual property. Footnote 13 to that provision indicates that there is no obligation to provide anti-counterfeit or anti-piracy border procedures for parallel traded goods or “goods in transit”. It was logical for the drafters of the TRIPS Agreement to frame these exceptions in such terms as “no obligation” to provide measures, rather than as a bar or ban, because the drafters were not attempting to define the outer limits of IP protection. In the case of parallel trade, it was understood that members might or might not provide border protection measures depending upon the local approach to the exhaustion question. At the time the TRIPS Agreement was negotiated, the practice of seizing goods in transit based on allegations of patent infringement was unknown; so members would not have contemplated such practice as an option when drafting the relevant provision. It places too much weight on footnote 13 to suggest that it was intended to authorise the seizure of patented goods in transit when the practice was almost certainly outside the contemplation of the drafters of the TRIPS Agreement.

There have been a substantial number of recent cases in which EU customs authorities have acted to seize pharmaceutical products in transit between developing countries where there are no patents in force.<sup>17</sup> These seizures have been based on

<sup>13</sup> The Panel in the *Colombia-Indicative Prices* case, at para.7.387, noted: “As its title indicates, Article V of the *GATT 1994* thus generally addresses matters related to ‘freedom of transit’ of goods. This includes protection from unnecessary restrictions, such as limitations on freedom of transit, or unreasonable charges or delays (via paras 2-4), and the extension of Most-Favoured-Nation (MFN) treatment to Members’ goods which are ‘traffic in transit’ (via paras 2 and 5) or ‘have been in transit’ (via para.6).”

<sup>14</sup> WTO TRIPS Agreement, art.2.

<sup>15</sup> WTO TRIPS Agreement, art.27.1.

<sup>16</sup> WTO TRIPS Agreement, arts 1.1, 29 and 62.

<sup>17</sup> See, e.g. John W. Miller and Geeta Anand, *India Prepares EU Trade Complaint*, *Wall Street Journal*,

patents in force in the “transit” EU Member States. The customs authorities of the Netherlands have been the most aggressive. This is ironic since the Netherlands earlier acted as a champion of access to medicines for developing countries, and now appears to have retreated from its supportive posture. The first case that received wide public attention was seizure by Dutch customs in December 2008 at Schiphol airport of a shipment of losartan, a blood pressure medication, in transit from India to Brazil.<sup>18</sup> Losartan is not patented in India or Brazil, but Merck asserts patent rights in the Netherlands. In this case, lawyers acting on behalf of Merck demanded that the producer, Dr Reddy’s, consent to destruction of the shipment. Merck eventually authorised release of the goods back to India in exchange for Dr Reddy’s acknowledgment of its Dutch patent. A second case involved a shipment of the antiretroviral medicine abacavir shipped from India by Aurobindo, where it is not patented, to Nigeria. Glaxo claims patent rights in the Netherlands. In this case, Glaxo advised Dutch customs authorities that it did not wish to initiate a legal action against the shipper, but Dutch customs authorities nevertheless referred the matter to a criminal prosecutor.<sup>19</sup> Remarkably in this case the goods had been purchased on behalf of UNITAID. Dutch customs authorities were interfering with a French-supported programme to supply generic antiretroviral medicines to Africa. Other recent cases involve seizure by Dutch customs authorities of a Cipla shipment of olanzapine en route from India to Peru based on a Dutch patent asserted by Eli Lilly, and a shipment of clopidogrel en route from India to Colombia based on a Dutch patent asserted by Sanofi Aventis.<sup>20</sup>

The European Court of Justice in *Montex Holdings v Diesel* raised serious doubt whether seizure of IP protected goods in transit and not intended for the European internal market was permissible.<sup>21</sup> The Court of Justice noted that violation of the 1994 IP Border Regulation (predecessor of the 2003 IP Border Regulation) was predicated upon infringement of an EU intellectual property right (in that case a trade mark), and that the Trademark Directive predicated trade mark infringement on entry into the EU stream of commerce. The ECJ said that unless direct evidence of third party action to place the goods into the EU stream of commerce was present, there could be no infringement under EU law; thus no seizure was authorised. The High Court of England and Wales recently affirmed this line of reasoning in *Nokia v UK Customs*, also with respect to trademarks, but on this occasion expressly interpreting the 2003 EU IP Border Regulation.<sup>22</sup> Dutch authorities and pharmaceutical patent holders, on the other hand, have relied on a decision of the Court of The Hague in the Netherlands, *Sisvel v Sosecal*, grounded in recital 8 of the 2003 IP Border Regulation. The Court of The Hague interprets the recital to establish a “manufacturing fiction”. Using this “fiction”, an act of patent infringement takes place by “use” of the patent for

August 6, 2009, and formal response by Dutch government on seizures and border measures in FTAs (to parliamentary questions), posted by Health Action International on IP-Health list server, April 25, 2009.

<sup>18</sup> See Frederick M. Abbott, “Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil”, (2009) 13(1) *Bridges Monthly* 13.

<sup>19</sup> Dutch Government’s response to Parliament, *supra* note 17.

<sup>20</sup> John W. Miller and Geeta Anand, “India Prepares EU Trade Complaint”, *Wall Street Journal*, August 6, 2009.

<sup>21</sup> *Montex* (C-281/05) [2006] E.C.R. I-10881.

<sup>22</sup> *Nokia v UK Customs* [2009] EWHC (Ch) 1903.

manufacturing in the Netherlands, even though it is absolutely clear that no such manufacturing takes place. It is a truly remarkable theory under which Dutch law is deemed to be violated by actions taking place in another country, e.g. India, as if those actions had taken place in the Netherlands.

It is hard to imagine a greater departure from the principle of independence of patents than the “manufacturing fiction” that is said to support a finding of infringement of a Netherlands patent by an action in India. The absence of a patent in India where the manufacturing takes place (and which is independent of the Netherlands) is completely ignored. There is no direct or substantial effect on the Netherlands that might be deemed to constitute a reasonable substitute for actual manufacturing. There is no harm in or to the Netherlands unless one reaches to the farthest levels of attenuation (which the European Commission has soundly rejected in the area of competition law).

It is also difficult to imagine what the international legal system will be like if the “fictional acts” theory of jurisdiction becomes widely adopted. American manufacturers might be sued in Europe for violating EU environmental law standards when manufacturing in the United States in compliance with US environmental law. Chinese companies could be sued in the EU for failing to provide EU-standard paid vacation for their workers on the fiction that they were manufacturing in France. A doctor performing a legal abortion in Germany could be prosecuted in Ireland on the theory that the abortion would have been illegal if performed in Ireland. An 18-year-old student drinking beer in Germany could be prosecuted in Florida because 21 is the legal drinking age in Florida. The concept of national sovereignty would be completely meaningless in this new “fictional acts” environment.

The European Commission has sought to justify implementation of the 2003 regulation on grounds that it is seeking to further the legitimate public policy goal of preventing the circulation of “counterfeit” drugs.<sup>23</sup> Since no one approves of counterfeiting, the Commission presumably considers that the public and legislators will ignore fundamental legal issues in favor of this “public good”.

Patent infringement and drug counterfeiting are completely different acts and involve different legal concepts. In order to infringe a patent, the infringer must infringe on each and every claim of the patent. The producer of a “patent infringing” drug should be producing the same thing as the patent holder or its licensee. Otherwise, there is no infringement. When a patent holder such as Merck alleges that Dr Reddy’s is infringing its losartan patent, it is alleging that Dr Reddy’s is producing the same drug as the one on which Merck holds its patent, but without its consent. Merck is not alleging that there is a risk to the public from a different or inferior product. The classic “generic” pharmaceutical product is the same as the originator “patented” product, produced by a third party, in a situation in which the patent does not apply.

The problem of “counterfeiting” in the pharmaceutical sector is a problem of misidentified substandard drugs placed on the market without concern for the well-being of the public. In the sense of pharmaceutical regulation, a counterfeit substandard drug does not infringe a patent because it is not the same thing as the patented drug.

<sup>23</sup> See Kaitlin Mara, “Generic Drug Delay Called ‘Systemic’ Problem at TRIPS Council”, *Intellectual Property Watch*, June 9, 2009.

It is neither the responsibility nor the right of WTO Members outside a country that has not granted patent protection to “cure” that situation in favor of a local patent holder by disregarding the decisions taken by authorities in the country that has not provided protection. The European Union has elected to disregard the sovereign rights of foreign WTO Members by refusing to give effect to their decisions as to patent status by the use of force—the seizure and detention by customs authorities of goods in transit. The allegations of infringement are purely for the convenience of a patent holder that happens to have chosen a particular transit country as a place to obtain a patent.<sup>24</sup> This is a form of “long-arm” extension of jurisdiction that the European Union has claimed to abhor when adopted by US antitrust authorities.

While the threat to the international economic system and foundations of international law are serious enough, an even more important negative consequence of the EU policy with respect to the seizure of generic pharmaceuticals in transit is the breach of the understanding reached at the WTO regarding access to medicines as embodied in the Doha Declaration on the TRIPS Agreement and Public Health. There was a bargain reached at the conclusion of the GATT Uruguay Round of trade negotiations in 1993 that provided a 10-year transition period for countries such as India that did not provide pharmaceutical patent protection to institute that protection.<sup>25</sup> That bargain acknowledged that public health systems and patients throughout the developing world relied on countries such as India to provide low-cost generic versions of pharmaceutical products on patent in the developed countries, and that a rapid transition to globalised patent protection would have significant adverse effects on public health. In good measure as a consequence of India’s decision to take full advantage of the transition period, a significant part of the developing world can and does continue to rely on that country for the supply of low-cost generic medicines. The Doha Declaration was born out of frustration by developing countries with aggressive tactics employed by the pharmaceutical originator industry, USTR and the European Commission that sought to eliminate through trade intimidation the flexibilities that had been negotiated and built into the TRIPS Agreement.<sup>26</sup>

The Doha Declaration is an agreement among WTO Members on interpretation of the TRIPS Agreement and provides that the TRIPS Agreement does not and should not interfere with the right of members to protect public health. It further recognises the objective of promoting “access to medicines for all”. Seizure of generic drugs moving legitimately in transit is a frontal assault by the EU on the object and purpose of the Doha Declaration. It is an effort to prevent developing countries from relying on the security of supply from Indian generic manufacturers, and to put them out of business

<sup>24</sup> Imagine, for example, if the German computer software firm SAP sought to ship program disks from Heidelberg to Bogotá through Miami, and US Customs seized and detained the program disks because of an allegation of patent infringement by IBM based on a US software patent. Since the EPO does not grant software patents, IBM presumably does not have protection in Europe. Would the European Union consider this a legitimate patent infringement action?

<sup>25</sup> Frederick M. Abbott and Jerome H. Reichman, “The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions”, (2007) 10 J. Int’l Econ. L. 921. While USTR eventually acknowledged the legitimacy of TRIPS flexibilities (as adopted by South Africa), the European Commission never did.

<sup>26</sup> See Frederick M. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO”, (2002) 5 J. Int’l Econ. L. 469.

(or force them into mergers with major originator companies). This cannot be justified as a means to control counterfeiting. If legitimate generic drugs are treated as counterfeit drugs the entire global public will suffer. Regrettably, the international patent system will again suffer a blow to its legitimacy.