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new scientific or technical information that might affect the assessment of the safety of a food additive on manufacturers or users. Furthermore, Member States shall maintain systems to monitor the consumption and use of food additives on a risk-based approach and report their findings with appropriate frequency to the Commission and the EFSA.

## IV. Conclusions

It would appear therefore that adequate protection systems are in place and that said systems are capable of ensuring a safe use of food additives in foodstuffs. Moreover, the continued surveillance and regular re-evaluation of food additives in the light of changing conditions of use and new scientific information will help to further define the needs and the setting of the order of priorities for the competent authorities *vis-à-vis* the assessment of the safety of food additives.

However, a proper assessment of the actual achievement of the objectives pursued by the Additives Regulation will only be conducted over the next few years.

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## Intellectual Property

*This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.*

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## Seizures of In Transit Generics at the EU Borders: India and Brazil v. the EU

Enrico Bonadio and Carlo Maria Cantore\*

### I. Introduction

The row between India and Brazil on the one hand and the European Union (EU) on the other regarding customs detentions of Indian generic drugs headed for developing countries may soon come to an end.

Indeed, negotiations between the parties are on going and there are constant rumours of an upcoming settlement of the dispute. Yet it remains interesting to analyse this dispute as other countries could take measures similar to those of the EU. In this case, WTO adjudicatory bodies might soon be called upon to assess the compatibility of these measures with TRIPS and GATT provisions.

The case was brought to the attention of the WTO on May 2010 by India and Brazil<sup>1</sup>. These states pointed out that customs rules in the EU, Regulation 1383/2003 in particular, allowed customs authorities to detain certain lots of Indian generics in transit to non-EU states<sup>2</sup>. From the point of view of India and Brazil, these measures contradict relevant TRIPS and GATT provisions<sup>3</sup>. The case has spurred a debate because these measures could affect or impede the protection of public health in some countries, namely the African and Latin American states that are usually the final destination of the Indian manufactured generics. Indeed – as India and Brazil have put it – most of these countries are in dire need of reason-

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1 Two separate complaints have been filed on May and June 2010, respectively, by India (DS 408, EU – Seizure of Generic Drugs in Transit) and Brazil (DS 409, EU – Seizure of Generic Drugs in Transit) against the EU and one of its Member States (The Netherlands). Hereinafter, for ease of reference, when referring to the defendants we will mention just the EU. Summaries of the two complaints are available on the Internet (India – EU, at <[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm)>; Brazil – EU, at <[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds409\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm)>, both last accessed on 22 October 2010).

2 Regulation 1383/2003 (Council Regulation (EC) No. 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, OJ 2003, L 196/7). India and Brazil also objected to other EU legislative acts (i.e. Commission Regulation (EC) No. 1891/2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, OJ 2004 L 328/16; Council Regulation (EEC) No 2913/92 establishing the Community Customs Code, OJ 1992, L 302/1; Directive 2004/48 (EC) of the European Parliament and of the Council on the enforcement of intellectual property rights, OJ 2004, L 195/16; Regulation (EC) No 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, OJ 2006, L 157/1) and Dutch provisions (e.g., certain provisions of the Dutch Patents Act and the General Customs Act of the Netherlands) as well as other relevant Dutch regulations, guidelines and administrative practices.

3 Namely Articles V and X of the GATT 1994 and various provisions of the TRIPs Agreement, namely, Article 28 read together with Article 2, Articles 41 and 42, and Article 31 read together with the provisions of the August 2003 Decision on TRIPs and Public Health.

ably priced generics and pharmaceutical products in general.

The facts of the case are the following. Between October and December 2008, Dutch customs authorities blocked a number of shipments of generic drugs coming from India and destined to various Latin American countries at Schiphol, the airport of Amsterdam. These products were detained on grounds that they might infringe patents that are owned by several pharmaceutical companies (e.g., Sanofi-Aventis, Glaxo, Ely Lilly, Du Pont, Merck) and that cover important drugs such as clopidogrel, abacavir, olanzapine, rivastigmine and losartan. Both India and Brazil stress that (i) the generics in question were produced in India<sup>4</sup> and were not directed to the EU market and that (ii) the patents invoked for blocking such products are valid in the EU Member States, but not in India nor in the countries of final destination.

India and Brazil, together with some health related NGOs, claim that these seizures contravene certain TRIPS and GATT provisions and also cause grave damage to public health in developing and least-developed countries by delaying or denying them access to life-saving drugs; e.g., the price of medicines would go up in the destination countries, since the transportation costs would inevitably increase.

The EU argues that patent protection in general and these measures specifically, far from intending to damage the access to medicine of above mentioned countries, do aim at protecting public health. In fact, the target of these measures is precisely to protect

public health. Indeed, by protecting patents – EU’s argument goes – the commercialization of counterfeit drugs is prevented and pharmaceutical companies have incentives to invest in the development of new and useful drugs: this is also to the benefit of the population of developing or least-developed countries<sup>5</sup>. Additionally, blocking generics in transit at the EU customs aims at preventing the old “nightmare” of Big Pharma – i.e. the re-importation of low-price products into the EU market – of recurring. Indeed such risk of re-importation is deemed to have a discouraging effect on R&D investments in the health sector<sup>6</sup>.

Other countries such as Colombia, Ecuador, Peru, Venezuela, Nigeria and South Africa are interested in the outcome of this case. Some of these countries regularly import generics manufactured by Indian companies and others might do so in the near future.

## II. Are the seizures in breach of TRIPS?

India and Brazil stress that the drugs in question are patented in EU states, but not in India or in the countries of final destination. This appears to be a strong argument. How can the EU – India and Brazil enquire – invoke intellectual property rights to block generics coming from and destined to countries where the drugs in question do not enjoy patent protection?

The EU instead argues that the Dutch authorities did not carry out “seizures” but merely “temporary detentions” of goods suspected of infringing patent rights valid within the EU, pursuant to Regulation 1383/2003. In particular, the EU might invoke Article 51 TRIPS<sup>7</sup> and its footnote 13, which allow WTO Member States to temporarily block products suspected of infringing intellectual property rights (IPRs) at their borders. Footnote 13 specifically states that “*It is understood that there shall be no obligation to apply such [customs] procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit*” (emphasis added). Therefore, arguing *a contrario*, WTO Member States would be entitled to apply customs procedure to goods in transit through their territories as well.

It is true that these TRIPS provisions allow states to temporarily block goods at their borders. However, it is important to note that such measures must comply with certain requirements<sup>8</sup>, e.g. those laid down in Article 52 TRIPS. This provision states that IPRs

4 For example, the Indian company Dr Reddy’s manufactures the generic drug Losartan.

5 Xavier Seuba, “Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border”, ICTSD Programme on IPRs and Sustainable Development, Issue Paper No. 27, International Centre for Trade and Sustainable Development (2010), p. 2, available on the Internet at <[http://ictsd.org/downloads/2010/04/seuba\\_web\\_10.pdf](http://ictsd.org/downloads/2010/04/seuba_web_10.pdf)> (last accessed on 22 October 2010).

6 In addition, the EU minimizes the facts of the case and in particular notes that the generics blocked at its borders were later released.

7 Article 51 provides that “*Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories*” (emphasis added).

8 See emphasis added, *supra* note 7.

owners who apply the customs procedures in question must provide adequate evidence that “under the laws of the country of importation” there is a *prima facie* violation of their rights. Also footnote 14 TRIPS provides definitions of counterfeit and pirated goods and refers to the “law of the country of importation” as the law that will judge the intellectual property violation<sup>9</sup>.

The identification of “the country of importation” has therefore become a determining factor<sup>10</sup>. Is the country of importation the EU Member State through which the generics transit? Or is it the country of final destination? Indeed, in the former case the detentions at the EU borders (and Regulation 1383/2003 which constitutes their legal basis) would be compliant with TRIPS, as the relevant patents are valid in said EU country. Accordingly, right owners could easily prove that the generics in question infringe their valid patents. Instead, in the latter case the detentions at issue as well as Regulation 1383/2003 that generated them would contravene Article 52 TRIPS. Indeed, in this scenario right holders could not give evidence of a patent infringement under the laws of the final destination country, as they enjoy no patent rights there.

It goes without saying that it would be helpful to have an authoritative interpretation from a WTO adjudicatory body to clarify the exact meaning of “country of importation”.

The debate surrounding the definition of the meaning of “country of importation” leads us to another focal point of this dispute: the alleged violation of the principle of “independence” of patents, enshrined in Article 4-*bis* Paris Convention for the Protection of Industrial Property. This principle is incorporated into TRIPS<sup>11</sup> and states that patents applied for in one country are independent of patents obtained for the same invention in other countries. This rule is closely related to another fundamental rule of intellectual property law, namely the territoriality principle, according to which protection offered in one state does not entitle a party to acquire identical protection in another one.

Having said that, some commentators believe that invoking patent infringement grounds to block goods coming from, and directed to, countries where those products do not enjoy patent protection contravenes the principle of independence of patents<sup>12</sup>. In other words, it is believed that these measures turn out to give patents valid in the EU an extra-territorial effect.

A pertinent example, affirmed by a Dutch court<sup>13</sup> and invoked by Dutch customs authorities when it came to blocking goods in transit (including the generics in the India-Brazil/EU dispute), is the “manufacturing fiction” principle. This allows authorities to fictitiously assume that products in transit have been manufactured in the Netherlands and thus can be subject to customs detentions on grounds of alleged infringement of a Dutch patent. This rule is believed to contravene the principle of independence of patents. As has been pointed out, “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 [...]”<sup>14</sup>.

A decision from WTO judicial bodies on the alleged incompatibility of the “manufacturing fiction” rule with the principle of independence of patents enshrined in Article 4-*bis* Paris Convention could shed some light on this controversial issue, and would be most welcome.

### III. Other relevant issues

Other factors must also be taken into consideration.

(i) There is a strong argument that the seizures at the EU borders amount to an unjustified barrier

9 Shashank P. Kumar, “Border Enforcement of IP Rights Against In Transit Generic Pharmaceuticals: An Analysis of Character and Consistency”, 32 *European Intellectual Property Review* (2010), pp. 506 *et seq.*, at p. 512.

10 Shashank P. Kumar, “International Trade, Public Health, and Intellectual Property Maximalism: The Case of European Border Enforcement and Trade in Generic Pharmaceuticals”, 5 *GT & CJ* (2010), pp. 155 *et seq.*, at p. 160.

11 Article 4-*bis* Paris Convention for the Protection of Industrial Property states that “Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.” See also Article 2.1 TRIPS which incorporates said provision.

12 See, for example, Frederick M. Abbott, “Seizure of Generics Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare”, 1 *WIPOJ* (2009), pp. 43 *et seq.*, at p. 44.

13 Court of Hague, Case 311378 *Sisvel v. Sosecal*. In this decision the court clarified that the Dutch customs authorities may suspend goods in transit on grounds of alleged infringement of a Dutch patent. In particular, it stressed that the “manufacturing fiction” principle could be inferred by Recital 8 Regulation 1383/2003.

14 Frederick M. Abbott, *supra* note 12, at p. 48.

to trade (namely a south-south trade) between countries and therefore contravene the spirit and the provisions of the GATT/WTO system and of TRIPS<sup>15</sup> in particular.

First, such measures would jeopardize the market liberalization objective pursued by the GATT/WTO system. Indeed, in the recitals of the Agreement that establish the WTO, Member States declare that they wish to expand “[...] *the production of and trade in goods and services*” (Recital 1) by means of “*arrangements directed to the substantial reduction of tariffs and other barriers to trade*” (Recital 3). The seizures discussed in this case, however, seem to go in the opposite direction.

India and Brazil claim that the detentions of Indian generics at the EU customs border – in transit from India to certain Latin American countries – contravenes Article V(2) GATT on “freedom of transit” in particular. This provision states that “[t]here 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”.

TRIPS also aims at reducing obstacles to international trade of goods. In particular, Recital 1 TRIPS stresses that WTO Member States wish “*to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade*” (emphasis added). Moreover, Article 41 obliges Members to ensure that enforcement procedures – including customs actions – are applied in such a manner that the creation of barriers to legitimate trade is

avoided, and to provide for safeguards against potential abuse. The underlying principle of the latter recital and provision is that an overprotection of intellectual property rights could be detrimental to international trade.

It could then be argued that detaining products in transit at the borders when they are patented neither in the countries of origin nor in the final destination countries constitutes an overprotection of intellectual property rights and creates obstacles to legitimate trade, thus infringing the above principles and provisions.

- (ii) An argument the EU might put forward is the following: the detentions of Indian generics at the borders are lawful, as the mere transit of IPRs-infringing goods through customs should be considered as an activity that can be prohibited by IPRs owners.

Yet, it should be noted that the very case law of the European Court of Justice (ECJ) is inconsistent on this matter<sup>16</sup>. Indeed, in two cases the ECJ basically held that goods in external transit (from a non-Community Member State to another non-Community Member State) suspected of infringing IPRs could be detained by customs<sup>17</sup>. In other cases the same Court basically concluded that the temporary storage in a customs warehouse of infringing goods with transit status and their external transit (in case no evidence of third party action to distribute the products within the EU market is brought) do not violate IPRs<sup>18</sup>.

Such inconsistent case law weakens the above argument. Indeed, how could the EU validly claim that the transit of Indian generics through its customs constitutes patent infringement and can therefore be lawfully blocked, while the very case law of its most important judicial body has given contradictory guidelines on this issue?<sup>19</sup>

- (iii) Moreover India, Brazil and a number of legal commentators believe that the seizures at the EU borders violate the spirit of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO Ministerial Conference on the 14th of November 2001<sup>20</sup>. Paragraph 4 of this declaration states that “*TRIPS Agreement does not and should not prevent members from taking measures to protect public health*” and that TRIPS “*should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all*”. From the point of view of

15 Xavier Seuba, *supra* note 5, pp. 22 *et seq.*

16 Enrico Bonadio, “Protecting Intellectual Property Rights through EU Customs Procedures”, 14(4) *International Trade Law & Regulation* (2008), pp. 80 *et seq.*, at pp. 85–88.

17 Case C-383/98 *See Polo/Lauren Co LP v. Dwidua Langgeng Pratama International Freight Forwarders* [2000] ECR I-2519; Case C-60/02 *Re Montres Rolex SA* [2004] ECR I-651

18 See Case C-405/03 *Class International BV v. Colgate – Palmolive Co* [2005] ECR I – 8735; Case C-281/05 *Montex Holdings v. Diesel SpA* [2006] ECR I-108881.

19 The ECJ might soon give more certain guidelines on this issue when delivering its decision in *Nokia v. Their Majesty’s Commissioners of Revenue and Customs* (Case C-495/09) which concerns an analogous matter.

20 See the Indian complaint with the WTO, *supra* note 1. See also Abbott, *supra* note 12, p. 49 (who seems to take such view).

India and Brazil, supplying generics to countries such as certain Latin American states in need of medicine at affordable prices is amongst those “*measures to protect public health*” that should not be hampered. In general, it is strongly believed that India’s generics industry makes a huge contribution to public health worldwide.

Moreover, Brazil and India contend that the EU seizures also jeopardize the target of the so-called Paragraph 6 system.<sup>21</sup> This mechanism specifically aims to allow WTO members to issue compulsory licences to export generic versions of patented medicines to countries with insufficient or no manufacturing capacity in the pharmaceutical sector<sup>22</sup>. Indeed, it is believed that the measures in question and customs’ interference with the international trade of generics in general are capable of discouraging the use of the Paragraph 6 system. For example, the search for potential licensees in the importing and exporting countries could be rendered more difficult<sup>23</sup>, since manufacturers of generics might be worried about possible customs intervention and accordingly refuse to act as licensees and to trade in such goods.

#### IV. Conclusions

As shown above, negotiations between the parties for an amicable settlement of the dispute are on-going and an agreement might soon be reached.

21 The system takes its name from paragraph 6 Doha Declaration which provides that “[...] WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”. The mechanism was then devised by the WTO General Council Decision of 30 August 2003 and Protocol of amendment to Article 31 TRIPS of 6 December 2005. In particular, the 2003 Decision introduced a temporary waiver to TRIPS Agreement and the 2005 Protocol made that permanent.

22 Actually this system has not been successful; thus far it has been used just once (by Rwanda).

23 Under the paragraph 6 system states which need to import generics should preliminarily identify two licensees, one in their territory and another in the exporting country.

24 Yet the risk of re-importation is often considered theoretical. Also the European Commission recognized that drugs destined to developing and least developed countries are seldom channelled back into rich markets such as the EU; see Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, World Health Organization (2002), Geneva, p. 32 (note 99), available on the Internet at <<http://archives.who.int/tbs/global/s2301e.pdf>> (last accessed on 22 October 2010).

In particular, the EU is likely to favour an amicable settlement envisaging a modification of Regulation 1383/2003 to avoid future detention of goods in transit suspected to infringe IPRs. Two main points lead us to believe this.

First of all the arguments in favour of EU seizures seem rather weak, as illustrated by the inconsistent decisions from the ECJ. Rather, a strong argument can be made that the seizures in question amount to a trade barrier between countries and contravene the spirit and the provisions of the GATT/WTO system and particularly TRIPS.

Second, the EU does not seem to have a strong commercial interest in blocking generics not directed to its internal market (except an interest in preventing re-importations<sup>24</sup>). India, on the contrary, does have a strong commercial interest in this trade. Indeed, the generics business is very lucrative for Indian undertakings, as the pharmaceutical industry of this country gets by far the highest percentage of its revenues from exporting generic drugs. If the EU and the Netherlands in particular do not change their customs legislation and policy regarding products in transit, Indian pharmaceutical companies could soon choose alternative commercial routes, such as the Panama Canal, instead of EU ports or airports.

### Mitigating Climate Change through the Promotion of Technology Transfer and the Use of Environmentally Sound Technologies (ESTs): The Role of Intellectual Property Rights

Meir Perez Pugatch\*

#### I. Introduction

Increasing energy consumption and rising greenhouse gas (GHG) emissions have led up to one of the most pressing challenges of the 21st century: climate change. Alarmed by the tangible changes in the climate, both developed and developing countries are making conscious efforts to explore technologies that would help mitigate this phenomenon. International bodies such as the United Nations Framework Convention on Climate Change (UNFCCC), the United Nations Environment Programme (UNEP) and lead-

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