

# Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit

By Xavier Seuba

This manuscript prepared by Xavier Seuba - Lecturer in Public International Law, Universitat Pompeu Fabra, Barcelona - at the request of the ICTSD Programme on IPRs and Sustainable Development, is made available to the public as a working paper in order to facilitate dialogue, broader understanding, consultation and further inputs.

It deals with a critical issue that has attracted recent attention: the relationship between access to medicines and the adequate enforcement of intellectual property rights. It focuses on recent cases of seizures of generic medicines in transit to some developing countries. The working paper examines the nature and scope of the existing EC regulations and their relationships with WTO obligations and particularly the TRIPS Agreement.

The paper is work in progress and interested persons and institutions are welcome to provide comments or inputs to the author directly or via ICTSD ([aabdellatif@ictsd.ch](mailto:aabdellatif@ictsd.ch) or [proffe@ictsd.ch](mailto:proffe@ictsd.ch))



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## ABBREVIATIONS AND ACRONYMS

AIPPI	International Association for the Protection of Intellectual Property
DSU	WTO Dispute Settlement Understanding
DSB	WTO Dispute Settlement Body
EC	European Community
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industries and Associations
GATT	General Agreement on Tariffs and Trade
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
PhRMA	Pharmaceutical Research and Manufacturers of America
TAXUD	EC Commission's Taxation and Customs Union Directorate-General
TBT	Agreement on Technical Barriers to Trade
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
US	United States of America
WHO	World Health Organisation
WTO	World Trade Organisation

## EXECUTIVE SUMMARY

Since the adoption of the TRIPS Agreement its main promoters have strived to raise the standards set forth therein and to guarantee the enforcement of TRIPS provisions. Due to difficulties in increasing the TRIPS standards through the adoption of new WTO obligations, the United States (US) and the European Community (EC) have followed different paths to enshrine new and higher intellectual property regulations. One of these paths has been the promotion of new bilateral, regional and multilateral agreements, an initiative that has been so successful that presently the normative landscape for the international protection of intellectual property rights is totally different and much stricter than it was in 1995, when the TRIPS entered into force. The non-discrimination principle -as enshrined in the TRIPS Agreement- has played a decisive role in extending the stringent standards set forth in said agreements. Moreover, these new covenants have been instrumental in securing intellectual property rights enforcement, an objective also pursued through additional means. Up until now, lists of allegedly infringing countries, retaliatory measures resulting from those lists, diplomatic and economic pressures, and national and international litigation have been the main tools identified by the US and the EC to guarantee intellectual property rights enforcement.

Although intellectual property policies and free trade agreements promoted by the US have been those receiving most of the attention, in the last five years the EC has emerged as a similarly active actor as far as intellectual property maximalist standards are concerned. In addition to new substantive matters such as data protection through temporal exclusivity and patent extensions, in the free trade agreements it promotes the EC is particularly persevering on intellectual property rights enforcement. But EC action on enforcement is not limited to the negotiation of free trade agreements. In fact, according to the EC, it is essential to focus on a vigorous implementation of the enforcement legislation, a goal to be attained both through internal and international actions. In 2004 the EC DG Trade adopted the *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, which mapped EC future actions in this field. The Strategy identifies numerous activities to guarantee the enforcement of intellectual property rights in third countries, such as identifying the priority countries, action in the context of bilateral and multilateral agreements, political dialogue, technical cooperation, retaliatory measures, dispute settlement and the creation of public-private partnerships aimed at the enforcement of intellectual property rights.

Some of the specific actions envisaged in the *Strategy* are of international scope. In this sense, the EC committed itself to launching an initiative in the Council for TRIPS in response to the allegedly insufficient enforcement of the said agreement. It also gave assurance that it would constantly supervise the TRIPS Agreement enforcement and it affirmed that it would review the intellectual property policy in EC-ratified free trade agreements. Additionally, and among other international measures, the EC gave the undertaking to regularly bring up the question of enforcement of intellectual property rights in committees set up to monitor bilateral agreements. Together with these international enforcement-related initiatives, one of the main tools devised within the Community is the EC customs regulation. Although envisaged to have effects within the European borders, the European legal system on customs, and more importantly, its use and specific interpretation, have noteworthy effects both in third countries and international trade.

Although its ultimate goal is the protection of intellectual property rights granted in EC Member States, EC Regulation 1383/2003 and the European Customs Code have proven instrumental for the enforcement of extraterritorial intellectual property rights. Presently, the EC controls the importation, exportation, reexportation, entry for a suspensive procedure and the mere transit of all goods protected by almost any intellectual property right as long as these goods pass through the EC territory. This is the outcome of the rapid evolution of EC Law on the matter, which has resulted

in a scheme of uncertain compatibility with World Trade Organization (WTO) law and fundamental intellectual property law principles and norms: the territorial nature of intellectual property rights and the rights conferred to intellectual property rights holders.

In 2008, the implementation of EC Regulation 1383/2003 resulted in several seizures of in-transit medicines that were otherwise legal in their exporting and importing countries, an activity that has continued to the beginning of 2009. To those holding that seizures have been minimal and the result of the MEDI-FAKE initiative - which targeted customs control on illegal medicines entering the EU-, others oppose that seizures have been neither incidental nor accidental, something which would indicate that a policy backing them may exist. Whatever the case, the detention of medicines in transit has aroused substantial attention and concern, because it forces the assessment of EC Regulation consistency with WTO law, it puts into question the feasibility of international generics trade and, more importantly, if norms that back the seizures were to become the general legal framework, the systemic effects on public health could not be more worrying. In fact, EC Regulation 1383/2003 implementation against in-transit generic medicines has heightened debates regarding the already conflicting relationships between, on the one hand, public health and intellectual property, and on the other hand, free trade and intellectual property.

In most of the cases, WTO Agreements are cumulative, which obliges consideration of all norms potentially involved in a controversy. That is to say, if two or more WTO agreements become of relevance, all of them will be taken into account. When assessing EC Regulation and border measures compatibility with WTO law, attention must be paid to the General Agreement on Tariffs and Trade (GATT), to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and to subsequent WTO Members instruments, particularly the Doha Declaration and the General Council Decision of 30 August 2003. WTO adjudicative organs have established that, when both the GATT and the TRIPS are involved in a dispute, a logical approach is to begin with TRIPS.

All intellectual property international treaties and national intellectual property laws enshrine or implicitly recognize a fundamental principle of intellectual property law, namely, the territoriality principle. According to this principle, intellectual property rights are territorial and its protection depends on each country's national legislation. EC Regulation 1383/2003 hardly reconciles with said principle because in seizing a specific product not intended for the EC market it mandates taking as reference the patent status in the European Member State in which application for customs action is made. Moreover, European Court of Justice (ECJ) jurisprudence on trademarks has traditionally linked right-holders entitlements, in relation to goods in transit, to those products potential diversion into the EC internal market. Thus, the subject-matter of a specific intellectual property right, and the rights of the title holder, would only be affected if IP infringing goods were placed on the internal market. By contrast, against the territoriality principle and against ECJ jurisprudence linking customs actions to the affectation of conferred title holder rights, the mere transit of goods presently permits the title holder to exercise all of its exclusive rights.

TRIPS alludes to the need to avoid intellectual property protection becoming an unnecessary barrier to trade, references being found both in the Preamble and several articles. TRIPS Article 41, which guides the implementation and interpretation of all TRIPS references to intellectual property enforcement, forbids enforcement measures becoming barriers to legitimate trade. Trade in generic pharmaceuticals is permitted in terms of WTO Agreements and jurisprudence. The fact that legitimate trade of generic products has been disrupted confirms that there is not only the potential of Regulation 1383/2003 being trade restrictive and easily abused, but that this is occurring in practice.

TRIPS Article 51 lays down the obligation to control the importation of goods protected by trademarks and copyrights. Adopting EC Regulation 1383/2003 the EC has made use of the power granted by

TRIPS article 1 to “implement in their law more extensive protection” bearing in mind that TRIPS places minimum standards on Member States. This power, however, is made conditional upon not contravening other TRIPS provisions. Some Regulation 1383/2003 provisions are in contradiction to the territoriality principle and broaden the rights conferred to intellectual property rights holders. Regulation 1383/2003 systemic disrupting effects on legitimate trade make a discussion on the matter between the EC and other WTO Members worthwhile. Such dialogue should help the EC to clarify its provisions so that, at least, the reference to the intellectual property law of the transit country when controlling in-transit goods and the power granted to holders to control goods not affecting their competitive position in the market where their rights are granted are amended.

In accordance with the Doha Declaration, a pro-public health interpretation of obligations and rights arising from the TRIPS would presently guide any patented medicines case at the WTO Dispute Settlement Body (DSB). In accordance with article 31.3.a) of the Vienna Convention on the Law of Treaties, when interpreting a treaty, any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions shall be taken into account. The Doha Declaration has, at least, this status and its command to interpret the TRIPS in a manner supportive of WTO members’ right to protect public health could be decisive in the panel’s ruling on the TRIPS compliance with EC Regulation 1383/2003 and its implementing measures. Another WTO subsequent instrument, General Council Decision of 30 August 2003 on compulsory cross-licensing, which presently works as a waiver and will probably amend TRIPS article 31, is also jeopardized by EC Regulation 1383/2003. If this was the case, the EC would probably need to amend EC Regulation 1383/2003. Moreover, the EC should also clarify EC Regulation 816/2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, which apparently may also be instrumental in blocking the transport of medicines not produced in the EC and addressed to countries without manufacturing capacity. Furthermore, and pursuant to the link established through DSU article 3.2 between WTO law and the rest of public international law, it is possible to resort to other international obligations in search of clarification of WTO norms.

Particular attention should be paid to the exportation to developing countries of Regulation 1383/2003. Through the transposition of the EC border measures scheme to the free trade agreements it concludes, the way is paved to similar seizures occurring in developing countries in the future. If that were the case, most of the generics trade would not be possible, something that also puts into question said free trade agreements provisions on border measures compatibility with the TRIPS. In this sense, it is argued that some of the TRIPS provisions on enforcement can be deemed not to be the floor as it was generally understood, but rather a ceiling that can not be exceeded.

Pharmaceutical products are covered by the liberty of transit mandated in GATT article V. However, this article permits the control of in-transit goods under the condition to not subject them to “unnecessary delays and restrictions”. European regulation on border measures raises doubts on whether it results in unnecessary delays and on whether it imposes unnecessary restrictions. However, GATT article XX(d) permits the adoption or enforcement of measures necessary to secure compliance with laws or regulations not inconsistent with the GATT. Both customs and patents regulations are recognized in article XX(d) as grounds that permit measures derogating from GATT obligations. National rules that are necessary for the implementation of the TRIPS Agreement would be regarded as laws or regulations which are not inconsistent with GATT within the meaning of article XX(d). To the contrary, if those rules were TRIPS inconsistent they could not be defended through the exception set forth in GATT article XX(d). Furthermore, both GATT article XX(d) make reference to measures’ necessity and GATT chapeau must also be taken into account when assessing its potential invocation.

Using “counterfeit” as a generic term to designate all intellectual property rights infringements and

simultaneously indicate products' lack of quality has become usual among international organizations, developed countries and R&D based companies. Nevertheless, this term sends a confusing message to border authorities, countries and international organizations, and it is at the background of the discussion on the measures to be taken in relation to in-transit medicines. The defining criterion to identify a counterfeit product is its deliberate mislabelling with respect to identity or source. If such mislabelling does not occur, there is no counterfeit. Counterfeit medicines are certainly related with trademark law but have a very marginal relationship with patent law. Although it is an unfortunate term due to the confusion it creates, "counterfeit" medicines may represent a public health problem if they are also substandard medicines, that is, medicines that do not conform to the pharmaceutical standards set for them. In terms of public health, this last phenomenon is a much more worrying phenomenon. Rather than concentrating on intellectual property law, to guarantee the quality of medicines it would be more useful to strengthen national drug regulatory authorities and reinforce World Health Organization (WHO) activities on medicines standardization and guarantees. This, however, opens new questions related to WHO technical standards precedence and the WTO Agreement on Technical Barriers to Trade (TBT).

## 1. The enforcement of intellectual property rights and the seizure of generic drugs in transit

In 2008 and in the first few months of 2009, several cases of generic medicines seizures while in transit in the EC were reported. The following were the known seized medicines and active ingredients: artovastatine, sildenafil, losartan, clopidogrel, valsartan, artovastatine, zidovudine, rivagstimine, olanzapine and abacavir. Seized quantities were relevant, in certain cases exceeding 500 kilos of a particular active ingredient (losartan) and in other cases more than 500,000 tablets of a specific product (olanzapine). Some of the involved right-holders companies (Pzifer, Dupont, Novartis, GSK, Sanofi-Aventis, Warner Lambert and Eli Lilly) sent letters to generic manufacturers informing them that their in-transit goods infringed patents and supplementary protection certificates granted in EC Member states.<sup>1</sup> Accordingly, generic manufacturers were threatened with the destruction of goods, a threat that had, in some cases, allegedly been executed. Except for a single product, the seized shipments source was India, and final destinations were several developing countries, such as Mexico, Brazil, Nigeria, Peru, Colombia and Ecuador. It is reported that other shipments would have been seized in France, the United Kingdom and Germany.

There are several reasons for particular concern regarding generics seizures at European borders. Both the European geographic position and transportation strength explain its role as a transit hub for an important percentage of international medicines trade, and even South-South trade. Additionally, many health-related NGOs have their headquarters in Europe, and the products they send to the field go through European customs territory. If legal pharmaceutical supplies are going to be regularly intercepted in transit countries on alleged patent infringement grounds, international generics trade can be seriously hampered. Moreover, the basis that supports the EC Law legality of said seizures, EC Council Regulation 1383/2003, is being exported to developing countries legislation through the conclusion of free trade agreements,<sup>2</sup> paving the

way for similar seizures occurring in developing countries once the implementation of provisions contained in free trade agreements commences. The potential for a deterrence of generics trade, and the importance attached to generics in controlling medicine prices and therefore facilitating access to medicines, explains the concern surrounding not only European actions but also legal arguments in this matter.

The timing and number of seizures give cause for the assessment of the legality of EC Regulation 1383/2003 in relation to WTO law. WTO Member States adopted the TRIPS *desiring* “to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”.<sup>3</sup> However, the TRIPS was also adopted “taking into account the need to promote effective and adequate protection of intellectual property rights”,<sup>4</sup> and it is certainly a treaty of minimums which allows Member States to adopt higher intellectual property protection standards. In this sense, albeit not expressly recognized in the TRIPS, the power of Member States to control intellectual property rights of protected products in transit could be a justifiable measure if it did not contravene WTO or other public international law obligations.

On 3 March 2009, in a session of the WTO TRIPS Council, Brazil pointed out several arguments according to which European seizures would infringe the TRIPS Agreement.<sup>5</sup> The first of those arguments stated that “seizure of goods in transit -any good: be it medicine or not- on grounds that they may be violating intellectual property rights registered in the country of transit is, in itself, a violation of GATT Article V”. However, this argument was not developed further and Brazil emphasized a rather different argument: as the medicines in question do not enjoy patent protection either in the country of exportation, or in the country of importation, whether or not the medicines are patent protected in the country of transit is irrelevant and cannot justify their seizure. To sustain this argument, Brazil

quoted TRIPS article 28 (rights conferred) and recalled the territoriality principle, a keystone rule of intellectual property rights law.

India, in its submission to the Council for TRIPS, focused its arguments on the legitimacy of the generics trade.<sup>6</sup> In this regard, India argued that TRIPS article 41.1 provides that enforcement procedures “shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse”. The legitimacy of generics, “particularly when there is no risk of diversion to the internal market”, would accordingly dismiss European arguments and forbid seizures. India also alluded to problems over access to medicines that validating European seizures would have, particularly to those patented products that could be compulsorily cross-licensed in export and import countries under the “paragraph 6 system”. As regards the latter, the possibility that right-holders could try to block compulsory-licensed products while in transit in Europe should be assessed against article 13 of the EC Regulation 816/2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.<sup>7</sup>

On the other side of the debate, EC Commission representative at the Council for TRIPS affirmed that seizures and Council Regulation 1383/2003 of 22 July 2003 are fully TRIPS compliant. He claimed that Regulation 1383/2003 merely develops and implements a power that can be inferred from TRIPS article 51, namely, the power to control patent protected goods even if they are in transit. Moreover, the EC representative sustained that detentions and not seizures had taken place. In their arguments, the EC established a link between intellectual property rights violations and public health protection. As a justification of this link -a rather common place EC intellectual property enforcement policy in recent years<sup>8</sup> -, the EC stated that border measures in Europe help to save lives in third countries because they are instrumental in impeding the trade of “counterfeit” medicines.<sup>9</sup> This is an interesting argument, because it helps the EC to construct a position that mixes public

health and intellectual property protection arguments in a way that it is just the opposite of what has been common over the last decade. Thus, according to the EC, intellectual property rights would not impede health protection due to its effects on medicines prices and access, but rather, intellectual property protection would save lives because of its supposed relationship with medicines quality. Additionally, the EC also affirmed that seizures had been incidental and by no means systematic, and assured that destruction of goods had neither been executed nor ordered. Finally, it has also been argued that seizures could have been the undesired outcome of the successful MEDI-FAKE initiative, which over a two month period commanded European Member States border authorities to focus their attention in the prevention of illegal medicines from entering the European Union.

In response to questions raised from MPs Ewout Irrgang and Farshad Bashir to the Minister for Foreign Trade, the State Secretary for Finance and the Minister for Development Cooperation, the Dutch government affirmed that “Dutch customs took the action it did on the basis of the applicable EU Legislation”.<sup>10</sup> However, Dutch authorities indirectly recognised that they had been surprised by the effects of EC Regulation 1383/2003 when they affirmed that “The position of the Netherlands is that in such situations, developing countries’ interest in access to medicine should be better protected than it currently is. As the enforcement of intellectual property law by customs is based on European legislation, the Netherlands has asked the European Commission to study this matter further. We have urged the Commission, if the current legislation poses impediments to access to medicine, to propose a solution that would facilitate access by developing countries.”<sup>11</sup> The Dutch government emphasised that “more clarity is needed about the scope of European legislation and the latitude that national governments have. As soon as this clarity has been achieved, the framework agreement will, if necessary, be modified.”<sup>12</sup>

As far as international organisations are concerned, both the WTO and the WHO issued

statements in reference to the seizures. WTO Director General Pascal Lamy, in response to a letter by several NGOs,<sup>13</sup> said that “the issue at stake is very important and sensitive”, however, it pointed out that “the matter is also being further explored at the bilateral level between the Members concerned. This is why I sense that at this stage article 5 of the DSU concerning disputes is not of relevance in this case”.<sup>14</sup> A stronger statement was made by the WHO, which issued a press release on its website stating that “recent events related to the handling of medicines in transit and the potential consequences for the supply of medicines in developing countries are of major concern to the organization” and asserted that “Ensuring that the interests of trade and health are appropriately managed, also means that the flow of legitimate medicines, including generic medicines, is not impeded.”<sup>15</sup>

The European Generic Medicines Association, in reaction to the seizures, affirmed that “the EC

is entitled under TRIPS to detain products under alleged patent infringement”, but it urged “for caution in this area to avoid detention that has no fundamentals and indeed presents no public health risk”.<sup>16</sup> The European Federation of Pharmaceutical Industries and Associations (EFPIA) stated that “it is neither the policy nor practice of our members to encourage Member States to use the powers of detention available to them to prevent the flow of legitimate generic products from manufacturer to customer”.<sup>17</sup> Finally, several health-related NGOs deemed seizures as unacceptable. According to these NGOs, combination of GATT article V and TRIPS articles 41 and 51 would render seizures of patented goods in transit against WTO regulations.<sup>18</sup> Médecins Sans Frontières, additionally, signalled out the confusion that the European position made between counterfeit drugs and quality generic drugs, something that was leading “to a dangerous situation where legitimate trade in generic drugs is blocked”.<sup>19</sup>

## 2. Patented products in transit control under the EC Council Regulation 1383/2003

Generic medicines in transit have been seized invoking EC Council Regulation 1383/2003, on 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.<sup>20</sup> This Regulation provides for the retention at the Community's border of goods that have not been cleared by customs, a detention aimed at enabling the right-holder to initiate the proceedings that should establish whether its rights have been infringed. Referring to European actions as "seizures" has been deemed inappropriate by the EC, which claims that only temporal detentions took place. In fact, EC Regulation 1383/2003 does not use at any moment the term "seizure", and instead refers to "suspension of release" and "detention", which are the envisaged actions by customs authorities against goods suspected of infringing certain intellectual property rights.<sup>21</sup> Said suspension and detention may result in the destruction of goods without passing through any "seizure" stage, and even without trial. Although "seizure" is a stronger term which logically embarrasses EC authorities, the fact is that the different meanings of "to seize" coincide with European actions: "to hold of suddenly and forcibly; take forcible possession of; take possession by warrant or legal right".<sup>22</sup>

Regulation 1382/2003 is the last step of a relatively fast process by which EC Law has expanded border measures to be taken in relation to goods allegedly infringing intellectual property rights. Said expansion has both affected the intellectual property rights categories covered and the situations enabling border authorities to take action, resulting in a very sophisticated legal framework aimed at curbing intellectual property rights infringements occurring in third countries. The first step in this process was carried out in 1986, when an EC Regulation was enacted ordering border measures to be merely taken regarding the importation of trademark infringing products, i.e. counterfeited goods.<sup>23</sup> Eight years later, a new Regulation was enacted mandating not only

the detention of counterfeited but also pirated merchandise, a control to be realized in the cases of their importation, exportation, reexportation and entry for a suspensive procedure.<sup>24</sup> Notably, and despite corporate demands, patent infringements were not yet covered. It was in 1999 when, through an amendment of said Regulation and after the Commission so recommended it,<sup>25</sup> patent and supplementary protection certificates infringements were introduced.<sup>26</sup> By that time, only the control of plant variety rights, geographical indications and designations of origin remained out of the Regulation's scope, a gap that EC Regulation 1383/2003 would remedy mandating the control of goods protected by said rights. Following Commission proposals, EC Regulation 1383/2003 strengthened right-holders position in several respects: it broadened the intellectual property rights categories covered, provided right-holders with cost-free access to the system, facilitated the destruction of allegedly infringing goods and, among other measures, extended the scope for *ex officio* action by customs authorities.

Recent European seizures of pharmaceutical products have been executed invoking patent rights and supplementary protection certificates, which are intellectual property rights categories foreseen in EC Regulation 1383/2003 article 2.1.c) (i) and (ii), respectively. Actions undertaken in relation to those products should fall into one of the circumstances addressed by EC Regulation 1383/2003 article 1.1, which constantly refers to the European Customs Code and distinguishes two sets of situations. On the one hand, subsection a) allows customs authorities taking action regarding goods suspected of infringing intellectual property rights and entered for release for free circulation, export or re-export. On the other hand, subsection b) covers the cases of goods also suspected of infringing intellectual property rights and found during checks when entering or leaving the customs territory, placed under a suspensive procedure, in the process of being reexported subject to notification or, finally, placed in a free zone

or warehouse. In fact, and despite that each one of those situations has its peculiarities, EC Regulation 1383 allows the taking of action in all kinds of customs situations regarding goods not subject to intra-community trade. Notably, as the third Recital of the Regulation establishes, the transshipment of goods is included among the covered situations.

EC Regulation scope could hardly be broader. It covers goods placed in all kinds of customs procedures (1.1.a) and also goods not subject to any custom procedure (1.1.b). Customs clearance is not, therefore, a requirement to control goods suspected of infringing intellectual property rights. This is particularly important when assessing the effects on international (free) trade that border measures aimed at the enforcement of intellectual property rights have. As the aforesaid facts regarding the seizure of medicines illustrate, the EC is seizing goods that have not been cleared by customs. The explanation is that, presently, at the EC, the mere transshipment of goods allows border authorities to take action. Next, and before introducing the control of goods merely passing through the EC or being transhipped, a brief outline of the potential situations is offered.

Four situations under which border authorities may take action can be distinguished. Firstly, the one concerning goods entered for release for free circulation, that is to say, merchandise entered into the EC to circulate without restrictions. Secondly, the one related to goods entered for export, re-export, and goods found during checks on goods in the process of being re-exported subject to notification. Exportation consists in sending European goods outside the European customs area, a process which is the contrary to release for free circulation. Re-exportation refers to the departure from the EC of non-Community goods introduced into the European territory without having been released for free circulation at any time. This process usually requires notification to the customs authorities, which explains the reference to “goods in the process of being re-exported subject to notification”. The third situation is the one concerning goods found during checks

on products entering or leaving the EC. As article 91 of the European Custom Code establishes, “goods brought into the customs territory of the Community shall, from the time of their entry, be subject to customs supervision.” Until a customs-approved treatment or use is assigned to goods, they remain under customs supervision and held in temporary storage. Fourthly, the last situation covers goods found during checks on merchandise placed under a suspensive procedure. Goods placed under one of the situations covered by the suspensive status (which the amended European Customs Code presently names “special procedures”) are not intended for the EC, and their relation with the EC is limited to transiting the European territory. Suspensive or special procedures include several possibilities: transit (external and internal), storage (temporary storage, customs warehousing and free zones), specific use (temporary admission and end-use) and processing (inward and outward processing).<sup>27</sup>

Seized in-transit pharmaceutical products either were under “external transit” special procedure or they merely were to be transhipped. The external transit regime allows non-Community goods to move from one point to another within the EC customs, without such goods being subject to import duties or other charges.<sup>28</sup> This status is particularly indicated for products arriving and leaving from different States integrating the EC customs area due to better transport connections or costs. For instance, under the external transit status, seized medicines in Schiphol airport the final destination of which were Ecuador, Mexico, Peru or Colombia could have potentially been transported to Madrid-Barajas airport, which is an important hub of EC-Latin America flights. The other potential -and much more likely- situation in which seized medicines were found was mere transshipment. In accordance with the available information, the goods arrived to the EC with the sole purpose of changing the means of transport and abandoning the EC customs area. According to Schneider and Vrins, transhipped goods would be included in the scope of article 1.1.b) of EC Regulation 1383/20003,<sup>29</sup> which permits customs authorities to take action when goods are found during checks on products entering or leaving the

EC in accordance with article 37 and 183 of the former EC Customs Code, presently articles 91 and 177 of the Modernised Customs Code. This is also the understanding in relevant countries of transit. As the Dutch Group of the AIPPI has recently stated,

“Article 16 of the APR (EC Regulation 1383/2003) stipulates what is to be done with goods that are found to infringe an IP right. This provision basically prohibits any further trade in these goods. This includes entry of the goods in the Community customs territory, release for free circulation, (re-)exportation, placement under a suspensive procedure or in a free zone or free warehouse, and removal of the goods from the Community customs territory. Article 16 also applies to goods in transit that have been found to infringe an IP right as meant in the APR.”<sup>30</sup>

According to EC Regulation 1383/2003, and regarding patent infringing products or processes, actions to be taken in accordance with said regulation must target goods which, in the Member State in which the application for customs action is made, infringe a patent under that Member State’s law. This is a sound provision if products are intended to be introduced in that Member State or EC internal markets. However, this stipulation, when applied to in-transit goods, is at odds with a traditional principle of intellectual property law, i.e. the territoriality principle, with one of the goals that the WTO aims to achieve, free trade, and with the rights conferred to intellectual property rights owners.<sup>31</sup>

Therefore, Regulation 1383/2003 is in a constant balancing act as regards the presumption against extra-territoriality of intellectual property law and with the TRIPS and other WTO provisions that compel not to impede legitimate trade. It is worth, therefore, to regularly check whether the “compromise between the imperatives of international trade, free movement of goods, and protection against intellectual property rights infringements” that authors sustain Regulation 1383/2003 represents is indeed respected.<sup>32</sup>

It is important to note that, as does the TRIPS Agreement, EC Regulation article 3.1 excludes parallel imported goods from the Regulation’s scope. As Regulation 1383/2003 deals with actions to be taken at EC external borders, it is assumed that pursuant to article 3.1 internationally parallel imported goods are out of the Regulation’s reach. ECJ jurisprudence is helpful in this point. In *Class International BV v Unilever NV and others*, the ECJ determined that external transit of parallel imported products did not breach right-holder trademark rights. Being this the case -as also a *contrario sensu* demonstrates, some scholars pledges to extend the regulation to allow the seizure of parallel imported products from outside the Community<sup>33</sup>, an intriguing question must be raised, that of understanding why parallel imported products (by definition, patent protected in importing and exporting countries) which are in transit in the EC customs escape from the Regulation’s scope while, on the other hand, products that are neither patented in the exporting nor importing countries but effectively patented in the EC can be seized while in transit in Europe.

### 3. The cumulative nature of WTO obligations

Several TRIPS and GATT provisions are of relevance in the dispute arising from European seizures of in-transit products. So, for the assessment of the legality of the same facts different WTO agreements become relevant. On the one hand, TRIPS specifically regulates patent protected products and addresses the suspension of release of goods allegedly infringing intellectual property rights. On the other hand, GATT article V establishes the principle of freedom of transit, and article XX lays down several general exceptions to the GATT provisions. Amongst the exceptions, subsection (d) of article XX may be of relevance in the construction of the EC legal position.

It is possible and even foreseeable that each of the parties involved in the controversy finds its interests better reflected in one specific WTO agreement relevant to the case, something which might result in the invoking of different norms by different parties depending on their own interest. Nevertheless, WTO Panels and the Appellate Body itself have stated on numerous occasions that from the fact that the WTO Agreement is a 'single undertaking' flows that "WTO obligations are cumulative and Members must comply with all of them at all times".<sup>34</sup> The application of this principle to the specific domain of the dispute settlement implies that both the GATT and the TRIPS must be taken into account when analyzing European seizures. This, however, does not clarify what is the exact path to follow when a specific controversy involves norms found in different WTO Agreements.

The specific interaction between the TRIPS and other WTO agreements has already been addressed by WTO adjudicative organs. In *European Communities-Protection of trademarks and geographical indications for agricultural products and foodstuffs*, the Panel pointed out that "Certain claims under the TRIPS Agreement and GATT 1994 relate to the same aspects of the measure at issue. There is no hierarchy between these two agreements, which appear in separate annexes to the WTO Agreement. One logical approach would be to begin in each instance

with the TRIPS Agreement".<sup>35</sup> Despite intuitively sharing panel's views, one may still wonder upon what is based said "logical approach".

A possible answer may be found in the *lex specialis* principle, which establishes that if a matter is being regulated by a general norm as well as a more specific rule, then the latter should take precedence over the former. *Lex specialis* does not only apply in the case of conflict of treaties, but also as a general rule of interpretation. In the case of the relationship between the TRIPS and the GATT, the TRIPS, as a more specific set of rules to apply to goods protected by intellectual property rights could, on the one hand, be read against the background of the general standards set forth in the GATT, and on the other hand be understood as a specification of the GATT principles.

Between the GATT and the TRIPS there are interactions that have to be duly taken into account, particularly the shared goal of avoiding the use of intellectual property rights to create barriers to legitimate trade. This interaction may help in attributing sense to general GATT principles not yet implemented in relation to the TRIPS. For instance, and of special importance given the matter under discussion, it may be worth analyzing the meaning given in the GATT to the notion of "disguised restriction to international trade", and apply such meaning to restrictions which find their origin in certain levels of intellectual property enforcement. But the interaction can also work the other way around, which permits look to the TRIPS Agreement as one containing "new rules and disciplines concerning the applicability of the basic principles of GATT 1994" as the TRIPS Preamble affirms. In this last regard, TRIPS provisions on border measures and in-transit goods could be considered as specifying the GATT provisions on the same subject, something which does not impede reading them in light of the GATT principles on the same subject, and also assesses the same facts against the GATT norms once analysis of the TRIPS is concluded.

## 4. The relationship between the TRIPS Agreement and free trade

Although the TRIPS Agreement affirms that one of its objectives is to reduce distortions and impediments to international trade, intellectual property rights are by their very nature trade restrictive. In fact, the incorporation of intellectual property into the multilateral trade system during the Uruguay Round has livened up an old debate, concerning the relationship between free trade and intellectual property. Numerous scholars have highlighted the existing contradiction between WTO trade liberalization objectives and the protectionism introduced by TRIPS into the intensive technological products market.<sup>36</sup> Certainly, a positive link between free trade and intellectual protection would have surprised XIX century free trade promoters. The then heated debate between intellectual property defenders and opponents had, as major players, on the one hand protectionism promoters aligned with intellectual property rights defenders, and, on the other hand, patent system opponents that simultaneously were free trade promoters.<sup>37</sup>

Circumstances have changed and a more encompassing argument has been elaborated, according to which free trade is not only a matter of increasing trade but trade in legitimate products. Nevertheless, this shared understanding has not avoided a certain consensus on the fact that the TRIPS Agreement was introduced into the multilateral trade system as a concession to developed countries, and not as an instrument to promote free trade. The tension between free trade and intellectual property protection persists and, to a certain extent, the TRIPS Agreement acknowledges such tension and tries to mitigate conflicting outcomes by framing specific articles on broad free trade promoting principles. This is why TRIPS alludes to the need to avoid intellectual property protection becoming an unnecessary barrier to trade, references being found in the Preamble and several articles. These references can be classified into two groups, depending on their influence over the whole agreement or their rather limited influence on a single topic or part of the Agreement.

The main general references to avoid intellectual property becoming a trade barrier are found in the Preamble and in article 8. The TRIPS Preamble starts by declaring the WTO Members' desire "to reduce distortions and impediments to international trade", and continues pointing out the need "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade". Additionally, TRIPS article 8, containing the principles to apply to the whole treaty's implementation, also recognizes the need to avoid both intellectual property rights abuses and practices that imply trade restrictions. More precisely, article 8.2 affirms that appropriate measures "may be needed to prevent the abuse of intellectual property rights by right-holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology." Article 40 further specifies this power and states that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade" and recalls the power granted to states "to prevent or control such practices".

As regards enforcement measures, TRIPS Part III Section 1 contains a single article, which encapsulates several general obligations regarding enforcement. Given its location and comprehensive nature, article 41 guides the implementation and interpretation of the rest of the enforcement part and sections, including Section 4, on border measures. This is important because the second sentence of article 41 "takes account of the public interest in the availability of IPR-protected products"<sup>38</sup> when affirming that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse". It recognizes, therefore, the protection against abuses by right-holders and the protection of legitimate trade as standards to be applied to the entire Part III and, consequently, on border measures legislation and implementation. It is argued that the mandatory language of TRIPS article 41,

added to the TRIPS article 1.1 condition imposed upon new standards to “not contravene the provisions of this Agreement”, impose a ceiling both to implementation of TRIPS Part III and to new standards related with enforcement.<sup>39</sup>

The article 41 reference to “legitimate trade” may well oblige one to think about the legitimacy of generic medicines international trade. If no disagreement existed on said trade legality, Brazilian Ambassador Roberto Azevedo would probably have been right when claiming at the Council for TRIPS that seizures responded to an “excessive and inappropriate interpretation of intellectual property law”.<sup>40</sup> The WTO Panel report in *Canada-Pharmaceutical Products* gave a definition of ‘legitimate’ in a matter also related to medicines and intellectual property rights. According to the Panel, ‘legitimate’ “must be defined in the way that it is often used in legal discourse -as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms”.<sup>41</sup> In this regard, and in addition to the fact that seized medicines were legitimate in exporting and importing countries, the validity of generics international trade is not contested at all. What is more, major international public health organizations, and also WTO Members, have individually, collectively, internally and internationally recognized the need to promote

such trade in order to guarantee access to medicines. This public policy goal, together with the human right status granted to access to medicines,<sup>42</sup> should end any debate regarding the “legitimacy” of generics trade.

On the basis of all the aforementioned, it is certainly possible for a WTO DSB panel to be asked as to whether EC Regulation 1383/2003 restricts legitimate trade and, thus, TRIPS Preamble and articles 1.1, 8, 41, 51 and 52 become relevant. The fact that the trade of legitimate generic products has been disrupted proves not only that Regulation 1383/2003 is potentially trade restrictive and can be abused, but that this is also the case in practise. Moreover, pharmaceutical companies’ allegations when challenging transit goods expose further problems related to their understanding of rights granted by their patents. Although EFPIA official statements would indicate the opposite,<sup>43</sup> the facts and above quoted letters show that R&D based companies understand that national patent rights permit disrupting international trade despite challenged goods not having effects in their jurisdictions and being legal in foreign jurisdictions. The EC Regulation is instrumental in fostering that view, which makes it necessary for the EC to clarify whether it also shares that understanding and what measures could be adopted to avoid EC Regulation 1383/2003 being used to stop legitimate trade.

## 5. TRIPS articles 51 and 52

TRIPS articles 51 and 52, devoted to the suspension of release by customs authorities and its application, are located in Part III of TRIPS, which sets general principles and detailed mechanisms for the enforcement of intellectual property rights. Part III includes civil measures and criminal and administrative procedures, and Section 4 of that Part (which includes articles 51 and 52) deals with border measures. Regarding actions to be controlled, TRIPS article 51 establishes the obligation to allow an application to be lodged for the suspension of the release into free circulation of imported infringing products. The imposition of border controls on importation operates as a “safety net in the event that enforcement at the source has not taken place”.<sup>44</sup> Certainly, Members *may* also provide for corresponding procedures concerning the suspension of the release of infringing goods destined for exportation, but this clearly remains a power of the contracting parties. Moreover, a footnote attached to article 51 provides that there shall be no obligation to apply such procedures to in-transit goods.

Not all enforcement measures contained in Part III refer to all intellectual property rights categories. Article 51, for instance, only establishes the obligation to deploy certain border measures with regards to specific intellectual property rights, namely trademarks and copyrights. In contrast, border measures are optional when applied to other intellectual property rights, such as patents. It is not by chance that customs have traditionally controlled only counterfeit and pirated goods,<sup>45</sup> that is to say, visibly infringing goods. Even today, other intellectual property rights border enforcement measures are rare, there being several explanations for this. Regarding patents, the most relevant argument against its border control feasibility relates to the difficulty in assessing patent infringements at first sight. This difficulty arises from the complexity of patents, as well as the technical complexity of products to which patents are attached. This appraisal requires an assessment of the scope of claims, a much more complex activity than the usual visual inspection

performed by customs authorities on products allegedly infringing trademarks and copyrights.<sup>46</sup> Moreover, determining medicines patent violations requires examinations that involve laboratory tests and other relatively complex procedures which in the majority of cases can not be performed by customs authorities.<sup>47</sup>

These are the outlines of the minimum requirements that TRIPS lays down on border measures. It is clear, therefore, that the detention of transit goods goes beyond the TRIPS requirements. In fact, EC Regulation 1383/2003 surpasses TRIPS standards regarding scope, entitled applicants, actions, sanctions and procedures. That is to say, EC Regulation expands TRIPS regime in almost every respect. Nevertheless, due to the minimum nature of the standards provided therein, this does not necessarily imply an infringement of the TRIPS Agreement. In fact, in adopting EC Regulation 1383/2003, the EC has made use of the power granted by TRIPS article 1 to “implement in their law more extensive protection than is required by this Agreement”. But it has to be duly taken into consideration that this is not an absolute freedom, because article 1 itself made that power conditional upon “such protection does not contravening the provisions of this Agreement”. In this context, there is a need to recall the above alluded condition to not unreasonably restrict legitimate trade imposed on measures and procedures to enforce intellectual property rights, and assess that requisite against the consequences of the EC TRIPS *plus* legislation on border measures.

A definition which rooted legitimacy on “public policies or other social norms” was offered above. According to said definition, generics trade is legitimate. Not only this, but one would naturally expect that WTO free trade aspirations would assume as a logical outcome the fostering of trade in legitimate products, both patented and generic. This is why there is a need to assess whether trade restrictions of generic medicines are backed by sound legal arguments. Companies compelling the EC to detain generic medicines

in transit understand that they can claim the rights conferred by TRIPS article 28 even though there is no possibility of those products entering European markets and, consequently, the subject matter of their rights not being affected at all.<sup>48</sup>

An argument against European seizures and Regulation can be found in TRIPS article 52, which states that right-holders must provide evidences “to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement”. GATT article V.1 distinguishes transit from importation, and several TRIPS articles allude to transit and importation separately. As European seizures have been carried out invoking the law of the country of transit, which is what EC Regulation 1383/2003 permits when it mandates measures to be taken if goods “in the Member State in which application for customs action is made, infringe: (i) a patent under that Member State’s Law”,<sup>49</sup> it can be sustained that both the regulation and the seizures are against TRIPS Article 52. Consequently, national regulations and practice that follow EC Regulation 1383/2003 would also be against TRIPS article 52. For instance, the Dutch Group of the AIPPI has recently stated that in order to establish whether or not goods in transit infringe an IP right

“Dutch courts apply a so-called legal fiction. In order to establish infringement, goods in transit should be regarded by way of fiction as goods which have been produced in The Netherlands. (...) The use of the legal fiction in The Netherlands has been cause of much debate among scholars and legal professionals. Goods which in their country of origin and destination do not infringe IP rights can still be detained by customs and found to infringe an IP right in the Netherlands as meant in the APR (EC Regulation 1383/2003) based on this fiction.”<sup>50</sup>

As it will be seen, this fiction contravenes ECJ jurisprudence regarding the rights conferred by intellectual property rights and the control of in-transit goods.<sup>51</sup> In this regard, in order to control

goods in transit that do not affect Dutch title holders competitive position in the Dutch or EC markets, Dutch courts fictitiously assume that goods have been produced in the Netherlands.

However, in reply it could be argued that the article 52 reference to take into account the law of the importing country when assessing the infringement might be related to the main situation addressed in article 51 -and the only one for which article 51 is mandatory-, that is to say, the suspension of release of *imported* counterfeited or pirated goods. Other situations, such as the exportation or transit, would not be the ones addressed in article 52 and could therefore be judged pursuant to the laws of the countries of exportation and transit. This last thesis is, nevertheless, far from clear, both due to legal and factual reasons. From the legal point of view, the territorial principle and the rights conferred by an intellectual property right would render a different conclusion.<sup>52</sup> And, from a factual point of view, the letters sent by rights-holders to generic companies in the context of the seizures case demonstrate that their actions assume that importation into the EC had taken place. In one letter, for instance, the patent holder affirms that “by *importing* clopidogrel, you are infringing the aforementioned intellectual property rights of Sanofi-aventis”.<sup>53</sup> In that case, no importation into the EC ever took place, but only transit through the EC customs space: the consignment was originated in India and was in transit in the Schiphol airport on its way to Colombia. In order to adjust the facts and argumentation to the second interpretation offered of TRIPS article 52 above, Sanofi-Aventis would have better alleged something along the lines of “by *transiting* clopidogrel through European customs zones, you are infringing...”. Although said argumentation would have surprised those familiar with fundamental intellectual property rights principles, not to say free trade promoters, it is in fact the one consistent with the second interpretation offered of TRIPS article 52. In any case, and regarding the proper meaning of TRIPS article 52, it can be sustained either that only the law of the final destination State is the relevant one, or

that the TRIPS Agreement is unclear on this matter, a vagueness that makes it worth asking for clarification through the WTO Dispute Settlement Understanding (DSU).

Another important point to make is that, according to TRIPS, Member states are free when deciding on the specific application of border measures to goods in transit. As TRIPS footnote No. 13 states, “there shall be no obligation to *apply* such 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*”. The reference to the *application* of such procedures and not to the legal incorporation of the same makes it clear that, even if enshrined in their legislation, Members are always free to disregard their application. That is to say, even if the title holder lodged an application for the detention or suspension of release into free circulation of such products in conformity with its internal law, a WTO Member would be free to disregard such an application in conformity with WTO law.

## 6. Intellectual property rights basics: the territorial nature of intellectual property rights and rights conferred by intellectual property rights

### 6.1 The territorial nature of intellectual property rights

It is commonplace to state that patents are territorial and their protection depends on the national regulation of each country. Given that each State grants its own patents, it comes as no surprise that conferred rights might be only enforceable in the issuing State.<sup>54</sup> Therefore, patent validity and applicability is only to be judged according to the *lex loci*. Both national intellectual property rights legislations and public international law recognize this rule. The United States (US) Patent Act, for instance, states that a person may be liable for patent infringement if he/she “makes, uses, offers to sell or sells any patented invention, *within* the United States”.<sup>55</sup> The Paris Convention for the Protection of Industrial Property article 4*bis*.1 enshrines the principle of independence, by which “patents applied for in the various countries (...) shall be independent of patents obtained for the same invention in other countries”. Consequently, this independence recognizes the liberty of each State to implement its own national patent regime. The TRIPS, acknowledging such liberty and independence, sets minimum standards and allows WTO Members to adopt higher levels of protection, something which, in fact, implies that intellectual property law may not have, on principle, extra-territorial effects, and that each State is responsible for the level of protection it grants.

Regarding patents, which are the most explicitly territorial among the categories of intellectual property,<sup>56</sup> this basic rule knows some limited exceptions.<sup>57</sup> Both the Paris Convention and the TRIPS recognize extra-territorial effects of patent rights in relation to the importation of products made by a patented process, importation that patent holders may impede pursuant to Paris Convention article 5 and TRIPS article 28.1.b). On the other hand, some extra-territorial activities with effects on national jurisdictions have been addressed by several national legislations. In this regard, and in response to a case where

separated components of a patented invention were exported and later on assembled and sold abroad,<sup>58</sup> the US Congress introduced a provision in the Patent Act prohibiting the exportation of components of patented products so as to “induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States”. In the same vein, the US has also forbidden the exportation of components that are meant for use only in a patented device.<sup>59</sup> A different case is the one concerning parallel imports, where no extraterritorial effects of foreign intellectual property rights are recognized, but effects to certain facts occurred abroad: the commercialization of a product and the resulting exhaustion of rights.

None of the exceptions to the territoriality principle, and none of the current legal responses to problems posed by network inventions<sup>60</sup> that also circumvent the territoriality principle,<sup>61</sup> are applicable to the seizures case. Generics in transit were neither the product of a patented process nor were they intended to be entered into the European market. Having ruled out the applicability of TRIPS 28.1.b) to generics, the generic medicines production did not require any exportation from countries where bioequivalent medicines are patented to take place.<sup>62</sup> By its own means, and in accordance with relevant national and international regulations, India produced and other countries bought perfectly legal non-patented medicines. However, with its seizures and the referral to the law of the country where they have been conducted to assess the legitimacy of goods, the EC may be challenging the implementation of Indian laws. Setting aside sovereignty considerations and the territoriality principle, the difficulties in EC assessing validity of foreign patents are insurmountable. In 1972, a US District Court noted that “courts in the foreign territories whose patents are involved here... (might)

disagree with this court's determinations on the validity of the patents. Those courts would at any rate be faced with the hard choice of accepting the inexpert determination of a foreign court or creating an unseemly conflict with the judgment of the court of another country".<sup>63</sup>

It could be argued that, despite not entering into the European internal market, medicines were certainly in European territory, albeit in the customs zone. Together with the legal arguments derived from the national scope of patent rights and the consequent independence of title holder's exclusive rights,<sup>64</sup> it is doubtful that an economic entitlement as a patent without economic effects in a specific jurisdiction can nevertheless be challenged in said jurisdiction. Although bizarre, this proposal is not unrelated to other cases. Professor Chisum recalls a seminal case that may be worth taking into account in this context. In *Brown v. Duchesne*, the US Supreme Court constricted the literal territorial scope of a US patent. A French vessel in US territory used a gaff on board covered by a patent, an unauthorized use in the US territory, which the Supreme Court did not, however, consider an infringement.<sup>65</sup>

Letters sent by European patent holders to generic companies affirm that in-transit goods infringe patents granted in EC Member States. These allegations are not only against the territoriality

principle and basic assumptions regarding the rights a patent confers but also against what the EFPIA, the voice of the European patents-based industry, has commented on. According to the EFPIA, "Where the product is not counterfeit and it is ascertained that no intellectual property rights apply at either country of origin or destination, the customs authorities should allow the product to be released, irrespective of the intellectual property status of the product in the EU".<sup>66</sup> Leaving aside EFPIA and its Members lack of coordination, an inherent contradiction exists between the territoriality principle and Regulation 1383/2003. Only this contradiction explains positions that claim that if products are not "counterfeit" according to the EC law and are not patent infringing in source and destination countries, they will be released for free circulation. So, from that standpoint, on the one hand EC Law becomes relevant to assessing the "counterfeit" nature of goods, and on the other hand patent status in third countries also becomes relevant. These *ex post* contradictory arguments can not let one forget that all that has been achieved is the disruption of generics trade invoking European patent rights of goods not intended for the EC market. Something that EC Regulation 1383/2003 allows, due to its understanding that the law of the transit country is the relevant one when assessing the legality of in-transit goods.<sup>67</sup>

## 6.2 Rights conferred by intellectual property rights

To state that conferred rights are only enforceable in the issuing State, that is to say, invoking the territoriality principle, is helpful at explaining why States different to that granting an intellectual property right cannot decide on the validity or enforcement of said right in the granting State or third States. From the point of view of intellectual property rights owners, the territoriality principle implies that the title holder will be able to claim his rights if the jurisdiction where the right is protected and the place of infringement coincide.<sup>68</sup> However, only by analyzing the rights conferred by each of the intellectual property rights categories will it be possible to determine where the title-holder rights end. Otherwise, there is nothing impeding

the title holder located in the transit country to claim his rights regarding goods in transit also invoking, precisely, the territoriality principle.

As far as patents are concerned, TRIPS article 28 states that, where the subject matter of a patent is a product, the owner has the exclusive rights of making, using, offering for sale, selling or importing said product. On the other hand, where the subject matter is a process, the owner can prevent third parties from the act of using the process, and from the acts of using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process. It is clear that transit is a different activity from the ones of making, using,

offering for sale, selling, or importing. Only the latter, importation, could be slightly related. Nevertheless, importation implies the placement of the protected goods into the market where they are protected, an extreme that transit does not imply. All the aforesaid activities occur within the jurisdiction of the granting state, and affect the competitive position of the title holder.<sup>69</sup>

On various occasions, the ECJ has dealt with the interaction between the territoriality principle, the rights conferred by different intellectual property rights categories and the push for enforcing local intellectual property standards which may have extra-territorial effects. Albeit in most of the cases the ECJ has dealt with controversies arising from trademarks litigation, the fundamentals of its jurisprudence are transferable to other intellectual property rights categories.

In 2000, when judging a well-known case, *The Polo/Lauren Company LP v. Pt Dwidua Langgeng Pratam*, the ECJ linked the validity of Regulation 3295/94 -which preceded the present Regulation 1383/2003- to one of the pillars of the EC, the then article 113, on common commercial policy. The Court affirmed that provisions on intellectual property affecting cross-border trade constitute an essential element in international trade legislation, and that the external transit of non-Community goods is not devoid of effect on the internal market. Alleging the possible diversion of those goods onto the European market, the Court upheld the legality of the Regulation.<sup>70</sup> In relation to that case, General Advocate Jacobs said that “the risk that counterfeit goods in external transit may be fraudulently brought on to the Community market is a relevant consideration in examining the validity of a regulation which seeks to empower customs authorities to take action when such goods are found during the course of checks on goods in external transit.”<sup>71</sup> The fact that the TRIPS may open the door to similar measures being taken in relation to patented products in transit is a sound basis for the EC to defend WTO conformity of Regulation 1383/2003. This conclusion, however, invites us to distinguish between the validity of a certain regulation as far as European and

WTO law is concerned and the admissibility of certain right-holders requests and implementing measures. Additionally, it must be remembered that the ECJ made the control of in-transit goods conditional on their potential diversion onto the EC market. While there is the possibility of deviating goods to the EC internal market under the external transit special procedure, this event is much more unlikely in the case of mere transshipment.

In *Montex Holdings Ltd. V. Diesel SpA*, the ECJ was assured that both intellectual property protected goods in the case were legal and that they would not be diverted onto the EC market. In that case, a cargo from a non-EC country was in transit through Germany, with Ireland as its final destination, a country where the goods were not trademark protected. In response to several preliminary questions, the Court affirmed that “external transit does not constitute use of the mark liable to infringe the right of the mark’s proprietor to control the putting of the goods in question on the Community market, because it does not imply any marketing of those goods.” This led the Court to conclude that the proprietor of a trademark can prohibit the transit through a Member State -in which that mark is protected- of goods bearing the trademark and placed under the external transit procedure “only if those goods are subject to the act of a third party while they are placed under the external transit procedure which necessarily entails their being put on the market in that Member State of transit.”<sup>72</sup> The ECJ also made it clear that the risk of diversion could not merely be a theoretical one. By contrast, the right-holder must demonstrate either “the existence of a release for free circulation” or “another act necessarily entailing their being put on the market” in the transit State.<sup>73</sup> In this regard, the Court made it clear that “placing non-Community products under a suspensive customs procedure does not make it possible for them to be put on the market in the Community in the absence of release for free circulation”.<sup>74</sup>

Advocate General Jacobs was even clearer in *Unilever NV and Others*. This case concerned genuine trademarked goods that the applicant

was trying to introduce in the European Economic Area. The defendants blocked the products at the Dutch border alleging legislation prohibiting the entry of counterfeit products, something that soon became clear was not the case. Among the questions Advocate General answered was whether a trademark proprietor may oppose the entry of legally trademarked goods from third countries into the territory of a Member state. Jacobs responded to the question by recalling that trademark owner exclusive rights are granted in order to enable the proprietor to protect his specific interests as proprietor. In this context, Jacobs affirmed that he could “not see how the essential function of a trademark can be compromised solely by the fact that goods genuinely bearing that mark are subject to the external transit procedure and hence by definition are not in free circulation within the Community”.<sup>75</sup> And even more importantly for the seizures case, Jacobs recalled the *Rioglass* case,<sup>76</sup> where the ECJ affirmed that the mere passing in transit did not involve any marketing of the goods and therefore could not infringe any rights, and stated that “if the Court took that view with regard to goods in free circulation in the Community it would apply a fortiori to non-Community goods in respect of which import formalities have not been completed.”<sup>77</sup>

ECJ jurisprudence on EC Treaty article 30 may also be helpful at laying down the limits of enforcement of measures adopted to secure compliance with regulations for intellectual property protection. EC Treaty article 30 authorizes prohibiting or restricting importation, exportation and transit of goods invoking the protection of industrial and commercial property. Intellectual property rights enforcement would be therefore a legitimate basis to move away from free trade principles. Even so, the ECJ made it clear that these actions can only be aimed “to protect the specific subject-matter of the right of industrial and commercial property”.<sup>78</sup> In the area of pharmaceutical products, and in the context of the jurisprudence related to the exhaustion of rights doctrine, the ECJ has stated that the specific subject matter of a patent is to use an invention for placing the goods resulting from said invention onto the market for the first

time.<sup>79</sup> It is difficult to find out how the mere transit of a product could affect this specific subject matter, since neither the invention would be used nor the product placed onto the market.<sup>80</sup>

So, under a very similar legal regime to the present one, the ECJ and its Advocate General have linked the detention and the suspension of release of protected goods in transit to the very fact those goods could be diverted on to the transited market. In itself, the transit of goods through a country where they are protected does not imply any infringement. The background argument is that only by placing the goods onto the internal market can the subject-matter of a specific intellectual property right, and the rights of the title holder, be infringed. Consequently, the seizure of in-transit goods would only be warranted if those goods threatened right-holder’s competitive position in the transit country. By contrast, in the seizures case no one questions that generics were not intended to enter in the European internal market. The introduction of the product, therefore, would be the only trigger that would allow the EC to initiate actions against products in transit that respect intellectual property laws of exporting and importing countries.

In this context, it might be necessary to point out other legislative constructions which better reflect the needed correlation between the territorial nature of intellectual property rights and the rights conferred to the rights-holder. A first option is the freedom of transit of goods when no affectation of the competitive position of the title holder in the transited market exists. This option matches TRIPS provisions requirements on border measures, and it is certainly fully respectful of both the territorial nature of intellectual property rights and the rights conferred to the title holder.

A second option, based on a fiction, consists in anticipating the moment and location of the protection of an intellectual property right. This is the case of Switzerland, where the Patents Act, in its article 8.3, establishes that “The transit of patent-infringing goods can only be prohibited when the patent owner can

also prohibit the import into the country of destination”.<sup>81</sup> Although there is no affectation of the specific-subject matter of a patent in the country of transit, the Swiss law permits anticipating the moment of the protection that the same title holder could demand in the destination country. Swiss authorities justify said anticipation “in view of the increasing international dimension of counterfeiting and piracy”.<sup>82</sup> Nevertheless, this option is far from unproblematic when assessed against both the prohibition of extraterritoriality of intellectual

property rights and the rights conferred to the rights holder. Firstly, because Swiss authorities might be found themselves in the situation of examining the validity of the patent in the importation country and, secondly, because the rights-holder may prevent the transit without its rights in the transit country having been affected at all. It may be argued, however, that this is a more plausible formulation than the much broader European one, because at least it takes into account the status of the good in the relevant country, which is the destination one.

## 7. The special status conferred to pharmaceutical products in the WTO legal system and the relevance of other public international law norms

Over the last fourteen years, the impediments that the TRIPS Agreement may pose to the access to medicines have provoked both a legal and political response in favour of interpreting the TRIPS Agreement in a manner supportive of public health. So-called TRIPS flexibilities have been emphasized and, in a legally binding way, all WTO Members gave an undertaking that the TRIPS “can and 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”.<sup>83</sup>

Numerous authors have explored the TRIPS margin of discretion and have offered interpretations that would reduce the impact of the TRIPS on medicines prices and access. To that scholar and civil society effort, developing countries added their strength at the WTO to obtain a compromise which ended doubts and favoured a pro-public health interpretation of the TRIPS. This is something that was achieved with the Doha Declaration on the TRIPS Agreement and Public Health. Despite the fact that a parallel movement to ratcheting up TRIPS standards mainly through free trade agreements has co-existed with said pro-public health legal interpretations and reforms, it may be well ascertained that a pro-public health interpretation would presently guide any case at the DSU that has to do with pharmaceutical products. Nevertheless, “the confiscation (EC seizure of losartan) is contrary to the letter and spirit of the Doha Declaration”.<sup>84</sup>

In a hypothetically *seizures case* at the WTO DSB, the panel would be probably confronted with the task of interpreting TRIPS articles 41, 51 and 52 together with GATT article V and XX(d). States confronting European seizures and regulations would almost certainly raise the public health problems caused by said actions and regulations. In accordance with DSU article 3.2, the panel would clarify TRIPS provisions “in accordance with customary rules of interpretation of

public international law”. Pursuant to the general rule of interpretation of international treaties, contained in article 31 of the Vienna Convention on the Law of Treaties, and more specifically, in accordance with article 31.3.a), when interpreting a treaty, any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions shall be taken into account. The Doha Declaration has this status, at least, and its command to interpret the TRIPS in a manner supportive of WTO members’ right to protect public health could be decisive in the panel’s ruling on the hypothetical *seizures case*.

Moreover, European regulation and seizures not only jeopardize the pro-public health interpretation of the TRIPS Agreement, but also the WTO General Council Decision of 30 August 2003 and the proposed amendment to TRIPS Article 31.<sup>85</sup> Under a certainly controversial system, both texts aim at overcoming the problem that countries lacking manufacturing capacity face in making use of the TRIPS provision on compulsory licenses. The system enshrined depends on cross-licensing patented products both in exporting and importing countries. The fact that nothing is said regarding transit countries could -in principle and under the EC law- allow title holders to block compulsory licensed goods in such transit countries. Again, if a EC clarification is not offered, the systemic effects of EC Regulation 1383/2003 could make recurring to the WTO dispute settlement system necessary.

The above mentioned clarification should not only cover the interaction between WTO and EC law, but also the relationship between certain pieces of EC legislation, such as EC Regulations 1383/2003 and 816/2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. In principle, taking into account the goals and spirit of Regulation 816/2006, one would expect that

it impedes European patentees from disrupting the transit of compulsory licensed medicines in third countries under the system of General Council Decision 30 August 2003. However, when analyzed in greater detail, the conclusions might be just the opposite. Article 13.1 of Regulation 816/2006 bans the import into the Community of products manufactured under a compulsory licence granted pursuant to the WTO General Council Decision of 30 August 2003 *and/or* Regulation 816/2006 for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse. Nevertheless, this prohibition is waived pursuant to article 13.2 in the case of re-export to the importing country cited in the *application*, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing country.<sup>86</sup> This constricts the exception provided in article 13.2, which would only cover products licensed in the EC, but not, for instance, those licensed in India and addressed to countries without manufacturing capacity. The reason is to be found in the term *application* and its referral to products licensed solely in the EC. In fact “application” is the term used in EC Regulation 816/2003, and it is absent in the wording of the General Council Decision 30 August 2003. Therefore, under this view, under the system established in Decision 30 August 2003 products licensed in States other than those of the EC would not benefit from the exception contained in article 13.2 and could be, consequently, detained in the EC while in-transit. This outcome might have not been that expected when EC Regulation was drafted, but presently patentees may understand that they have the power to disrupt the transit of compulsory licensed medicines in non-EC States.

But not only Vienna Convention article 31.3.a) could be of relevance. Among the Vienna Convention rules to which DSU makes reference there is also article 31.3.c), which lays down that, when interpreting a treaty, and together with the context, any relevant rules of international law applicable in the relationships between

the parties shall be taken into account. Article 31.3.c) comes into play whenever a certain norm is ambiguous, when a term has a specific meaning in customary international law or when terms are open and need further references to other public international law norms to specify its meaning.<sup>87</sup> In this regard, a WTO panel affirmed that when the application of article 31 gives several possible interpretations as a result, the interpreter will be obliged to choose that which better matches other applicable norms of public international law.<sup>88</sup> Given the nature of seized goods, and their relevance to the protection of health, European actions may result in a shortage of medicines in developing countries, something which would have an impact on the right to health of the patients of said countries. This right, as enshrined in the International Covenant on Economic, Social and Cultural Rights, not only obliges States to adopt internal measures but also to “provide international assistance and cooperation”. Due to their restricting effects on access to medicines, EC border measures mandating the seizure of legitimate in-transit generic medicines would counter against said ICESCR obligation, something that could, therefore, be taken into account by WTO adjudicative bodies when interpreting the GATT and TRIPS provisions involved in the case.

Lastly, also commitments undertaken by EC Member States in the WHO should be taken into account when analyzing European border measures and their impact on public health. The World Health Assembly resolution 61.21, which laid down the *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property*, entered all WHO Member States into a compromise to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights”.<sup>89</sup> Undoubtedly, EC Regulation 1383/2003 and resulting actions fall into said compromise scope.

## 8. Freedom of transit of patented and generic products pursuant to GATT articles V and XX(d)

Already quoted is the WTO *Communities - Trademarks and geographical indications* Panel report affirming the absence of any hierarchy between the TRIPS Agreement and GATT 1994, that is, “One logical approach would be to begin in each instance with the TRIPS Agreement”. Consequently, after having dealt with the TRIPS Agreement now follows the analysis of the European regulations and seizures under the GATT provisions.

There are several GATT articles potentially relevant to the case, among them, various article V subsections and also article XX(d). In fact, some of the legal arguments raised regarding the WTO legality of European seizures have focused their attention on GATT article V, which sets the legal framework of the freedom of transit principle. Article V:1 states that goods and means of transport shall be deemed to be in transit when the passage across the territory of a contracting party “with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party”. Having established the definition of in-transit goods, article V:2 lays down the fundamental principle of freedom of transit. Despite its transcendence, this principle was only interpreted for the first time by a WTO panel in April 2009, in the *Colombia - Indicative prices and restrictions of ports of entry* dispute.<sup>90</sup>

The Panel established for that dispute specifically dealt with article V subsections 1, 2 and 6. Regarding subsection 2, the Panel agreed with the parties that subsection 1 -that is, the above alluded to definition of transit- informed the scope of obligations under V:2. According to the Panel, “When applied to Article V:2, ‘freedom of transit’ must thus be extended to all traffic in transit when the goods’ passage across the territory of a Member is a only a portion of a complete journey beginning and terminating beyond the frontier of the Member across whose territory the traffic passes. Freedom of transit must additionally be guaranteed with or without trans-shipment,

warehousing, breaking bulk, or change in the mode of transport.”<sup>91</sup>

In its report, the Panel specified the meaning of the first and second sentences of article V:2.<sup>92</sup> According to the Panel, the provision of freedom of transit pursuant to Article V:2, first sentence “requires extending unrestricted access via the most convenient routes for the passage of goods in international transit whether or not the goods have been trans-shipped, warehoused, break-bulked, or have changed modes of transport. Accordingly, goods in international transit from any Member must be allowed entry whenever destined for the territory of a third country. Reasonably, in the Panel’s view, a Member is not required to guarantee transport on necessarily any or all routes in its territory, but only on the ones “most convenient” for transport through its territory.”<sup>93</sup> As far as the second sentence of article V:2 is concerned, the Panel considered that “the obligation in Article V:2, second sentence is clear on its face: Members shall not make distinctions between goods which are ‘traffic in transit’ based on the flag of vessels; the place of origin, departure, entry, exit or destination of the vessel; or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.”<sup>94</sup>

At first sight, the liberty of transit mandated by article V:2 would clearly prohibit seizures of generic drugs in transit. However, GATT article V contains other subsections and must be contextualized in a broader framework and in relation to other GATT provisions. In this regard, GATT articles V.3 and XX(d) become fundamental. To begin with, GATT article V:3 modulates said freedom of transit when stating that “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 and shall be exempt from

customs duties and from all transit duties”. Two points may be raised with regards to subsection V:3.

Firstly, EC authorities could state that by detaining and analyzing medicines patent status they are merely implementing the power granted in V:3 to apply “custom laws and regulations”. This argument assumes that Regulation 1383/2003 is part of EC customs law and not EC intellectual property law, and it is thus included under the scope of GATT article V:3. Several arguments support said thesis. EC Regulation 1383/2003 refers to the EC Customs Code to determine customs situations covered, so the EC can defend that intellectual property control of goods exported, imported, re-exported or in transit is part of its customs law and enforcement system. Certainly, a major goal of European Customs authorities is to fight against intellectual property infringing goods crossing European borders, which explains why, within the Commission, surveillance of Regulation 1383/2003 is under the mandate of Customs Policy Division of the DG for Taxation and the Customs Union (TAXUD). In a similar sense, Regulation article 21 grants advisory role in relation to the regulation implementation to the Customs Code Committee established by article 247 of the Customs Code.

GATT V:3 also forbids *unnecessary delays or restrictions*. This, despite being rather ambiguous terminology, it is no stranger to WTO DSB jurisprudence, where the so-called “necessity test” is well-known. According to this test, if the party had other less trade-restrictive and equally effective alternatives to achieve a certain public policy goal, it should have chosen those alternative measures. If it is accepted that goods might be temporally detained in order to determine whether they infringe a particular intellectual property right, attention must focus on measures that integrate the inspection regime. In this particular case, and in line with TRIPS article 55, EC Regulation prescribes a relatively short period of time for the right-holder to inspect the product and decide what to do (10 days)<sup>95</sup> which, in principle, makes it difficult to challenge the Regulation as such for resulting in “unnecessary delays”. This, however, does not

preclude a different conclusion regarding specific cases where time-frames have been outstandingly longer, exceeding even 80 working days,<sup>96</sup> as the Dutch authorities themselves have recognized.<sup>97</sup> That is to say, it would be possible to raise an issue at the DSB regarding EC Regulation *as applied*.

Together with the potential infringement of GATT V:3 caused by EC Regulation 1383/2003 as applied (i. e. the temporal dimension which would refer to the prohibition of unnecessary delays established by V.3), it is also necessary to evaluate the existence of *unnecessary restrictions*. It has already been said that the parallelism between the temporal frameworks set forth in TRIPS and in the EC Regulation regarding the actions of border authorities could justify the EC Regulation compatibility with article V.3 as such. Another parallelism could deliver the opposite conclusion as far as the existence of an infringement of the condition set forth in article V:3 to not cause “unnecessary restrictions”. If it is established that the provisions governing European border authorities action concerning goods in-transit infringe the TRIPS Agreement, as was affirmed above, then it can also be sustained that European interruption of the traffic of generic drugs in transit implies unnecessary restrictions.

Should the existence of GATT inconsistencies be proven, the EC could still find its regulation and measures justified pursuant to GATT article XX, and more precisely, XX(d). The chapeau of article XX and the text of article XX(d) provide that “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 where the same conditions prevail, 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 those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices.” Both customs enforcement and the

protection of patents are thus recognized in article XX(d) as grounds that permit measures derogating from GATT obligations.

As the Appellate Body has affirmed, in order that the justifying protection of Article XX may be extended to it, the measure at issue must not only come under one or another of the particular exceptions listed under article XX; it must also satisfy the requirements imposed by the opening clauses of article XX.<sup>98</sup> The first condition, in any case, is to identify a provisional justification under exception (d), which requires demonstrating two elements. “First, the measure must be one designed to ‘secure compliance’ with laws or regulations that are not themselves inconsistent with some provision of the *GATT 1994*. Second, the measure must be ‘necessary’ to secure such compliance. A Member who invokes Article XX(d) as a justification has the burden of demonstrating that these two requirements are met.”<sup>99</sup>

In determining whether a measure is designed to secure compliance with laws and regulations as provided in Article XX, a WTO Member raising a defense should identify the laws or regulations for which it seeks to secure compliance, establish that those laws or regulations are not themselves WTO-inconsistent, and demonstrate that the particular measure at issue is itself designed to secure compliance with the relevant laws or regulations.<sup>100</sup> Any national rules that are necessary for the implementation of the TRIPS Agreement would be regarded as laws or regulations which are not inconsistent with GATT within the meaning of article XX(d).<sup>101</sup> Nevertheless, if it is established that EC Regulation and measures are inconsistent with the TRIPS, the justification under article XX(d) would be hardly sustained. In any case, before the Panel the EC would maintain not only the consistency of its measures but also its necessity. In this second regard, the increasing importance attached to the fight against counterfeiting, piracy and other intellectual property rights infringements could be a sound basis to sustain the necessity of certain border measures. Nevertheless, the so-called ‘necessity test’ is a demanding one.

Regarding the ‘necessity test’ and the evaluation of EC regulation and measures according to the same, the Appellate Body in *Korea - Various Measures on Beef* clarified the term “‘necessary’” when affirming that a “‘necessary’ measure is, in this continuum, located significantly closer to the pole of ‘indispensable’ than to the opposite pole of simply ‘making a contribution to’”.<sup>102</sup> Nevertheless, the Appellate Body accepted that a measure that is not absolutely indispensable may be deemed necessary if it overcomes a weighing and balancing process. According to the Appellate Body, the weighing and balancing process “is comprehended in the determination of whether a WTO-consistent alternative measure which the Member concerned could ‘reasonably be expected to employ’ is available, or whether a less WTO-inconsistent measure is ‘reasonably available’.”<sup>103</sup> The fact that among WTO Members very different legal frameworks exist to address the same problems that EC Regulation 1383/2003 aims to tackle, would be an important factor when assessing either the availability of WTO-consistent alternative measures or the availability of less WTO-inconsistent measures.

In the WTO DSB, “the burden of proof rests upon the party, whether complaining or defending, who asserts the affirmative of a particular claim or defence. If that party adduces evidence sufficient to raise a presumption that what is claimed is true, the burden then shifts to the other party, who will fail unless it adduces sufficient evidence to rebut the presumption”.<sup>104</sup> However, even if the EC could demonstrate that EC Regulation and measures overcame said highly demanding test, measures and Regulation would still be assessed against the requirements set forth in article XX chapeau, namely, they could not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade. As above mentioned, restrictions which find their origin in highly-demanding levels of intellectual property enforcement may be an element to prove the existence of disguised restrictions to international trade.

## 9. Background discussion: the blurring of lines between substandard and “counterfeited” medicines

In recent years, some developed economies and major intellectual property rights title holders companies have been pushing for the establishment of a stronger international regulatory framework against “counterfeit” medicines. They have argued that in order to protect public health, enhanced action must be taken in the intellectual property field, an argument that has been deployed, for instance, at the Council for TRIPS.<sup>105</sup> In a similar sense, the EC Regulation 1383/2003 preamble establishes a clear correlation between intellectual property rights infringements and public health,<sup>106</sup> while the International Chamber of Commerce has affirmed that actions against counterfeiting “will be effective in stopping the flow of unsafe, unhealthy and poor quality products”.<sup>107</sup> Along a similar vein, PhARMA has stated that “America’s pharmaceutical research companies are doing their part to help combat intellectual property abuse and the counterfeiting that is result of such abuse”.<sup>108</sup> According to PhARMA, counterfeiters “are stealing the peace of mind of patients worldwide who rely on safe and effective medicines”.<sup>109</sup>

Although terminology is of the utmost importance in this field, up until now it has been possible to observe great confusion with far-reaching consequences. Public health terminology has been appropriated by intellectual property rights holders, who use public health terms and concerns to defend their own stakeholders’ interests. Innovator companies often refer to generic medicines of guaranteed quality as pirated, counterfeited, substandard or spurious. Legally and technically speaking, the first two terms refer to copyright and trademark law infringements,<sup>110</sup> while the second ones are traditional in the pharmaceutical terminology. Using “counterfeit” as a generic term to designate all intellectual property rights infringements—something common among developed countries,<sup>111</sup> some scholars<sup>112</sup> and intellectual property based industries<sup>113</sup>—and, at the same time, to indicate the lack of quality of certain products is certainly problematic.

This misuse confuses border authorities, developed and developing countries and even international organizations, and it is at the basis of the discussion of the measures that can or should be taken in relation to medicines in transit.

Exemplifying the consequences of said confusion, several of the letters sent by right-holders companies to importers of Indian generic medicines interchangeably referred to seized medicines as *counterfeit* and patent infringing. Moreover, they also made reference to public health concerns. For instance, in the letter sent by Sanofi Aventis to a Colombian distributor of active ingredients in relation to a clopidogrel in-transit shipment seized at the Dutch border, Sanofi Aventis, as a patent holder, threatened to destroy the goods after affirming that “Dutch customs suspected that these products might be counterfeit and suspended their release”. In fact, Sanofi was invoking its patent rights.<sup>114</sup> In another case, the letter sent by Eli Lilly to Cipla Ltd. regarding the seizure of 500,010 olanzapine tablets at the Dutch border stated that “Eli Lilly is the owner of European Patent n° 045-436 with validity in The Netherlands (...) Eli Lilly has determined that the Tablets indeed *infringe the patent* (...) the Tablets are not genuine Eli Lilly products and they have not been produced by Eli Lilly or any of its licensees worldwide. As such, the Tablets *may not be safe or effective*”.<sup>115</sup>

The present situation and its relationship with the very viability of generic medicines free trade calls for a brief clarification of terms. For the WHO, the defining criterion to identify a counterfeit product is its deliberate mislabelling with respect to identity or source. That is, falsified medicines. If such mislabelling does not occur, there is no counterfeit. The WHO states that “counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with

insufficient active ingredients or with fake packaging.”<sup>116</sup> It is very important to notice that for the WHO, “counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals”.<sup>117</sup> That is to say, products whose composition and ingredients do not meet the correct scientific specifications and which may be either ineffective or dangerous to the patient.<sup>118</sup> That is, “medicines that do not conform to the pharmaceutical standards set for them”.<sup>119</sup> It is, therefore, a public health problem that has a limited relationship with trademark law and a very marginal relationship with patent law. This last should come by no means as a surprise. As it has been demonstrated elsewhere,<sup>120</sup> only 1 percent of “counterfeits” are exact copies of original products and could, in consequence, and assuming that the original product was patented, imply a patent infringement. The rest of cases involve trademark violations and, much more importantly, quality shortcomings. This is reason why it must be stressed that originator companies and some developed countries have misplaced intellectual property at the center of the debate.

There is an important ongoing international debate on how to tackle the problems derived from the lack of quality of certain pharmaceutical products. In fact, some of the problems associated with substandard medicines are related to trademark law. In this sense, it is clear that one of mechanisms to commercialize substandard products is through the deception on the identity of the product’s source. However, no convincing arguments linking patent infringements and product quality have been developed up until now, and probably those arguments are not possible at all. Right up to now, said link has only been used to defend interests from intellectual property rights holders, who nevertheless have managed to introduce a great deal of confusion in a very important matter, namely the quality of medicines.

It is stated that “Substandard medicines represent a far larger risk to public health than counterfeit medicines”.<sup>121</sup> Nevertheless, the fact

that counterfeit drugs undermine the markets of pharmaceutical companies while, in contrast, there is little commercial incentive to invest in the fight against the proliferation of substandard medicines, would explain that most of the attention is concentrated in the counterfeit phenomenon.<sup>122</sup> Certainly, to guarantee the quality of medicines it would be more useful to strengthen national drug regulatory authorities and reinforce WHO activities on medicines standardization and guarantee, activities which are being replaced by the ones of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).<sup>123</sup>

The EC alleges that its intellectual property rights border measures pursue public health objectives, namely, the protection of public health in third countries. In fact, European authorities have said that “Especially in the case of counterfeit medicines, which is a problem that mainly concerns developing countries, the EU considers it a duty to also prevent -to the extent possible- any adverse effects trade in such products could have in vulnerable populations in their countries”.<sup>124</sup> If that were the case -and with all of the reservations this topic deserves due to its specific nature- then the focus would be better placed not in the TRIPS Agreement and Regulation 1383/2003 but in the WTO Agreement on Technical Barriers to Trade (TBT). If the EC wanted to protect public health in third countries - a certainly controversial goal from numerous points of view - then it should enact European regulations that matched international standards “of reference” on pharmaceuticals quality and which were specifically devoted to products in transit. Setting aside the fact that the TBT does not foresee the application of technical regulations to goods in transit, the adoption of such a regime would open several new and interesting debates. Among them, that of deciding whether the international standards of reference are the ones adopted by the WHO or rather the ones promoted by the ICH.<sup>125</sup> However, any prospect of seeing the European Medicines Agency acting as an international

agency for the control the quality, safety and efficacy of pharmaceutical products in transit in European ports and airports is highly dubious, so the question, therefore, is why TAXUD and national customs authorities should develop

such activity. If this is the case, and if patent infringements bear almost no relationship with products quality, then EC arguments and actions linking border measures and public health are difficult to justify.

## 10. Final Remarks

Developed countries efforts to improve intellectual property enforcement can, in some cases, contradict the WTO legal regime. It is necessary to ask whether EC Regulation 1383/2003 is one of those cases, particularly due to EC Regulation potential trade restricting effects and also due to its difficult coexistence with basic intellectual property law principles. Considering the systemic consequences of that regulation and given that it affects both third countries markets and the integrated global market, it would be worth asking a DSB panel on the EC Regulation's compatibility with WTO Law. When assessing such compatibility, both the GATT and the TRIPS must be taken into account. This cumulative reading has been mandated by WTO DSB organs, which have also affirmed that one logical approach is to begin the analysis with the TRIPS Agreement.

It is necessary to distinguish between the WTO compliance of EC Regulation 1383/2003 and the WTO compatibility of Regulation's implementing measures. As far as the former is concerned, particularly problematic are its trade restrictive provisions, the rights it grants to patentees and the reference to the transit law to assess the legality of products not intended for the European market. According to ECJ jurisprudence, said Regulation would only be justified as a means to avoid introducing goods infringing intellectual property rights in the European market, but not to control the protection of intellectual property rights in third countries. If a DSB panel assessed the necessity of such a legal scheme, as well as its relationship with other WTO obligations and its practical consequences, it would probably take into account the apparent contradiction between the ECJ restrained jurisprudence and EC Regulation 1383/2003 almost unrestrained stance.

The TRIPS only mandates controlling the importation of potentially counterfeit and pirated goods. However, it permits the adoption of a more extensive protection under the condition said protection does not

contravene the TRIPS itself. The practical consequences of the EC Regulation when mandating the implementation of all kinds of border measures in relation to goods protected by almost all types of intellectual property categories are problematic and may be TRIPS infringing. At least, directly affected are *i)* the traditional principle regarding the territoriality of intellectual property rights; *ii)* article 28 regime on the rights conferred to patentees; *iii)* TRIPS references to avoid intellectual property becoming a barrier to legitimate trade; *iv)* the pro-public health interpretation mandated by the Doha Declaration; and, *v)* the feasibility of the scheme created by the WTO General Council 30 August 2003 Decision and the Decision to permanently amend Article 31 of TRIPS.

Regarding the practical consequences that would be presented to a WTO panel, the EC is seizing products that are not intended for the European market and for which no peril of diversion exists. Moreover, those products are legal in exporting and importing countries. In practical terms, under the current EC legal framework even if a product is not patent-protected in its destination, patent holders are able to block it at the hubs where it necessarily transits, which implies disrupting generic medicines distribution and access. Hence, if seizures continue, the goals pursued by the Doha Declaration and the mechanism operationalized in the 30 August 2003 Decision may be nullified.

In contradiction with the obligation enshrined in EC Regulation to follow the law of the State in which the application is made when controlling in-transit products, and also contradicting letters addressed to generic manufacturers and importers, the EC and the EFPIA have recently affirmed that if products are not patent protected in exporting or importing countries, no action will be taken against them. In fact, it seems as if the EC had been surprised either by the real power EC Regulation 1383/2003 grants to European right-

holders or by the public outcry that its border measures on life-saving drugs have provoked. In any case, to sustain the affirmation that the EC Regulation does not impede legitimate drugs transit through European customs, it would be necessary to amend -or at minimum to clarify- EC Regulation 1383/2003 article 2.1.c) (i) and (ii), and also article 10, which make the seizure of a specific good dependant on the status of patents and supplementary protection certificates in the transit country. The ongoing process to amend Regulation 1383/2003 is a good opportunity to introduce said changes.

Among other potential findings, a WTO Panel could establish that EC Regulation impedes the respect of the free transit principles laid down in the GATT and in the TRIPS, grants patentees rights not foreseen in TRIPS article 28, badly reconciles the territorial nature of intellectual property rights and imposes unnecessary restrictions that impede the fulfilment of GATT article V. Moreover, it could also conclude that GATT article XX(d) is of no application. If these were the conclusions, it should be recalled that article XXVI.4 of the Agreement Establishing the WTO lays down that "Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements".

Two additional issues must be considered when assessing recent seizures. On the one hand, the European push for the introduction in developing countries of legislation that parallels the EC one and, on the other hand, the problematic misuse of "counterfeit" terminology when assessing patent infringements and public health problems.

Through the conclusion of association agreements, economic partnership agreements, partnership and cooperation agreements and free trade agreements the EC is trying

to export fully or partially EC Regulation 1383/2003 to developing countries. This was a goal clearly stated in the EC *Strategy for the enforcement of intellectual property rights in third countries*, where the Commission DG Trade undertook to "revisit the approach to the IPR chapter of bilateral agreements, including the clarification and strengthening of the enforcement clauses" taking EC Regulation 1383/2003 as a "source of inspiration and a useful benchmark". The EC has already managed to introduce a twin regime for the seizure of protected products while in transit in the EC-CARIFORUM Agreement, and has proposed a stricter regime to Andean and Asean countries, this last one covering all intellectual property categories. If the power granted to right-holders to detain in-transit goods on alleged patent infringements is extended, generics trade will be at risk of being seriously hampered. Moreover, forcing developing countries to concentrate their resources on highly sophisticated intellectual property rights enforcement regulations is of dubious compatibility with European undertakings in the health and intellectual property field.

A worrying and not entirely accidental confusion regarding the "counterfeit" term has been created. The use of "counterfeit" as a generic word that refers to a mix of public health concerns, trademark violations and unrelated patent conflicts has been instrumental in giving extra-legitimacy to patentees' claims. This explains why in the controversy that has arisen from European seizures of safe and legitimate products the EC and the European rights-holders invoke public health worries to justify their actions. It is necessary to address the misuse of the counterfeit terminology, something which is important not only to avoid the reoccurrence of cases such as the *seizures case*, but also to not create confusion among consumers that until now have relied on generic drugs as a safe and effective tool.

## ENDNOTES

- 1 Letters sent by Sanofi-Aventis Patent Department to Bftalactamicos on 29 October 2008 regarding clopidogrel; Eli Lilly lawyers (Baker & McKenzie) to Cipla on 9 December 2008 regarding olanzapine; Novartis AG lawyers (Freshfields) to Grey Inversiones, KLM and Cipla on 22 December 2008 regarding rivastigmine; Du Pont and Merck lawyers (Lovells) to Dr. Reddy's Laboratories on 24 December 2008 relating to losartan; (on file with the author).
- 2 See. X. Seuba, *Health Protection in the European and Andean Association Agreement*, Amsterdam: HAI, 2009, pp. 50-53, <http://www.haiweb.org/23032009/18%20Mar%202009%20Policy%20Paper%20EU-CAN%20Association%20Agreement%20FINAL.pdf>.
- 3 TRIPS Agreement Preamble.
- 4 *Ibid.*
- 5 See, for all, *Statement by Brazil*, TRIPS Council, 3 February 2009. Agenda item "M" -OTHER BUSINESS- Public Health Dimension of the TRIPS Agreement. [www.ip-watch.org/weblog/wp-content/uploads/2009/03/intervention-by-brazil.pdf](http://www.ip-watch.org/weblog/wp-content/uploads/2009/03/intervention-by-brazil.pdf) (Consulted March 2009).
- 6 *Statement by India*, TRIPS Council, 3 March 2009. Agenda item "M" -OTHER BUSINESS- Public Health Dimension of the TRIPS Agreement [www.ip-watch.org/files/India%20Statement%20to%20General%20Council%20Jan2009.doc](http://www.ip-watch.org/files/India%20Statement%20to%20General%20Council%20Jan2009.doc) (Consulted March 2009).
- 7 See Section 7 below.
- 8 See this paper's last point for further details regarding the link between intellectual property rights enforcement and public health protection.
- 9 *Cfr.* "it is important to allow the customs authorities to control goods in transit suspected to infringe IP rights so that they can stop the traffic of potentially dangerous products, such as fake medicines"; "a significant and worrying level of trade in illegal medicines indicating a potentially serious public health and safety issue, which fully justify the control of medicines in transit suspected to infringe IP rights". (Ip-health) *Intervention by European Communities at the TRIPS Council (Dutch Seizures)*, <http://lists.essential.org/pipermail/ip-health/2009/March/013528.html> (Consulted March 2009).
- 10 "Formal response Dutch government on seizures and bordermeasures in FTAs (to parliamentary questions)", <http://lists.essential.org/pipermail/ip-health/2009/April/013674.html> (consulted on April 2009).
- 11 *Ibid.*
- 12 *Ibid.*
- 13 [http://www.keionline.org/misc-docs/seizures/WTO\\_seizures\\_18feb.pdf](http://www.keionline.org/misc-docs/seizures/WTO_seizures_18feb.pdf) (consulted February 2009).
- 14 [www.keionline.org/misc-docs/seizures/dglamyresponse.pdf](http://www.keionline.org/misc-docs/seizures/dglamyresponse.pdf) (consulted April 2009).
- 15 <http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/index.html> (consulted March 2009).
- 16 EGA, Letter addressed to Mr. László Kovács, 20 February 2009 (on file with the author).

- 17 EFPIA, *EFPIA Statement. Customs seizures of in-transit medicines*, 13/3/2009, [dhttp://www.efpia.eu/content/default.asp?PageID=559&DocID=6574](http://www.efpia.eu/content/default.asp?PageID=559&DocID=6574) (consulted March 2009).
- 18 KEI, IQsensato, BUKO-Pharma, HAI, Essential Action, Consumers Action, Health GAP, Medico International, Oxfam International, Third World Network, U.S.PIRG, “Seizures of Medicines as goods in transit to developing countries”, letter sent to Pascal Lamy, WTO Director General, See. [www.keionline.org/misc/docs/seizures/WTO\\_seizures\\_18feb.pdf](http://www.keionline.org/misc/docs/seizures/WTO_seizures_18feb.pdf) (consulted February 2009). Some of these NGOs, three weeks later, issued a joint press release focused on public health grounds. *Joint press release from Knowledge Ecology International, Health Action International and Oxfam. Call on the EU to allow life-saving generic medicines to reach world’s poorest*, 6 March 2009.
- 19 Cfr. Alexandra Heumber, IP policy adviser for MSF, in W. New, “Alarm escalates over delayed generic drug shipment as action sought”, *Intellectual Property Watch*, 6 March 2009.
- 20 *Council Regulation (EC) No 1383/2003, of 22 July 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) No L 196/7.
- 21 See EC Regulation 1383/2003 third Recital and articles 4, 9.1 and 11.
- 22 *Concise Oxford Dictionary*, tenth edition, revised, 2001. Another term, used by the Dutch authorities themselves, is “confiscation” See question No. 2 of the “Formal response Dutch government on seizures and border measures in FTAs (to parliamentary questions)”, <http://lists.essential.org/pipemail/ip-health/2009/April/013674.html> (consulted on April 2009.)
- 23 *Council Regulation (EEC) No 3842/86 of 1 December 1986 laying down measures to prohibit the release for free circulation of counterfeit goods*. OJ (1986) No L 357/1.
- 24 *Council Regulation (EC) No 3295/94 of 22 December 1994 laying down measures to prohibit the release for free circulation, export, reexport or entry for a suspensive procedure of counterfeit and pirated goods*, OJL (1994) No 341/18.
- 25 *Report from the Commission on the implementation of Council Regulation (EC) No 3295/94 of 22 nd December 1994 as regards border controls on trade in goods which may be counterfeit or pirated, and Proposal for a Council Regulation (EC) amending Regulation (EC) No 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods*, COM(1998) 25 final, OJ [1998] C108/63.
- 26 *Council Regulation (EC) No 241/1999 amending Regulation (EC) No 3295/94 laying down measures to prohibit the release for free circulation, export, re-export or entry for a suspensive procedure of counterfeit and pirated goods*, OJL (1999) L 27.
- 27 See article 135 of Regulation (EC) No 450/2008 of the European Parliament and of the Council, of 23 April 2008, laying down the Community Customs Code (Modernised Customs Code).
- 28 ECJ, *The Polo/Lauren Company LP v. Pt Dwidua Langgeng Pratam*, C-383/2000, (ECR I-2519), par. 26.
- 29 M. Schneider, O. Vrins, “Regulation(EC) 1383/2003”, M. Schneider, O. Vrins, *Enforcement of Intellectual Property Rights Through Border Measures*, Oxford: Oxford University Press, 2006, p. 95, 3.116.

- 30 *Netherlands, Report Q208, Border Measures and other means of custom Intervention against Infringers*, In the name of the Dutch Group of the AIPPI by Gertjan Kuipers (Chariman), Manon Rieger-Jansen, Bas Pinckaers, Faisal Van Vesel, Jef Vandekerckhove, 2009, [www.aippi.nl/uploads///Q208%20NL%201.PDF](http://www.aippi.nl/uploads///Q208%20NL%201.PDF) (consulted April 2009).
- 31 See, sections 4 and 6 below.
- 32 M. Schneider, O. Vrins, op. cit., p. 66.
- 33 A. Clark, “Parallel imports: a new job for customs?”, *European Intellectual Property Review*, vol. 21, n° 1, 1999, pp. 1-7; M. Schneider, O. Vrins, op. cit., p. 110.
- 34 *Turkey- Restrictions on Imports of Textile and Clothing Products*, Report of the Panel, 31 May 1999, WT/DS34/R, par. 9.92.
- 35 *European Communities - Protection of trademarks and geographical indications for agricultural products and foodstuffs*, Report of the Panel, WT/DS290/R, 15 March 20, par. 7.87.
- 36 R. C. Dreyffus, A. F. Lowenfeld, “Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together”, *Virginia Journal of International Law*, vol. 37, 1997, p. 280. It has been affirmed the TRIPS is an anomaly in the WTO regime, in this sense, see R. Weissman, “A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries”, *University of Pennsylvania Journal of International Economic Law*, n° 17, 1996, p. 1069.
- 37 *Vid.* F. Machlup, E. T. Penrose “The patent controversy in the nineteenth century”, *The Journal of Economic History*, vol. X, n° 1, 1950, pp. 4-6, 9; See also P. Roffe, G. Vea, “The WIPO Development Agenda in a Historical and Political Context”, N. Netanel (Ed.), *The development agenda: global intellectual property and developing countries*, New York: Oxford University Press, 2008, pp. 82-83.
- 38 UNCTAD-ICTSD, *Resource book on TRIPS and Development*, New York: Cambridge University Press, 2005, p. 581.
- 39 See for an in-deep analysis of the TRIPS enforcement provisions as a ceiling, H. Große Ruse - Khan, T. Jaeger, “Policing patents worldwide? EC Border Measures against Transiting Generic Drugs under the EC - and WTO Intellectual Property Regimes” (*forthcoming*).
- 40 *Op. cit.*
- 41 *Canada-Pharmaceutical Products*, Report of the Panel, WT/DS/114/R, 17 March 2000, par. 7.69.
- 42 See section 7 below.
- 43 EFPIA, *EFPIA Statement. Customs seizures of in-transit medicines*, 13/3/2009, [dhttp://www.efpia.eu/content/default.asp?PageID=559&DocID=6574](http://www.efpia.eu/content/default.asp?PageID=559&DocID=6574) (consulted March 2009).
- 44 A. Otten, H. Wager, “Compliance with TRIPS: The Emerging World View”, *Vanderbilt Journal of Transnational Law*, vol. 391, 1996, p. 405.
- 45 The first ones to be controlled were counterfeit goods. Only at a later stage -and on some occasions very recently- were pirated goods also subjected to control.

- 46 C. Correa, “The Push for Stronger Enforcement Rules: Implications for Developing Countries”, *The Global Debate on the Enforcement of Intellectual Property Rights and Developing Countries*, Geneva: ICTSD, 2009, p. 49.
- 47 A recent report of the Dutch group of the AIPPI states that only in The Netherlands are customs authorities offices equipped with laboratories, *See Netherlands, Report Q208*, op. cit., p. 8.
- 48 See section 6.2 below.
- 49 EC Regulation 1383/2003 article 2.1(c)(i). In the same vein, article 10 states that “The law in force in the Member State within the territory of which the goods are placed in one of the situations referred to in Article 1(1) shall apply when deciding whether an intellectual property right has been infringed under national law”.
- 50 *Netherlands, Report Q208*, op. cit., p. 12.
- 51 In particular, as the AIPPI affirms, *Montex v. Diesel*. See below Section 6.2.
- 52 See below Section 6.
- 53 Letter sent 28 October 2008 by the Patent Department of Sanofi-Aventis to the Colombian enterprise Bftalactamicos regarding “Clopidogrel - Suspension of the release of goods by the Dutch customs (container nr. 074-6946 9582)” (on file with the author).
- 54 See, for instance, *Restatement (Third) of the Foreign Relations Law of the United States*, § 415 cmt. i., which states that “patents are considered territorial, having legal effect only in the territory of the issuing state”. Regarding Europe, see article 22.4 of *EC Council Regulation 44/2001 of 22 December 2000 on Jurisdiction and the Recognition and Enforcement of Judgements in Civil and Commercial Matters*, (2001) OJ L 12, p.1, which establishes that “The following courts shall have exclusive jurisdiction, regardless of domicile: 4. in proceedings concerned with the registration or validity of patents (...) the courts of the member state in which the deposit or registration has been applied for, has taken place ...”.
- 55 35 U.S.C. § 271(a).
- 56 D. S. Chisum, “Normative and Empirical Territoriality in Intellectual Property: Lessons from Patent Law”, *Virginia Journal of International Law*, vol. 32, 1996-1997, p. 604.
- 57 The rule is not so strict when applied to copyright and trademarks.
- 58 *Deepsouth Packing Co. V. Laitram Corp.*, 406 U.S. 518 (1972).
- 59 See for both prohibitions 35 U.S.C. § 271(f), sections 1 and 2 respectively.
- 60 For instance, computer and communications systems pose features escaping from current infringement provisions. These network systems “are designed to span large distances. The situation can arise where some of the components of the patented network invention may be used, or steps in the patented network process may be performed, in two or more locations by different entities. Even if a patent to a network invention is obtained in every country, the situation may arise where the invention as a whole is not practiced in any single jurisdiction. Despite valid patents, there could therefore be no infringement in any single country because the invention as a whole is not practised in any one of them”. J. R. Dinges, “Extraterritorial Patent Infringement Liability After *NTP, Inc. v. Research In Motion, Ltd.*”, *The Journal of Corporation Law*, vol. 32, Fall, 2006-2007, p. 224.

- 61 For a different view of the responses, see J. R. Dinges, *op. cit.*, pp. 218-236.
- 62 And, even if this had been the case, the Paris Convention and the TRIPS Agreement only grant extra-territorial enforcement of patents in case of the importation of products made from a patented process.
- 63 *Packard Instrument Co. v. Beckman Instruments Inc.*, 346 F. Supp. 408, 175 U.S.P.Q. (BNA) 282 (N.D.Ill. 1972), Quoted from D. S. Chisum, *op. cit.*, p. 611.
- 64 See A. von Mühlendahl, D. Stauder, “Territorial Intellectual Property Rights in a Global Economy - Transit and other Free Zones”, W. Prinz zu Waldek und Pymont, R. Brauneis, M. J. Adelman, D. J. Drexel (Eds.), *Patents and Technological Progress in a Globalized World. Liber Amicorum Joseph Strauss*, Berlin: Springer, 2009, p. 660.
- 65 D. S. Chisum, “Normative and Empirical Territoriality in Intellectual Property: Lessons from Patent Law”, *Virginia Journal of International Law*, vol. 32, 1996-1997, p. 605.
- 66 EFPIA, *EFPIA Statement. Customs seizures of in-transit medicines*, *op. cit.*
- 67 See *supra* section 5.
- 68 See A. von Mühlendahl, D. Stauder, *op. cit.* p. 654.
- 69 Moreover, as explained *supra*, importation and transit are differentiated both in the GATT Agreement and in the TRIPS Agreement.
- 70 “There is a risk that counterfeit goods placed under the external transit procedure may be fraudulently brought on to the Community market”, ECJ, *The Polo/Lauren Company LP v. Pt Dwidua Langgeng Pratam*, C-383/2000, (ECR I-2519), pars. 33 and 34.
- 71 Opinion of Advocate General Jacobs, 26 May 2005, par. 34.
- 72 *Montex Holdings Ltd. V. Diesel SpA*, C281/05, pars. 25 and 27. The ECJ had sustained very similar arguments one year before in Case C-405/03, *Class International BV v. Colgate-Palmolive et al.*, 2005, ECR-I-8735.
- 73 *Ibid.* par. 25.
- 74 *Class International BV v. Colgate-Palmolive et al.*, 2005, ECR-I-8735, par. 47.
- 75 Opinion of Advocate General Jacobs, 26 May 2005, par. 29.
- 76 In *Rioglass* the Court affirmed that “Article 28 EC is to be interpreted as precluding the implementation pursuant to a legislative measure of a Member State concerning intellectual property, of procedures for detention by the customs authorities of goods lawfully manufactured in another Member State and intended, following their transit through the territory of the first Member State, to be placed in the market in a non-member country”. Case C-115/02, *Administration des douanes v. Rioglass S.A.*, (2003), ECR I-12705, par. 30.
- 77 Opinion of Advocate General Jacobs, 26 May 2005, par. 32.
- 78 Case C-23/99, *Commission / France*, [2000] ECR I-7653, par. 38.
- 79 See, for instance, Case 15/74, *Centrafarm / Sterling Drug*, [1974] ECR 1147, par. 9.

- 80 For further details on the importance of the rights conferred when analyzing potential limitations to the control of in-transit goods, see section 6.2 below.
- 81 For more details regarding the Swiss formulation, see Swiss Federal Institute of Intellectual Property, *Interpretation of the Patents Act*, [www.ige.ch/e//jurinfo/documents/j10030e.pdf](http://www.ige.ch/e//jurinfo/documents/j10030e.pdf) (Consulted May 2009).
- 82 *Ibid.*
- 83 *Doha Declaration on the TRIPS Agreement and Public Health*, 20 November 2001, WT/MIN(01)/DEC/2, par. 4.
- 84 F. M. Abbott, “Worst Fears Realised: The Dutch Confiscation of Medicines Bound from India to Brazil”, *Bridges*, February-March 2009, p. 13.
- 85 Decision of the General Council of 30 August 2003, “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, IP/C/W/405.
- 86 All emphasis added.
- 87 D. French, “Treaty Interpretation and the Incorporation of Extraneous Legal Rules”, *International and Comparative Law Quarterly*, vol. 55, April 2006, pp. 303-304; C. McLachlan, “The principle of systemic integration and article 31(3)(c) of the Vienna Convention”, *International and Comparative Law Quarterly*, vol. 54, April 2005, p. 312.
- 88 *European Communities - Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)*, Report of the Panel, 21 November 2006, WT/DS291/R, WT/DS292/R, WT/DS293/R, par. 7.69.
- 89 WHA, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHA61.21, 2008, Annex par.36, point 5.2 (b).
- 90 The Panel set up to issue the report recognized that the task was “arduous since it will be necessary to interpret article V of the GATT without any meaningful guidance”. *Colombia - Indicative prices and restrictions on ports of entry*, Report of the Panel, 27 April 2009, WT/DS366/R, par. 7.388.
- 91 *Ibid.*, par. 7.396.
- 92 In its first sentence, article V.2 prescribes that “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”. In its second sentence, article V.2 establishes that “No distinction shall be made which is based on the flag of vessels, the place of origin, departure, entry, exit or destination, or on any circumstances relating to the ownership of goods, of vessels or of other means of transport.”
- 93 *Colombia - Indicative prices and restrictions on ports of entry*, op. cit., par. 7.401.
- 94 *Ibid.*, par. 4.402
- 95 EC Regulation 1383/2003 article 13.
- 96 In the losartan case, for instance, the shipment was detained on 4 December 2008 and was released on 8 January 2009. This period of time included 23 working days. In the abacavir

case, the shipment was seized on 12 November 2008 and released on 12 March 2009, a period which exceeds 80 working days.

- 97 *Cfr.* “The customs authorities did not respect the time limits for detention and disposal of this case”. See “Formal response Dutch government on seizures and border measures in FTAs (to parliamentary questions)”, *op. cit.*
- 98 *United States - Standards for Reformulated and Conventional Gasoline*, Appellate Body Report, 20 May 1996, WT/DS2/AB/R, p. 22.
- 99 *Korea - Various Measures on Beef*, Appellate Body Report, 10 January 2001, DS161/AB/R, par. 157.
- 100 *US - Shrimp (Thailand)*, Report of the Panel, 15 May, 1998, WT/DS58/R, par. 7.174. See also Panel Report, *US - Customs Bond Directive*, par. 7.295.
- 101 E. McGovern, *International Trade Regulation*, Exeter: Globefield Press, Third edition, 1995, p. 21.12-1.
- 102 *Korea - Various Measures on Beef*, Appellate Body Report, *op. cit.*, par. 161.
- 103 *Ibid.* par. 166. The Appellate Body also followed this approach to the word ‘necessary’ as used in paragraph (b) of Article XX in *EC - Asbestos*, 5 April 2001, WT/DS135/AB/R, par. 172.
- 104 *United States—Measures Affecting Imports of Woven Shirts and Blouses*, Appellate Body Report, 23 March 1997, WT/DS33/AB/R, p. 14.
- 105 In a joint communication referring to counterfeiting and drafted in general terms, and not only related to public health, the EC, Japan, Switzerland and the US affirmed that “This activity (counterfeiting) has harmful effects on society as a whole: it puts public health and safety at risk, threatens legitimate commerce, and entails loss of jobs and government tax revenues. This activity is also often linked to organized crime and other types of crimes”. Joint Communication from the European Communities, Japan, Switzerland and the United States at the Council for TRIPS, *Enforcement of intellectual property rights*, IP/C/W/485, 2 November 2006, par. 2.
- 106 In point No. 2 of the Preamble, it states that “The marketing of counterfeit and pirated goods, and indeed all goods infringing intellectual property rights, does considerable damage to law-abiding manufacturers and traders and to right-holders, as well as deceiving and in some cases endangering the health and safety of consumers.”
- 107 ICC, *Statement on protecting intellectual property. Presented to the 2007 G8 Summit, Heiligendamm*, p. 1.
- 108 PhARMA, *PhARMA Participates in Capitol Hill Press Conference Highlighting Dangers of Intellectual Property Violations and Counterfeits*, Press release, June 14, 2007, [www.pharma.org](http://www.pharma.org) (consulted March 2009).
- 109 *Ibid.*
- 110 The TRIPS Agreement introduced the “counterfeited and pirated” terminology, but only in reference to trademark and copyright infringements. TRIPS footnote 14(a) alludes to “counterfeit trademark goods” as “any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark,

and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation”.

- 111 For instance, the last report title of DGTAUX on intellectual property rights infringements and its control at the European borders makes reference to “counterfeit and piracy”. However, in its content not only trademarks and copyrights are addressed, but also patent and other IP categories. See EC DGTAUX, *Report on Community customs activities on counterfeit and piracy. Results at the European Border - 2007*, see [ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/statistics2007.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf) (Consulted March 2009).
- 112 According to M. Blankeney, “The terms counterfeiting and piracy in relation to goods refer to the manufacture, distribution, and sale of copies of goods which have been made without the authority of the owner of the intellectual property”. See. M. Blankeney, “The Phenomenon of Counterfeiting: Factual Overview and Legal and Institutional Framework”, O. Vrins, M. Schneider, *Enforcement of Intellectual Property Rights Trough Border Measures*, op. cit., p. 4.
- 113 For instance, according to Orgalime (The European Engineering Industries Association), counterfeiting is “the illegal reproduction / imitation of products”, and it may take place regarding copyrights, trademarks, patents, designs”. Orgalime, *Combating counterfeiting. A practical guide for European engineering companies*, 2001, p. 10. See [www.orgalime.org/publications/guides/counterfeiting\\_guide\\_en.pdf](http://www.orgalime.org/publications/guides/counterfeiting_guide_en.pdf) (consulted March 2009).
- 114 *Op. cit.*
- 115 Letter sent on 9 December 2008 by Ely Lilly lawyers to CIPLA. *Op. cit.*, emphasis added.
- 116 [www.who.int/impact](http://www.who.int/impact) (consulted March 2009).
- 117 “Combating counterfeit medicines”, *WHO Drug Information*, vol. 18, n° 2, 2004, p. 133.
- 118 *Ibid.*
- 119 R. H. Behrens, A. I. Awad, R. B. Taylor, “Substandard and counterfeit drugs in developing countries”, *Tropical Doctor*, vol. 32, n° 1, 2002, pp. 1-2.
- 120 C. Correa, op. cit., p. 56.
- 121 J-M. Caudron *et al.*, “Substandard medicines in resource-poor settings: a problem that can no longer be ignored”, *Tropical Medicine and International Health*, vol. 13, n° 8, 2008, p. 1068.
- 122 *Ibid.*
- 123 X. Seuba Hernández, “Autoridad privada y bienes públicos en la regulación farmacéutica. El caso de la Conferencia Internacional sobre la Armonización de los Requisitos para el Registro de Fármacos para Uso Humano”, X. Seuba (Coord), *Salud Pública y Patentes Farmacéuticas*, Barcelona: Librería Bosch, 2008, pp. 243-270.
- 124 Letter addressed by Catherine Ashton -European Commissioner for Trade- and László Kovács -Commissioner for Taxation and Customs Union-, to Médecins Sans Frontières, on 25 March 2009, CAB24/CA/PH/caD(09)256A(09)324 (on file with the author).
- 125 *Ibid.*

