MSF - Oxfam - HAI Analysis of IMCO Report: Revision of Regulation Concerning Customs Enforcement of IPR

Introduction

As a part of strategic framework outlined in the Communication from the Commission of 3 March 2010 on a Single Market for Intellectual Property, the Commission Proposal to review the Customs Regulation (COM(2011)285 final) aims to reinforce customs actions in fighting the trade in goods infringing intellectual property rights (IPR). In March of this year, the Committee on the Internal Market and Consumer Protection (IMCO) released a report recommending several modifications to the Commission Proposal.

The IMCO Report and, to a lesser extent, the Commission Proposal do not adequately address the risk of legitimate generic medicines being seized and/or destroyed at the border. The Commission Proposal, especially if modified as proposed by IMCO, poses a serious risk to the continuing availability of quality, legitimate generic medicines for patients in developing countries. Generics are a lifeline, especially for patients in developing countries. Their continued availability is central to the sustainability of public health programs everywhere, including programs that may be funded in whole or in part by the EU or its Member States.

If IPR enforcement at the EU border is retained, through adoption of a new regulation to replace the earlier Customs Regulation 1383/2003, this legislation must be judiciously drafted to avoid undermining trade in legitimate generic medicines.

Moreover, despite explicit references throughout the Explanatory Memorandum to the proceedings initiated against the EU by India and Brazil before the WTO, the IMCO Report, like the Commission Proposal, fails to adequately reflect and respond to the legal and political concerns raised by India and Brazil in their WTO complaints.[1] In addition, it does not properly implement the recent ruling of the European Court of Justice (ECJ) in the Philips and Nokia cases on the legitimate scope of customs' enforcement of IPR related to goods in transit.[2]

To respond to the legal and political concerns relating to the risk of legitimate generics being seized and even destroyed at the border, Medicines Sans Frontières (MSF), Oxfam International (Oxfam) and Health Action International (HAI) Europe have identified four principles that should guide the development of a new regulation for EU customs enforcement of IPR. To ensure respect for each principle, we recommend modifying or deleting certain amendments set forth in the IMCO Report; in some places, we have also recommended changes to the Commission Proposal.

Principle 1: The scope of IPR enforcement in the Regulation should be limited to counterfeit trademarked goods.

Border enforcement of IPR should be limited to criminal activities involving "counterfeit trademarked goods" as defined in TRIPS, which are produced and distributed willfully and on a commercial scale. As a minimum, in connection with medicines, suspected infringement of patents and supplementary protection certificates, as well as civil trademarks, must be excluded from the scope of the Regulation.

[1] Brazil (2010), 'Request for Consultations by Brazil with the EU and a Member State – seizure of generic drugs in transit', World Trade Organization, WT/DS409/1, (Geneva); India (2010), 'Request for Consultations by India with the EU and a Member State – seizure of generic drugs in transit', World Trade Organization, 19 May 2010, WT/DS408/1, Geneva.

[2] ECJ, 1 December 2011, *Philips/Far East Sourcing* and *Nokia/ITA*, joined cases C-446/09 and C-495/09.

Background:

IPR infringements do not in general put consumers at risk, though they may undermine the economic interests of rights holders. Therefore, it is not appropriate to portray enforcement of *all* IPR as a safety or health issue. Only in connection with counterfeit trademarked goods can there be any health and safety rationale for enforcing IPR. Specifically, some trademark-infringing products may also pose a threat to EU consumers.

Counterfeit trademarked good is a term used to describe products, including but not limited to medicines, with a fraudulently misrepresented source. True counterfeits involve use of a trademark that is identical or indistinguishable from a registered trademark, and they are produced on a commercial scale. The WTO's intellectual property agreement (TRIPS) limits its definition of counterfeit to the willful commercial use of a sign that is *identical* to the brand owner's trademark.[3] It is only this specific type of IPR infringement that can be linked to trade in dangerous counterfeit medicines.

In contrast, patent and civil trademark infringements have in principle nothing to do with counterfeiting. IPR infringements other than counterfeit trademark infringement constitute merely commercial disputes occurring in the course of legitimate trade between private parties. These kinds of disputes should be handled and reviewed by competent legal authorities rather than customs officials. There is no need and no compelling public rationale to use customs resources, which are costly and prone to error, to target anything other than true counterfeit trademarked goods at the border.

Moreover, it is not within the expertise of customs officials to make the more complex legal assessment as to whether other types of IPR have been infringed. Determining counterfeit trademark infringement at the border involves a relatively straightforward assessment of whether the sign/design used by the alleged infringer is identical to the original product and/or trademark. Establishing other types of IPR infringements involves

[3]Footnote 14(a), Article 51, TRIPS.

a complex legal assessment for which customs authorities are neither educated nor equipped.[4]

Recent experiences of wrongful seizures have demonstrated the risk that customs authorities can make mistakes or misuse their authority when assessing patent and civil trademark infringement of in-transit goods; in other words, the risk is not hypothetical. Seizures in the Netherlands and Germany, in 2008 and 2009, which drew broad public attention, indicated that border measures to enforce IPR may be carried out based on only superficial analysis by border officials.[5]

Proposed modifications to the IMCO Report/Commission Proposal:

a) ***Limit scope to counterfeit trademarked goods only.***

- **Amendment 1** should be modified to reflect that health and safety risks can only be linked to counterfeit trademarked goods. MEPs should be mindful of this reality when debating the Regulation.

- Contrary to **Amendment 3**, border enforcement of all types of IPR does not constitute a judicious use of Government resources. Commercial disputes, for instance those involving alleged infringement of patents, supplementary protection certificates, or civil trademark rights, should be addressed by appropriate judicial authorities. Mistakes by border officials, when attempting to carry out the complex legal assessments involved with such disputes, can result in a waste of Government resources to rectify mistakes.

[4]Establishing whether any similarity between signs or trade dress and a registered trademark is legitimate or confusing involves a complex legal assessment where judges need to take into account many factors. The same applies for assessing patent infringements, which involves an assessment of the patent claims and the ingredients/process etc used in the allegedly infringing product.

[5] *Dutch seizure puts pressure on access to medicines in developing countries* 6th February 2009 ; and ; *Another seizure of generic medicines destined for a developing country, this time in Frankfurt.*5June2009 .

- Where the draft regulation references "suspected IPR infringement", this should be restricted to mean only counterfeit trademarked goods. **Article 2** of the Commission Proposal should be amended accordingly.

- **Amendment 29** should be modified to refer to the definition of counterfeit trademarked goods found in TRIPS Article 51, footnote 14: "any goods, including packaging, bearing without authorisation a trade mark identical to the trade mark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trade mark, and which thereby infringes the rights of the owner of the trademark in question in the country of importation". It should further explicitly exclude any trademark infringement other than that associated with counterfeit trademarked goods that are produced and distributed willfully and on a commercial scale.

- Especially worrisome in this respect is the IMCO proposal to extend the so-called simplified procedure to all types of IPR infringements (in contrast to the Commission Proposal, which limited the scope of application of this procedure to cases of counterfeit/piracy) in **Amendments 12, 13, 74, 75, 82 and 83**. This simplified procedure allows for the destruction of goods detained at the border with fewer procedural safeguards, for example without the holder of the goods being heard. This waiver of normal procedural guarantees should only be applicable in cases of counterfeit trademarked goods where there is a health and safety rationale for such waiver, and where risk of misuse/misjudgment is more limited as the analysis involves a less complex legal assessment.

b) ***As a minimum exclude patents, supplementary protection certificates, and civil trademark infringement as a basis for seizing medicines at the border.***

- Any potential commercial benefits that IPR holders could derive from the abuse or misuse *ex officio* by customs authorities, or at the request of an IPR holder to detain competitors' medicines at the border cannot offset the damage to public

health should legitimate generic medicines be targeted.
It is important to note that even ACTA excludes patents and undisclosed information from the purview of border measures. At a time when four committees of the EU Parliament and the Dutch Parliament have already recommended rejection of ACTA, the internal law of the European Union should not be ACTA-plus on the issue of IPR enforcement. Article 2, and **Amendments 12, 13, 74, 75, 82, 83, and 29,** should be amended accordingly.

Principle 2: There should be no IPR enforcement in the in-transit area absent demonstration, based on adequate evidence, of a clear and imminent risk of diversion.

Products that are passing in transit through the territory of the European Union – especially medicines – should not be subject to IPR enforcement actions. The only exceptions could be cases where there is clear and compelling evidence of imminent, intended entry into EU channels of commerce. Clear and transparent guidelines for customs authorities to use in identifying such cases are needed.

Background:

MSF, Oxfam, and HAI Europe oppose IPR enforcement actions against medicines that are in transit through the EU. Border actions targeting medicines passing in transit can interrupt the global supply of quality, legitimate generic medicines. They may do so directly, through detentions and even destruction, or indirectly, by forcing producers to transship via more expensive routes, and/or by creating a "chill" for the global generics industry. Given the lack of nexus between in-transit products and the EU, it is unwarranted to risk such adverse impact on global access to medicines. The interruption of medicines supply chains, even temporarily, has grave consequences for patients, especially in developing countries. In many developing countries, often only a limited stock of medicines is kept, in which case any interruption would be extremely harmful for patients with chronic illnesses who must take medicines at regular intervals.

The ECJ has repeatedly declared – most recently in 2011 in the Philips and Nokia cases – that in-transit products placed under a suspensive customs procedure cannot by the mere fact of being held in transit infringe IPR in force in the EU. A specific product that is in transit may well comply with IP rules in both the country of exportation and importation; therefore the ECJ declared that it is *"essential that those goods be able to pass in transit, via the EU […], without that operation being hindered, even by a temporary detention, by Member States' customs authorities"*.[6] The ECJ hereby also clarified that the so-called manufacturing fiction – the premise that goods in transit may be considered to have been manufactured in an EU Member State, applied by *inter alia* the Netherlands – can no longer apply to products in transit.

Goods in transit can therefore in principle not be suspended or destroyed by customs for alleged infringement of IPR that are in force in EU Member States. To deal with the risk of diversion into the EU, the ECJ makes two exceptions. Suspension of goods in transit is allowed only if there is clear and concrete evidence, based on facts, of a risk of fraudulent diversion into the EU. For any customs decision after suspension, for example to abandon or destroy the goods, the threshold is even higher, including for instance evidence of sale of the goods to EU consumers.[7]

With this recent case law, the ECJ has provided explicit and clear rules on the scope of enforcement of EU IPR on goods passing in transit: it is not allowed without "clear and convincing evidence of a substantial risk of diversion". Amendments 11 and 18 proposed in the IMCO Report attempt unsuccessfully to implement this standard of proof.

Proposed modifications to the IMCO Report/Commission Proposal:

- **Amendment 27** should be modified to exclude in-transit products – or at least in-transit medicines – from the scope of the new regulation, other than cases where

[6]ECJ 2011: Nokia and Philips cases, par. 56, 63.
[7]ECJ 2011: Nokia and Philips cases, par. 525-62, 78.

there is clear and convincing evidence of a substantial risk of diversion to the EU market.

- **Amendment 19** proposes that medicines that bear a false trademark or trade description misrepresent their origin and quality and should be treated as falsified medicines under the Directive 2011/62/EU. This should be subject to a clear exception for in-transit medicines.

- The application of the manufacturing fiction to determine the IP status of in-transit goods should be explicitly excluded under the regulation. **Amendments 31 and 32** should be modified to make this explicit.

- The so-called simplified procedure allows for the destruction of goods detained at the border with less procedural safeguards without the holder of the goods giving its consent or even being heard. Following the ECJ ruling in the Nokia and Philips cases, this simplified procedure is not allowed in cases of goods in transit suspected of infringing IPR in an EU Member State, unless it has been "proven that the goods are intended to be put on sale in the EU". **Amendments 12, 13, 74, 75, 82, and 83** should be amended to state that, at least in relation to in-transit goods, IPR infringement must be established before customs officials may decide on destruction/abandonment of the goods detained.

- In addition to the proposed modification of **Amendment 27**, procedures should be established to ensure that products that are falsely portrayed as being in-transit do not escape scrutiny by customs officials. Specific criteria should be developed to assess the likelihood of imminent entry of products into EU commerce. The ECJ standard of proof should be implemented in the operative part of proposed regulation, with the burden of proof on rights holders or customs officials to establish, with evidence, a substantial likelihood of diversion.

- **Amendment 18** dealing specifically with medicines in transit makes an attempt to implement the ECJ's standard of proof, but sets the bar too low and inappropriately cites the holder of the goods' marketing authorization or reimbursement status in the EU as sufficient evidence to establish a risk of diversion. This is highly circumstantial evidence, which does not meet the standard of proof of clear and factual evidence of a substantial risk of diversion.

- **Amendments 11, 53, and 59** inappropriately place the burden of proof on the holder of the goods, requiring him to provide evidence that the final destination of the goods is outside of the EU. These amendments provide for the "presumption" by customs officials that the final destination of the goods is the EU unless there is clear and convincing evidence to the contrary. In contrast, the ECJ is quite clear that no action can be taken by customs in respect of goods in transit unless there is clear evidence demonstrating a risk of diversion. As goods passing in transit can in principle not infringe EU domestic rights, the burden of proof to establish *prima facie* evidence of a risk of diversion lies clearly with the customs authorities (or rights holders). The ECJ mentions the fact that the destination is not *declared* as one of the relevant circumstances in making this assessment. Requiring evidence substantiating this final destination – and going further by making suspension of the goods directly dependent on the holder providing this evidence – is inconsistent with ECJ case law and with the principle of free movement of goods in transit laid down in the WTO Agreements. In addition, the declarant should have more time to respond to such requests from border authorities, especially as he will often be established outside the EU; we recommend 10 days rather than the proposed 3.

Principle 3: The balance in procedural rights and safeguards must be improved.

Requirements for specific evidence of infringement before action can be taken must be incorporated in the Regulation to curb possible abuse by IPR holders of the

procedures set out in the Regulation, and/or to mitigate the risk and impact of abuse or errors by customs officials.

Proposed modifications IMCO Report/Commission Proposal:

- "Clear and convincing evidence" should be required in support of all actions taken by border officials. Customs officials should not be authorized to detain or seize medicines on an *ex officio* basis, because they have "reason to believe" the goods infringe an intellectual property right. "Sufficient reason to believe" IP infringement has taken place – set forth in **Amendment 10** – is not an appropriate basis for detaining and even destroying goods. This should be modified. Evidentiary requirements in the text must be strengthened. **Amendment 30** should also be modified so that "sufficient reasons" is changed to "clear and convincing evidence" or, at a minimum, "adequate evidence".

- Similarly, "confirmation" by a right holder that an IPR has been infringed is not an adequate basis for action. Mere "confirmation" is not the same as demonstration, based on evidence. The TRIPS Agreement requires that, when requesting that border actions be taken, the right holder submit adequate evidence to satisfy competent authorities there is a *prima facie* case of infringement. At the very least, the new Regulation must adopt this standard, and **Amendment 13** should be modified accordingly.

- The declarant, as well as appropriate judicial authorities, should be involved in decisions as to whether to detain or suspend the release of goods. Before decisions are taken by officials to detain or to suspend the release of goods into circulation, customs officials must have obtained all necessary information from the applicant for a decision, and the declarant must have been given adequate opportunity to express his views. **Amendment 58** should be struck, restoring the text proposed by the Commission. **Amendment 52** should be modified to provide more time for the declarant to respond; we recommend 5 days rather than 3.

- The holder of a decision to detain or suspend the release of goods into commerce must be required to immediately initiate proceedings to determine whether an IPR has been infringed – within 10 working days of the decision, as proposed by the Commission. **Amendment 77** should be struck, restoring the Commission's text.

- Declarants should be given adequate opportunity to express their views about actions taken against goods under their control; at least 20 working days should be provided. Accordingly, **Amendment 87** should be struck.

- Anti-abuse sanctions should be included in the regulation for IPR holders that repeatedly file frivolous applications for action by customs officials; sanctions could apply if such applications are consistently determined to be unfounded within a specific time period.

Principle 4: The negative external effects of the new Regulation must be limited.

The EU should not pressure countries to dedicate resources to IPR enforcement rather than public health measures to improve the safety and quality of medicines.

Background:

Low and middle-income developing countries tend not to prioritize IPR enforcement. This is both rational and appropriate, given: (1) they have scarce resources, especially for public health; (2) they face serious health challenges, including but not limited to lack of access to affordable quality medicines, and they therefore need to spend available funds in a cost-effective manner to generate the best health outcome possible; and (3) they are concerned about the counterproductive impact on health and access to medicines that can result from expansive IPR enforcement laws and regulations.

A critical step towards improving the safety and quality of medicines supplies in developing countries is improving drug regulation. Low-income countries often have

inadequate – or even no – medicines regulation and oversight of the market. In our experience, in order to improve health and safety of patients, resources should be dedicated to building drug regulatory authorities' (DRA) capacity rather than enforcing intellectual property rights. Such investments over time enable countries to enhance medicines safety and quality in a sustained way.

In contrast, IPR enforcement can generate only a minimal positive impact on health and safety. Action against counterfeit medicines targets only those medicines that intentionally infringe a registered trademark. Some but not all of these medicines may also be of insufficient quality. Medicines meeting the first criterion (trademark-infringing) do not necessarily also meet the second (poor quality). And there are many poor quality, ineffective, and/or unsafe medicines in some markets that do not abuse a registered trademark; such products, which pose a risk for patients, are not removed from the market by IPR enforcement. Thus, IPR enforcement makes only a minimal contribution to medicines safety and quality, and should never replace the activities of a functioning, adequately-resourced DRA. The value of IPR enforcement to a safe medicines supply, and therefore to the health and safety of consumers, must not be oversold.

Moreover, not only is IPR enforcement an imperfect tool for improving public health, but any positive effect on medicines safety derived from IPR enforcement is vastly outweighed by the very negative impact that it can have on sustained access to quality, affordable medicines. Especially when IPR enforcement laws target more than counterfeit trademarked goods – targeting also patent or civil trademark infringement, for instance – legitimate generic medicines can be targeted for removal from the market. Customs officials, who are not properly trained to determine whether IPR infringement has occurred, especially in complex cases involving alleged infringement of IPR other than true counterfeiting, may mistakenly target products as IPR-infringing when in fact they are not. Inappropriate removal of legitimate, affordable generics from the domestic market and/or international trade – even for short periods of time – can have a devastating impact on patients and public health.

Proposed modifications to the IMCO Report/Commission Proposal:

- IPR enforcement should not be required of developing countries on the basis of Free Trade Agreements, bilateral aid, or bilateral pressure. **Amendment 21 s**hould be struck from the text.

- The report on implementation of the regulation which is proposed in **Amendment 105** should include analysis of the regulation's impact on availability of quality generic medicines, in the EU as well as globally.