Position paper on the recast of the EU Trademark package

Directive of the European Parliament and of the Council to approximate the laws of the Member States relating to trademarks (recast)
&
Regulation of the European Parliament and of the Council amending Council Regulation (EC) No 207/2009 on the Community trademark

Médecins Sans Frontières, Oxfam International and Health Action International Europe are deeply concerned that provisions proposed by the Commission in the recast of the trademark package on goods in-transit will have a negative impact on access to medicines. If adopted in their current form, the provisions will increase the likelihood of seizure of legitimate and lifesaving generic medicines in-transit through Europe that are ultimately destined for developing countries.

The new rights in the in-transit area proposed by the Commission will most often be enforced by customs authorities *at the request of the trademark proprietor* (with the risk of abuse and/or over-enforcement to deter generic competitors). The provisions also:

- are in excess of what is required under WTO rules, particularly TRIPS article 51
- are in breach of GATT Article V (freedom of transit)
- are in breach of the prevailing case law by the European Court of Justice, which determines that only goods that are intended to be diverted into the European Union market can infringe trademarks granted in Europe (Nokia/Philips case, joined cases C-446/09 and C-495/09, 2011).

Recent examples of seizures of generic medicines in-transit in Europe (in Germany and the Netherlands in 2009) illustrate to what degree these detention measures can be damaging for access to medicines, because of the potential delay in allowing life-saving drugs to reach patients. Further, detention (and the risk of destruction) can have a chilling effect on trade in generics or can increase costs of generics since manufacturers may need to take additional measures to ensure the security of shipments or to account for the risk of possible seizure and destruction of shipments.

For example, for some diseases up to 90% of the drugs that MSF uses in its treatment programmes are generics. MSF has multiple supply centres in Europe that buy and store these generic medicines in-transit before they are shipped for use in the field. The Commission's proposal as it stands creates barriers that could have an impact on MSF suppliers, MSF Supply Centers and MSF operations.

Although we acknowledge the attempt to address concerns with respect to access to medicines, the amendments the Rapporteur has proposed in JURI will not address the possible detention and destruction of generic medicines. The mere fact that a trademark is also validly registered in the country of destination does not provide sufficient

information to establish a *prima facie* counterfeit trademark infringement in the country of destination (use can be authorised, for example).

In-transit provisions should be completely removed from the text as the TRIPS Agreement neither requires nor encourages enforcement of intellectual property rules by one country on behalf of others. However, since it is clear that the EU wants to seize counterfeited goods (as defined by TRIPS) on behalf of third countries, we propose a clear exception to the enforcement rules for medicines in-transit, so to avoid customs enforcement authorities confusing generics with trademark infringements. We also propose clear anti-abuse provisions.

Directive Recital 22/ Regulation Recital 18

Commission proposal	**Rapporteur proposal Amendment 5 (Dir. &Reg.)**	**MSF, HAI, OXFAM proposal (Dir&Reg.)**
With the aim of strengthening trademark protection and combating counterfeiting more effectively, the proprietor of a registered trade mark should be entitled to prevent third parties from bringing goods into the customs territory of the Member State without being released for free circulation there, where such goods come from third countries and bear without **authorization** a trademark which is essentially identical to the trade mark registered in respect of such goods.	With the aim of strengthening trade mark protection and combating counterfeiting more effectively, the proprietor of a registered trade mark should be entitled to prevent third parties from bringing **counterfeit** goods into the customs territory of the Member State without being released for free circulation there, where such goods come from third countries and bear without **authorization** a trademark which is essentially identical to the trade mark registered in respect of such goods. **In order not to hamper legitimate flows of goods, this rule should only apply if the proprietor of a trademark is able to show that the trademark is validly registered also in the country of destination. This rule should be without prejudice to the Union's right to promote access to medicines for third countries**.	*With the aim of strengthening trade mark protection and combating counterfeiting more effectively, the proprietor of a registered trade mark should be entitled to prevent third parties from bringing* ***counterfeit*** *goods into the customs territory of the Member State without being released for free circulation there, where such goods come from third countries and bear without* ***authorization*** *a trademark which is essentially identical to the trade mark registered in respect of such goods* ***or which cannot be distinguished in its essential aspects from such a trademark.*** ***In order not to hamper the production, circulation and distribution of generic medicines, with respect to medicines this rule should only apply if the proprietor of the trademark is able to demonstrate clear and documented evidence of a substantial risk of fraudulent diversion of the allegedly counterfeit medicines into a Member State. The European Commission shall develop***

		and implement binding guidelines for national customs authorities with clear indicators on how to establish such substantial risk of fraudulent diversion; the list will reflect the importance of unrestricted trade in generic medicines and will be in line with prevailing ECJ case law within three months after signing the law.

Justification: Amendment uses TRIPS definition (article 51, footnote 14) of counterfeit trademark infringement since the new definition introduced in the Commission proposal is unnecessary and confusing. The amendment also creates an exception to the general rule for medicines in-transit, which follows ECJ case law that requires *documented evidence of a substantial risk of fraudulent diversion* of the allegedly counterfeit goods into a Member State in order to allow seizure.

Directive Recital 22 (a) NEW / Regulation Recital 18 (a) NEW

Recognising that the main public health concern lies with the quality of the medicines and not with trademark or other intellectual property enforcement, and should be addressed by other measures, including better regulation through quality standards.

Justification: The problem of unregistered, unsafe and substandard medicines is much broader and more serious than the problem of trademark counterfeit medicines. Trademark counterfeit medicines are not registered and therefore are not of assured quality, safety, and efficacy, but there are many other medicines that do not infringe trademarks, but which misrepresent their origin or ingredients, or that have not met or maintain quality standards from manufacturing through final distribution. As a result, other measures instead of trademark counterfeit enforcement are needed to address this much broader problem

Directive article 10 - point 5 / Regulation article 1 - point 12

Commission proposal	**Rapporteur proposal amendment 25 (Dir.) & 20 (Reg.)**	**MSF, HAI, OXFAM proposal**
The proprietor of a registered trade mark shall also be entitled to prevent all third parties from bringing goods, in the context of commercial	The proprietor of a registered trade mark shall also be entitled to prevent all third parties from bringing goods, in the context of commercial	*The proprietor of a registered trade mark shall also be entitled to prevent all third parties from bringing goods, in the context of commercial*

activity, into the customs territory of the Member State where the trade mark is registered without being released for free circulation there, where such goods, including packaging, come from third **countries** and bear without authorization a trademark which is identical to the trade mark registered in respect of such goods, or which cannot be distinguished in its essential aspects from that trade mark.	activity, into the customs territory of the Member State where the trade mark is registered without being released for free circulation there, where such goods, including packaging, come from **a** third **country** and bear without authorization a trademark which is identical to the trade mark **validly** registered in respect of such goods, or which cannot be distinguished in its essential aspects from that trade mark, **on condition that the proprietor proves that the trade mark is also validly registered in the country of destination.**	*activity, into the customs territory of the Member State where the trade mark is registered without being released for free circulation there, where such goods, including packaging, come from **a** third **country** and bear without authorization a trademark which is identical to the trade mark **validly** registered in respect of such goods, or which cannot be distinguished in its essential aspects from that trade mark.* ***In order not to hamper the production, circulation and distribution of generic medicines, with respect to medicines this rule should only apply if the proprietor of the trademark is able to demonstrate clear and documented evidence of a substantial risk of fraudulent diversion of the allegedly counterfeit medicines into a Member State. The European Commission will develop implement binding guidelines for national customs authorities with clear indicators on how to establish such substantial risk of fraudulent diversion; the list will reflect the importance of unrestricted trade in generic medicines and will be in line with prevailing ECJ case law within 3 months after signing the law.***

Justification: Amendment creates an exception for medicines in transit, which follows ECJ case law that requires *documented evidence of a substantial risk of fraudulent diversion* of the allegedly counterfeit goods into a Member State.

Directive article 10 - point 5 (a) NEW/ Regulation article 1 - point 12 (a) NEW

When dealing with medicines in transit, the relevant authorities shall require the proprietor of a trade mark who applies for customs suspension, detention and seizure of alleged counterfeit goods to:

(a) provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse;

(b) pay the importer, consignee, distributor and owner of the alleged infringing goods appropriate compensation for any injury caused to them through the wrongful suspension, detention and seizure of goods; and

(c) pay purchasers, consumers, and patients appropriate compensation for any injury caused to them through the wrong suspension, detention and seizure of the goods.

Justification: In order to ensure that the general allowance for in-transit goods is not being used for over-enforcement by rights holders anti-abuse provisions should be introduced. The language of point a) and b) comes from art. 53 and 56 TRIPS. Point c) comes from the UNDP Discussion Paper – Anti-Counterfeit Laws and Public Health: What to Look Out For, 30-31 (2012) http://www.undp.org/content/dam/undp/library/hivaids/English/UNDP%20Discussion%20Paper%20-%20(revised).pdf