CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES

MEDECINS SANS FRONTIERES

CUSTOMS REGULATIONS AND BORDER MEASURES

IMPACT ON ACCESS TO AFFORDABLE GENERIC MEDICINES

Briefing document, April 2011

The establishment of a precedent on border measures for IP enforcement:

The EC Customs Regulations[1] that allow European customs officials to detain generic medicines at transit points (ports and airports) were already in place in 2003.

European Customs authorities have since then detained shipments of legitimate generic drugs including antibiotics and AIDS medicines, which were in transit through the EU to patients in developing countries on the grounds that they infringe European intellectual property law (patents and trademark). However, it turned out that the medicines were not in violation of IP laws (where they come from and are going), but were legitimately produced by mainly Indian generic companies and were being imported by Brazil, Peru, Colombia, Mexico, Nigeria and other developing countries at affordable prices.

India has filed a **WTO dispute ("Seizure of Generic Drugs in Transit", Dispute DS408)** with the EU on the seizure of medicines in transit on grounds of patent infringement.

EU is now promising to amend its customs regulations, but it is at the same time continuing to pursue similar measures in the **Anti-Counterfeiting Trade Agreement (ACTA)**[2], the **EU- India FTA negotiations** and in FTA negotiations with other countries.

For instance, **border measures** that allow in-transit seizure of medicines on grounds of patent infringement are contained in **Article 10.67 of the recently concluded EU-South Korea FTA**.

Despite the negative impact of its own customs regulations, EU wants to push other countries from where medicines are exported or through which medicines are transiting, to apply local customs/border laws in a manner that will make it easier for rights holders (companies) to make allegations of IP infringement against their generic competitors, with no serious safeguards against abuse.

Exporting EU- style border measures for IP enforcement:

[1] Council Regulation (EC) No 1383/2003

[2] See **Article 16, Border Measures, ACTA.** The United States Trade Representative has released the text of the Anti-Counterfeiting Trade Agreement. **Text available at: http://www.ustr.gov/webfm_send/2379.** This text, dated 15 November 2010, is the agreed finalised version, according to a USTR press release. According to the press release, "Following legal verification of the drafting, the proposed agreement will then be ready to be submitted to the participants' respective authorities to undertake relevant domestic processes." **USTR Press release available at: http://www.ustr.gov/about-us/press-office/press-releases/2010/november/us-participants-finalize-anti-counterfeiting-trad**

In 2005, the European Commission (EC), EU's trade body, had in place its **Strategy for the Enforcement of Intellectual Property Rights in Third Countries** aimed at enhancing intellectual property enforcement outside the European Union.

Therefore, in the **EU-India FTA negotiations** which started in 2007, the EC has put forward a proposal on border measures – similar to its customs regulations - in the articles that cover intellectual property enforcement. This provision on border measures if accepted by India can ultimately affect the distribution and availability of affordable generic medicines across the developing world.

Border measures first proposed in the FTA are similar to EC's customs regulations in intent:

The article on border measures in the EU-India FTA is based on existing EU customs regulations. The specific provision on border measures is part of the IP chapter in the section titled 'enforcement of IP rights'. The **EU's first proposal[3] on border measures in its FTA with India** outlines what goods will attract the border detention and seizure measures includes goods like pharmaceutical products that infringe intellectual property - the definition of which covered patents and all trademarks disputes.

These border detention and seizure measures would apply to goods that are being imported by India, exported by India or are in transit via India's ports or airports. Europe appears to want, that the FTA force Indian lawmakers to frame customs/border measures similar to its customs regulations authorizing companies to lodge complaints with Indian customs authorities to detain, or suspend the release of, or even destroy shipments of generic medicines on the basis of mere allegations of intellectual property infringement (trademark disputes/patents) without judicial review or even notification to the generic producer.

Although it is likely that the provisions in the EU-India FTA on border measures would be influenced by the outcome of the WTO Dispute, we are writing to raise concerns about the impact of some of the safeguards that may be under consideration and their impact on access to medicines.

Safeguards to protect access to generic medicines:

1. **If we remove patents from the in-transit border measures will the legitimate trade in generic medicines be safe?**

In our view it is not enough that the EU and India propose language **carving out patents from the text of the border measures** to protect against the seizure of generic medicines by customs authorities.

Detentions on grounds of trademark infringement can also disrupt supply of medicines and should also be taken into consideration.

An illustration of a customs seizure of a legitimate consignment of an essential antibiotic based on allegations of trademark infringement is available. In June 2009, EU customs at Frankfurt detained a consignment of generic amoxicillin on mistaken grounds of trademark infringement. Customs officials seized the generic drug amoxicillin as they confused the international non-proprietary name (INN) of the medicine with the brand name 'Amoxil' owned by GlaxoSmithKline (GSK) and detained it believing it to be an infringement of a trademark. The consignment was released only once GSK confirmed that there was no trademark infringement as amoxicillin is an international non-proprietary name (INN) in the public domain and as such is not the trademark of GSK.

Multinational pharmaceutical companies too may have trademark infringement disputes with their generic competitors over similar named, coloured or shaped medicines or packaging of generic medicines. Such

[3] Annexure 1, EU-India FTA negotiations: Latest texts on goods, SPS and IPR, 24 February 2009. Downloaded from: http://file.wikileaks.info/leak/eu-india-fta-feb-2009.pdf

confusions and disputes over commerical trademarks should be excluded from enforcement measures that authorize seizures and detention of in-transit medicines at the borders.

As such, it is useful here to clearly state what should be excluded from border measures in the IP enforcement text of the FTA. Besides patents, **trademark infringement disputes** that companies may have with generic competitors over similar named, coloured or shaped medicines or packaging should not be considered as willful trademark counterfeiting (a deliberate intention to deceive) and therefore should be excluded from enforcement measures including those that authorize seizures and detention at the borders.

As noted above, a safeguard limited to only excluding patents from border measures is unlikely to prevent the detention of generic medicines on grounds of commercial trademark infringement. It is critical therefore India **exclude both patents and trademark infringement disputes from the border measures** proposed in the EU-India FTA draft text.

2. If we exclude goods in transit from border measures will medicines be safe?

Recognizing the impact of the EU seizures of medicines in transit, India in the negotiations is likely to seek a specific safeguard that **goods in transit via its territory or European territory are not subject to any enforcement procedures relating to infringement of IPRs**[4].

While EU ports and airports might be a key transit point for medicine consignments, in India the issue of border detention and seizure measures must be viewed more on its role as producer and supplier of essential medicines to developing countries. Consignments of generic medicines are regularly **exported** from Indian ports and airports to other countries.

India should therefore also consider the impact of including **exports** in border measures as is being asked for by the EU. If exports are not excluded from border measures, multinational pharmaceutical companies could lodge complaints with local customs authorities to seize shipments of generic medicines meant for exports on the basis of IP infringement allegations - effectively creating a blockade at Indian ports and customs.

Under border measures proposed in the FTA by the EU, it is certainly **TRIPS-plus to require that border measures be applied to export or goods in transit** (Art. 51 of the TRIPS agreement only requires application to IMPORTS).

The TRIPS agreement only requires that countries apply border measures to imports. This is particularly important to preserve the territoriality principle, a keystone rule of intellectual property rights law. IP such as patents and trademarks are territorial and it is for the importing country based on their national laws to decide if an import will breach national IP laws. If India accepts that border measures for IP enforcement be applied to export consignments meant for other countries then it will limit the policy space of importing countries to apply their own IP laws. The system would also be difficult to implement. Particularly as Indian customs officials would then have to know what patents are valid and what trademarks applied in every other country.

EC customs regulations, border measures in FTAs and ACTA are part of the same strategy:

Increased enforcement of IP laws has already been used as a tool by European pharmaceutical companies within EU to limit the legitimate trade in high-quality generic medicines between developing countries. Extending IP enforcement rules related to border measures to third countries through ACTA and bilateral FTAs - which both go beyond the enforcement measures required in the TRIPS agreement - and do not contain safeguards against abuse, widens the opportunities to disrupt the trade in generic medicines.

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[4] Annexure 2, EU-INDIA FTA NEGOTIATIONS: CONSOLIDATED IPR TEXT, Draft consolidated version of the IPR text in preparation for IPR discussions during the week of 12th July in Delhi. Downloaded from http://www.bilaterals.org/IMG/pdf_ip_euindia_july2010.pdf

Such measures also effectively provides public resources for the enforcement of private IP rights of European pharmaceutical companies in countries like Mexico, India, Korea. The customs officials in these third countries become the IP police at the borders for pharmaceutical companies.

The dangers of this approach are clear. The EU is using ACTA and its bilateral FTAs with countries like India to export flawed regulations that allow the use of IP allegations in the area of pharmaceuticals to stop trade in legitimate generic medicines.

Draft EU-India border measure text in the FTA negotiations:

For easy reference, copied below is the text of the **border measures first proposed (Feb 2009)** by the EU in the bilateral negotiations with India. The text was accessed from wiki leaks and is also attached as Annexure 1:

Border Measures	**Footnotes [border measures]**
Article 27 **1.** Parties shall, unless otherwise provided for in this section, adopt procedures [Footnote 2] to enable a right holder, who has valid grounds for suspecting that the importation, [EC: *exportation, re-exportation, entry or exit of the customs territory, placement under a suspensive procedure or placement under a free zone or a free warehouse*] of goods infringing an intellectual property right" [Footnote 3] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation or the retain of such goods. Any rights or duties established in Section 4 of the TRIPS Agreement concerning the importer shall be also applicable to [EC: *the exporter*] or to the holder of the goods	2. It is understood that 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. 3.For the purposes of this provision, "goods infringing an intellectual property right" means: (a) " counterfeit goods", namely: (i) goods, including packaging, bearing without authorisation a trademark identical to the trademark dully registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark holder's rights; (ii) any trademark symbol (logo, label, sticker, brochure, instructions for use or guarantee document), even if presented separately, on the same conditions as the goods referred to in point (i); (iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i); (b) "pirated goods", namely goods which are or contain copies made without the consent of the holder, or of a person duly authorized by the holder in the country of production, of a copyright or related right or design right, regardless of whether it is registered in national law; (c) Goods which, according to the law of the Party in which the application for customs action is made, infringe: (i) a patent; (ii) a plant variety right; (iii) a design; **(iv)** a geographical indication