THE ENFORCEMENT PROVISIONS OF THE EU-INDIA FTA
IMPLICATIONS FOR ACCESS TO MEDICINES

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Background

- EU-India FTA negotiations began in 2007. There have been several rounds of negotiations and parties are currently finalizing provisions related to intellectual property enforcement and border measures.
- MSF has raised concerns about several provisions within the draft agreement that would have serious negative implications for access to medicines and public health. As the negotiations have progressed, certain damaging provisions have been removed- patent term extensions for example. However the enforcement and investment provisions within the draft agreement are still a matter for serious concern as unchanged they will have significant negative implications for access to affordable medicines in India and throughout the developing world.
- The EU is now publicly saying that it will not ask India to go beyond its exiting law. This so called consolidation of India's existing domestic law approach is problematic as it will transform several procedural and case law based flexibilities into statutory and treaty obligations which India will not be in a position to adjust at some later stage.
- For details on the problematic provisions within the Investment Chapter please see 'The Investment Chapter of the EU-India FTA: Implications for Health' available at www.msfaccess.org.
- 80% of the generic HIV medicines used in developing countries are produced by generic manufacturers based in India. Therefore the provisions in the draft agreement that would undermine the access to medicines regime in India would have serious implications for access to generic medicines throughout the developing world.

Enforcement Provisions that Threaten Access to Medicines

The EU's proposed text on enforcement of intellectual property rights undermines the legitimate interests of poor patients and Indian generic manufacturers. The EU is proposing an ambitious enforcement mechanism involving courts, executive authorities, private parties and customs authorities. The provisions would widen the scope of actors that could have penalties brought against them and also increase the likelihood that wrongful searches, seizures and legal actions against legitimate suppliers of generic medicines will be carried out. These stricter enforcement measures proposed by the EU go beyond the requirements of the 1994 TRIPS Agreement and will negatively affect millions of people relying on affordable generic medicines produced in India.

1. Wide Scope of the Enforcement Provisions

The 1994 WTO TRIPS agreement limits stringent enforcement provisions and remedies to trademark counterfeiting and copyright piracy. Moreover, even the controversial Anti-Counterfeiting Trade Agreement (ACTA) allows countries to exclude patents from the scope of the enforcement provisions. By contrast the proposed FTA text extends enforcement measures to cover all areas of Intellectual Property (IP). Though Part III of the TRIPS Agreement has a general application but the EU's proposed text goes beyond the obligations of the TRIPS and India should insist on the exclusion of patents to limit the scope of enforcement provisions.

Trademark counterfeiting and copyright piracy should be distinguished from patent infringements as patent infringement cases are complex and much harder to determine. Such claims require a technical analysis of the extent of the patent claim before any decision can be reached about whether a breach has in fact occurred. The inclusion of patents will mean that generic manufacturers will likely be subject to excessive and unwarranted patent infringement suits- squeezing what little space remains for these companies to continue to produce life saving medicines.

2. The Third Party Liability Regime

The EU's proposed text contains provisions which would expose third parties to the risk of patent enforcement. The EU wants to give patent holders the ability to draw all actors involved in the manufacturing and supply chain of medicines into litigation. This could include active pharmaceutical ingredient (API) manufacturers, drug distributors, and treatment providers such as Médecins Sans Frontières that purchase and distribute medicines.

In the case of what are termed 'provisional injunctions'- where judicial authorities are given powers to issue injunctions to prevent suspected but not yet proved infringement- this could include the possibility of issuing restraining orders against an intermediary whose services are being used by a third party to infringe IP rights. For example, an API manufacturer could be stopped from supplying a drug manufacturer; and medicines purchasers like MSF, could be prevented from continuing to purchase or distribute the medicines. These provisional injunctions would take immediate effect and even if a court later found that there was in fact no infringement, the negative consequences for access to medicines will not be reversible.

Moreover, the very possibility that legal proceedings could be initiated against such third parties could dissuade them from working with generic producers. From the perspective of patients and access to medicines this chilling effect on the entire production and supply system of generic medicines is of grave concern as it could limit the availability of affordable generic medicines in pharmacies or through treatment programmes. The EU further proposes mandatory disclosure of information about "third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution."

3. Harsh injunction provisions and Seizure of goods

The EU is asking for provisional injunctions and other court orders to be made available for courts to stop the production or order the seizure or surrender of goods suspected of infringing IP rights. This would allow for the physical seizure of goods, materials and implements used in the production and /or distribution of such goods, even in cases where infringement has not yet been established. In patent infringement cases involving medicines the damage to the generic company of having its goods seized and assets frozen will be irreversible even if a court ultimately finds that a patent is not infringed. The implications for patients relying on this supply of affordable medicines are of deep concern. Precautionary seizures suggested by the EU are proposed without appropriate safeguards mentioned in the TRIPS Agreement. These provisions are even harsher than the requirements of the ACTA which contain a number of conditions before precautionary seizures are made.

Whilst Indian courts already have the power to grant provisional and final injunctions against an infringer in the case of IPR infringement; in practice the courts have distinguished the case of life saving drugs from other cases of IPR infringement- balancing commercial and public health interests and making use of a variety of alternative remedies rather than routinely granting provisional injunctions. The Delhi High Court observed that in the case of pharmaceutical products, courts have to tread with care. Holding that an injunction would stifle Article 21 of the Indian Constitution which guarantees the right to life, the court ruled that, "price differential in the case of a life saving drug -- or even a life improving drug in the case of a life threatening situation, is an important and critical factor which cannot be ignored by the court."

If the EU is successful in its demands, India will be obligated to provide a 'provisional injunction regime' which courts can use to prevent any imminent infringement. This regime will not allow for differentiation between different types of IP rights, but provide for the use of injunctions in all IP infringement cases.

4. Border Enforcement Measures

Border measures give powers to customs authorities to seize or detain goods suspected of IP infringement. In the FTA negotiations the EU is asking for both the importation and exportation of 'counterfeit trademarks, pirated copyright goods, designs or geographical indications' to be included in the scope of the border measures. Whilst the exclusion of patents from the scope of these measures is a positive step, in reality unnecessary and harmful interruptions to medicines supplies have taken place and will continue if 'civil trademark infringement' is not also excluded. On May 5th 2009 a consignment of Amoxicillin, a generic antibiotic, was stopped in Frankfurt airport by custom officials that suspected the amoxicillin had infringed the trademark 'Amoxil' owned by GlaxoSmithKline (GSK). It 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 property of GSK. These antibiotics originated in India and were destined for Vanuatu, a least-developed country.

Further, the measures pushed by the EU will allow for a right holder to apply directly to custom authorities to seize and detain a consignment of generic drugs on the basis of suspected trademark infringement. This will not involve a court's declaration or judicial determination of infringement and is therefore open to abuse. India regularly exports generic medicines from Indian ports and the application of border measures to exports is a matter of concern. This demand goes beyond the requirements of the TRIPS Agreement which limits the enforcement of border measures to imports.

The ex officio seizures proposed by the EU extends the scope of requirements to include exports, and makes no mention of a prima facie evidence requirement or limited duration of the suspension pending a determination on the merits. This goes much beyond the TRIPS provision of Article 58 that imposes restrictions on the ability of border officials to take ex officio action to halt goods at the border without any complaint from a rights holder. Further rights holders could also use this customs authority to launch harassing actions against legitimate competitors.

Furthermore, unlike earlier drafts, the latest text on border measures fail to categorically mention that provisions under this section will not be applicable on transit goods. Such a clear and unambiguous statement is crucial for India as several consignments of Indian generic drugs have been detained in Europe since 2007 and currently the EU is at the final stage of revising its relevant Customs Regulation.

Recommendations

In order to ensure that the EU-India FTA will not undermine access to medicines, the additional threats posed by the enforcement provisions must be addressed. Médecins Sans Frontières strongly recommends that intellectual property provisions be excluded from the FTA altogether. At a minimum, the following safeguards must be taken to ensure that damage caused to people's access to medicines is minimised:

- India should not agree on TRIPS plus intellectual property enforcement provisions.
- Patents and civil trademarks should be excluded from the scope of the enforcement provisions;
- IP infringement cases should be confined to the direct parties and any third party liability regime should be avoided;
- In order to preserve the existing flexibilities of the judicial system, specific provisions dealing with injunctions should not be included in the enforcement provisions;
- Provisions dealing with search orders and freezing of assets should be dropped;
- Border enforcement should be limited to the requirements of the TRIPS Agreement and as such exclude exports.