



## The Enforcement Provisions of the EU-India FTA: Implications for Access to Medicines

### Background

- EU-India FTA negotiations began in 2007. Starting 10 February 2012 both parties will meet for the EU- India Summit. It is expected that key decisions on the shape of the agreement will be taken at this Summit.
- 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.
- 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.msfacecess.org](http://www.msfacecess.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 Trade-Related Aspects of Intellectual Property Rights, or 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 World Trade Organization (WTO) TRIPS agreement limits stringent enforcement provisions and remedies to trademark counterfeiting and copyright piracy. By contrast, the proposed FTA text extends these stringent enforcement measures to cover patent infringements.

Trademark counterfeiting and copyright piracy are 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 enforcement measures on claims of patent infringement - squeezing what little space remains for these companies to continue to produce life-saving medicines.

#### 2. Third Parties drawn into litigation

The EU's proposed text contains a number of 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.

The EU wants what are termed 'provisional injunctions', where courts are given powers to issue orders to prevent suspected but not yet proved infringement - to include the possibility of issuing restraining orders against an intermediary whose services are being used by a third party to infringe IP rights or to stop goods being sold. 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. 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.

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.

### 3. Harsh injunction provisions and Seizure of goods

By generally focusing on harsh remedies before infringement has been proven, the EU seeks to shift the risk on to the generic manufacturers rather than waiting until the IP holder has proved its case. The possibility of issuing injunctions and seizing medicines on a mere suspicion or allegation of patent or trademark infringement is extremely problematic and goes beyond what is required under the TRIPS agreement. This will have a chilling effect on the manufacturers of generic medicines.

When deciding whether or not to grant an injunction, Indian courts have distinguished the case of life-saving drugs from other cases of IP infringement - balancing commercial and public health interests and making use of a variety of remedies that meet the needs of patients, rather than routinely granting interlocutory injunctions. In a case involving the Swiss multinational pharmaceutical company, Roche, and the Indian generic company, Cipla, 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 held 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 remove or limit the flexibilities currently used by the Indian courts as to how such provisional measures should be applied. 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.

The EU is demanding further specific enforcement measures that are not required under the TRIPS agreement: court orders that would allow for the physical seizure of goods, materials and implements used in the production and/or distribution of such goods and the freezing of bank accounts, even in cases where infringement has not yet been proved.

In patent infringement cases involving medicines, the damage to the generic company of having its goods seized or assets frozen will be immediate, 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.

### 4. Border Enforcement Measures

The impact of border measures on access to treatment is evident from the recent seizures of Indian generic medicines by the EU. The EU proposal expands the TRIPS requirement on border measures for import to export as well. India is one of the largest exporters of generic medicines for the developing world, and the application of border measures to exports threatens to disrupt this lifeline for patients.

The scope of the border measures is also damagingly wide. Whilst the exclusion of patents from the scope of these measures is a positive step, in reality unnecessary and harmful interruptions to medicine supplies have taken place and will continue if trademark infringement is not also excluded. On 5 May 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.

## **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:

- Patents should be excluded from the scope of the enforcement provisions;
- IP infringement cases should be confined to direct parties and any third party or intermediary liability regime should be avoided;
- In order to preserve the existing flexibilities of the judicial system, specific provisions dealing with injunctions and seizures of goods should not be included in the enforcement provisions;
- Border enforcement should be limited to the requirements of the TRIPS Agreement and as such exclude exports, and trademark infringement.