EU-India Free Trade Agreement:
Investment and Intellectual Property Chapters Threaten Access to Medicines

The draft Free Trade Agreement (FTA) endangers access to medicines for poor people – in India and around the world.

Generics sourced from India, the "pharmacy of the developing world", have been critical to improving access to medicines for poor people in many low-income countries. A 2010 study found that 80 per cent of the AIDS medicines used by donor-funded programmes were sourced from India.[1]

Since 2007, the EU and India have been negotiating a Free Trade Agreement that includes intellectual property (IP) and investment rules. The negotiations are scheduled to end this year. Provisions in the IP and investment chapters of the draft FTA are of great concern from a public health perspective as they would limit the capacities of India and the EU to use the public health safeguards and flexibilities in the WTO TRIPS Agreement.

A previous draft of the IP chapter of the proposed FTA contains dangerous TRIPS-plus IP protections, including data exclusivity and TRIPS-plus IP enforcement measures. These provisions would compromise India's ability to continue supplying quality generic versions of new medicines. However, the IP chapter is not the only concern for public health advocates.

The investment chapter sets forth new "TRIPS-plus-plus" rules that limit government action to promote public health and, in particular, access to affordable medicines.

Based on analysis of leaked negotiating texts, the India-EU FTA provides for extensive investor protections that have been demonstrated, in the context of other trade and investment treaties, to undermine governments' abilities to regulate in the public interest.

In the draft EU-India FTA investor protections apply to IP rights in addition to factories, mines, and other investments. This means that foreign IP holders' rights are extended under the TRIPS-plus IP chapter *and also* under the investment chapter.

The investment provisions sought by the EU that are of concern include:

- Definition of "investment" that includes intellectual property rights, along with "goodwill, know-how and technical processes;"

- Prohibition of the direct and indirect expropriation of foreign investments, without compensation. In addition to direct "taking" of foreign investments, government actions that interfere with foreign investors' enjoyment of their investments (including IP rights) would be prohibited as indirect regulatory expropriation, unless compensation is paid;

- Requirement that all foreign investors be given "fair and equitable treatment" with no definition of what this standard entails. On the basis of this language, government actions could be struck down by arbitrators based on their own interpretation of what is not fair and equitable; and

- An investor-to-state arbitration mechanism that enables foreign investors to challenge government actions before arbitral tribunals, by-passing the domestic judicial system entirely. Such proceedings, which are usually secret, have resulted in multi-million dollar settlements against countries seeking to regulate in the public interest, on the grounds that such action purportedly constituted indirect expropriation.

There has been some effort to include safeguards for public health and other regulations in the negotiating text. However, the safeguards are narrowly drafted and unlikely therefore to protect legitimate public health measures

[1] http://www.unicef.org/supply/files/sources_and_prices_2010(1).pdf.

from challenge by foreign investors. Critically, in the context of other investment agreements, it has been extremely difficult for governments to rely on public interest safeguards to defend their actions before arbitral tribunals.

The investment and IP chapters of the EU-India FTA threaten access to affordable medicines for poor people not only in India but across the developing world, given India's role as the leading supplier of quality generic medicines. In addition, because the EU would likely use them as a template for negotiating future agreements, these chapters set a dangerous precedent for national-level regulation and use of TRIPS flexibilities by developing countries.

The WHO, together with other actors in the global health community, should voice concern regarding IP and investment agreements that undermine access to medicines.

In light of the threat posed by TRIPS-plus IP protection to access to affordable medicines, the WHO should warn its Member States about the risks associated with the types of IP and investment provisions that have been included in the draft EU-India FTA. The threat is particularly acute in relation to this FTA in that provisions that curb India's ability to produce, sell, and export quality generic medicines would impact poor patients everywhere.

With regard to the EU-India FTA, the undersigned organizations recommend the following:

- The investment chapter should not include any "investor-to-state" arbitration mechanism;
- The definition of "investment" should exclude IP;
- "Indirect expropriation" and "fair and equitable treatment" should be precisely and narrowly defined to protect legitimate government regulations in support of public health, access to medicines and other public interests from challenge by foreign investors; and
- The IP chapter should not include data exclusivity or TRIPS-plus IP enforcement measures.

Challenges by foreign IP holders to public health regulations

The provisions in the draft investment chapter do not pose a mere theoretical risk. On the basis of similar rules, companies have sued governments for enacting measures in the public interest, including health.

In February 2010, the Swiss tobacco giant Philip Morris challenged a public health measure enacted by Uruguay that requires larger warnings on cigarette packets and the partial removal of branding from cigarette packets. Philip Morris sued the government under the investor-state dispute mechanism contained in a 1991 Switzerland-Uruguay Bilateral Investment Treaty (BIT).[2] The basis for the challenge is "expropriation" of the company's trademarks, abuse of its investment rights and a breach of bilateral trade agreements and the TRIPS Agreement.[3]

Pharmaceutical companies have also demonstrated their willingness to challenge governments for pursuing pro-health measures on the grounds of "expropriation of IP." For instance, in 2007, the Brazilian government issued a compulsory license for efavirenz, an anti-retroviral medicine. In response, Merck issued a press release expressing "profound disappointment" and calling this an "expropriation of intellectual property."[4]

[2] http://www.iareporter.com/articles/20100303.
[3] See submission of Phillip Morris International in response to the request for comments (by USTR) concerning the proposed Trans-Pacific Partnership Trade Agreement.
[4] http://www.merck.com/newsroom/news-release-archive/corporate/2007_0504.html.