

WORD COUNT: 803

Letter to the Prime Minister: What is Really Behind the EU-India Free Trade Agreement

There is no such thing as “free” trade. Everything comes at a cost. Troubling news reports indicate that Prime Minister Manmohan Singh supports signing a newly minted European Union-India Free Trade Agreement, which would permit large multinationals to circumvent visionary safeguards built into India’s 2005 Patents Act, widely seen as one of most progressive patent laws in the world. Prime Minister Singh must reject this sham agreement.

Over the past decade, India fought hard to bring its laws into full compliance with international standards, while simultaneously protecting public health and safeguarding India’s pharmaceutical industry. Now, the EU is trying to take away those gains.

The EU campaign to mislead India may be summarized in four parts:

Paying Lip Service to Public Health. The EU frequently pays lip service to public health, but in a leaked draft agreement it has been gunning for restrictions on drug-safety data—known as “Data Exclusivity”—that would harm India’s flourishing drug industry, and impede production of low cost drugs for India’s own citizens and other developing countries. Data exclusivity opens a backdoor channel for multinationals to “evergreen” their drugs, by adding anywhere from five-to-ten years of market exclusivity before a generic producer can access clinical data necessary to secure government authorization for generic manufacturing.

Medecins Sans Frontieres, a renowned humanitarian group, notes that data exclusivity will jeopardize production, as 80 percent of the HIV drugs it is using to treat AIDS in developing countries are produced in India.

The World Trade Organization’s trade agreement—which India must comply with—does not require data exclusivity. The EU wants India to add this *optional* restriction on drug-safety data for the benefit of European-based drug companies, not for the benefit of India. That’s why, until now, India’s Commerce and Health Ministries have strongly opposed it. So has Brazil, India’s closest economic cousin.

Gutting India’s Own Laws: Astonishingly, even if India’s own patent office determines that a product does not warrant patent protection, data exclusivity could be used to subvert India’s Patent Act. The Act’s framers strived very hard to limit patents to truly inventive products. That’s why India’s law does not permit patents on a new drug that offers only modest revisions to an existing drug compound (e.g. by altering dosage), which does nothing to enhance therapeutic benefits.

Early this month, for example, India rejected Abbott Laboratories' request for a patent on its HIV drug Kaletra, because it did not consider it inventive. Kaletra is a combination of two earlier HIV medications, lopinavir and ritonavir. Now, as a result, Indian firms can proceed with production of cheaper, generic versions of this critical drug, which attacks HIV-virus mutations that have become resistant to older drugs.

Tragically, if the EU-India agreement is signed, legal decisions like this one will be meaningless. Data exclusivity will impede production of generic drugs for TB, cancer, and other chronic diseases. Unlike patents, however, data exclusivity cannot be challenged under Indian law.

The Myth of Compulsory Licensing: The EU wants India to think that a "compulsory license"—which allows waiver of patent protection in exceptional circumstances—is sufficient to protect India's interests. In a 6th January 2011 letter, EU Commissioner Karel De Gucht wrote that "nothing in the [EU-India Free Trade] agreement will prevent India from using compulsory licensing for manufacture and export of medicines to other developing countries in need." De Gucht's statement is misleading. First, compulsory licensing is a long and nearly impossible process. Second, Thailand and other countries have been subjected to harsh retaliatory trade sanctions after such licensing. Third, de Gucht hides the fact that a compulsory license can only override a patent, not data exclusivity.

Limiting Transparency: Finally, the EU has kept Indian citizens in the dark by failing to make a complete draft agreement available for public review. What's more, Indian authorities have failed to solicit input from civil society groups and experts, even though prior national debates over intellectual property have produced special commissions with substantial citizen input.

This Free Trade Agreement should be seen for what it is: a Trojan Horse that the EU has rolled into New Delhi, under the cover of darkness, to subvert India's visionary Patents Act. A final decision on this agreement is scheduled for March, so there is no time to waste.

First, India must recognize it is not required to implement data exclusivity under international law; it should reject EU pressure to do so. Second, it is imperative that all future debate around this EU-India agreement involve genuine transparency and public consultation. Every Indian citizen has a stake in this debate: If this agreement passes, it will harm Indian industries, gut India's public health system through higher drug prices, and jeopardize global public health. Prime Minister Singh and the Indian public need to take action to protect the national interest, and the world's poor.

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