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EU's pharma trade hoax

The proposed India-EU trade pact is riddled with intellectual property provisions that would harm India's 2005 Patent Act.

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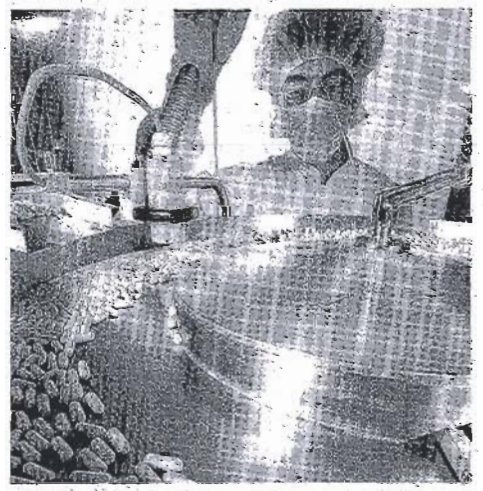

The EU's proposed trade agreement appears to prioritise placating its domestic drug industry.

Last month, the global health community cheered when India's patent office ruled that Abbott Laboratories, a major US-based pharmaceutical firm, could not block Indian generic drug makers from producing low-cost versions of Aluvia, a critical AIDS drug. Now, however, the European Union and multinational firms are launching a back-door campaign — disguised as a "free trade" pact — to undo this momentous victory.

This EU deception must stop. India's Aluvia ruling is likely to dramatically reduce the cost of treating HIV throughout the world. Currently, 33 million patients worldwide are living with HIV/AIDS, and only 5 million receive treatment. Aluvia is a critical, second-line anti-retroviral (ARV) drug, which attacks new HIV-virus mutations that have grown resistant to earlier ARV drugs. Prior to India's ruling, Abbott priced Aluvia at roughly $1,000-$3,800 per patient per year in many developing countries.

After the Clinton Health Access Initiative negotiated with generic producers, Aluvia's price-tag dropped to roughly $440 — a huge savings. Most experts agree India's ruling will spur generic competition and cut Aluvia's price still further, just as it did for earlier ARVs, whose prices plummeted from roughly $10,000 to $79.

IN EU'S SELF INTEREST

The EU's proposed trade agreement, which could be signed as early as April, is titled the Broad-based Trade and Investment Agreement (BTIA). But it should be called BPTH for "Big-Pharma Trade Hoax." The agreement purports to enhance trade between India and the EU, its largest trading partner. However, in reality, the agreement is riddled with intellectual property provisions that would harm India's 2005 Patent Act, and block public-interest rulings such as the Aluvia decision.

Why is the EU meddling with Indian laws? That's an excellent question. Clearly, the EU is placating its domestic drug industry, which wants to stave off generic competition and hold drug prices high for as long as possible. It also means that the EU is using the trade agreement to keep India from technologically catching up.

India's Patent Act strives to achieve the right balance between rewarding research and innovation (through monopoly patents) and protecting public health (through competition and access to affordable medicines). As such, India's law permits patents on truly novel inventions. But it does not allow companies to "game" the patent system by simply making minor changes to a previously patented compound to gain twenty years of additional market exclusivity. In India, a new patent is valid only if it enhances the therapeutic value of the original invention.

NOT A NEW INVENTION

In the Aluvia case, India ruled that Abbott's drug is not a new invention. This is correct because Aluvia — Abbott's second largest grossing drug in 2009, which generated $1.4 billion in global sales that year — is a combination of two older ARVs, Lopinavir and Ritonavir, both previously patented.

Later, Abbott acquired another company's patent on a heat stabilisation technology, which made Aluvia more suitable for hot climates lacking adequate refrigeration. This heat treatment was unquestionably beneficial. However, in the eyes of India's patent office, Aluvia was not inventive. The whole point of India's progressive 2005 Patent Act was to stop this kind of double, triple, quadruple patenting.

The Economist recently reported that some international observers see the Aluvia decision as "another example of India's failure to comply with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement drawn up by the World Trade Organisation which India has signed." This is false.

India's current patent laws are fully TRIPS-compliant. The EU and its industry allies want India to adopt what are known as "TRIPS Plus" provisions, which are entirely optional under international law.

One of these provisions — known as "data exclusivity" — would allow the industry to withhold critical drug-safety information, thereby functioning as a back-door mechanism to delay generic drug production by anywhere from four-to-ten extra years. Other lobbying efforts have targeted Section 3(d) of India's Patent Act, the precise section that blocks firms from "gaming" the patent system to obtain new patents on older patented inventions.

SIGN OF SUCCESS

The Aluvia decision demonstrates not the failings of India's patent system, but rather its remarkable success in keeping pace with technological progress. Since 1992, Abbott has sought to patent Lopinavir and Ritonavir, the two drugs in Aluvia, more than 75 times. This is precisely the kind of "gaming" that India's patent laws now effectively prevent.

India has an obligation to balance the rights of inventors with the rights of patients who need affordable, life-saving medicines. No other country has devised a patent system that serves these two goals so admirably, or so fairly, in full compliance with international law. India's citizens and parliamentarians should be proud of the 2005 Patent Act. They should defend it vigorously, and tell the EU and the pharma industry to stop this trade hoax.

(The authors are the Directors of www.i-mak.org, a non-profit organisation).