EU-India FTA - the data exclusivity dilemma

by Javier Delgado Rivera

14 July 2011

Conflict between European and Indian pharma industries might be played out again in FTAs with other nations

Early last month, it was announced that data exclusivity will not be part of the prospective European Union-India free trade agreement. Such a provision would have protected clinical test data, impeding generic manufactures who use this material to produce cheap drugs. The move unleashed a wave of criticism from two camps. One side indicating that it still falls short of guaranteeing access to affordable, life-saving medicaments. The other side arguing that it undermines the competitiveness of the Indian pharmaceutical industry.

From the very outset of the ongoing EU-India FTA negotiations, Brussels pushed hard to toughen Delhi's intellectual property rights - data exclusivity being a major bone of contention. For almost four years, India has been compelled to allow European pharmaceuticals to patent medicines researched or produced in its territory. The hard-fought exclusion of data exclusivity represents the greatest achievement of Indian negotiators so far.

Adjusting to World Trade Organisation requirements in 2005 - India opened up its intellectual property regulation on pharmaceutical products, authorising certain medicines to be patented. But, if the medicine is considered to be in the interest of the public health, Indian law does not secure drug manufacturers the full protection of their research data. This permits local pharma to produce cheaper generic versions, using the resulting material.

Millions of impoverished Indians benefit from this principle, giving them access to vital drugs that would otherwise be too costly for their subsistence income. It fuels a €15bn generic industry, of which more than 50 per cent is exported to developing countries. Many poor African states depend on generics for 90 per cent of their healthcare needs. The EU's abandonment of data exclusivity may be disastrous news for the European pharma industry, but looks like a life-saver for millions of poor people worldwide - in particular HIV and AIDS patients.

Nonetheless, Brussels believes that granting data exclusivity to the European pharma would not have equalled to undermined the reliance on generic of millions across the world. "Protection of test data can be reconciled with ensuring access to medicines, including through instruments such as compulsory licences or exceptions for public health needs," EU Trade Commissioner Karel de Gucht said in April. Such conviction is also upheld by Richard Bergström, director general of the European Federation of Pharmaceutical Industries and Associations. He told PublicServiceEurope.com that "the inclusion of provisions for IPRs would not impact in the Indian generic industry ability to supply low-cost essential medicines to developing countries".

Yet, the EU's withdrawal of the data exclusivity demand does not entail the outright supply of cheap medicines in India and beyond. The FTA will more than likely sanction European "investors to challenge Indian regulation at international arbitration tribunals -with a track record of favouring the investor- by claiming that their IPRs have been affected" – according to an email from Katrien Vervoort of Oxfam Belgium.

Such concern is shared by most development organisations. The FTA puts "us at risk of litigation or court orders that prevent us from delivering medicines to patients," says Michelle Childs from Médecins Sans Frontières, an organisation that sources more than 80 per cent of its HIV medicines from manufacturers of generics in India. European pharmaceuticals might also try to shield their patents from being utilised by the Indian generic industry if, as the largest groups at the European Parliament requested to the European Commission, the FTA includes "a binding state-to-state dispute settlement mechanism and provisions on mediation on non-tariff barriers to trade, as well as an effective safeguard clause".

Oddly enough, India policymakers may spare Europe's pharma firms from claiming IPRs in court if - as health groups warn - a data exclusivity regulation eventually gets passed in the Indian parliament. The Indian pharma industry has for years been hammering out a deal to better protect its IPRs. An enduring lobby enterprise that many believe will pay off. Indian and European pharmaceuticals alike not only argue that investing in drugs research in India risks being seen as unattractive by investors - as generic manufacturers can use much of the resulting capital-intensive data. They also contend that it erodes the competitiveness of the Indian pharma industry. Some even go as far as assuring that such a lack of regulatory protection will backfire to the very generic business. The "growth of the generic industry in the long term will only be sustained if there is patent expiry of innovative products," points out Ranjit Sahani - president of the Organisation of Pharmaceutical Producers of India.

Many think that India cannot keep on lifting millions out of poverty by sticking to well-intentioned, but misguided non-trade barriers. India is in a critical need of foreign investment, reads the mantra chanted in the country's bustling metropolises. The exclusion of data exclusivity in the eventual EU-India FTA -expected to be signed off before the end of the year - may prompt scores of European investors to overlook the Indian market, when deciding where to pour their pharmaceutical-bound capital.

In a bet to sustain its trading might, Brussels has embarked on a FTA spree with Asia, the world's fastest growing region. Although not at India's level, some Asian markets still keep certain restrictions on the full enjoyment of IPRs. The recent victory of Indian negotiators over data exclusivity will certainly be capitalised on by other Asian capitals - when discussing their FTA terms with the EU. Nevertheless, it seems that powerful pharma firms may be able to manoeuvre their way through the intricate rules of international trade. As a result, achievements at the negotiating table could well be watered down in the actual business of trading.

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