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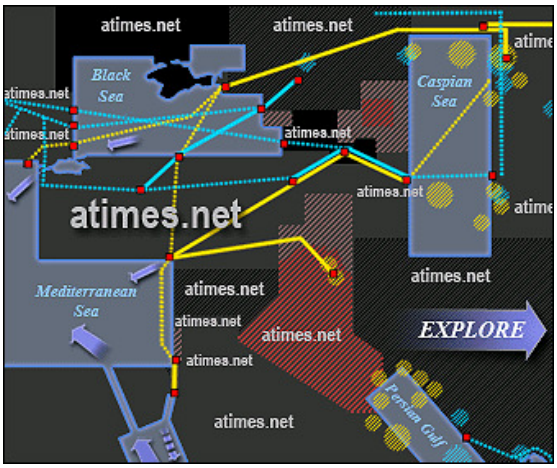
Trade pact worrying India's drugmakers

By Keya Acharya

NEW DELHI - Their ongoing negotiations remain shrouded in secrecy, but there are already reports that India and the European Union (EU) will have a free-trade agreement ready by the end of August, and that they will be putting signatures to it before the end of 2010.

Yet it is a potential development that is causing more nervous chatter than joyous jitters in India, where drug manufacturers in



particular have raised concerns over India's trade interests and intellectual property rights (IPR) issues.

India's US$7.5 billion drug industry is among the world's top five bulk medicine producers. It is also among the world's 20 top pharmaceutical exporters, with its export business growing at 17.8% per year.

A large segment of its reasonably priced generic drugs, including life-saving HIV anti-retrovirals and anti-cancer drugs, are exported to other developing nations in Asia and Africa. But now Indian drug exporters are worried that any potential growth for their business overseas is bound to disappear should India capitulate to several EU stipulations in the trade talks.

The talks have drawn concern since they began in 2007, especially since they integrate bits from other controversial

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bilateral negotiations between industrialized nations.

These include the Anti-Counterfeit Trade Agreement (ACTA), the World Customs Organizations's Standards to be Employed by Customs for Uniform Rights Enforcement (SECURE), and the World Health Organizations's (WHO) International Medical Products Anti-Counterfeiting Task Force (IMPACT).

ACTA, IMPACT, and SECURE have all drawn consistent protests from developing countries for being formulated in secrecy and without their consent.

More importantly, countries like India and Brazil say that ACTA's definition of counterfeit drugs is ambiguous enough to include generic drugs, while SECURE's IPR enforcement allows Interpol to decide by itself, or by a third party, what is counterfeit and seize it in transit.

As a result, they say, the definition of generic drugs has become restricted, in turn allowing their seizure in transit through EU countries. Essentially, such acts override previous laws under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) that allowed patented drugs classified as "essential" or crucial to health to be manufactured in developing countries.

On its website, the EU says that "nothing in the proposed agreement would limit India's freedom to produce and export life-saving drugs in accordance with the TRIPS agreement."

Officials at India's Department of Commerce, responsible for dealing with the EU and WTO issues, for their part were tightlipped when queried on the matter by IPS. In June, however, India's commerce and industry minister, Anand Sharma, in response to MP Maneka Gandhi's query in parliament on IPR and access to medicines in the India-EU talks, said, "Final positions have not emerged and therefore no agreement has been reached in any sector including IPRs."

Still, Gopal Krishnan, adviser to the Mumbai-based Indian Drug Manufacturers' Association (IDMA), notes, "What is being agreed on needs to be seen. None of us in the field have seen the document."

The concerns may not be unfounded. In 2009, the Mumbai-based Indian Drug Manufacturers Association (IDMA), with over 600 small, medium, and large Indian pharmaceutical companies as members, asked India's Ministry of Commerce to exclude the EU's clauses on IPR since these were already included in TRIPS.

An issue dropped in the World Intellectual Property Organization (IPO), the EU's terms of "patent linkage", whereby one patent is applicable worldwide, had apparently reappeared in the terms of the India-EU agreement.

In the meantime, cases of "fake medicines" have prompted global trade regulators to formulate anti-counterfeit measures.

In 2009-2010, for example, several consignments of fake anti-malarial medicines from China to Nigeria, labelled "made in India", caused India take the issue up with China. The latter country is reported to have "apologized" to Nigeria.

K M Gopakumar of Third World Network in New Delhi, says, however, that "the talks are extending the counterfeit concept to

all IPR." He asserts that the anti-fake mechanisms have become more a means of market control by richer nations.

Gopakumar adds, "If India 'gives in' to concerns we have raised inside the FTA talks, what consequences will this have for ACTA?"

Yet India has not been taking things sitting down. In May, it filed a case against the EU in the WTO dispute settlement court regarding repeated seizures, on patent infringement grounds, of generic drugs transiting through the Netherlands. India says the seizures are illegal under TRIPS. Brazil, Canada, Ecuador, China, Japan, and Turkey have since joined in the case's consultations.

Prominent Mumbai-based IPR lawyer Gopakumar Nair feels India's case at the WTO needs to be settled first before an agreement on the FTA with the EU can be inked.

He also points out that in the early 2000s, the Substantive Patent Law Treaty within TRIPS, which gave sweeping powers on the patent system to WIPO and thus disempowered developing countries from formulating their own systems, was dropped due to opposition from the likes of India and Brazil.

"The key issue now," says Nair, who was once IDMA president, "is that industrialized nations are bypassing the dropping of this Substantive Patent Law Treaty, and the EU-FTA provides an opportunity for this."

In June 2010, another international group of lawyers, academics and health organizations signed the Berkeley Declaration that called on all developing nations to approach intellectual property enforcement and anti-counterfeiting initiatives with caution.

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