"Anti-counterfeit deal threatens accessibility of drugs"

By Adam Robert Green

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LONDON: A proposed anti-counterfeit trade deal between 10 countries and the European Union (EU) could create "a new set of barriers to the export of generic medicines to low income countries".

This warning comes from Rohit Malpani, senior advisor at Oxfam America, who spoke to IPS on the eve of the ninth round of negotiations on the Anti-Counterfeiting Trade Agreement (ACTA) taking place from June 28 to July 1 in Lucerne, Switzerland.

ACTA is aimed at tackling the trade in fake products -- from luxury watches and cosmetics to car parts and medicine - and those persons infringing on intellectual property (IP) rights by strengthening powers of customs officials in signatory countries to seize counterfeit goods.

International trade of IP-infringing products is worth over 150 billion euro per year, according to estimates of the Organisation for Economic Cooperation and Development (OECD), representing rich countries.

Instigated by the US and Japan in 2006, the ACTA negotiators now include the EU, Australia, Canada, Korea, Mexico, Morocco, New Zealand, Singapore and Switzerland.

But, critics warn, by not clearly distinguishing between fake medicines and legal generic drugs, which are often subject to patent dispute, the agreement could lead to the wrongful seizure of generic medicines en route to developing countries.

"ACTA is not just focusing on issues related to trademark law - that is, medicines that are illegally and deceptively mislabelled - but will also include patent law, which means that generic drugs will be covered," explains Joel Lexchin, MD, professor in the school of health policy and management at York University, Canada.

A patent involves the exclusive right, granted by a government, to use an invention for a specific period of time.

According to Lexchin, ACTA's inclusion of patents "could substantially impede the flow of generic medicines. For instance, a company could claim that its IP rights have been violated in the production of a generic drug." That drug could then be seized by customs officials when it enters the country.

According to the World Trade Organisation's (WTO's) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), WTO members must grant exclusive patent rights on medicines.

However, they can in some circumstances allow the production of lower-cost, generic versions of patented drugs in exchange for royalties paid to the patent holder.

But, crucially, TRIPs only allows such medicines to be sold in the domestic market of the developing country that produces it. Problems thus arise when low income countries, which cannot make their own generics, import them from larger developing countries like India, and in transit they enter a country where the patent is active.

"Under ACTA, a multinational pharmaceutical company can say to customs officials in the transit country: 'That product infringes our patent in this territory, so even though the medicine is safe and can be legally exported from one developing country to another, we still want you to prevent it from reaching its destination'," Malpani explains.

Such seizures occurred after the European Commission (EC) issued a crackdown on IP infringement which led to shipments of generic drugs being wrongfully intercepted.

Companies from India - dubbed the "pharmacy of the developing world" for its leading generics sector - had HIV, cardiovascular disease and common infections drugs, on their way to African countries, turned back by overzealous EU customs officials.

A famous case concerns the antiretroviral medicine, abacavir, shipped from India with Nigeria as destination but intercepted in the Netherlands. GlaxoSmithKline, the patent-holder, did not wish to initiate a legal action but Dutch customs authorities still referred the case to the criminal courts.

Felix Addor, deputy director general of the Swiss Federal Institute of Intellectual Property, told IPS that such outcomes mean the broad approach is unworkable.

"Initially we did not see how you could discriminate between different IP rights. But having analysed the various transit cases, we now advocate that ACTA should either exclude patent-protected goods entirely or at least exclude these products from any border measures.

"We expect that this decision will ultimately be supported by other delegations."

Swiss pharmaceutical companies deny civil society accusations that the industry wants to use ACTA to crack down on competing generics.

"It is neither the policy nor the practice of our member companies to encourage authorities to use IP law enforcement to prevent the flow of legitimate generic products," says Bruno Henggi, head of public affairs at Interpharma, which represents major Swiss multinationals including Novartis and Roche.

"We advocate that ACTA excludes patents from its scope. Our companies contribute to improving access to medicines in developing countries via large-scale donation programmes, preferential pricing and voluntary licensing, as well as through extensive participation in not-for-profit partnership activities."

If ACTA includes patent-protected generics and more developing countries sign up to the agreement, generics will be obstructed. This will cause "competition to be delayed, (hence) medicine prices will increase," Malpani predicts.

"Ultimately, high prices for medicines encourage counterfeiters to sell those very fake medicines that ACTA is trying to stamp out."

The justification that ACTA will tackle fake medicines, which account for almost 10 percent of world medicine, is widely rejected. Wilfully mislabelled medicines are already illegal under TRIPS, and patent infringement "has nothing to do with fake or dangerous medicines", Malpani argues.

Lexchin adds that, "the public health problem related to counterfeits is that substandard medicines will be used or medicines will contain contaminated or substituted ingredients."

The way to address this, though, "is through better regulation of the pharmaceutical supply chain from producer to end user, particularly by strengthening regulatory authorities in developing countries".

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