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Pharma

Is Big Pharma's Heart for Real?

An independent mechanism that protects the patent rights of Big Pharma while allowing generic firms to sell cheap, copycat HIV drugs to poor countries is a progressive idea—but only if Big Pharma gives more, says Divya Rajagopal

Last month, when Emcure Laboratories became the third company to tap an open patent pool, it was more validation of a novel mechanism that seeks to address a conundrum central to the industry: how to make available cheap life-saving drugs to the poor while giving their creators a fair return on their large investment?

This mechanism for HIV drugs, which has as many critics as backers, is the creation of Medicines Patent Pool (MPP), an independent organisation based in Geneva. It brings together two sets of pharma companies perpetually at loggerheads over patent rights—Big Pharma (which has a large portfolio of patents) and generic companies (which copy patents liberally)—to supply cheap HIV drugs to poor countries.

MPP, which started in 2010, asks companies to contribute their HIV patents. MPP, in turn, allows any company to use the patents in its pool to manufacture low-cost drugs for sale in certain countries, while paying a nominal royalty to the patent holder. So far, three companies have tapped the pool: MedChem Labs, Aurobindo Pharma and Emcure.

All three have signed agreements with the $8 billion, US-based Gilead Life Sciences. "About 85-90% of people in the developing world have access to anti-retroviral medicines (ARVs, or HIV drugs) thanks to Indian generic manufacturing capacity," says Ellen't Hoen, executive director of MPP, which is promoted by UNITAID, an organisation that supplies cheap HIV, TB and Malaria drugs to poor countries.

cheap drugs to poor countries through direct tie-ups with generic companies.

The second criticism of MPP is that patent holders don't give universal access to markets. Gilead, for instance, lets its Indian MPP licencees sell predominantly in African countries but excludes low- and middle-income countries in Latin America and parts of Asia, both of which have large numbers of HIV-infected.

"There is a huge problem on how the market has been carved in the pool and who gets to choose it," says Anand Grover of Lawyers Collective, an activist grouping of lawyers. He adds that by allowing the patent-holder to dictate terms and conditions, the pool legitimises bad voluntary patent practices. "The MPP should tells us who they are serving—the company or the community," states Grover.

COMPULSORY CLAMOUR

Cipla, one of the largest suppliers of low-cost HIV drugs to poor countries, has stayed away from the pool. "The concept is laudable, but its implementation is not easy," says YK Hamied, chairman of Cipla. He adds the pool gives patents for countries that anyway do not need a licence to sell HIV drugs. "Give me patents for those countries that have a valid patent law."

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royalty rate. Aurobindo's MPP agreement with Gilead, for instance, allows it to sell four HIV drugs, currently under development, in over 100 countries. "We also avoid the long—and often expensive and uncer-

for drugs made after 1995, and Tenofovir is pre-1995. In 2006, Gilead sought a new patent of Tenofovir and its enforcement on the grounds that it had improved its efficacy. In 2009, the court ruled in favour of Cipla

MIDDLE GROUND

Despite not making a single drug discovery, Indian drug makers are the largest—and cheapest—suppliers of HIV drugs. For example, Atripla, the world's largest-selling HIV drug, costs $12,000 per month in the US. By comparison, its copycat versions made by Indian companies like Cipla and Natco Pharma cost $192 per year.

Indian companies can sell at a fraction of the US drug's cost because patent laws in certain countries let them. But this draws the ire of Big Pharma, which owns the patents to most HIV drugs.

In the context of this faceoff, and society's pressing need, MPP is a middle ground. Generic companies can copy some HIV drugs while avoiding long and expensive legal battles with innovator companies. And innovator companies can retain some control over royalty, and maintain a modicum of balance between profitability and their societal responsibilities.

Big Pharma does such licensing arrangements outside the MPP too, but for a higher royalty rate. Aurobindo's MPP agreement with Gilead, for instance, allows it to sell four HIV drugs, currently under development, in over 100 countries. "We also avoid the long—and often expensive and uncertain—process of negotiation with patent holders," says Tathagato Roychoudhury, assistant GM of Aurobindo.

ONE-SIDED AGREEMENT

Noble as the MPP seems, activists say the patent pool is flawed because of its voluntary nature. They contend the pool's benefits are overstated, and that it detracts from other intellectual-property strategies and flexibilities with better outcomes.

They point to its shallow depth: just six drugs from two entities. The US National Institutes of Health has given the patent for Darunavir. And biotech firm Gilead has contributed five products: Tenofovir, Emtricitabine, Cobicistat, Elvitegravir, and the 'Quad', a combination of the other four products. In this set, the four drugs other than Tenofovir are at a late development stage. "We push and try very hard, and rely on many more people to push the companies," says Hoen.

In December 2011, Johnson & Johnson, which makes key HIV drug combinations like Etravirine and Rilpivirine, declined to join the pool, saying it was supplying

MPP asks companies to contribute HIV patents. It, in turn, allows anyone to pay a nominal royalty and use these patents to sell cheap drugs in poor nations

Hamied feels patent laws are national, and that an independent mechanism like the MPP cannot stop companies and countries from accessing drugs. "Third-world countries do not need patent pools," he says. "They need a pragmatic compulsory-license system." Compulsory licensing is a system under World Trade Organisation rules where a government allows generic companies to produce patented products or use such processes without the patent owner's consent.

Cipla challenged Gilead's Tenofovir patent in India. India recognises patents only for drugs made after 1995, and Tenofovir is pre-1995. In 2006, Gilead sought a new patent of Tenofovir and its enforcement on the grounds that it had improved its efficacy. In 2009, the court ruled in favour of Cipla under a clause that deems certain inventions non-patentable. This meant Cipla could sell Tenofovir to any country without paying Gilead any royalty. But around the time Cipla went to court, some other Indian drug makers decided to avoid a legal battle with Gilead and signed license agreements with it to supply Tenofovir to 95 countries at a royalty of 5%.

Kajal Bhardwaj, an independent lawyer working on HIV, says Indian firms have business compulsions in mind. "They are seeking to build relationships with their multinational counterparts," she says. "Otherwise, it is difficult to understand how licenses that restrict and control their business operations are being considered as serious business propositions."

Even as Big Pharma and civil-society players take positions, MPP represents an introspection and realignment happening in the pharma sector, globally, towards seeking more sustainable solutions. New mechanisms, greater drug access for the poor and even a newfound urge to research neglected diseases of the developing world only signify a turn for the better.