India: Big Pharma's new offensive against world poor

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In 1989, 39 pharmaceutical giants sued the government of AIDS-stricken South Africa, seeking to stop it from implementing a law to improve the poor's access to life-saving AIDS drugs. That aggression sparked a public outcry within South Africa and elsewhere, leading to an international campaign that only ended in 2001 when the 39 companies dropped their case.

One of them, the Swiss-based Novartis AG, has staged a comeback. This time it's over a cancer drug — Gleevec/Glivec — and the immediate stage is in India, where Novartis seeks to obtain a patent for Gleevec. Yet according to the Indian authorities, the drug is only a minor modification of an existing medicine.

Given India is a major supplier of cheap generic medicines to the Third World, a Novartis success in its patent application would, as Medecins Sans Frontieres (MSF — Doctors Without Borders) described in a statement, "see patents being granted far more widely, heavily restricting the availability of affordable generic medicines".

India didn't grant patents on medicines before 2005, enabling it to produce cheaper generic medicine for domestic consumption as well as for export. It's one of the few underdeveloped countries that has the capacity and scale of economy to produce and sell generic medicine at a fraction of Western prices. According to MSF, over half of the medicines currently used for AIDS treatment in the underdeveloped world come from India. Of the 80,000 AIDS patients that MSF projects are treating today, 80% rely on generic medicines from India.

But having joined the World Trade Organisation in 1995, India, like the WTO's other Third World member-countries, was compelled to change its patent law after a 10-year "grace period" to be consistent with the WTO's Big Pharma-friendly "intellectual property" rules. The rules are formally called Trade Related Aspects of Intellectual Property Rights (TRIPS).

Once a medicine secures a patent in India, the country will no longer be able to produce generic varieties of it until the patent expires — usually after 20 years. According to MSF, while only a few new medicines have been patented in India so far, applications have already been lodged for almost 10,000 medicine patents.

MSF warned: "If India begins to grant patents the same way wealthy countries do — where medicines are routinely protected by several patents covering each small modification — it could mean the end of affordable medicines in developing countries."

Novartis applied for a patent for Gleevec in India in 2005, on the basis that the "new" drug could be more easily absorbed by the body. But early last year, the Indian authorities rejected the application, having assessed that the medicine is only an insignificant modification of an existing medicine. A few months later, Novartis filed two law suits against the Indian government challenging both the Gleevec decision as well as a section of India's patent law that's designed to promote cheaper generic medicines for the poor. Based on public health considerations, this section is designed to

prevent minor modifications to an existing medicine from being resurrected via a fresh patent, which is a common practice in countries such as the US and can result in the indefinite extension of existing monopolies that will make the production of generic copies impossible.

Novartis's action sparked an international petition that had collected some 250,000 signatures by January. But on January 29 Novartis filed an appeal against the court's earlier decision.

In defending the company's action, Novartis spokesperson John Gilardi claimed to the January 30 New York Times that the Gleevec case was "not about access to medicines", but about clarifying intellectual property rights.

In response, Oxfam's Make Trade Fair head Celine Charveriat said: "Novartis claims it is simply trying to protect its intellectual property over a single drug. But the truth is this is a direct attack against India's sovereign right to protect public health."

The Novartis case will have a devastating impact on access to medicines, as the example of Gleevec shows. In countries where Novartis has obtained a patent for this drug, it is sold at US$2600 per patient per month, where in India the generic version of it costs less than $200 per patient per month.

Moreover, competition among generic medicine producers had helped bring AIDS treatment cost down from $10,000 per patient's annual treatment in 2000 to $130 per patient today. This sort of price reduction would no longer be possible if Novartis wins the lawsuits.

The MSF assessed that just the threat of new patents has stalled the production of generic copies by Indian manufacturers, such that the prices for newer AIDS medicines can be up to 50 times more expensive than the older varieties.

Partly linked to the considerable public pressure regarding accessible medicine in the Third World, the 2001 WTO ministerial meeting assured its underdeveloped country members the right to access or produce cheaper generic drugs — that is, including breaking patents — in the event of a public health crisis.

But that assurance has been undermined in practice ever since. For example, quoting public health experts and government officials, the April 19, 2006 International Herald Tribune reported that there is a "quiet worldwide campaign by the administration of President George W. Bush to coax developing nations to barter away their patent-breaking rights in exchange for lucrative trade benefits". The paper highlighted the free trade agreement between Thailand and the US as an example.

The report continued: "Specifically, Washington is pushing bilateral and regional trade agreements in which countries enact 'superpatents' that prolonged U.S. drug makers' monopolies and limit the conditions under which their patents can be broken."

"These new rules", the IHT added, "once they are adopted by developed countries, roll back the patent-breaking rights that were confirmed by the 2001 declaration at World Trade Organization talks in Doha, Qatar."

Pharmaceutical companies often defend the "need" for patents on the grounds that the lucrative profits thus guaranteed would help stimulate innovation and research into more powerful medicines. But these claims stand on dubious grounds.

According to an April 2005 survey by La Revue Prescrire, 68% of the 3096 new products approved in

France between 1981-2004 brought “nothing new” compared to previously available alternatives. The September 2005 edition of the British Medical Journal also reported on a study that rates barely 5% of all newly patented medicines in Canada as “breakthroughs”. In addition, the scrutiny of more than 1000 new medicines approved by the US Food and Drug Administration between 1989-2000 concluded that more than 75% of them have no therapeutic benefit over existing products.

Novartis scooped up a net profit of SFr9 billion (US$7.2 billion) in 2006, or 17% more than 2005. Its profit rate for 2006 was nearly 20%, based on its 2006 sales of $37.02 billion.

[Sign the international petition against Novartis’s action on “http://www.msf.org”.]

P.S.

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