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INTELLECTUAL PROPERTY OR INDIVIDUAL PROSPERITY?

A decade after India drastically amended its patent laws, the US and global MNCs have renewed efforts to effect more changes that will serve their interests, says ALAM SRINIVAS

FTE [illegible] process to product patent in [illegible], the US, cajoled by [illegible] and allied by multilateral deals, [illegible] to rule in this [illegible] again to force her to further change the laws. Prime Minister Narendra Modi is willing. During his visit to the US, he said that India will adopt global rules to be in sync with the developed world. There was mayhem among the Indian pharma companies, civil society and the under-developed world.

During the Indo-Africa summit, most of the African nations urged New Delhi not to bow down to Washington's diktats. Civil organisations, which along with poor countries and global health agencies had opposed the 2005 amendments, went ballistic. Like in the past, they claimed that if India adopted the new changes, the prices of life-saving drugs would shoot by up to 1,000 percent. It was back to the same old battlefield, although the issues have changed.

Today, it is not about process or product patents, [illegible] than a [illegible] patent regime allowed Indian firms to dramatically cut down costs and make the same drugs through alternative chemical processes. Today, it is about whether all the new medicines can be patented, and whether there [illegible] exemptions to the rules, especially in cases where drugs have to be supplied at cheap prices for the poor.

In technical terms, the fears are about 'ever-greening', whereby MNCs prolong their patents and 'compulsory licensing', where the government asks third parties to make a drug at a cheaper price even if it is patented. There is also the question of private expenditure on R&D (Research and Development). The MNCs claim that they need stronger patent laws to earn higher profits. The billions of dollar of surplus can be spent on R&D to discover new medicines that are more effective and safer. Their critics contend that the [illegible] public health [illegible]

Drumming up support *A patent application for a key AIDS drug triggered a protest in 2006*

PHOTO: VIJAY PANDEY

Green shoots or ever-green

In 2005, when India opted for product patent to fulfil its commitments under the [illegible] aspects of Intellectual Property Rights (TRIPS) agreement, there was an intense debate on the proposed amendments. Under pressure from Parliamentarians, domestic corporate lobby and civil society, the new laws deliberately left a gaping loophole. When confronted with a future reality, where drug prices could zoom, Section 3(d) was added to the Indian Patent Act. Although the wordings were vague, it was a major victory for the critics.

While Section 2 of the Act spelt out what could be defined as a new invention, the Section 3(d) specified that all new inventions might not necessarily be patented. Its sole objective was to prevent ever-greening, whereby MNCs made incremental changes to the chemical composition of a medicine, claiming that the 'new' drug has either higher efficacy or safety and renewed the patent after it had expired. Thus, they continued to hold the patent for decades.

Since incremental patent applications were rejected, it allowed the Indian pharmaceutical firms and others in developing nations like China, to make these off-patent medicines, or generics, at cheaper costs. This kept the prices low, not just in India but globally, as India and China emerged as huge suppliers of generics to the under-developed nations. In many cases, the differential between the prices of the patented drug and its generic substitute was 500-1,000 percent.

Obviously, the MNCs were dead against Section 3(d). They felt that it prevented them from getting a genuine patent, earning extra profits and spending the billions of dollar required to make a new chemical discovery. Over the years, they were shocked; when the Indian judiciary ruled that the basic philosophy behind the Section was to curtail the patent rights of erring MNCs. In the famous Novartis case in 2013, the Supreme Court (SC) accepted the distinction between invention and patentability. It said that this distinction "was at the [illegible] and [illegible] reinforced by the [illegible] Amendment in Section 3(d)."

The apex court rejected the contentions of Novartis, a global pharma MNC. The latter's lawyers claimed that Section 3(d) "is a provision put in ex abundanti

> **The MNCs were against Section 3(d) of the Indian Patent Act. They felt that it curtailed their prospect of maximising profits**

cautela non nocet (abundant caution does no harm) to remove all doubts." They added that the clause operated "only as ex major cautela (out of abundant caution)" that "mere discoveries can never... be considered inventions" under Section 2 of the Indian Patent Act. According to them, while Section 3(d) was aimed to prevent ever-greening, it was never intended to discourage "incremental inventions".

In response, the apex court observed, "The submission (of Novartis) may appear plausible if the scrutiny of the law is confined only to the Act as it stands today after undergoing the amendments in 2005. But examined in the larger perspective of the development of the law of patent over the past 100 years and especially keeping in mind the debates in Parliament preceding the 2005 amendment, it would appear completely unacceptable." It added that during the Parliamentary debates, Section 3(d) "was the only provision cited by the Government to allay the fears of the opposition members concerning the abuses to which a product patent in medicines may be vulnerable."

Most observers felt that the judgment gave discretionary powers to the Patent Office and patent-related appellate body to decide whether an invention qualified as a patent, or was it a mere discovery. Unless the pharma company could prove a huge increase in efficacy, the Patent Office could reject an application. This proved to be a booster for the generics firms.

Exclusive or compulsory licensing

As the members of the World Trade Organisation (WTO), discussed the language of TRIPS, the developing and poor nations voiced their concerns related to the exorbitant prices of patented life-saving medicines. To address these issues, says a document by Medecins Sans Frontieres (MSF; Doctors Without Borders), TRIPS gave the members the right "to allow a third party to produce a generic version of the (patented) drug in question by granting a compulsory license; for example, if that drug is deemed unaffordable or unavailable by the 'Patent Controller' or the government."

In 2012, India issued the first compulsory license for a cancer drug which brought down the price by 97 percent within no time. Subsequently, the judiciary ruled against the MNC, which complained against the license. In the well-known Bayer's case, the MNC unsuccessfully challenged the compulsory license given to NATCO before the appellate board and Mumbai High Court. Last year, the apex court rejected Bayer's special leave petition against the high court order.

In the Bayer-NATCO case, the price differential between the two versions of the drug was huge. While Bayer charged ₹ 280,000 per patient per month, the domestic generic was priced at a mere ₹8,000 per patient per year. In compulsory license, the third party does pay a royalty to the inventor; in this case it was six percent. When Bayer contested this in the Supreme Court, the former was asked to furnish unaudited accounts of the R&D expenses. Bayer's excuse that 98 percent of

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