



# Understanding India's New Patent Laws

## Did the 2005 Patents Act engender a Western intellectual property rights culture in the country?

When its legislature passed the landmark Patents (Amendment) Act in April 2005, India congratulated itself on having conformed to its obligations under the 1995 World Trade Organization (WTO)/trade related aspects of intellectual property rights (TRIPS) agreement. Its intellectual property rights (IPR) culture seemed to be changing rapidly. The research and development budgets of the major Indian biopharmaceutical companies were rising sharply and Indian pharmaceutical company patent filings, previously concerned mostly with processes for generics drug manufacturing, were shifting decisively towards applications for new drug molecules.<sup>1,2</sup>

But as we outline in our new report, *Advances in Biopharmaceutical Technology in India*, the 2005 Act fell short of a complete westernization of India's IPR laws. Indian generics makers still retain significant scope for copycatting patented Western drugs, legally or illegally, without penalty. And Western companies have seen relatively few of their patent applications approved. Industry observers who expected India's IPR climate to suddenly change after the 2005 Act may have been overly optimistic in their estimate of how fast things can change in this industry.



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### PROTECTIONS FOR EXISTING INDIAN GENERICS

India's shift toward a Western IPR culture was never meant to be disruptive. For example, to hold down the price increases expected after the introduction of patents, the 2005 Act provided that any generics drug made in India before 2005 could legally continue to be made and sold, even if an Indian product patent was granted to the drug's

inventor. Under this provision, the generics maker need only pay a reasonable royalty, determined by India's Patent Office (IPO).

### COMPULSORY LICENSING

Indian generics makers are further protected by compulsory licensing provisions, including a standard competition boosting provision in the existing law, and also the following export licensing expansion added to the 2005 Act during final negotiations to ensure passage:<sup>3,4</sup>

*92A. (1) "Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector ..."*

The provision protects populations in underdeveloped countries from a sudden cutoff in their supply of Indian generics. It also allows Indian generics makers to continue to reverse-engineer, make, and sell Western drugs to these countries. In 2005, for example, Cipla, the Indian generics maker, announced its intention to sell a copied version of Roche's Tamiflu, despite a Roche patent application on file with the IPO. The company presumably intends to rely on compulsory licensing to avoid infringement penalties.<sup>5,6</sup>

Such cases prompt an interesting question: Will Indians tolerate paying significantly higher prices for drugs that their own country's factories sell more cheaply elsewhere in the world? These compulsory licensing provisions may likely maintain downward pressure on drug prices in the Third World no matter where product patent laws are extended.

### ANTI-EVERGREENING AND THE NOVARTIS CASE

TRIPS gives signatories substantial leeway to deny the evergreening of drug patents. Under the new Indian patent law, as under the old law, new uses for an existing drug are not patentable at all.

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The IPO also has considerable freedom to deny applications for new molecules, which may be existing molecules with minor changes.<sup>4</sup>

The IPO's use of this provision has already become controversial. In 2006, it denied a patent to Novartis for its cancer drug Gleevec (marketed as Glivec in India). The IPO's argument was that the drug was not demonstrably more efficacious than what was covered by the first Gleevec patent and that the patent had been issued in 1993, while India's new law recognized only patents first granted in 1995 or later. Novartis argued that the beta-crystalline form, patented elsewhere in 1998, and used in clinical trials, was more stable and showed greater bioavailability. But the IPO considered that argument insufficient.<sup>7,8</sup>

### Enhancement of Known Efficacy

The anti-evergreening provision states that drug molecules cannot be patented in India if they result from "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance."<sup>4</sup> The phrase enhancement of the known efficacy is vague. Its meaning is really for the IPO to decide in each case.

### Lack of Recourse

To protest the IPO's decision, Novartis brought two cases in the Chennai High Court. The first, which protested the IPO's decision, was referred back to the IPO's appeal board.<sup>7</sup> The second, against the 2005 Act itself, claimed that its anti-evergreening clause had violated TRIPS. The Chennai High Court dismissed

this second case simply because it lacked the jurisdiction to determine whether Indian laws comply with international trade agreements. Provided that the IPO complies with Indian law, foreign companies in Novartis's situation have no legal recourse on their own, other than an appeal to India's Intellectual Property Appellate Board. Only a state has the standing to take up a TRIPS-compliance case before the WTO, and in Novartis's case, Switzerland was not going to do so.<sup>7</sup>

### Public Pressure Against Patent Protection for Expensive Drugs

Novartis's case inspired opposition from nongovernmental organizations (NGOs) and other groups, ranging from India's Cancer Patients Aid Association and the All-Action Drug Network to the Swiss-based Doctors Without Borders, who wanted access to less expensive drugs. The result was negative publicity for the company and pressure on the Indian government to rationalize a rejection of Novartis's claims. The NGOs' point was that a Novartis victory would have cut off access to existing Gleevec generics costing less than a tenth of what Novartis charged.<sup>8</sup> It was even alleged that despite Novartis's free supply of the drug to some needy Indian patients, a number of other patients died or became bankrupt after the company was granted exclusive marketing rights to Gleevec in 2003 and most competing generics makers were barred from the market.<sup>7</sup>

### OPPOSITION PROVISIONS & DELAYS

Another anti-Western provision of the 2005 Patent Act is the wide

scope it gives to interested parties to oppose the granting of patents, including grounds such as:<sup>4</sup>

- "that the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention,"
- "that the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim," or
- "that the invention so far as claimed in any claim of the complete specification was anticipated having regard to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere."

Indian generics makers have made use of these provisions by filing pre-grant oppositions to patents for Western-developed drugs. The targets of these tactics have included Novartis's Gleevec, Astra Zeneca's Rosuvastatin, Lilly's Tadalafil, Pfizer's Voriconazole, Gilead's Viread, and many others.<sup>9-11</sup>

Taking their cue from the Novartis case, India's generics manufacturers have frequently argued that a drug is not really new. If nothing else, these opposition filings have succeeded in delaying the granting of patents to Western pharmaceutical companies.<sup>10</sup>

### A DIFFICULT SITUATION

Some IPR proponents in the West view the recent changes to India's Patents Act as cosmetic, and the overall IPR situation remains hazardous. Greg Kalbaugh, director and intellectual property counsel for the US-India Business Council, based in Washington, DC, has been quoted saying that "Indian patent laws make it difficult for outside companies to get their product patented in India, while at the same time making it easier for

Indian companies to violate their intellectual property."<sup>12</sup>

"Patent and copyright laws in India are old and [out]dated, and they nowhere match the world standards," according to Franklin Lavin, US undersecretary of commerce for international trade, as quoted in the journal *Managing Intellectual Property*.<sup>13</sup>

Western firms doing business in India have a rather broad set of complaints over IPR issues there, extending beyond the weakness of India's patent law to include the patent office's growing backlog, India's slow judiciary process, and the theft of proprietary information.<sup>14,15</sup>

Alluding among other things to "unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their products," and also to "weak enforcement" against IPR violations, the Office of the US Trade Representative (USTR) retained India on its IPR "watch list" in 2006, despite the country's patent law changes. India was placed on the USTR's "priority watch list" in early 2007.<sup>16-18</sup>

Will such measures force a deeper transformation in India's IPR processes? The need to maintain access to medicines for a large and relatively poor population, the need to keep local generics producers happy, and perhaps the general feeling that local businesses deserve a helping hand, all suggest that it would be politically problematic for India to adopt a fully Western IPR regime too quickly. Stern words from a few officials in the West are unlikely to change things.

Moreover, there is no real economic pressure to back up those words. Far from curtailing trade with India, the West is outsourcing services and consuming Indian export goods at a prodigious rate—and the consumption of Indian pharmaceuticals is no exception.

According to Milind Antani of Nishith Desai Associates, a legal counseling firm in Mumbai, "Even though we're seeing R&D and CRO outsourcing being done in India today, until data exclusion and IP protection laws are enacted and enforced, multinational corporations will need to think twice about entering into large-scale CMO relationships in India."

### WHAT'S THE SOLUTION?

There is no obvious solution here, other than perhaps to wait for India to expand economically so that its culture changes and its citizens are sufficiently wealthy to manage within a more Western-style IPR system. Meanwhile, pharmaceutical patents in such a country may be of limited use to Western innovators, who find they may have to sell their drugs much more cheaply than they do in the West, and more often by licensing them to the same Indian drugs companies that contest their patents.<sup>11</sup> When it comes to obtaining and enforcing drug patents in India, it may be that Indian drug companies have the advantage, being less likely to attract NGO opposition to their lower-priced drugs, and perhaps less likely, by virtue of their connections, to encounter delays in the patent application process. In this sense, the primary beneficiaries of India's new patent laws are the very Indian companies the laws were originally thought to threaten. ♦

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