



India and the Drug Patent Wars

By Roger Bate

India's introduction of product patents in 2005 heralded innovation and rapid development of that nation's pharmaceutical sector and delivery of new medicines to its population—until, that is, the government's interpretation of an obscure provision of the law undermined this potential advance. In a case to be heard soon at the high court at Chennai, Swiss drug company Novartis is suing the Indian government, claiming that the provision of the law is unconstitutional and violates international trade rules.¹ India is at a crossroads. The Indian high court should overturn that section of the patent law to stimulate drug innovation in India.

In 1970, under pressure from companies duplicating Western-manufactured drugs, the government of then–prime minister Indira Gandhi abandoned the idea of product patent protection. Between 1970 and 2005, Indian patent law only allowed for “process patents,” which provided little protection for those making long-run investments in drug research and development (R&D). As a result, a thriving generics industry specializing in “reverse engineering” and copying Western products developed in India. By some estimates, there are currently as many as 22,000 drug makers—of vastly varying quality—working in India.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) sets minimum levels of protection for many forms of intellectual property (IP), including drugs.² Impelled by enlightened self-interest and with the support of larger, more research-capable Indian-based firms—notably Ranbaxy Laboratories—the Indian government signed the TRIPS agreement in 1995. By 2005, to the delight of many patent holders seeking access to the increasingly important Indian health-care market, India extended its patent protection to pharmaceutical products as stipulated under the TRIPS agreement.

Roger Bate (rbate@aei.org) is a resident fellow at AEI.

With these improvements in intellectual-property protection, India's thriving domestic drug industry was poised to expand into original research and drug development, thus improving public health. By creating an environment that rewarded innovation, India was set to become a world leader in medical technologies. To the outside world, it showed that India was open for business.

Idiosyncratic India

Escaping the attention of most India observers—except those following the TRIPS agreement guidelines and access-to-medicines debate—the actual patent law, known as the Patents Act of 2005, contains certain peculiar provisions.

One such provision is section 3(d).³ Section 3(d) creates additional hurdles for pharmaceutical companies seeking patents on their products. It states that derivatives of known substances cannot be patented unless they can be shown to differ in terms of efficacy. In other words, if a drug is developed and patented but a newer (and arguably better) version is subsequently created, the original patent would not hold for the new version.⁴ Unless clinical improvements are demonstrated to the satisfaction of the Indian government, new patents would not be granted

for these new versions. So to acquire a patent, one has to go beyond merely demonstrating the usual “novelty, commercial applicability and non-obviousness” criteria outlined under the WTO TRIPS agreement.

There are several reasons why the terms outlined in section 3(d) are not compatible with the WTO TRIPS agreement:

- Article 27 of the TRIPS agreement⁵ provides a bounded list of patentable subject matter that can be excluded from patent coverage. “New forms of known substances lacking enhanced efficacy” are not included in this bounded list.
- The TRIPS agreement forbids WTO member states to make it more difficult to obtain a patent in one technical field, such as engineering, over another, such as drug development. Only patents filed for drug development have to comply with section 3(d).
- The “other derivatives of known substances” clause of section 3(d) of the Indian patent law is nebulous and arbitrary. It could be interpreted to deny nearly any new patent claim since so many drugs are derived, at least in part, from previously known substances. And even if a patent was granted, it could be easily challenged by some party that currently copies it (or would want to). Section 3(d) is so arbitrary that it encourages litigation and undermines incentives for innovation.

Revisiting Section 3(d)

At the time the Patents Act was enacted, the Indian government established the Mashelkar Committee (named after its chairman, R. A. Mashelkar, a highly respected IP expert) to assess the law, and in particular to determine whether section 3(d) is TRIPS-compatible. The Mashelkar Committee submitted its report to the Ministry of Commerce and Industry on December 28, 2006, and made it public on January 16, 2007.⁶ The committee found that the limitation of patentability to “new chemical entities” (NCE) is beyond the scope of TRIPS flexibilities approved by the WTO—namely,

that the new patent requirement violates international trade rules.⁷

The committee’s findings initiated a fierce debate in India because they ran counter to those who had promoted the Patents Act amendment. The Indian Pharmaceutical Alliance (IPA) opposed the Mashelkar Committee’s findings, which is unsurprising given its constituency of numerous reverse-engineering companies. Most members of the domestic pharmaceutical sector fear that if the law is amended according to the Mashelkar panel’s recommendations, they would be denied the opportunity to modify older molecules and commercialize them.⁸ One influential exception in this pharmaceutical consortium, however, was Ranbaxy Laboratories. The largest member of the IPA, Ranbaxy has openly opposed the alliance’s stand on patent issues and has sided with the Mashelkar Committee.⁹ Ranbaxy is one of the few truly impressive innovative pharmaceutical entities in India. Its annual revenue as of December 2006 was just over \$2 billion.¹⁰ According to India’s *Business Standard* newspaper, “Though the IPA maintained that the decision was ‘unanimous,’ a Ranbaxy spokesperson said the company had opposed the IPA stand on all occasions.”¹¹

Furthermore, Ramesh Adige, executive director of corporate affairs at Ranbaxy Laboratories, told the *Business Standard*:

Ranbaxy is of the strong opinion that incremental inventions should be patented. However, we oppose patenting frivolous inventions. As Mashelkar rightly pointed out, rules should be very clear to see that frivolous patents are not granted. Rules should be very clear, and guidelines should be framed so that patent officials can differentiate between frivolous patents and incremental patents. The three-way test for patentability should be novelty, innovation and commercial utility.¹²

Perhaps Ranbaxy’s clearest avowal is made in the annexure of the Mashelkar Committee report:

We are of the opinion that incremental innovations in terms of developing new forms, new

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derivatives and new delivery systems of existing drugs should be granted patent protection provided they are new, involve an inventive step and have commercial utility. Restricting patentability to NCEs may appear to be an attractive solution in the short-term to companies with a “reverse-engineering” mindset, but will not benefit hundreds of scientists working in our public [and] private R&D centres. Restriction of patentability to NCEs alone is likely to benefit only [multi-national corporations] which have the resources and the experience to develop NCEs. Indian companies that have far less resources are better placed to benefit from early commercialization of incremental innovations. A prerequisite to successful licensing deals for such products is the protection of the IP in the form of a patent, preferably in the country itself since products are being manufactured here.¹³

The position taken by Ranbaxy is encouraging and provides hope that the Indian law will be overturned. For an industry whose members have historically stood shoulder to shoulder against Western patent laws, the gap between Ranbaxy and the rest of the IPA is significant. With talented scientists and revenues of over \$2 billion, Ranbaxy could compete internationally with pharmaceutical giants like Novartis and Merck & Co. To do so, however, it needs a sensible legal environment.

Although Ranbaxy may get an opportunity to challenge the law, a more immediate examination of the law is about to begin. But this time, the high-profile plaintiff is drawing significant international media attention to the case.

The Case for Glivec

Novartis’s suit against the Indian government claimed that it should have been granted a patent for its drug Glivec (known as Gleevec in the United States).¹⁴ The patent for the cancer drug was rejected by the Indian Patent Office in December 2005. The company argues that section 3(d) is unconstitutional because the Indian government had previously agreed to abide by the patent provisions of the WTO TRIPS agreement. Novartis is

demanding that section 3(d) be repealed, clearing the way for its patent to be approved.

According to international medical journals and press coverage of the case, a U.S.-backed pharmaceutical giant is leading an assault on India to prevent the poorest from receiving lifesaving drugs.¹⁵ *The Lancet*, one of the world’s top medical journals, recently editorialized in

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favor of a campaign “defending the legal rights of the world’s poorest people to access the essential medicines they need.”¹⁶ The journal lauded the campaigners who are “calling for the rules of Trade Related Aspects of Intellectual Property . . . a binding World Trade Organisation agreement, to be upheld and are targeting the pharmaceutical industry and the US Government.” *The Lancet’s* editorial continues: “Novartis is taking the Indian Government to court

over its decision last year not to grant a patent for the cancer drug. . . . [T]he patent was rejected under . . . legislation that India implemented two years ago. Section 3(d) stipulates that patents should only be granted on medicines that are truly new and innovative but Novartis is challenging this rule.”¹⁷

The reality, of course, is far more complex. Most physicians and patients would agree that Glivec represents an innovative anti-cancer breakthrough and deserves a patent. In 1983, Novartis scientist Dr. Alex Matter led the charge for a new drug that would target only cancer cells: “I believed we could tackle the disease in a better fashion.”¹⁸ As greater genomic knowledge became available, Novartis scientists were successful in creating such a drug, resulting in the development of Glivec.

Novartis first sought a patent for Glivec in Switzerland in 1992, but the first patent was granted in 1994 in Taiwan and then in 1996 in the United States. Leukemia patients were first treated with Glivec in 2001.

Today, Novartis has about 20,000 patients on the Glivec International Patient Assistance Program in eighty-three countries. According to Novartis, these patients receive the drug free of charge: “In over five years since its approval, Glivec continues to fundamentally change outcomes for most adult patients with . . . chronic myeloid leukemia (CML). CML deaths have been reduced by almost 75 percent in the United States since the launch of Glivec.”¹⁹

Like all research companies, Novartis continued to work on the drug, developing a beta crystal version. It is

this version for which Novartis sought patent protection under Indian law in July 1998, and once the drug passed clinical trials, Novartis was given a license to produce and distribute it in India.

Ironically, had India had product patent laws when Novartis first started filing globally in 1992, the company probably would have received an Indian patent, since it would have tried to patent the original version, which would have passed section 3(d). The Indian government denied Novartis a patent for Glivec under section 3(d) on the grounds that the second version was not sufficiently distinct from the first.

Even under Indian law today, Novartis could arguably be awarded a patent. The beta form of the drug is more stable than the alpha form at room temperature. It has what biochemists call the lowest risk of spontaneous conversion into another crystalline form. This is important because if the crystalline structure were to change, it could affect quality, bioavailability, shelf life, and efficacy. Indeed, the beta form performs better in some tests—30 percent better on bioavailability of the drug than the alpha form—implying that it is a clinical improvement over the older version, just as section 3(d) demands. This improvement, however, has only been established anecdotally, and to prove it to the satisfaction of the Indian government would require an expensive and largely pointless clinical trial. After all, Glivec (including the beta form) is patented in forty countries worldwide.

Novartis is no villain keeping the poor from receiving needed drugs. Rather, Indian patent law is what constricts India's drug market. India's patent hurdles discourage drug companies from operating there, innovating, and working on diseases unique to India. The subcontinent has severe problems with dengue fever and leishmaniasis, yet there is no cure for dengue and no inexpensive cure for leishmaniasis. None of the research on dengue or leishmaniasis is done in India, and no Indian drug company produces the medicines to cure leishmaniasis—a horrid disease known as “Baghdad Boil” by the unfortunate U.S. troops who have contracted it. Ironically, it is Novartis that leads the world in research for a cure for dengue.

The Novartis case is one of principle. It will not affect most Indian patients, for Novartis distributes the drug free to 99 percent of those who need it in India—

over 6,000 patients.²⁰ The remaining 1 percent can probably afford the drug. It is not the majority of patients who are hoping that Novartis loses its court battle but the generic producers of Glivec. For while there is only a small market for drugs to combat CML, copied drugs to combat other diseases like cancer, hypertension, and heart disease are more lucrative.²¹

The outcome of the Glivec case will set a precedent. If Novartis loses the case, the producers of generics will continue to make money, most notably in non-CML medications, but Novartis might reevaluate its commitment to India. If it does, it will send a signal to competitors that India does not welcome foreign drug companies.

Novartis officials did not want to pursue a legal battle in the high court, but it saw no other alternative. Only countries can demand arbitration at the WTO over breaches of the TRIPS agreement, and no country has complained. The U.S. trade representative (USTR) has not issued a statement on whether she would pursue an action against India over section 3(d), but a spokesman said that the USTR's office is “watching the case with interest.”²²

India is at a crossroads, and the Novartis case may determine its direction. It can follow the route it has taken

in software engineering, with sensible intellectual-property protection that spurs growth, or it can travel the opposite route with idiosyncratic rules that limit growth and innovation.

AEI research assistant Kathryn Boateng and editorial assistant Evan Sparks worked with Mr. Bate to edit and produce this Health Policy Outlook.

Notes

1. Amelia Gentleman, “Novartis Files Suit against India Ruling on Drug Patents,” *International Herald Tribune*, January 29, 2007.

2. World Trade Organization, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, “Agreement on Trade-Related Aspects of Intellectual Property Rights” (April 15, 1994), available at www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm (accessed January 30, 2007).

3. *The Patents (Amendment) Act*, No. 15, 56th year, Parliament of the Republic of India, *Gazette of India* 18 (April 5, 2005): 2, available at www.patentoffice.nic.in/ipr/patent/patent_2005.pdf (accessed January 30, 2007).

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4. In fact, section 3(d) is more devastating than this. “Derivatives of known substances” encompasses far more than an improvement in an existing patented product; salts, esters, ethers, polymorphs, and vast numbers of other derivatives are included under this definition. As many as 70 percent of currently patented drugs in the United States derive from such prior knowledge.

5. World Trade Organization, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, “Agreement on Trade-Related Aspects of Intellectual Property Rights,” Article 27, “Standards Concerning the Availability, Scope and Use of Intellectual Property Rights” (April 15, 1994), available at www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (accessed January 26, 2007).

6. R. A. Mashelkar, ed., *Report of the Technical Review Group on Patent Law Issues* (December 2006).

7. P. B. Jayakumar, “Decision on Patentability Criteria and Data Protection Soon,” *Pharmabiz.com*, January 8, 2007.

8. One legitimate concern of nongovernmental organizations and generics companies is over Western pharmaceutical companies “evergreening” patents. The Mashelkar Committee report makes a sensible distinction between evergreening and “incremental innovation.” It says that while “evergreening” refers to an extension of a patent monopoly achieved by executing trivial and insignificant changes to an already existing patented product, incremental innovations are sequential developments that build on the original patented product. The report says that given the current level and type of R&D innovations that the Indian pharmaceutical industry is undertaking, protecting “incremental inventions” may be of tremendous value in a country like India. What is not entirely clear is whether the Mashelkar Committee sees protection of various forms of the same substance (salt, esters, polymorphs, metabolites, pure form, particle size, isomers, mixture, etc.) as incremental innovation or as evergreening.

9. Joe C. Matthew, “Patent Row: Ranbaxy Takes On IPA,” *Business Standard* (New Delhi), January 21, 2007.

10. “Company Snapshot: Ranbaxy Laboratories Ltd.,” India Infoline, available at www.indiaonline.com/company/compsnap.asp?lmn=4&co_code=469 (accessed January 30, 2007).

11. Joe C. Matthew, “Patent Row: Ranbaxy Takes On IPA.”

12. *Ibid.*

13. R. A. Mashelkar, ed. *Report of the Technical Review Group on Patent Law Issues*, 18.

14. The case was supposed to begin on January 29, 2007, but the judge asked Novartis to allow him to consider the findings of the Mashelkar Committee report. The case is expected to be heard some time this month.

15. Doctors Without Borders, “As Novartis Challenges India’s Patent Law, MSF Warns Access to Medicines Is Under Threat,” news release, September 26, 2006, available at www.doctorswithoutborders.org/pr/2006/09-26-2006_1.cfm (accessed January 31, 2007).

16. “Undermining TRIPS: Protectionism at Its Worst,” editorial, *The Lancet* 369, no. 9555 (January 6, 2007): 2.

17. *Ibid.*

18. Alex Matter, personal communication to author, January 23, 2006.

19. Novartis spokeswoman Michele Galen, personal communication to author, January 28, 2006.

20. Tove Gerherdsen, “Novartis Persists with Challenge to Indian Patent Law Despite Adversity,” *Intellectual Property Watch*, October 19, 2006, available at www.ip-watch.org/weblog/index.php?p=430&res=1024_ff&print=0%20Novartis (accessed January 31, 2007). Like all Western drug companies, Novartis refuses to comment on the pricing and profitability of individual drugs, but Glivec is probably used by about 30,000 paying patients, providing a decent return on the innovation in Western countries.

21. There is little information on how many of these branded copies are actually sold in India. Patients receiving these copies are almost certainly doing so through a limited reimbursement system operated by the Indian government. They are probably not paying for the copies out-of-pocket. Drug companies Ranbaxy, Natco, and Cipla have copies named Zoleta, Veenat, and Imatib respectively.

22. USTR spokesman Christopher Wilson, email to author, January 29, 2007.