



## Taking TRIPS to India — Novartis, Patent Law, and Access to Medicines

Janice M. Mueller, J.D.

In August and September 2006, patients with cancer, lawyers for patient advocacy groups, and representatives of nongovernmental organizations (NGOs) converged on the offices of Novartis in

Mumbai, India, to protest the company's efforts to obtain an Indian patent on Gleevec, the company's brand-name version of imatinib mesylate. Gleevec (spelled Glivec outside the United States) is used to treat chronic myeloid leukemia, and Novartis has patented the drug in 35 countries. The protesters also decried the drug's high price: Novartis sells it in India (where only 5% of people have private health insurance) for \$26,000 per year; generic-drug manufacturers offer the drug at less than one tenth that price.<sup>1</sup>

Citing its right to recoup enormous research-and-development expenditures, Novartis refuses to

drop the legal petitions it filed in the Chennai High Court in May 2006, challenging the Indian Patent Office's denial of a patent. According to Novartis, there is "no faster way to kill access to the latest life-saving drugs for people in India than to avoid offering patent protection."<sup>2</sup> The company also emphasizes that 99% of Indian patients now receiving the drug get it free through the company's patient-assistance program.

The Gleevec challenge is the latest controversy facing India since its January 1, 2005, implementation of substantially enhanced patent protection for phar-

maceuticals. India's membership in the World Trade Organization (WTO) means that for the first time in 35 years, drug products (the pharmaceutical compositions themselves, rather than merely the processes for making them) must be considered potentially patentable in India. The Indian government supports the expanded availability of patent protection as a catalyst that may enable India's enormous drug-manufacturing sector to evolve from reverse engineering to innovation.

It will take years, of course, to evaluate the effects of enhanced patent-based incentives on India's pharmaceutical industry. The immediate concern is patients' access to essential medicines that are manufactured in India and exported around the world. In the absence of notable patent-law restraints before 2005, India devel-



oped a world-class generic-drug-manufacturing sector, spawning major generics firms such as Ranbaxy, Cipla, and Dr. Reddy's, in addition to hundreds of smaller firms. India boasts more drug-manufacturing facilities that have been approved by the U.S. Food and Drug Administration than any country other than the United States. Indian generics companies, for instance, supply 84% of the AIDS drugs that Doctors without Borders uses to treat 60,000 patients in more than 30 countries.<sup>3</sup>

Will India's patenting of medicines put patients around the world at risk of losing a critical source of lifesaving generic drugs? The risk is currently minimal, thanks to public health safeguards developed by the Indian government. For example, the government has imposed price controls on essential medicines since 1970, and recent reports suggest that it may be expanding the list of drugs that are subject to such controls.<sup>4</sup> More to the point, a number of safeguards have been built into the new patent law itself. These provisions resulted from years of intense public debate, government study, and legislative compromise.

First, patent coverage for phar-

maceutical products will apply only prospectively to applications filed with the Indian Patent Office on or after January 1, 1995. Second, the law imposes powerful limitations on patents applied for between that date and December 31, 2004. Any Indian generics firm that began before 2005 to manufacture a drug that was subsequently covered by an Indian patent can continue to make and sell that drug, though it might have to pay royalties established by the government to the patent holder.

The law also includes the world's most extensive provisions on "compulsory licensing." Generics firms can legally copy patented drugs for export to the least-developed countries, which lack domestic manufacturing capability. Furthermore, generics firms and patient-advocacy groups are already making active use of robust "opposition" provisions in the law; indeed, it was opposition by a group of patients with cancer that led to the patent office's rejection of the Gleevec application. And clearly, the culture engendered by 35 years of prohibition of the patenting of pharmaceuticals will not be changed overnight. Two years into the new

patents regime, the government has granted only one patent on a pharmaceutical product — to Hoffmann-La Roche, for its hepatitis C therapy, peginterferon alfa-2a (Pegasys).

Still other protections included in the law ensure that only truly innovative advances will be patented. The Novartis lawsuit is the first legal challenge to the most controversial safeguard, a provision against "evergreening" that targets attempts to patent minor improvements to old drugs. Section 3(d) of India's Patents Act forbids the patenting of derivative forms of known substances (e.g., salts, polymorphs, metabolites, and isomers) unless they are substantially more effective than the known substance. Neither the Indian patent statute nor its implementing rules define "efficacy." They give the patent office no guidelines for applying the new test. Novartis has asked the Chennai High Court to strike down this section as inconsistent with the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). TRIPS requires that patentable inventions be new and involve an "inventive step." Novartis contends that TRIPS

gives WTO members the option of providing patent rights more generous than these basic criteria would mandate but does not allow members to go in the opposite direction by implementing stricter requirements for obtaining a patent.

The counterargument is that TRIPS does not define “inventive step.” It permits (but does not require) WTO members to equate this criterion with the “nonobviousness” requirement of U.S. patent law — and thus gives member countries the flexibility to fine-tune their inventive-step criteria to reflect national socioeconomic conditions.

Moreover, Section 3(d) of India’s patent law does not necessarily impose stricter requirements than are used elsewhere; it may be seen as simply creating a general presumption of nonpatentability for modifications of known chemical compositions — and shifting to patent applicants the burden of rebutting this presumption in each particular case. For example, the U.S. Patent and Trademark Office may reject a claimed drug as “prima facie obvious” on the basis of its structural similarity to existing chemical compositions. A classic way to overcome the rejection is to demonstrate the drug’s unexpectedly good results. India’s new efficacy test might well operate in a similar fashion.

The Chennai High Court considered these issues of sufficient importance to merit referral to a two-judge panel. By late January

2007, the panel had not issued a decision. NGOs were disappointed by the court’s refusal to dismiss Novartis’s challenge outright. But the Indian judiciary must analyze and rule on the viability and

## *Indian patent law includes the world’s most extensive provisions on “compulsory licensing.”*

uncertain contours of the new patentability test. Until it does so, the patent office retains virtually complete discretion in its application of Section 3(d). The court must also determine whether the patent office followed correct administrative procedures in rejecting Novartis’s application. The company contends that among other errors, patent examiners ignored data demonstrating that Gleevec has greater manufacturing stability than does the imatinib free-base form, as well as 30% greater bioavailability.<sup>5</sup>

India has an independent judiciary and an established rule-of-law tradition. Novartis’s litigation needs to run its course, and the system must be allowed to do its job, since a number of important results could flow from this case. Indian courts probably

cannot use the WTO’s rules to strike down laws enacted by India’s parliament, but the Chennai High Court will have to grapple with the meaning of Section 3(d) and other untested patent rules. Regardless of the outcome, the system will benefit from the judicial analysis. And even if Novartis ultimately obtains an Indian patent on Gleevec, the current safeguards give the government multiple options for ensuring public access to this and other life-saving drugs.

An interview with Ms. Mueller is available at [www.nejm.org](http://www.nejm.org).

Ms. Mueller is a professor of law at the University of Pittsburgh School of Law, Pittsburgh.

1. Novartis challenges the Indian patent law. Zurich, Switzerland: Berne Declaration, October 9, 2006. (Accessed January 18, 2007, at <http://www.evb.ch/en/p25011414.html>.)

2. NGOs attack Novartis over drug access. Geneva, Switzerland: Swissinfo/Swiss Radio International (SRI), October 12, 2006. (Accessed January 18, 2007, at [http://www.swissinfo.org/eng/In\\_depth/detail/NGOs\\_attack\\_Novartis\\_over\\_drug\\_access.html?siteSect=107&sid=7159190&cKey=1160714785000](http://www.swissinfo.org/eng/In_depth/detail/NGOs_attack_Novartis_over_drug_access.html?siteSect=107&sid=7159190&cKey=1160714785000).)

3. As Novartis challenges India’s patent law, MSF warns access to medicines is under threat. Press release of Médecins sans Frontières, September 26, 2006. (Accessed January 18, 2007, at [http://www.doctorswithoutborders.org/pr/2006/09-26-2006\\_1.cfm](http://www.doctorswithoutborders.org/pr/2006/09-26-2006_1.cfm).)

4. Bhargava A, Srinivasan S. Price regulation of essential medicines. The Hindu. October 17, 2006. (Accessed January 18, 2007, at <http://www.thehindu.com/2006/10/17/stories/2006101702601000.htm>.)

5. Novartis: writ petition against denial of Gleevec patent. Affidavit filed on behalf of the petitioner: Novartis AG v. Union of India et al., W.P. No. 24754 of 2006 (Mad. High Ct.) (May 19, 2006). (Accessed January 18, 2007, at <http://www.lawyerscollective.org/>.)

Copyright © 2007 Massachusetts Medical Society.