

Case 15 ♦ India vs. Big Pharma

In April of 2013, India's Supreme Court rejected Novartis' bid to patent a new version of Glivec, a popular leukemia drug.¹ Glivec's original formulation, which has held a U.S. patent since 1993, has never had patent protection in India. The country did not begin issuing pharmaceutical patents until 2005.² However, as a member of the World Trade Organization (WTO), India has had to adopt the patenting of pharmaceutical products and processes, in accordance with the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs).³

Being a long-time supplier of low-cost medicines, India drafted patent legislation that would protect its ability to produce affordable pharmaceuticals, while also complying with TRIPs. According to India's Patent Act, section 3(d), variants of pharmaceutical compounds cannot be patented unless they "show enhanced efficacy." Thus, the newer, crystalline form of Glivec was deemed unworthy of a patent, according to Indian law. This decision means that generic drug manufacturers in India can continue to sell the drug for only a fraction of Glivec's sticker price (\$2500).

Representatives of *Médicins Sans Frontières* hailed the ruling, stating that lower drug costs will "save a lot of lives in the developing world."⁴ Novartis, however, maintained that the company had been providing Glivec free of charge "to 95 percent of patients prescribed the drug in India."⁵ In their eyes, the court's ruling was a sanctioning of intellectual property theft, which, in the end, would discourage pharmaceutical companies from investing in new drug research.

The effects of India's Supreme Court ruling are likely to reverberate across national borders, by setting a precedent against a practice known as "ever-greening" or incremental pharmaceutical innovation - the attempt to obtain a secondary patent on a product by making small changes to its chemical structure. India's stance against ever-greening has been criticized by the U.S.-India Business Council and defenders of patent rights.⁶ Strong protection of intellectual property rights, so the argument goes, "attract[s] foreign research and development investment in developing countries and promote[s] technology transfer."⁷ In fact, according to Dr. Alan O'Neil Sykes, a scholar on economics and international law, the absence of protection for the intellectual property of pharmaceuticals in developing nations has been concomitant with, if not causally responsible for, the "dearth of research into the diseases"⁸ that disproportionately affect these countries.

Case from the 2013 Regional Ethics Bowl. Copyright, Association for Practical and Professional Ethics.
<http://apeonline.com/ethics-bowl/regional-ethics-bowl/>

¹ Mark Memmott, "Patent Ruling In India Could Boost Exports Of Cheap Medicine To Third World," NPR, April 1, 2013, <http://www.npr.org/blogs/thetwo-way/2013/04/01/175916808/patent-ruling-in-india-could-boost-exports-of-cheap-medicine-to-third-world>

² Bhaven Sampat, Kenneth C. Shadlen, and Tahir M. Amin "Challenges to India's Pharmaceutical Patent Laws," *Health*, 2012, 4:6.

³ Thomas Pogge, "Human Rights and Global Health: A Research Program," *Metaphilosophy*, 2005, 36: 182–209.

⁴ Soutik Biswas, "Novartis India Case: Campaigners Hail Patent Rejection," BBC News, April 1, 2013, <http://www.bbc.co.uk/news/business-21992724>

⁵ Richard Knox, "Novartis Ruling Reverberates Past India's Borders," NPR, April 2, 2013, <http://www.npr.org/2013/04/02/175997129/novartis-ruling-reverberates-past-indias-borders>

⁶ "The Value of Incremental Pharmaceutical Innovation: Benefits for Indian Patients and Indian Businesses," U.S.-India Business Council, 2010, <http://www.ahealthyindia.org/wp-content/uploads/2010/03/USIBCIIncrementalInnovationReportFinal.pdf>

⁷ Penelopi Goldberg, "Alfred Marshall Lecture Intellectual Property Rights Protection in Developing Countries: The Case of Pharmaceuticals," *Journal of the European Economic Association*, 2010, 8: 326–353.

⁸ Alan Sykes, "TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution'." University of Chicago Law & Economics, Olin Working Paper 140, 2002, http://www.law.uchicago.edu/files/files/140.Sykes_.TRIPs_.pdf