

Balancing innovation and access: India's pharmaceutical patent laws

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Writing in Science, LSE's Kenneth Shadlen, Bhaven Sampat (Columbia) and Tahir Amin (Harvard) debate the implications of an upcoming Indian Supreme Court decision on pharmaceutical patents for variants of existing compounds and its impact on the accessibility of affordable drugs.

The Indian Supreme Court will soon hear final arguments in a challenge by the pharmaceutical company Novartis against the Indian Patent Office's (IPO) rejection of a patent for the leukemia drug, Glivec. The outcome of the case is likely to affect patent terms and access to drugs in the developing world.

The World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), in effect since 1995, requires all WTO countries to allow patenting of pharmaceutical products and processes. Global extension of pharmaceutical patents, which will be the effect of TRIPS when fully implemented, has fuelled concerns about drug prices and, subsequently, access to lifesaving medications.

The introduction of pharmaceutical patents in India has been particularly controversial. Indian producers have long been suppliers of low-cost medicines domestically and also to other low- and middle- income countries. In amending its patent law to meet new international obligations, India, like many developing countries, attempted to take advantage of flexibilities in TRIPS to ameliorate potentially negative effects that pharmaceutical patents might have on the supply of medicines. India used its full transition period, waiting to introduce pharmaceutical product patents until 2005 (pharmaceutical process patents were already available, prior to TRIPS). Applications dating from 1995 onwards were received, but not examined until 2005.

India also introduced a clause designed to restrict the number and type of pharmaceutical patents granted: Section 3(d) of the Patent Act prohibits patents on variants of existing compounds that do not show enhanced efficacy. Section 3(d) has been extremely contentious since its introduction in 2005. The transnational pharmaceutical industry regards it as establishing an unacceptably high barrier to patenting, as do many foreign governments. But many observers, including the United Nations Programme on HIV/AIDS and civil society groups, defend 3(d) and point to India as a model for developing countries attempting to use TRIPS flexibilities to promote public health.

In 2006, the IPO, citing 3(d), rejected Novartis's application for a patent on a crystalline form of Glivec's basic compound, imatinib mesylate. Glivec is widely recognised as having revolutionised treatment of chronic myeloid leukaemia and demonstrated the potential for targeted drug development. As a result of the IPO's decision, Glivec is not protected by a patent in India.

Novartis appealed against the rejection, and the case has worked its way to the Supreme Court. Though the case is meant to determine whether the rejection was appropriate, the broader issues of how the IPO interprets and applies 3(d) are likely to be considered by the Court, making the case a referendum on 3(d). Novartis, making its case before the court of public opinion, has emphasised that the drug has received patents in over 40 other countries, implying that if even Glivec cannot be patented in India, 3(d) must be setting unreasonable standards. Meanwhile, civil society groups have called on Novartis to drop the suit, emphasising the crucial role that section 3(d) has in India's ability to supply low-cost generic pharmaceuticals.

The Supreme Court is scheduled to resume hearings in August. The Court's ruling will have profound implications for the questions of whether and how countries with newly introduced pharmaceutical patent regimes limit "evergreening" of existing molecules and patent portfolios. Evergreening is a term used to describe the sequential accumulation of secondary patents on drugs, including alternative forms of active ingredients, new formulations,

dosages and uses.

For more information on this topic and the debate around secondary patents, see the complete version of this article, with references, in [Science Express](#) or the 27 July issue of *Science*. The article reviews alternative approaches to combatting evergreening and analyses the Indian approach.

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