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## Novartis vs. the government of India: patents and public health

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In early April, India's Supreme Court rejected an application by the Swiss multinational pharmaceutical company Novartis for a patent on a modified version of the leukemia medication imatinib mesylate.



[1]

Naturally, the outcome of the case affects the affordability of the drug. But the core issue was the right of the Indian government to take account of public health in designing intellectual property rights (IPR) legislation.

In India, Novartis charges about US\$26,000 per patent per year for the drug, marketed as Glivec (Gleevec in the United States). But generic versions produced by local companies are available for less than US\$2,500. Novartis's price excludes all patients except the extremely rich, although the company supplies Glivec for free to some patients. The Indian government and [civil society groups](#) <sup>[2]</sup> see this situation as health policy being held hostage to corporate charity. And to them that is unacceptable.

The Novartis case confirms the right of India's parliament to implement public health safeguards available under the Agreement of Trade-Related Intellectual Property Rights (TRIPS). These include the definition of patentability criteria, the central issue in this case. Such 'flexibilities' mostly revolve around the conditions for market entry of alternative generic brands — the term generic drug refers to a copy of an original product whose patent has expired.

In India, all drugs were generics before 2005 because there were no product patents for

pharmaceuticals. India became fully TRIPS compliant in 2005 through the introduction of pharmaceutical patents, with legislation that included safeguards to protect public health. In particular, section 3(d) of India's Patent Act was included to prevent the extension of patent protection through minor product modifications, unless a 'significant enhancement of efficacy' can be demonstrated.

Novartis took legal action against the Indian government to challenge the constitutionality of section 3(d). When this was rejected, the company sought to have imatinib mesylate recognised as patentable. But it did not even purport to demonstrate enhanced efficacy. Novartis aimed to put a stop to generic competition in the imatinib mesylate market. And it was also attempting to prevent the export of locally produced, more affordable brands to other developing countries. In its judgment, the court determined that imatinib mesylate is not patentable as it 'fails the test of section 3(d)'.

The Supreme Court judgment has given rise to an enormous amount of global commentary. Public health advocates and patients greeted the outcome with great relief. [Médécins Sans Frontières](#) <sup>[3]</sup>, [Joseph Stiglitz](#) <sup>[4]</sup> and [various media outlets](#) <sup>[5]</sup> hailed the decision. They see it as a good precedent for drug affordability in developing countries in general. In contrast, Novartis and fellow corporate giants [such as Pfizer](#) <sup>[6]</sup> reacted with dismay. For example, [Novartis is reported](#) <sup>[7]</sup> to have 'threatened to stop supplying India with new medicines'. This overwrought reaction points to a crisis in their traditional business model. The industry is being reshaped due to issues such as steadily falling R&D productivity and political mobilisations for access to medicines for all.

The Novartis case is important because it highlights that it's no longer acceptable to the global public that hundreds of millions of people are denied access to life-saving drugs because of monopoly pricing. And the case shows that governments in developing countries with some economic and political clout, such as India's, are prepared to fight the big pharmaceutical companies. But Novartis and its peers will not abandon the Indian market in reaction against measures to make drugs more affordable. India is too important an economy and continues to [offer plentiful opportunities](#) <sup>[8]</sup> for international pharmaceutical companies. And Indian firms are large-scale suppliers of low-cost generics to Western markets as well. These firms have an impact on global industry dynamics, and many collaborate with the international companies.

India has changed a lot in regards to its pharmaceuticals market. Between independence in 1947 and the 1970s it was highly dependent on imports of expensive medicines. But between 1970 and 2005 India abolished product patents on medicines. The Indian government also put in place industrial policy measures and public sector research institutions to collaborate with local producers. The result was a strong and vibrant Indian generic industry. The entry of generics lowers prices and widens access to medicines. And it is much more effective in achieving these outcomes than philanthropy or the model of tiered or differential pricing strategies preferred by multinational companies. The patenting of trivial modifications, known as 'evergreening', is one of a host of 'life-cycle management' techniques employed in response to generics competition.

Nevertheless, the Indian government will continue to face challenges from international

pharmaceutical companies seeking to stifle generic competition. [Bayer recently sought to overturn](#) <sup>[9]</sup> a precedent-setting compulsory license on another cancer drug awarded to Hyderabad-based Natco Pharma in 2012. An appeals court in March this year rejected Bayer's application. The Novartis and Bayer cases suggest that India is well placed to defend and extend pharmaceutical and IPR policies aimed at balancing economic development with public health.

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[1] <http://www.eastasiaforum.org/wp-content/uploads/2013/04/novartis.jpg>

[2] civil society groups: <http://www.cpaaindia.org/>

[3] Médecins Sans Frontières:  
<http://www.msf.org/msf/articles/2013/04/indian-supreme-court-delivers-verdict-in-novartis-case.cfm.htm>

[4] Joseph Stiglitz:  
<http://www.project-syndicate.org/print/the-impact-of-the-indian-supreme-court-s-patent-decision-by-joseph-e--stiglitz-and-arjun-jayadev>

[5] various media outlets:  
[http://www.huffingtonpost.com/matthew-kavanagh/drug-patents\\_b\\_3007729.html](http://www.huffingtonpost.com/matthew-kavanagh/drug-patents_b_3007729.html)

[6] such as Pfizer:

<http://online.wsj.com/article/SB10001424127887323296504578395672582230106.html>

[7] Novartis is reported:

<http://www.guardian.co.uk/world/2013/apr/01/novartis-denied-cancer-drug-patent-india>

[8] offer plentiful opportunities:

[http://www.pwc.in/en\\_IN/in/assets/pdfs/pharma/pharma-summit-report-31-10-12.pdf](http://www.pwc.in/en_IN/in/assets/pdfs/pharma/pharma-summit-report-31-10-12.pdf)

[9] Bayer recently sought to overturn:

<http://www.thehindu.com/business/companies/natco-pharma-wins-cancer-drug-case/article4475762.ece>

[10] *School of Humanities and Social Sciences:*

<http://www.deakin.edu.au/arts-ed/shss/staff-directory2.php?username=hvml>