

India court ruling significant for South Africa

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A landmark decision by the Indian Supreme Court to uphold India's Patents Act in the face of the seven-year challenge by pharmaceutical company Novartis has been hailed across the world as a major victory for access to affordable medicines in developing countries.

The ruling, announced on Monday in Delhi, has great significance for South Africa and other countries with high prevalence of HIV and TB, where access to newer and affordable drugs is crucial.

In Khayelitsha almost one in five people (17.4%) on ARV treatment for five years have had to switch to second line regimen, which costs the government over five times more than the first line combination.

The only reason for this price difference is that most second line drugs are still only available from originator companies holding patents. Had Novartis succeeded in India, there would have been no alternatives to brand drugs and drug prices would inevitably go up.

India began granting patents on medicines to comply with international trade rules, but designed its law with safeguards including a clause known as Section 3(d) -that prevent companies from abusing the patent system. Section 3(d) prevents companies from gaining patents on modifications to existing drugs, in order to ever extend monopolies.

The Novartis ruling is critically important for South Africa, as the Department of Trade and Industry (DTI) is currently drafting amendments to the countrys outdated patent laws. South Africas patent system does not include protections like Indias Section 3(d) at all. Instead, South Africa allows companies to easily register patents and extend monopolies through minor drug modifications.

South Africans are missing out on affordable versions of life-saving medicines because generic competition is blocked by frivolous patents that prevent or delay generic competition, said Julia Hill of Mdecins Sans Frontires Access Campaign in Johannesburg.

While India for example avoided patenting cancer medicine imatinib (Gleevec), South Africa granted Novartis an initial patent on imatinib in 1993, which expires this month.

However, secondary patents granted by South Africa, including one on imatinib mesylate salts, extend Novartis monopoly until 2022. As a result, treating a patient with imatinib for a year in South Africa costs \$33,896 (R312,234) - 259 times more expensive than the least expensive Indian generic alternative.

MSF said South Africa could implement similar rules to India without violating international trade rules.

As South Africa's new patent law is drafted, including provisions similar to India's Section 3(d), and implementing a patent examination system will better ensure small changes to existing medicines do not warrant new patents that keep them out of reach of those in need. MSF urges South Africa to follow India's lead. By developing a strong legal framework, South Africa could better guarantee affordable access to life-saving medicines, Hill said.

Novartis first took the Indian government to court in 2006 over its 2005 Patents Act because it wanted a more extensive granting of patent protection for its products than offered by Indian law.

Novartis had been refused a patent for Gleevec, on the grounds that the medicine was simply a new form of an old medicine with a trivial change, something which cannot be patented under Indian law.

Novartis was not only seeking to overturn this decision but also to challenge the law itself and the way in which India has implemented international trade rules on intellectual property.

In other countries where Novartis has obtained a patent for Gleevec, it is sold at US\$2,600 per patient per month. In India generic versions of the drug are sold for less than US\$200 per patient per month.

[See the topic on aegis.org](http://aegis.org)