

# India's Patent Act on Trial

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In May 2006, Novartis challenged India's standard for patentability of an invention as being unconstitutional and not in compliance with the WTO's TRIPS Agreement. The outcome of the case is likely to have major implications for many developing countries.

The challenge is significant on two counts. The key issue in the case goes to the root of how flexible TRIPS is when countries attempt to set stricter patent standards for the purpose of safeguarding public health, socio-economic and technological development. The other issue of note is that the challenge against a Member state's implementation of TRIPS was brought by a non-state actor in a domestic court rather than at the WTO.

## Background

On 1 January 2005, India was required to come into compliance with the TRIPS obligation to introduce patent protection for pharmaceutical products. One of the key issues during the legislative process on creating a TRIPS-compatible patent regime was the 'evergreening' of pharmaceutical product inventions and its potential impact on affordable access to medicines. After intense debate, the Indian government elected to set out a stricter standard of patentability than international norms: under Section 3(d) of the Patents Act, the mere discovery of a new form of a known substance would not be considered an invention unless a significant difference in properties – resulting in an enhancement of efficacy over the known substance – could be shown (see box).

Despite the legislative debate in Parliament, the application and scope of the newly established S3(d) was not defined. That task was left to the Indian Patent Office in Chennai. The opportunity to put the provision into practice duly arose following pre-grant oppositions<sup>1</sup> filed by generic companies and a cancer patients group against Novartis's patent application for the leukemia drug Gleevec/Glivec. Novartis's application was rejected on the grounds that the claimed subject matter was anticipated and obvious in the light of prior art, but also because it was only a new form of known substance which did not show any enhancement of efficacy.

## The Novartis Claim

Novartis has not only challenged the patent office's decision; it has also taken the bold step of challenging the validity of S3(d) in the face of the TRIPS Agreement and the Indian Constitution. Its main contention is that the provision flouts the requirements of TRIPS Article 27, which Novartis believes requires Members to provide uniform standards of patentability without discrimination as to the subject matter. In addition, Novartis is claiming that S3(d) is unworkable and ambiguous as the Act not only fails to define what amounts to efficacy, but also that discoveries of new forms of known substances require human intervention and an inventive step.<sup>2</sup> Accordingly, such new forms are inventions and should not be subjected to a test of efficacy.

### Section 3 of the Indian Patents Act

The following are not inventions within the meaning of this Act:

Section 3(d): *'The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one reactant.'*

*'Explanation – For the purpose of this clause salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance unless they differ significantly in properties with regard to efficacy.'*

## A Valid Challenge?

Novartis's decision to challenge the validity of S3(d) and India's right to use the Article 27 ambiguities when defining what is an invention is questionable. Although TRIPS provides minimum standards for the criteria Member countries must meet in determining the patentability of a product, its negotiation history suggests that they are not required to create uniform and harmonised patent regimes. The lack of a definition of what an invention is for the purpose of TRIPS compliance suggests that Members have some degree of flexibility for defining the term. Indeed, varying standards already exist for the granting of patents in WTO Member countries.

More significantly, the argument that S3(d) discriminates against subject matter and is not TRIPS compliant is also misleading. When read closely, S3(d) not only permits the granting of pharmaceutical product patents, but also new forms of known substances provided the required standard of efficacy can be shown. The fact that Novartis has chosen to cite the recent report of the government-appointed Technical Expert Group on Patent Law Issues, otherwise known as the Mashelkar Committee, as support for its case against S3(d) is to misunderstand the ambit and findings of the report.<sup>3</sup> The committee was asked to determine whether, in addition to S3(d), it would be TRIPS compliant to limit the grant of patents for pharmaceutical substances only to new chemical/medical entities involving one or more inventive steps.

However, where Novartis's challenge may succeed is in helping to interpret and set the standard for determining what amounts to a 'significant difference in properties with regard to efficacy' and an 'enhancement of efficacy'. The provision currently lacks any guidelines from the patent office.

It also remains to be seen whether the High Court of Chennai has the authority to de-

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cide on S3(d)'s compliance with TRIPS and suggest its removal or re-drafting. Novartis could be told that Indian courts are not the appropriate forum for challenging India's implementation of TRIPS. However, that could leave private actors like Novartis in the cold as the WTO's dispute settlement procedures are designed only for Members to bring actions against other Members.

### The Potential Impact

Following the challenge, the future of S3(d) is uncertain and it could be some time yet before its fate is decided, most likely by the Indian Supreme Court. However, the outcome of the case could impact more than just one provision in the Patents Act.

Should Novartis succeed, the removal of S3(d) could have a significant impact on how patents are granted for pharmaceutical products in India given that many of the mailbox applications and indeed pharmaceutical products being filed for today, including by Novartis<sup>4</sup>, are salts, esters, polymorphs, derivatives and combinations of known substances. As a result, any change in the law could also weaken the pre-grant opposition procedure. This would inevitably lead to a number of potentially non-meritorious patents on essential medicines being patented and the decline of affordable generics for such products.

A decision in favour of Novartis would also raise the question of whether Novartis will then allow companies that were already producing generic versions of Gleevec prior to 1 January 2005 to continue provided they pay a reasonable royalty as permitted under Section 11A(7). Or will Novartis seek to challenge this provision as well?

It would also send a warning to other developed and developing countries, such as the Philippines, which might be seeking to rely on S3(d) as a model for the implementation of more public health-friendly patent laws.<sup>5</sup>

On the other hand, if the Indian courts reject Novartis's challenge and provide guidance on how S3(d) should be interpreted in light of the Parliament's intention for the provision, it could spell the beginning of a change in an ailing patent system and a flexible TRIPS Agreement.

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### ENDNOTES

<sup>1</sup> Section 25(1) of the Indian Patents Act permits any person to submit a representation of opposition anytime before the granting of a patent on the grounds of novelty, inventive steps and exclusions from patentability, including S3(d).

<sup>2</sup> The patent office held that an increase in 30 percent bioavailability over the free base imatinib did not meet the requirement of efficacy. However, the Patent Controller omitted his reasons from the decision as to why this was the case. As a result Novartis has also challenged the Indian Patent Office's interpretation of efficacy.

<sup>3</sup> The report of the Technical Expert Group – set up to answer two questions raised in the legislative amendment debate, one being the limiting of patents to new chemical entities – has been much criticised for its lack of reasoning and analysis of submissions made by various experts on why TRIPS Article 27 could be interpreted as allowing patents to be granted only to new chemical entities.

<sup>4</sup> For pending patent applications published for opposition and grant by the Indian Patent Office, see <http://india.bigpatents.org/>

<sup>5</sup> The Philippines is currently debating an amendment to its patent laws and has included a mirror provision of S3(d) in its draft.

## Novartis Under Pressure

The dispute has aroused intense interest worldwide. More than 300,000 people have signed a petition urging Novartis to drop the case. The People Before Patents campaign led by the Nobel Peace winner Médecins sans Frontières emphasises that millions of people around the world rely on affordable medicines produced in India. Among the signatories are Archbishop Emeritus Desmond Tutu, former UN Special Envoy for HIV/AIDS in Africa Stephen Lewis and Dr Michel Kazatchkine, the new head of the Global Fund to Fight AIDS, Tuberculosis and Malaria. Former Swiss President Ruth Dreifuss, who chaired the 2004-2006 WHO Commission on Intellectual Property Rights, Innovation and Public Health, has called on Novartis to discard the wider challenge against Section 3(d) and focus court action on just determining whether the Glivec patent does in fact fulfil recognised criteria for patentability. Five members of the European Parliament have issued a declaration calling on the European Commission to request Novartis to withdraw its complaint. EU Trade Commissioner Mandelson said the Commission was following the case closely and would take a position should that become necessary.

Novartis, on the other hand, argues that the dispute is not about generics versus patents, but about the reasons why “a patent for Glivec – granted in nearly 40 countries, including China – was denied in India in 2006.” Novartis claims that 99 percent of the people treated by Glivec in India receive it free from the company, and that generic versions of the drug would “remain on the market in India regardless of the outcome of this legal action.” The company insists it fully supports the flexibilities that now exist for granting compulsory licenses for public health reasons, and poor countries' right to import generics manufactured in another country under compulsory license. Nevertheless, Novartis maintains that patent protection is essential to create incentives for the development of innovative medicines, and “that Indian patent laws do not comply with the intellectual property standards the country agreed to when it joined the WTO in 1995.”