

Questions & answers

1. What is happening with the legal challenge?

The High Court in Chennai dismissed the writ petition challenging the constitutionality of Section 3(d), and deferred to the World Trade Organization (WTO) forum to resolve the TRIPS compliance question.

In the separate Glivec patent appeal, Novartis petitioned the High Court in Chennai for a new technical member of the Intellectual Property Appellate Board (IPAB). We disagreed with the appointment of the former Controller General of the Indian Patent Office to the IPAB. The High Court accepted the approach put forth by the Government of India suggesting that the Glivec patent appeal be heard at the Intellectual Property Appellate Board by a two member Bench comprising a Chairman and Vice Chairman, instead of the official three-member panel structure. The Court ruled that the Chairman could also act as a technical member of the Bench. IPAB hearings continue. We expect the opportunity to have our case heard by an impartial board, Glivec – our life-saving drug for cancer, which is patented in nearly 40 countries – should be granted a patent in India.

2. What is the Appellate Board?

The Intellectual Property Appellate Board (IPAB) will hear appeals from most of the decisions, orders or directions made by the Patent Controller under the Indian patent law.

The Patents Amendment Act of 2002 introduced the IPAB, and it became operational on April 2, 2007. All members of the board are appointed by the Indian Government. The Government of India formed this IPAB for patent matters a few weeks before the High Court in Chennai was set to render a decision on the appeal concerning the rejection of the Glivec patent.

3. How does the move to the IPAB impact your case?

We expect the IPAB to conduct an independent and impartial review of our Glivec patent appeal and to ensure transparency in the decision-making process..

4. Why was the patent for Glivec rejected?

Although Glivec / Gleevec has been awarded a patent for the beta crystal form in nearly 40 other countries, including China, the Indian Patent Office said the application did not satisfy its requirements for "novelty and inventive step."

A section of the Indian patent law introduced a new "improved efficacy" hurdle for patentability for new forms of known compounds. Glivec / Gleevec, a life-saving drug for cancer, is one of the medical breakthroughs of the 20th century.

5. Are you trying to extend patent protection for a new version of Glivec?

No, we are not trying to extend the patent for Glivec. No patent exists in India for Glivec because India did not have patent laws allowing patents for pharmaceutical products when we filed for the Glivec patent throughout the rest of the world. The beta crystal form – the form under discussion in India – is the only form of Glivec that Novartis has marketed worldwide.

6. Why is Novartis pursuing the case?

We are seeking clarity. Knowing we can rely on patents in India benefits government, industry and patients because research-based organizations will know if investing in the development of better medicines there is a viable long-term option.

Novartis requests that the patent for Glivec / Gleevec is granted in India and that hurdles to recognizing genuine innovation are removed from the Indian patent law. In its current form, the patent law in India does not protect incremental innovation and does not recognize that incremental innovation provides benefits beyond enhanced efficacy.

At Novartis, we firmly believe that patents save lives by stimulating research, leading to innovative medicines. We commend the progress India has made in advancing intellectual property rights, but more needs to be done to align this increasingly important industrial country with international standards.

7. Why is incremental innovation so important?

Incremental innovation provides benefits beyond enhanced efficacy in terms of patient safety and compliance, manufacturing efficiency (effecting product cost), and product stability during storage and transport. For example, if an insulin pill were developed, it would be an incremental innovation on current insulin injections. In spite of incredible value for patients, this innovation might not be patentable in India under Section 3(d). Although it would meet the 'inventive step' requirement, it might not pass the 'enhanced efficacy' hurdle in Indian law.

Breakthrough innovations are rare in medical research. Incremental innovation, therefore, is hardly incremental – in the pharmaceutical industry, it is the major means for improving medicines and benefits patients worldwide. As it stands, Section 3(d) will exclude these important developments – developments that could be a component of the next stage of economic growth for pharmaceutical research and development in India..

8. Are you just trying to sell more Glivec in India?

No. There is no market for Glivec / Gleevec in India. In fact, in India, 99% of patients who receive Glivec / Gleevec receive it free from Novartis through the Glivec International Patient Assistance Program (GIPAP).

9. What is GIPAP?

When we launched Glivec, Novartis committed that no patient in need should be denied this life-saving cancer treatment. We fulfilled this commitment by establishing the Glivec International Patient Assistance Program (GIPAP), which is one of the most far-reaching patient assistance programs ever implemented on a global scale.

- In India, Novartis currently provides Glivec at no cost to more than 6 700 diagnosed patients.
- GIPAP is accessible for patients who are properly diagnosed, not covered by local reimbursement or insurance, and have no other financial resources.
- In India, there are 87 registered physicians throughout the country in leading hospitals and institutions working with GIPAP.
- GIPAP also provides patients with access to support groups, treatment/disease information and education, and emotional support through partners.

For more information, please visit the program administrator, the Max Foundation, at <http://www.themaxfoundation.org>.

10. How long do patients receive Glivec for free through GIPAP?

Patients in GIPAP receive Glivec completely free from Novartis for as long as they need it. It is completely untrue that patients receive Glivec free for only one or two months.

To hear what patients and physicians think of GIPAP, please see [patient and physician stories](#)

11. If Novartis isn't making any money from Glivec in India, then why pursue the case?

This is about safeguarding incentives for better medicines so that patients' needs will be met in the future. History has shown that patents save lives by stimulating research which leads to innovative medicines. With effective patent laws, companies continue to bring improvements and innovations to patients and societies.

12. Are you trying to block generics?

No. It is important to know that generic versions of Glivec / Gleevec will remain on the market regardless of the outcome of our case. Even our critics, however, recognize that generic versions of Glivec / Gleevec are not the solution for the poor in India because the cost of a year of treatment is four to five times the average annual income. Furthermore, generic makers in India have yet to come forward with an access program for generic Glivec / Gleevec. Clearly generics alone do not solve the issue of access.

As a manufacturer of generics, Novartis understands and recognizes the contribution of generics once drug patents expire; our concern is with the non-recognition of intellectual property rights that ultimately help sustain and advance pharmaceutical research and development.

13. Why is changing the Indian Patent Law so important to Novartis?

Protecting innovation is the foundation for massive R&D investments made by the pharmaceuticals industry that are vital to medical progress. For a research-based company such as Novartis, patents are not negotiable. Patents save lives by stimulating research and development of new and better medicines for patients and societies. Aligning Section 3(d) with minimum international standards would not hinder the supply of medicines to poor countries. Provisions in international trade agreements allow for export of medicines produced under compulsory licenses that are issued for public health reasons. These provisions have been put in place to safeguard access to medicines to poor countries that do not have sufficient local production capacity. Novartis fully supports these provisions and our case regarding Section 3(d) didn't challenge them.