

Improving Indian patent law benefits patients and societies

We have received concerns regarding our ongoing legal challenge against one provision of the Indian Patent Act, following the denial of the patent for our ground-breaking cancer treatment Glivec®/Gleevec®. We have heard these and want to clarify our perspective.

In India, Novartis is faced with a **globalization dilemma** that characterizes many emerging economic powers today: **two markets within one country**. India has a booming middle class on one hand, and a vast number of extremely poor people on the other.

In order to make responsible business decisions, we have carefully considered the following aspects in our thinking:

- Access to our cancer treatment Glivec in India and globally
- India as an emerging growth market and global competitor
- India's current role in supplying medicines to the developing world

As a result, in India, we are pursuing a dual, **patient-focused strategy**. We are aware of the many obstacles poor patients face regarding access to medical care there, and that is why **99% of patients** who receive Glivec in India **receive it free from Novartis**. At the same time, we take affluent India seriously as a formidable world power with all the international rights and obligations that such status brings with it. We seek to establish effective protection for genuine pharmaceutical innovation in India.

Our actions in India do not hinder the supply of medicines to poor countries given the international safeguards now in place. The decision to acknowledge innovation by granting a patent is unrelated to the access to medicines issue. Instead, improving access to medicines is a matter of making medicines available in a complex environment.

At Novartis, we firmly believe that **patents save lives by stimulating research** that leads to innovative medicines. Only with effective patent laws can we continue to bring therapeutic improvements to patients that ultimately result in better patient care.

We are **seeking clarity about India's patent laws**. Knowing if we can rely on patents in India is good for government, industry and patients because research-based organizations will know if investing in better medicines for India is a viable long-term option. We believe that limiting patents to new chemical entities only does not recognize genuine innovation that is necessary to create better medicines. Medical progress happens through steps in innovation, also called incremental innovation.

Novartis requests that the patent for Glivec is granted in India and that hurdles to recognizing genuine innovation in the Indian patent law are removed.

In the following, we outline our approach in more detail:

Novartis has secured access to Glivec both in India and globally

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 7000 diagnosed patients. Glivec treats two rare cancers: chronic myeloid leukemia (CML) and gastrointestinal stromal tumors (GIST). GIPAP covers every person in India who is prescribed Glivec and cannot afford this life-saving medicine. For more information, please visit the Max Foundation which administers the program, www.themaxfoundation.org.

Glivec is not an exception. As a matter of business principle, Novartis is deeply concerned that patients have access to the medicines they need, as demonstrated by our well-regarded record in social responsibility.

In 2006, our access-to-medicines programs reached 33.6 million patients. Novartis spent more than one billion Swiss francs last year alone on programs and research. We seek to move beyond philanthropy to develop new business models. That is why we engage in many innovative public-private partnerships with efforts spanning a number of disease areas, including our partnerships with WHO to combat leprosy, malaria and tuberculosis. Novartis also established an Institute for Tropical Diseases in Singapore dedicated entirely to drug discovery for neglected diseases.

We take India seriously as an emerging growth market and global competitor

While we are committed to access to Glivec, it is clear that we seek business opportunities in India's growing economy. We also compete with Indian companies globally in attractive markets, and the export of copies of our products into richer countries is a major concern to us.

Protecting innovation is the foundation for massive R&D investments made by the pharmaceuticals industry that are vital to medical progress. Companies can continue to bring improvements and innovations to patients and societies only with effective patent laws. For a research-based company such as Novartis, patents are not negotiable.

Glivec is a tremendous innovation and this is widely recognized throughout the scientific community; it has received numerous awards for innovation. Glivec has been awarded a patent in nearly 40 other countries, including China and Russia. The journey of Glivec through the patent process in India illustrates the difficulties faced in a country in transition. The Indian patent law creates new hurdles for pharmaceutical innovation, unjustifiably and illegally narrowing what is patentable.

Section 3(d) of the Indian patent law will limit pharmaceutical research and development in India because it limits the ability to patent incremental innovation. 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.

Respect for intellectual property will strengthen, not weaken, the Indian economy, helping India reach its aspiration of becoming a pharmaceutical powerhouse. Incremental innovation is exactly the area where local Indian companies have made first steps into research and development and registered patents worldwide. Indeed, Indian companies have agreed with our request to remove Section 3(d) from the Indian Patent Law.

Our actions in India do not hinder the supply of medicines to the poor

We are contesting the provision of Indian Patent Law that has led to the rejection of the Glivec patent in India. Our case does not challenge provisions that provide for access under international trade agreements, specifically the TRIPS agreement (trade-related aspects of international property rights) and the Doha Declaration. These flexibilities allow production for export under compulsory licenses that have been issued for public health reasons. They have been put in place to allow poor countries that do not have sufficient local production capacity to safeguard access to medicines. In fact, political agreement on the Doha flexibilities has been reached in order to mitigate the impact of TRIPS implementation in India. Also, other flexibilities within the Indian Patent Law (called the "grandfather clause") mean that generic versions of patented drugs on the market before 2005 will remain on the market.

Sustainable access to medicines in developing countries is complex and requires much more than the availability of generic drugs. Generics alone do not solve the issue. For example, in India the cost of a one year treatment with generic imatinib (the compound in Glivec) is USD 2100, or 4.5 times the average annual income. Even our critics recognize that generic versions of Glivec are not the solution for the poor in India.

Acknowledging innovation by granting a patent is unrelated to the access to medicines issue. Improving access to medicines is a matter of making medicines available. Medicines can be made available through access safeguards in international agreements and, in the case of essential and life-saving medicines, special pricing arrangements in developing countries can, and must, be made.

Access to medicines in the developing world is a complex problem in which medicine prices and intellectual property rights are but two pieces of the puzzle. A range of underlying or related issues such as appropriate infrastructure and distribution networks must be addressed in parallel. This can only be achieved through the collaboration of all involved stakeholders working together to ensure that patients in need receive proper care. We seek an open dialogue with all groups, one based on mutual trust and tolerance with the aim of long-term success – not only in access-to-medicines initiatives but also in day-to-day business activities.

Thank you for reading this perspective. For more information about this legal challenge, please see our [India Glivec information center](#). To read about our extensive corporate responsibility and patient access programs, please visit Citizenship@Novartis.