What is Glivec® and why is it important?

Glivec (imatinib mesylate) has been widely recognized as one of the major medical breakthroughs of the 20th century and has revolutionized the way specific cancers are treated. Glivec is approved for ten indications to treat all phases of Philadelphia-positive chronic myeloid leukemia (Ph+ CML), metastatic and/or unresectable (inoperable) KIT (CD117)-positive gastrointestinal stromal tumors (KIT+ GIST), as well as other rare cancers.

What is the Glivec case?

On 10 August 2009, Novartis filed a Special Leave Petition (SLP) with the Indian Supreme Court challenging the decision of the Indian Intellectual Property Appellate Board (IPAB) to uphold the 2006 denial of the Glivec beta crystal patent by the Indian Patent Office. On 4 February 2011, the Indian Supreme Court agreed to allow Novartis to present the merits of our case and we are currently awaiting the ruling.

Glivec has been awarded patents in nearly 40 other countries, including China, Russia and Taiwan, but the IPAB is denying one for India. The IPAB acknowledges that Glivec satisfies the international requirements for novelty and inventiveness, but it does not find Glivec to meet the requirement under Section 3(d) of the Indian Patents Act of 2005. This act introduced a new efficacy enhancement hurdle for patenting new forms of known compounds. We believe that Section 3(d), the Indian legal paragraph intended as a hurdle for evergreening, should not be applicable to the breakthrough medicine Glivec, which has changed the lives of patients with rare cancers.

The misconception regarding the innovation of Glivec is based on a patent that was granted in 1993 (not in India) for the synthesis of the molecule imatinib. This molecule, without further development, could not safely be administered to patients and represented only the first step in the process to develop Glivec as a viable treatment for cancer. We selected the mesylate salt of imatinib and then developed the beta crystal form of imatinib mesylate to make it suitable for patients to take in a pill form that would deliver consistent, safe and effective levels of medicine. The research and development process (R&D), which took years, created more than just an incremental improvement it was a breakthrough, life-saving cancer medicine.

How will the outcome of the Glivec case impact access to essential medicines?

The outcome of the case will not hinder the supply of essential medicines because international trade agreements include safeguards to ensure patient access. Novartis’ legal case does not challenge these safeguards, but even with them in place and 98% of the World Health Organization’s (WHO) essential drugs available at off-patent prices, more than a third of the world population still lacks access due to political, economic and logistical barriers. Furthermore, currently available generic drugs launched in India before 2005 including HIV/AIDS medicines and generic versions of Glivec will continue to be available regardless of the legal outcome of the case.

As a leader in both innovative and generic medicines, Novartis strongly supports the contribution of generics to improving public health once drug patents expire, but also recognizes that many patients need further assistance to gain access to the medicines they need. Novartis’ GIPAP program, in collaboration with the Max Foundation and Axios, is currently helping more than 31,000 patients in 80 countries, and more than 16,000 patients in India (more than 95% of the Glivec patients in India) receive the medicine free of charge through this program. More than 37,000 patients have been helped through GIPAP since the program began in 2002. In addition, Novartis designed an expanded new access program for eligible Glivec patients in India. The program, Novartis Oncology Access (NOA), provides access to Glivec for patients in India who can afford to contribute some (but not all) of the cost of their annual treatment, as well as those who cannot afford to pay anything.
How will the outcome of the Glivec case impact medical progress?

The Glivec case will provide further clarity on what is considered innovative and what innovations warrant protection in India. The case will ultimately set an industry precedent as to whether pharmaceutical companies will be able to invest in R&D in innovative medicines for India and will determine whether or not innovation will be fostered in light of India's patent law.

The Glivec case raises important issues that are essential to the future of intellectual property law and the innovative pharmaceutical business in India. The ability to rely on patents in India benefits government, industry and patients alike because research-based organizations will know if investing in the development of better medicines for patients in India is a viable and sustainable long-term option.

Breakthrough innovations are rare in medical research. In the pharmaceutical industry incremental innovation 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.

At Novartis, we firmly believe that patents save lives by stimulating research that leads to innovative medicines for patients in need. 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.

References


