



## **History of Glivec in India**

Glivec has helped oncology patients, their families and physicians in India since 2002. The timeline below tells the story of Glivec in India.

**1993:** The base compound of Glivec, imatinib, is patented worldwide. There is no patent filed in India at this time, as India does not have patent laws for pharmaceutical products. Imatinib is a research substance that cannot be taken by patients, and only the first step in the development process of Glivec.

**1995:** India joins the World Trade Organization (WTO) and begins its mandated 10-year transition period to bring its patent laws into alignment with TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights).

**JULY 1998:** Novartis files a mailbox application in India for imatinib mesylate in crystalline form, the active ingredient of Glivec, in accordance with India's provisions for obtaining patents.

**DECEMBER 2001:** Novartis obtains marketing approval for Glivec in India prior to the drug's launch.

**APRIL 2002:** Glivec launches in India. Novartis receives numerous scientific awards in recognition of Glivec's innovation in cancer treatment, including:

- International Prix Galien Innovative Drug Award
- Intellectual Property Law Association Award
- Warren Alpert Foundation Prize from the Warren Alpert Foundation

**SEPTEMBER 2002:** Novartis launches the Glivec International Patient Assistance Program (GIPAP) in India. GIPAP is one of the most far-reaching cancer patient assistance programs ever implemented on a global scale.

**NOVEMBER 2003:** Novartis is awarded Exclusive Marketing Rights (EMR) for Glivec, marking the first time a pharmaceutical firm is granted an EMR in India. The EMR protects the beta crystal form of the drug for five years, or until the review of the mailbox application. Prior to Novartis receiving the EMR, nine Indian companies obtain approval for commercializing copies of Glivec. Novartis asks that the EMR be enforced; three companies are allowed to continue. Before obtaining the EMR and with copies of Glivec on the market, GIPAP continues with currently enrolled patients, but temporarily stops accepting new patients in India and reopens again when the EMR is granted.

**APRIL 2005:** The Indian Patents Amendment Act of 2005 is enacted, introducing product patents for pharmaceuticals to fulfill India's obligation to WTO/TRIPS.

**JANUARY 2006:** Novartis is denied a patent for Glivec under Section 3(d) of the Indian Patents Act 2005, which introduced a new "improved efficacy" hurdle for patentability of new forms of known compounds. The Indian Patent Office contends that Glivec does not satisfy the requirements of novelty and inventiveness. This rejection automatically terminates the EMR.

**AUGUST 2006:** Novartis challenges the January 2006 ruling by the patent office denying its application for Glivec on the grounds that the ruling lacks legal or factual basis and justification.

Novartis asks the High Court of Chennai to declare Section 3(d) unconstitutional and in breach of India's obligation under TRIPS.

**DECEMBER 2006:** The number of current GIPAP patients in India reaches 6 700, representing 99% of Indian patients taking Glivec.

**FEBRUARY 11, 2007:** GIPAP patients, physicians and caregivers gather at a meeting in Kolkata, organized by the Max Foundation, to show their support for Novartis.

**FEBRUARY 13, 2007:** Patients arrive at Novartis offices in Mumbai to present banner of support with hundreds of signatures from Indian patients and their families and physicians.

**FEBRUARY 23, 2007:** The court agrees with the Novartis request to convert one part of its case – the challenge to the patent office's decision to not grant a patent for Glivec – from a writ petition to an appeal. This allows the court to review data and evidence about the effectiveness of Glivec. To date, Glivec is patented in nearly 40 countries, including China, Russia and Taiwan.

**MARCH 2007:** The Max Foundation's "I am alive and living with dignity" petition in support of Novartis exceeds 5 300 signatures. GIPAP reaches 22 000 patients around the world. An average of 200 patients are added to the program in India each month.

**MARCH 5-6, 2007:** The court hears matters relating to the conversion of the writ petition into an appeal, and the Chief Justice announces that the Glivec appeal will be heard by the existing bench.

**APRIL 2, 2007:** The Intellectual Property Appellate Board (IPAB) becomes operational for patent review in India. The newly-appointed technical member of the appellate board is the former Controller General of the Indian Patent Office, who was responsible for the original decision on the Glivec patent in 2006 and is acting as a party in the current Court case.

**APRIL 3, 2007:** The High Court in Chennai determined that our appeals matter on the Glivec patent should be heard by the newly-operational Intellectual Property Appellate Board (IPAB) in India.

- **High Court / Section 3(d) Matter**

**APRIL 2007:** Arguments on the Section 3(d) matter have closed, and the writ petition is still under deliberation in the High Court in Chennai.

**AUGUST 6, 2007:** The High Court dismisses challenge on constitutionality and defers to WTO to resolve question on compliance with TRIPS.

- **IPAB / Glivec patent review**

**APRIL 2007:** Mr. Chandrasekaran – the former Controller General of the patent office – is appointed technical member of the IPAB.

**JULY 2007:** Novartis petitions the High Court for a new technical member.

**OCTOBER 2007:** Government of India suggests a revised approach consisting of a two-member review panel.

**NOVEMBER 13, 2007:** High Court accepts the approach put forward by the Government of India.

**DECEMBER 2007:** Natco appeals against decision before the Supreme Court.