

Supreme Court denial of Glivec patent discourages future innovation in India

01 April 2013 | News | By BioSpectrum Bureau

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A decision issued by the Indian Supreme Court regarding the Novartis breakthrough medicine Glivec (imatinib mesylate) provides clarification on Indian patent law and discourages innovative drug discovery essential to advancing medical science for patients.

The Supreme Court denied an appeal challenging the rejection of a patent for Glivec, a life-saving medicine for certain forms of cancer, patented in nearly 40 countries including China, Russia, and Taiwan. Novartis filed a Special Leave Petition with the Indian Supreme Court in 2009 challenging the denial of the Glivec beta crystal form patent on two grounds, based on Sections 3(d) and 3(b) of the Indian patent law. In addition to seeking a patent for Glivec, the company filed the case to help clarify these unique aspects of the patent law.

Reacting to the Supreme Court's verdict, Mr Ranjit Shahani, Vice Chairman and Managing Director, Novartis India said, "Novartis has never been granted an original patent for Glivec in India. We strongly believe that original innovation should be recognized in patents to encourage investment in medical innovation especially for unmet medical needs. We brought this case because we strongly believe patents safeguard innovation and encourage medical progress, particularly for unmet medical needs. This ruling is a setback for patients that will hinder medical progress for diseases without effective treatment options."

The primary concern of this case was with India's growing non-recognition of intellectual property rights that sustain research and development for innovative medicines. As a leader in both innovative and generic medicines, Novartis strongly supports the contribution of generics to improving public health once drug patents expire.

Novartis maintained that it remains committed to patients and access to medicine. Through its full donation programs, Novartis provides Glivec free of charge to 95 percent of patients prescribed the drug in India, currently more than 16,000 patients. The remaining 5 percent of patients are either reimbursed, insured, or participate in a very generous co-pay program. Since Novartis began its first donation program in 2002, the company has provided more than \$ 1.7 billion worth of

Glivec to patients in India.