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ARCHIVES

March 2007

February 2007

January 2007

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November 2006

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September 2006

Email the editor

Intellectual Property In India: Novartis Gleevec Patent Battle Will Go On Without Government Document Supporting "Evergreening" (Part 1 of 3)

Accusations from India's generic drug makers that a government commission report used the same wording as a research paper funded by brand-name drug manufacturers have thrown a wrench in Novartis' plans to use the report's findings to strengthen its court case challenging the Indian government's denial of a patent for a beta-crystalline form of **Gleevec**, known as **Glivec** in India.

In an effort to establish patent rights for its chronic myeloid leukemia drug imatinib mesylate in India, Swiss drug giant Novartis has taken on the Indian government and several generic drug manufacturers, challenging that an amendment to the Indian Patent Act of 1970 violates the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights TRIPS agreements. The particular amendment to the patent law, Section 3(d), forbids the patenting of derivative forms of known substances, unless the new product shows it is substantially more efficacious than the original formulation.

The case is pending before the Madras High Court, with hearings scheduled to resume March 26.

The report Novartis had hoped to use in support of its suit was created in response to a debate in the Indian Parliament regarding amendments to existing patent laws.

In becoming TRIPS compliant in June 2005, India reinstated product patents, making "reverse engineering" and copying Western drugs illegal for products patented after 1995. That same year, Parliament convened an expert panel to examine whether granting intellectual property protection only to new chemical entities or to new medical entities "involving one or more inventive steps" and denying patents for microorganisms would be compatible with TRIPS. In February, the committee, headed by R.A. Mashelkar, former director general of India's Council of Scientific and Industrial Research, issued its report, which found limiting patents to NCEs would not be TRIPS compliant.

Following the report's release, Paul Herrling, head of corporate research at Novartis, told *"The Pink Sheet" DAILY* that "the report of the commission, the way we read it, actually supports our view, that the amendments were not compatible with the TRIPS agreement."

However, India's left-leaning parties and generic drug manufacturers questioned the integrity of the

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China State Food And Drug Administration

India Central Drugs Standard Control Organization

Japan Ministry of Health, Labour And Wealthfare

Japan Pharmaceuticals and Medical Device Agency

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