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Intellectual Property In India: Novartis Gleevec Suit Is First Challenge To Law Restricting New Formulation Patents (Part 2 of 3)

Novartis' lawsuit to gain a patent for a new formulation of **Gleevec** is the first legal challenge to Section 3(d) of the Indian Patent Act, which seeks to bar "evergreening" by restricting patents for minor improvements to old formulations.

Under the provision, derivative formulations must be significantly more efficacious than the original formulation. What constitutes "efficacy," however, is not defined in the statute, leaving room for inconsistencies and subjectivity in the patent controller's decisions.

The Indian Patent Office in January 2006 rejected Novartis' patent for a beta-crystalline form of imatinib mesylate, reasoning that it did not meet the requirements under Section 3(d), since the beta-crystalline formulation did not show sufficient efficacy improvement over the original free base form of the drug filed prior to 1995.

In May, Novartis filed writ petitions in the Madras High Court against the Indian government and generic manufacturers Cipla, Natco, Sun Pharma and Ranbaxy, challenging the patent controller's decision to deny its patent application, and alleging that Section 3(d) of the Indian Patent Act was vague, ambiguous, and contrary to the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement.

Under TRIPS, "any invention" that is new and involves an "inventive step" may be patented. Since TRIPS does not define what is an "inventive step," there is disagreement as to how much flexibility WTO member nations have to adjust the regulations to reflect socio-economic realities on the ground.

In 2001, 142 nations, among them the United States, signed the "Declaration on the TRIPS Agreement and Public Health," which stated that intellectual property regulations "can and should be interpreted and implemented in a manner supportive of WTO Member's rights to protect public health, and in particular, to promote access to medicines for all."

Novartis contends that India's interpretation of the law is too strict and violates Article 14 of the Indian Constitution which ensures equality and prohibits discrimination. Meanwhile, Indian generic drug firms contend that India has a right to implement provisions under Section 3(d) in line with its public health needs, and that the provision does not restrict innovation, but simply holds a higher bar for incremental improvements.

However, the patent statute's singular focus on

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