Novartis's Second Bite at the Section 3(d) Apple

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Access to medicines activists might still be confused about why Novartis is getting a second chance to attack India's strict patenting standards reflected in Section 3(d) of its 2005 Amended Patents Act. After all, Novartis lost a decisive lawsuit in 2007 when it unsuccessfully challenged the constitutionality of Section 3(d) and its compliance with the WTO TRIPS Agreement, which establishes global norms for minimum standards of intellectual property rights and their enforcement. The Madras High Court basically threw Novartis's case out by the seat of its pants in August of 2007, holding that Section 3(d) was rational and a constitutional exercise of legislative authority by the India Parliament.

However, in addition to firing a legal canon directly at Section 3(d), Novartis has also pursued a second case arguing for two legal principles: (1) that the "enhancement of efficacy" standard in Section 3(d) is a light-weight provision that should do little rein in the practice of evergreening a patent by making minor improvements to an existing medicine, and (2) that Novartis's blockbuster cancer medicine, Glivec, satisfies the light-weight standard because the beta-crystalline form of imatinib mesylate (the active ingredient of Glivec) is 30% more bioavailable than imatinib myselate which was patented in 1993 in the U.S.

Most credible experts in the field of pharmacology would argue that that finding a more active specific crystalline form of a salt form of a known compound is not high art, but rather a routine discovery. It is on this ground that the Patent Controller of Chennai issued a lucid decision finding that the Glivec patent application lacked novelty, inventive step (two general patentability criteria straight from TRIPS) and that it was also excluded from patentability under Section 3(d) because there was no significant enhancement of efficacy.

Unfortunately, this landmark decision was partially undermined in an appeal before the Intellectual Property Appellate Board, which wrongly concluded that novelty and inventive step were present, but which fortunately also concluded that the "enhanced efficacy" standard was not met. The IPAB thereby upheld the construction of efficacy standard that has emerged in Indian law that routine improvements to medicines, such as increased bioavailability, improved stability, enhanced solubility, etc., do not meet the anti-

evergreening standard embodied in Section 3(d).

Novartis and its contingent of high-priced lawyers is now taking a second-bite at the Section 3(d) apple trying to eviscerate its efficacy in ensuring that 20-year patent monopolies are granted to new versions of existing medicines only under the most stringent conditions - when there is a surprising and important therapeutical effect that significantly enhances treatment of human illness. By thus limiting unwarranted patent monopolies, the India Patent Act is designed to rewards true innovations but to simultaneously prevent the renewal and re-renewal of monopolies so that robust competition among lawful generic producers can drive down the costs of medicines both for Indian patients and for patients throughout the developing world.

Let's hope that the judges hearing this appeal abide by the letter and spirit and the Indian Patents Act and that they remain cognizant of the human right to health. But shame on Novartis for continuing its relentless pursuit of monopoly protections so that it can - as its has stated in the past - sell its medicines at high prices to rich and middle-class Indians who can afford it hyper-profitable medicines. To maximize its profits, Novartis would undermine an entire edifice of public interest protections designed to put a little more balance into the highly imbalanced international intellectual property regime.

To put this case in a little perspective, if Novartis wins, generic equivalents of Glivec will disappear from the market, and the price of this life-saving medicine will rise ten-fold or more. Novartis's profits will shoot up while cancer patients' survival rates shoot down. This second bite is not only outrageous, it is dangerous to health throughout the developing world.

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