

Novartis Shown Its Place

In one of the first challenges posed to the Indian courts on the award of patents in the pharmaceutical sector, it is heartening to note that judges of the Chennai High Court have spoken in favour of the Indian people and their right to affordable health care. The case refers to the patent filed by the Swiss drug multinational Novartis in 1998, for its cancer drug Glivec. Under the mailbox provision provided during the transition from the Uruguay GATT round at the end of 1994 and the time that countries amended their patent acts to introduce both process and product patents, Novartis had enjoyed several years of Exclusive Marketing Rights (EMR) on Glivec.

The Chennai Patent Office rejected the Novartis' application in 2006 on the grounds that it was not innovative enough. The patent office said that the new claim was for different forms of the same drug (salt and crystalline) and did not involve any inventive steps, hence did not merit a patent. In order to block the efforts of pharma giants to 'evergreen' their patents by extending the patent period by introducing frivolous changes, the Indian Patent Act has incorporated a provision under Section 3(d) according to which slight variations of the original product are not patentable unless there is a significant difference in the efficacy of the drug as a result of the small change. This was not the case with the Novartis drug.

On being denied the patent, Novartis took the unprecedented step of moving the Chennai High Court against the order of the Chennai Patent Office. If this was not brazen enough, it challenged the validity of the Indian Patent Act itself, saying that it was not compliant with WTO/TRIPS. Then it went one step further and challenged the constitutionality of Section 3(d), further accused India of not meeting the 'agreed' deadline to become compliant with TRIPS (Trade Related Intellectual Property Rights), that is, not changing its Patent Act early enough. After this, for good measure, Novartis came up with another bald faced idea and challenged the appointment of Sri C Chandrashekhara to the Indian Patent Appellate Board (IPAB), accusing him of being biased and suggesting his decisions would be unfair. And if all this was not brazen enough, Novartis began to issue threats that it would move its business out of India and deny India life-saving drugs because of its actions in not acceding to all of Novartis' indefensible claims.

The Novartis example is a good test case since it offered up almost the entire repertoire of threats and intimidations that corporations are known to indulge in to get their way with developing country governments. In this case, Novartis had no hesitation in breaching the (sometimes thinly held) limits normally maintained by outside agencies that must steer very clear of interfering in the affairs of a sovereign nation.

It is to the credit of the Chennai Bench that heard the Novartis case which instead of being persuaded by the aggressive onslaught, as has sometimes been witnessed in the past, they stood up clearly on the side of justice and the side of the poor. Not only did they uphold the appointment of Sri Chandrashekhara, Justices R Balasubramanian and Prabha Sridevan summarily rejected the audacious challenge made by Novartis and told the company to seek relief in the WTO dispute process for its complaints about India's compliance or lack of it with the WTO provisions. The Bench also dismissed the attempts to interfere in India's Patent Act (with reference to Section 3(d)), stating that the Indian law was the law of a sovereign nation; it was in consonance with the country's constitutional obligations and invoking Section 3(d) to restrict the ever greening of patents to achieve the goals of justice.

I would add a final chapter to the Novartis saga. That is to issue the threat of banning products made by Novartis so that a message goes out to other corporations who have such intimidating tactics in mind. Many years ago ,when I was a researcher at the Human Genetics Institute in Heidelberg,an issue came up about enforcing the patent on a very basic technique used in all genetics labs,the Polymerase Chain Reaction (PCR). The patent on PCR was held by another Swiss multinational called Hoffman La Roche which was also a pharmaceutical company.Enforcing their patent on the use of PCR would mean that no genetics research could be conducted without paying royalties to Hoffman La Roche.The genetics research institutions in Heidelberg took a decision that if Hoffman La Roche actually enforced their patent and tried to extract royalties from every genetics lab,the university hospitals would retaliate by banning drugs produced by the company.The message must have been conveyed.Roche never enforced the PCR patent!

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