Nominated for the Public Eye Swiss Award 2007
by CPAA (Cancer Patient Aid Association), India

Novartis AG

Headquarters:	Basel, Switzerland
Branche of trade:	Pharmaceuticals
Turnover / Profit:	US$ 32.2 billion / US$ 4.6 billion (2005)
CEO:	Daniel Vasella
Owned by:	Publicly-traded corporation
Employees:	90,900 (2006)

Summary

In 2003, the Patent Office in Chennai (formerly Madras), India, awarded temporary exclusive marketing rights (EMR) for the commercialization of the cancer drug Imatinib Mesylate (Glivec®) to the Swiss pharmaceutical company Novartis. This led to a halt in production of generic equivalents in India. Since generic versions – costing one-tenth as much as Glivec® – could no longer be sold, thousands of patients worldwide lost access to an affordable drug that delays the advancement of leukemia.

In January 2006, owing to a protest by the Cancer Patients Aid Association (CPAA), the Chennai Patent Office denied Novartis' patent application for Glivec®, and at the same time canceled the EMR. The production of generics could therefore restart. Novartis opposes the decision, and is doing everything it can to regain the EMR. It has filed two patent suits: one against the Patent Office's decision, and another against section 3(d) of the Indian Patent Act, on which the decision was based.

Irresponsible corporate behaviour

Imatinib Mesylate (Glivec®) is a drug from Novartis AG that extends the lives of patients suffering from chronic myeloid leukemia (CML). Although the drug controls the growth of cancer cells, it is not a cure. Consequently, CML patients must take the drug for the rest of their lives. Various smaller companies produce generic drugs in India, and they have found a market at home as well as in numerous other developing countries. While Glivec® costs a patient US $26,000 per year, a generic equivalent costs only US $2,100.

Novartis applied for Indian patent rights on Imatinib Mesylate (Glivec®) with the Chennai Patent Office in 1998. In 2003 it received temporary exclusive marketing rights (EMR), set to last until the patent was granted. However a patent review would only begin once pharmaceutical product patents were recognized under Indian law, beginning on January 1st, 2005. Novartis asserted its

EMR, and Indian producers of generics were forced to halt production. With the disappearance of the competition, Glivec® remained the only effective drug against CML available on the world market. This led to unsustainable costs for former generics users. Aid groups, among them CPAA, were forced to withdraw their support for CML patients and leave them to their fates.

In order to conform to the TRIPS[1] Agreement, the Indian parliament revised the Indian Patent Act. The revision included section 3(d), which prevented firms from receiving patents for similar forms of known substances and for new uses of known molecules. This provision is an acknowledged safeguard against misuse of the product patent regime by pharmaceutical firms. In addition, the new law allows any individual or group to oppose a patent application. On behalf of CML patients, CPAA successfully opposed the patenting of Glivec® on the grounds that the application makes a claim to a new form of an existing drug. The patent application was rejected in January 2006, which brought relief to thousands of CML patients.

A response from Novartis came swiftly. In May 2006 it filed two suits with the Chennai High Court. The first suit criticized the decision of the Chennai Patent Office and called for the granting of the Glivec® patent. The second suit called into question the constitutionality of section 3(d) of the Indian Patent Act; according to Novartis, it contradicts the WTO's TRIPS Agreement.

Consequences

Since court proceedings began on August 23, 2006, uncertainty and anxiety reigns with CML patients and their relatives; the ongoing process and its possible outcome places the patients' lives in danger. If Novartis is successful, it will receive a monopoly on the vital cancer drug. If section 3(d) of the Indian Patent Act is ruled invalid, it will have far-reaching consequences for the availability of Indian generics, not only for the cancer drug Imatinib Mesylate, but also for drugs to treat other illnesses such as HIV/AIDS.

Current status and demands

The proceedings at the Chennai High Court are intense, with Novartis and CML patient representatives on opposite sides. The next hearing is scheduled for January 29th, 2007. CPAA can no longer accept the injustice of the dispute, and calls on Novartis to abandon the court proceedings in Chennai and to dismiss both lawsuits.

Further information:

- www.cpaaindia.org
- www.evb.ch (www.evb.ch/en/p25011414.html)
- www.glivec.com
- www.novartis.com

[1] Implementation of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is required of all WTO member countries.

Submission deadline for nominations: 20 September 2006. Subsequent developments were considered as known.