

Bayer takes patent linkage case to India's Supreme Court

India's Supreme Court will hear an appeal by German drug maker Bayer in a case that aims to link the country's IP office and its drug regulator.

The Court granted Bayer's special leave petition on February 26, but rejected the company's request that it issue an injunction to prevent Indian drug maker Cipla from selling its generic version of cancer treatment drug sorafenib tosylate.

Bayer filed a writ petition in October 2008 against the government of India and Cipla that asked the Delhi High Court to direct the Office of the Drug Controller General of India not to grant regulatory approval for Cipla's own version of the drug because Bayer owns the patent.

Bayer, which markets sorafenib under the brand name Nexavar, also argued that Cipla's drug was "spurious". India's Drugs and Cosmetics Act states that a drug is spurious if it is "an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive".

In August last year the Delhi High Court dismissed the writ petition and imposed costs on Bayer. The judge stated that "the gulf dividing what is sought for, and what exists on the statute, is of oceanic proportions".

Bayer appealed to the Division Bench of the Delhi High Court. On February 9 this year the Bench upheld the initial ruling and again criticised Bayer, stating that unless there are specific provisions



The Supreme Court will hear the case in the third week of April. Prathiba Singh, of Singh & Singh, who is advising Cipla in the case, told *Managing IP* that she was "not at all surprised" that the Court had taken on the case. "We are happy that the Court did not grant an injunction," she added. Remfry & Sagar is advising Bayer in the case.

Pravin Anand, a partner of Anand & Anand said that Bayer had "some very good arguments".

These include that there is already, Anand argues, a clear connection

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in the Drugs and Cosmetics Act, "it is not possible for this court to read such a requirement into the law".

Bayer expressed disappointment and said that it has been granted exclusive marketing rights by the Indian Patent Office. It went on: "It is Bayer's position that there are provisions in the relevant Indian laws prohibiting the grant of a marketing authorization in such a situation."

between the patent and drug approval processes. For example, Section 107A(a) of the Patents Act, which creates a so-called Bolar exemption, is designed to harmonise certain rules under the Drugs and Cosmetics Act.

But Shammad Basheer, an IP academic and founder of the Spicy IP blog, described Bayer's legal strategy as "flawed".

"The statute doesn't permit linkage – the drug control authority can't do it."

Bayer's linkage dispute - a timeline

- October 31 2008 - Bayer sues Cipla and names the government of India in the suit, arguing that the DCGI should not grant marketing approval for a patented medicine.
- November 7 2008 - An interim ex parte order is passed restraining the DCGI from granting marketing approval for the drug.
- February 17, 18 and 25 2009 - The Delhi High Court hears the case.
- August 18, 2009 - Delhi High Court dismisses Bayer's writ petition.
- February 9 2010 - Division bench of the Delhi High Court upholds the decision.
- February 19 - Bayer files an appeal at the Supreme Court.
- February 26 - The Court accepts and schedules a hearing for April.

Tido von Schoen-Angerer of Médecins Sans Frontières' Campaign for Access to Essential Medicines said that he was "delighted" with February's Delhi High Court decision. "In India we are seeing a number of multinational pharmaceutical companies trying to use litigation to stifle generic competition," he said in a statement.

The dispute has not deterred the German company from investing in India. Bayer Schering Pharma, a subsidiary, said on March 12 that it intends to double its sales team in India. Alok Kanti, the company's Asia-Pacific head, added that the company was considering a specific acquisition in India.

If it does buy an Indian generic drug maker it will be following in the footsteps of Daiichi Sankyo, which bought Ranbaxy in 2008, and Abbott Laboratories, which bought Solvay Pharma in October last year. Anglo-Swedish pharmaceutical company AstraZeneca signed an alliance with Indian drug maker Torrent Pharmaceuticals in March. Although patent disputes continue to make headlines in India, the country's generic industry and the innovator pharmaceutical companies are finding ways to do business together. ■