

INDIA: THE SUNITINIB CASE



Sugen's patent for anti-cancer drug sunitinib has been revoked by the Indian Patent Office. Ranjna Mehta-Dutt and Swarup Kumar at Remfry & Sagar explain the details of the matter.

In October 2007, Sugen Inc was granted a patent for anti-cancer drug sunitinib (Patent No. 209251) by the Indian Patent Office (IPO). In September, 2012, this patent was revoked by the IPO on grounds of obviousness in a post-grant opposition proceeding filed by Cipla. The patentee challenged this decision by filing a writ petition before the High Court of Delhi primarily claiming that principles of natural justice were not followed since the opposition board's recommendations were not supplied to it for rebuttal.

During the pendency of the writ, the Delhi High Court granted an order restraining Cipla from marketing a generic version of sunitinib, against which Cipla appealed at the Supreme Court. The Supreme Court in November 2012, lifted the injunction against Cipla and directed the Controller to dispose the post-grant opposition after giving both parties an opportunity to present submissions on the joint recommendations of the opposition board.

Accordingly, fresh hearings were conducted by the Controller of the IPO eventually leading to

the issue of a decision revoking the patent of Sugen Inc.

What are the issues at stake in the case?

There were primarily two issues:

- (1) Whether the invention claimed in Patent No. 209251 was obvious or not in view of the documents cited by Cipla during the post grant opposition; and
- (2) Whether appropriate information in accordance with the requirements of Section 8 of the Patent Act was disclosed by the patentee or not.

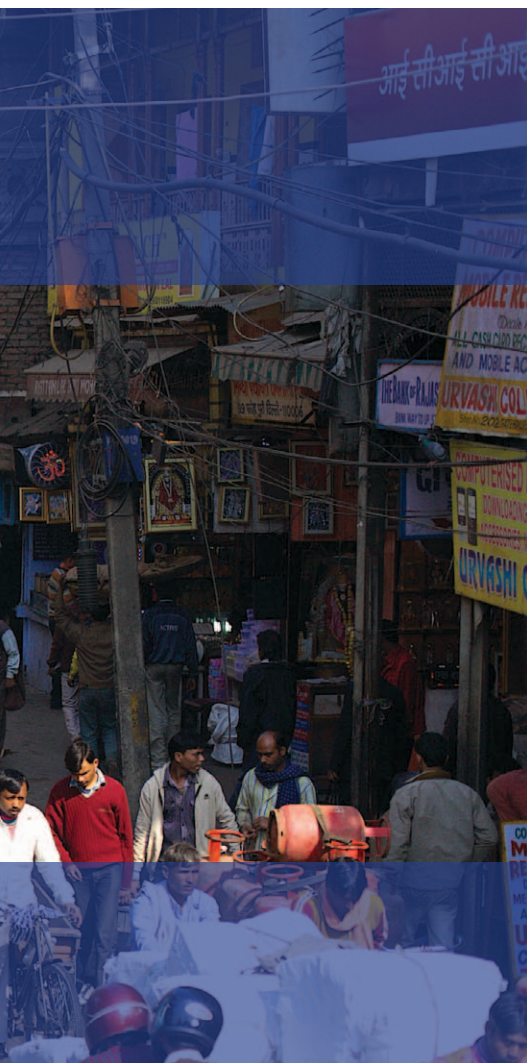
What did the Controller decide?

The Controller upheld the recommendations of the opposition board that the invention claimed in the patent did not involve inventive step and was obvious to a person skilled in the art in view of cited prior art.

To elaborate, it was held that invention claimed was obvious in view of documents

D1 (US5886020), D2 (WO9850356) and D3 (WO9961422). Interestingly, all the three cited documents are in the name of Sugen, Inc. The Controller observed that teaching of D1 and D2 could be modified to introduce the polar group Z taught by D3 to formulate a compound which does not possess the (alkyl) group but retains the protein tyrosine kinase inhibitory activity. The Controller also relied upon the fact that the compounds disclosed in D1, D2 and D3 were used for treatment of the same category of disease as the impugned patent.

On the second issue, the Controller held that the patentee had fulfilled its duty to furnish all the information required under Section 8. On the allegation by the opponent that many details/documents were not furnished to the IPO, the Controller held that "The details cited by the opponent are from the World Intellectual Property Organization (WIPO) website and espacenet which is freely available to the Controller and Examiner." Therefore, this ground for revocation was not maintainable.



Is there anything unusual about the case?

The aspects which could be considered to be unusual are:

- (1) The efficacy data provided by the patentee, in the language of the Controller “for few selected compounds” which were not the closest prior art, were considered not to be good enough for considering the claimed compound inventive. This stance could be considered by some to be an ‘inventive step-plus’ requirement such as under Section 3(d) of the act. While sufficiency of increase in efficacy has arguably been considered pertinent for judging whether a compound or derivative is a mere new form of a known substance or not, applying a similar parameter for judging inventive step could be considered to impose a stricter requirement.
- (2) The expression ‘inventive step’ is defined in Section 2(1)(ja) of the Patent Act 1970, as “a feature of an invention that involves technical advance as compared to the

existing knowledge or having economic significance or both ...”. Contrary to this, the Controller held that “the commercial success of the instant product (sunitinib) as submitted by the patentee cannot be considered as an evidence of a patentable invention”. Therefore, the criteria of economic significance appear not to have been taken into account in this judgment.

- (3) The Controller has drawn support from two foreign judgments and an Indian author’s comment, while there has of late been a plethora of judgments from various forums, including the Intellectual Property Appellate Board (IPAB), on this and related issues, which have not been taken into account.

Do you think there will be an appeal?

Given the importance and background of the matter and the commercial success of this crucial drug it is, in our opinion, most likely that the decision of the Controller will be appealed by the patentee.

What grounds might form the basis of an appeal?

The grounds of an appeal should be limited to the grounds on which a patent has been revoked which, in the present instance, is lack of inventive step and the invention being obvious in view of cited prior art. The basic grounds on which the appellants (patentee) could, *inter alia*, rely is that the patent has been revoked erroneously. In other words, the claims of the patent, contrary to what the Controller held, are non-obvious and involve inventive step. The point that no reliance was placed on the criteria of economic significance while judging on non-possession of inventive step could as well be challenged.

What implications does the case have for industry in India and internationally?

This revocation on a narrower interpretation of inventive step criteria could further compound problems for innovative companies who are already battling the might of Section 3(d) of the Patent Act.

On the other hand, the Controller’s decision on compliance with the requirements of Section 8 is a pragmatic and practical step forward for the patent applicants. ■

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Patent in question: IN209251

Owner: Sugen licensed the patent to Pfizer

Patent covers: Sunitinib, a drug used to treat renal cancer

Opponent: Cipla

Ruling authority: Indian Controller General of Patents Designs and Trademarks

Decision: Patent revoked

Organisation: Pfizer

Founded: 1849

Headquarters: New York City, US

Business: Pharmaceuticals

2011 revenue: \$67.4 billion

Organisation: Cipla

Founded: 1935

Headquarters: Mumbai, India

Business: Generic pharmaceuticals

2012 revenue (year to March 31, 2012): Rs 6977.50 crore (\$1.27 billion)

Ranjna Mehta-Dutt is a partner at Remfry & Sagar. She can be contacted at: ranjna.dutt@remfry.com

Swarup Kumar, managing associate at Remfry & Sagar. He can be contacted at: swarup.kumar@remfry.com