Roche Vs Cipla: Final leg of battle over Tarceva Patent

In the final leg of battle over Tarceva patent, Cipla has approached Supreme Court challenging High Court's Order holding it guilty of infringing Roche's patent on Tarceva.

Cipla in its plea to Supreme Court contended that Roche's product Tarceva was subject matter of a rejected patent application in India and was therefore in public domain, for which it has been accused of infringement. The Supreme Court while granting the leave (and admitting the Appeal) has scheduled the hearing on March 16, 2016 when it would also examine whether High Court should have taken expert opinion as provided under the Patent Act before deciding the case.

Roche's Patent

The case concerns two patents and one of them was refused as per details below:

- The Suit Patent (774), Application Number: 537/DEL/1996, Granted patent: IN196774 ('774)

The first claim of the '774 patent reads as:

"A novel [6,7-bis(2-methoxyethoxy)quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride compound of the formula A."

On plain reading, this appears to be a claim covering the compound: "Erlotinib Hydrochloride". This compound may exist in several polymorphic forms, but any such forms are likely to be subsumed within this patent.

- **Patent Application ('507):**

A later patent application claiming a specific polymorph B of Erlotinib hydrochloride was filed in India (IN/PCT/2002/00507/DEL) (hereinafter the '507 application). This corresponds with US patent 6900221 (the '221 patent). This was filed in India in 2002 and rejected in December 2008 after an opposition was filed by Cipla primarily on the grounds of section 3(d).

Case History:

The story started with the grant of a patent in India on Erlotinib hydrochloride (Tarceva) in 2007 to Roche (as explained above).

Roche's patent claim was on the "Erlotinib Hydrochloride"- without being limited to any of its polymorph, however Roche was commercialising a particular polymorph of the claimed drug molecule(i.e. polymorph B), which was being marketed as Tarceva. Cipla manufactured and marketed the drug which was based on the polymorph B of Erlotinib Hydrochloride at one third the cost of Roche.

The seven long years of litigation:

The on-going litigation between Cipla and Roche can be divided into two phases. 'Phase I' was primarily focused on Roche's attempt to seek interim injunction pending final outcome of its prayer for permanent injunction and damages. In 'Phase II' parties concentrated on final decision post trial.

PHASE-I

a) Roche sued Cipla for patent infringement in January 2008 soon after Cipla announced its intent to launch a generic version of Erlotinib (i.e. Erlocip) at Rs.1,600 per tablet, compared to Roche's selling price of Rs.4,800 per tablet. Cipla said it hadn't infringed the innovator's patent as it sold a polymorphic form of the drug.

b) **Single Judge Ruling**

The single judge declined a temporary injunction on the ground of "public interest" i.e. the lower priced generic version of Cipla would enable "more access" to this life saving drug in India. Although Cipla challenged the validity of Roche's patent in this suit and even claimed non infringement, the single judge found that Roche had established a "prima facie" case of infringement. However, the judge curiously noted that Cipla had raised a "credible challenge" to the patent.

c) **Both Roche and Cipla Appealed to the Division Bench**

Roche lost before the two judge bench (aka the Division Bench). The order of Division bench proved much more detrimental for Roche. Not only did the Appellate bench uphold the key findings of the trial judge, it went on to impose costs on Roche for suppression of material "patent" information. It also went on to find that Roche had not established a prima facie case of infringement, since the patent in question did not seem to be implicated by Cipla's generic product and in any case, the court suggested that Roche's patent was susceptible to a serious validity attack.

d) **Roche appealed to Supreme Court**

Supreme Court dismissed the special leave petition filed by Roche, challenging the order passed by the division bench of the Delhi High Court. However, the court ordered that the ongoing trial at the Delhi High Court be expedited. The order also clarified that nothing in the Division bench order would bind the trial court judge, who is expected to decide the case on final merits.

Phase-II

a) **Trial completed and matter heard by single judge**

The single judge dismissed the claim of Roche. The single judge in his September, 2012 order held that Cipla was not infringing Roche's patent and refused to grant any injunction against them.

b) **Cipla and Roche appealed against the order**

Cipla and Roche, both challenged the single judge's order of September 7, 2012 to the Division Bench (two judge bench). The Division Bench refused to revoke Roche's patent as sought by Cipla. The Division Bench while ruling in favour of Roche made the following observations on the scope of claim and its comparison vis-a-vis alleged product:

- Roche claim in IN196774 ('774) is *"sufficiently broad claim that is clearly not limited to any polymorphic version of Erlotinib Hydrochloride, but to Erlotinib Hydrochloride itself. This compound may exist in several polymorphic forms, but any and all such forms will be subsumed within this patent."*

- As *Cipla's Erlocip is admittedly one particular polymorphic form of the Erlotinib Hydrochloride compound (Polymorph B), it will clearly infringe the IN '774 patent."*

- The court holding that single judge conclusion was erroneous observed *"Thus, it is apparent that the Learned Single Judge has referred to two distinct things i.e. Claim 1 of IN '774 and Tarceva, interchangeably, to determine the infringement question and comes to what appears to us to be an erroneous conclusion."*

- The court also came down heavily on product comparison methodology adopted by Single judge holding *"It is an incorrect analysis of product patent infringement in a case like the present, to use methodologies like X-Ray diffraction to ascertain whether the competing products are identical in nature. The correct test of infringement in this case is to map Cipla product against the Roche's patent claims, which we find has not been done by the learned Single Judge, and this is the third infirmity on this aspect of the dispute."*

- The court elaborated on the methodology adopted by the judge to say *"the comparison would have to be between a product made on the basis of Roche's patent claim and Cipla's product and not between Roche's product as sold in the market and Cipla's product. This subtle distinction is important to be kept in mind because the holder of a patent is by no means limited to only manufacture and sell only those products that are disclosed in the claims of the patent and hence a different polymorph manufactured by the patent holder which is not the subject of the registered patent cannot be used for the purpose of comparison with the infringer product; the very product disclosed in the patent claims must be used."*

The court, in its final decision rejected Roche's plea for an injunction on Cipla's product, considering the patent was due to expire in March 2016. However, Cipla was ordered to render accounts concerning manufacture and sale of Erlocip to determine profits made by them on account of infringement.

Resultantly, Cipla appealed against the decision of the division bench to the Supreme Court. It will be interesting to watch which side does Supreme court takes as two very different outcome and reasoning have been adopted by the single judge and the Division bench (the Appeal Court).

Our comment

The comparison of the marketable form (or the commercial embodiment) of the claimed product for determining the possibility of infringement may not be a fair parameter as there may be difference in the claimed scope and the commercial product of the patentee. In other words, the patentee may not have a product at all, but may still sue a defendant who manufactures a product with the overlapping ambit to that of its claim. Therefore, it does seem Division Bench finding is more reasonable and on a sound footing.

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