

Business Standard

HC: Cipla violating Roche's patent in lung cancer drug

The court said Erlocip is one form of erlotinib hydrochloride, which is Hoffman-La Roche's drug

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The Delhi High Court on Friday held that drug manufacturer Cipla infringed Swiss pharmaceutical company Roche's patent in lung cancer drug erlotinib hydrochloride, sold under the name of Tarceva.

A Bench of justices Pradeep Nandrajog and Mukta Gupta said Cipla's lung cancer medicine, Erlocip, was one polymorphic form of the erlotinib hydrochloride compound, which may exist in several forms, and Roche's patent claim was not limited to any one such version.

The court, however, did not grant an injunction in favour of Roche, as the patent granted to it will expire next March. The

Bench said a single judge, who heard the matter earlier, had not passed an interim injunction order and Cipla continued to manufacture and sell Erlocip.

The court imposed Rs 500,000 as costs on Cipla. The Bench has remanded the case to the single judge for rendition of Cipla's accounts for determination of profits from sale of Erlocip. "Thus, there could be other financial implications for Cipla and the company may have to pay damages to Roche, which will be quantified on the basis of Cipla's accounts," said advocate Sagar Chandra, who specialises in intellectual property law.

"This is one of those rare cases where a final decision of the court was rendered on patent infringement after a conclusive trial," said Ajay Chandru, senior member of Intellectual Property team, Nishith Desai Associates.

"The division Bench analysed whether Cipla's Erolcip falls within the scope of the patent granted to Roche and came to an affirmative conclusion on this analysis. Hence, the court held that Cipla infringed Roche's patent," Chandru said.

While Cipla's Erlocip, launched in 2008, costs Rs 1,600 per tablet, Roche's Tarceva cost Rs 4,800 per tablet. Roche was granted the patent in India for erlotinib hydrochloride on February 23, 2007.

Cipla did not comment on the decision. The order is a setback for Cipla, which has been pursuing the cause of affordable health care in India and Africa. But on several occasions the company has run into issues with multi-national drug companies that have accused it of copying their products.

Roche welcomed the order. "Roche is a leading investor in the research and development of new medicines... In order to sustain the research, companies must be sure that any resulting innovations will be protected through patents for an agreed period of time," company said.

The court in its 106-page judgment said that as Cipla "could not establish prima facie that the suit patent was obvious", its plea for invalidating Roche's patent on the ground of 'obviousness', "fails". An invention is said to be obvious if it lacks inventive steps.

The verdict came on the pleas of Cipla and Roche, both of which had challenged the single judge's order of September 7, 2012. The single judge in his order had held that Cipla was not infringing Roche's patent and refused to grant any injunction against the Indian company. The judge had also refused to revoke the patent of the Swiss company as sought by Cipla.

The division bench held that the single judge "erroneously compared the products of Roche and Cipla when he ought to have mapped the claims of the suit patent against Cipla's product".

Cipla in its plea had urged that while the patent sought to be enforced was for polymorphs A+B of the compound, the product under manufacture by both Roche and Cipla was polymorph B, which ought to be assumed to be in the public domain and, hence, the Indian company's activities were non-infringing in nature.

Roche in its plea had contended that the basic patent was not confined to any polymorphic form of erlotinib hydrochloride and, hence, as long as the compound was present in Cipla's product Erlocip, it infringes the patent.
