

Cipla v Roche – Generics Industry Rejoices!

For the last two years, the Delhi High Court has been the battle ground for a pharmaceutical war between Roche and Cipla over Roche's patent for the anticancer drug 'erlotinib', sold by Roche as 'Tarceva'. On 24 April 2009, the Division bench of the Delhi High Court dismissed Roche's appeal against the refusal of a single judge to grant an injunction restraining Cipla from manufacturing, offering for sale, selling and exporting its generic version of 'erlotinib'. Both Roche and Cipla drugs are based on a compound that goes by the name of 'Erlotinib Hydrochloride'. This case is regarded as a very important case in a series of high profile patent battles between multinational pharmaceutical companies and Indian generic drug companies.

Facts of the case

Roche, along with Pfizer (as a joint applicant), claimed that it had been granted a patent in February 2007 for 'erlotinib', the molecular [6, 7-bis (2-methoxyethoxy) quinazolin-4-yl]-(3-ethynylphenyl) amine hydrochloride. The patented product, which Roche introduced onto the Indian market in 2006, was marketed under the brand name TARCEVA. In December 2007 and January 2008, Indian newspapers reported Cipla's plan to launch a generic version of 'erlotinib', and soon after Roche commenced patent infringement proceedings.

In response to Roche's claims, Cipla filed a detailed defence and counterclaim arguing that:

1. It had been selling its drug under the brand name ERLOCIP since December 2007
2. Roche's patent was invalid because 'erlotinib' was a derivative of Quinazolin, which had been used in cancer treatment. Pursuant to s.3(d) of the Indian *Patents Act*, a derivative of a known compound is not patentable
3. Roche's invention, as disclosed in the complete specification and claims was obvious or did not involve any inventive step, having regard to what was publicly known or publicly used in India, or what had been published in India or elsewhere before the priority date
4. The complete specification did not sufficiently and fairly describe the invention or the method by which it was to be performed
5. The huge difference in price between Roche's drug (Rs.4,800 tablet (approx. US\$ 100) and Cipla's drug (Rs.1,600 (approx US\$ 33) should be taken into account when deciding whether or not to grant an interim injunction. Cipla strongly argued that because the drug in question was a life saving drug, the public interest issue was an important factor to be taken into account

Roche's submissions:

1. Section 3 (d) of the *Patents Act* is not applicable as it prohibits only derivatives of 'a known substance'. 'Erlotinib' is not 'salts, esters, polymorphs, particle size, mixture of isomers, etc.' of a 'known substance'. It is a novel compound
2. The prior art argument was adequately dealt by the Patent Office during opposition proceedings. In any case, 'erlotinib' is a different compound; its properties differ from those of Astra Zeneca's Gefatinib, which was cited as prior art

3. When determining where the balance of convenience lies, it is appropriate to consider the issue of 'accessibility' to, and use of, the invention in the territory. It is not, however, necessary that the drug should be manufactured in India.

Single judge ruling

While hearing the case, the judge noted the following points:

- **Public interest:** The generic drug version of 'erlotinib' manufactured and marketed by Cipla is available at one-third the price of Roche's drug, Tarceva. Further, the Court noted that Tarceva is not manufactured in India, it is imported. The Court noted that the right to access to life-saving drugs, and the need for secure long term supplies, is a serious issue in India. In cases of this sort, the injury that would be caused to the general public if the generic version of the drug were not available is a strong point in favour of a refusal to grant an injunction.
- **Validity of the patent:** The doubts about the validity of the patent raised by Cipla on the ground of obviousness, and 'erlotinib' being a derivative of a known compound which did not meet the 'increased efficacy' requirement provided for in s.(d) of the *Patents Act*, were dismissed by the judge as having been adequately dealt by the Patent Office at the opposition stage. The Court reviewed the observations that had been made by the Controller while granting the patent, and concluded that Cipla had not substantiated this objection.

Overall, the judge was of the view that while Roche had established a strong case in support of its patent infringement claim, the 'public interest' and lower pricing of Cipla's drug tilted the balance in favour of Cipla.

Division bench ruling

Roche filed an appeal against the Order of the single judge, primarily arguing that since it had made out a *prima facie* case of infringement, an injunction should have been granted. Roche further argued that a failure to protect the rights of the patentee, is contrary to the public interest of encouraging further research in the pharmaceutical field. The division bench in its ruling observed:

- **Non infringement:** The bench was of the view that the patent in question related to a mixture of Polymorphs A and B, whereas Roche's Tarceva drug consisted of only Polymorph B, for which a patent had not yet been granted. The division bench considered that this fact ought to have been disclosed by Roche both at the time of examination, and during the proceedings before the single judge. The bench gave weight to the fact that Polymorph B of 'erlotinib hydrochloride' was the subject of a later patent application, and that this had not been considered by the single judge.

The bench criticised Roche for:

1. its failure to provide a sufficient and fair description of the invention; and
2. for not having filed X-ray diffraction data for Tarceva and Erloricip that would have shown whether or not the crystalline structure of Cipla's Erloricip tablets corresponded to Roche's patented invention.

The Court dismissed Roche's appeal, and upheld the order of the single judge. It did not fully elaborate the public interest point relating to the pricing of the drugs, basing its judgment instead on the ground that Cipla had raised a credible challenge to the validity of the patent..

Our comments

The weight that should be given to criteria such as 'public interest' and 'affordability of medicines' when deciding whether or not to grant an interim injunction has sharpened the debate over patent protection in India. There are obviously two schools of thought.

One group, led by research companies, argues that the 'affordability' issue is wholly irrelevant as the 'compulsory licensing' provisions and 'the power of the Indian drug authorities to control the price of drugs' give adequate power to the Indian Government to control a patentee's monopoly. The purpose of the *Patents Act* is to grant a statutory monopoly that will enable the patentee to exploit research in which it has invested considerable time and money. Any dilution of the patentee's rights will be counterproductive in the long run as patentees begin to question the attractiveness of India as a low cost research destination.

NGOs and generic drug companies, on the other hand, argue that, in patent infringement cases involving life saving drugs, practical realities must be taken into account. They also argue that the grant of a restraining Order in these circumstances would violate a fundamental patient right that is provided for in Article 21 of the Indian Constitution: the 'right to life'. As the cost of medicines is beyond the reach of many, access to medicines and treatment is illusory. In the final analysis, the question is whether, if all other conditions are satisfied, an injunction can be refused solely on the basis of 'price differential'.

An appeal to the Supreme Court by Roche is expected to be filed soon. However, given that the trial and appellate courts have refused to grant an injunction, it seems unlikely that the Supreme Court will grant an injunction. However, the Supreme Court is expected to comment on the division bench interpretation of Roche's claims and its suggestion that Cipla's drug does not infringe Roche's patent.

With the Indian pharma industry growing annually at 9%, obviously much is at stake for the major players in the pharmaceutical industry.