

## **The curious case of Roche, Cipla and public interest**

Patent litigation in India is gathering considerable international attention with the issue of generics and a provision in the Indian patent law preventing 'evergreening'. Last year, Justice Ravinder Bhatt of the High Court of Delhi passed an order rejecting an interim prayer of the plaintiff, F. Hoffman-La Roche Ltd ('Roche'), to injunct the defendant, Cipla Ltd ('Cipla'), from manufacturing a generic version of its drug Erlotinib for treating advanced or metastatic non small cell lung cancer (NSCLC). Although the main ground of rejection of the interim prayer in F. Hoffman-La Roche Ltd & Anr v. Cipla Ltd was Section 3(d) of the Indian Patents Act, 1970 that prevents "evergreening" of a drug, it created ripples among the IP community owing to certain observations by Justice Bhatt on public interest.

On April 24, 2009, a two-judge Bench of the High Court of Delhi (the Division Bench) rejected an appeal filed by Roche against the said order and imposed on it costs of Indian Rupees 500,000 (approximately USD 10,000).

### ***Proceedings before the Single Judge***

The genesis of the suit was certain media reports in January 2008 that Cipla was about to launch a generic version of Erlotinib. Roche's claims before the Single Judge in the interim application were briefly as follows:

- Erlotinib was administered in the form of a tablet and had been imported and sold under the trademark 'Tarceva' in India sometime since April 2006;
- A patent had been granted to Roche by the patent office in New Delhi bearing number 196774 (hereinafter "774") on February 23, 2007;
- Cipla had no rights to manufacture, sell or offer to sell any version of Erlotinib and any such action as announced by Cipla would be in blatant violation of the legal rights of Roche;

In defense, Cipla raised the following arguments before the Single Judge:

- The complete specification of the patent was not disclosed in the plaint and was provided to Cipla only at the hearing of the interim injunction application
- 774 patent was hit by Section 3(d) of the Patent Act as Erlotinib was a derivative of a known patent "Quinazoline" and that there were at

- least three EU patents dating back to 1993 which disclosed the Quinazoline derivative;
- One such patent disclosed the exact chemical structure of the 774 patent except for one substitution which was “obvious to any person skilled in the art”.
  - Roche had not proved that there was “any improved efficacy of the said drug”;
  - Roche’s product was highly priced and in any event no sales figures had been given by Roche;
  - Roche’s tablet cost Indian Rupees 4800 (approximately USD 100) and Cipla’s cost 1600 (approximately USD 30) and in the context of life saving drugs, it was in the public interest that the drug should be made available at cheap and affordable prices.

Section 3 of the Patent Act lists what are not inventions and sub section (d) is as follows:

“the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

Just a day before hearing the arguments in the interim injunction application in the suit, Cipla filed an application for rejection of the patent on the following brief grounds:

- Roche had suppressed that the 774 patent which was in relation to Erlotinib Hydrochloride in the form of polymorphs A and B had been known to it in the year 2000 as it corresponded to one of its US patents;
- Since Roche itself stated that the compound was not stable enough to be manufactured as a tablet, Cipla purchased a sample of the Tarceva manufactured in August 2006 and performed an x-ray diffraction to determine the crystalline structure of the same. A report obtained pursuant to the test showed that it was not a mixture of polymorphs A and B, but was wholly polymorph B. Hence, the drug sold in India by Roche under the mark Tarceva did not relate to the 774 patent and, in fact, there was a pending patent application (which was also not disclosed by Roche) before the Indian Patent Office filed by Roche for polymorph B;

Additionally, Roche filed a counter claim against Cipla challenging the validity of the 774 patent on the following brief grounds:

- There was no data filed by Roche to demonstrate that the claimed compound 'Erlotinib Hydrochloride' in 774 patent had a higher therapeutic efficacy;
- A US patent granted to Roche in May 2005 stated that Erlotinib Hydrochloride was a mixture of two polymorphs A and B and that it was necessary to separate and purify the B polymorph so as to get to the claimed compound for acceptable efficacy, and, therefore, the 774 patent granted subsequently clearly defeated the inventive step of the alleged invention;
- 774 patent failed to disclose that Erlotinib Hydrochloride was a mixture of polymorphs A and B which was useless for pharmaceutical use and that Roche capriciously withheld this material information.

An order was passed rejecting the interim injunction application on March 19, 2008 without adverting to the claims in the application for rejection of the plaint. The main grounds for rejection of the prayer were that invention in the patent was obvious to the unimaginative person skilled in the art and that the court could not be unmindful of the general access to life saving products and irreparable injury would be caused to the public if the injunction was granted as the public would be deprived of Cipla's products.

### ***Appeal proceedings***

Roche went in appeal before the Division Bench of the High Court of Delhi before whom the entire case record before the Single Judge including the application for rejection of plaint and counter claim were placed. One of the significant issues raised by Cipla while opposing the appeal, which had a bearing on whether Roche had made out a prima facie case for grant of injunction was that the specification of the 774 patent showed that it was in respect of Erlotinib Hydrochloride Polymorphs A and B which was on their own showing an unstable form which could not be administered as such. Cipla contended that the case of Roche itself was that it was Polymorph B which was a more stable form of the compound which could be administered in the tablet form. To prove this, Cipla relied on the x-ray diffraction report. Needless to say, Roche did not yet hold a patent for Polymorph B in India

and its application for the same was pending consideration. In other words, the patent application for the drug which was marketed by Roche was still pending before the patent office, a fact which was suppressed by Roche in the application for the suit patent as well as the suit.

### ***Non-Disclosure***

The Division Bench observed that if the Controller of Patents, while he considered the application for the 774 patent, was cognizant of the fact that there had been another application pending in respect of polymorph B in which Roche stated that “polymorph B is claimed to be thermodynamically more stable and it helps in providing improved oral dosage in solid form”, he would have had to address the issue whether it was the combination of polymorphs A and B or polymorph B alone which satisfied all the patentability tests vis-à-vis section 3(d) namely, showing an enhanced efficacy over the closest prior art. Accordingly, the court held that the failure by Roche to bring these facts including the prior US patents at the time of consideration of their application was not consistent with the requirement of a full disclosure.

It was noted by the Bench that Roche was changing its stand with respect to polymorph B in the pending application before the Controller of Patents to the effect that polymorph B was subsumed in polymorphs A and B and that the US patent was for the main compound Erlotinib Hydrochloride which included all possible polymorphs of the main compound known and unknown. It was further contended by Roche that their claim was that of a “selection invention” limited only to polymorph B which was substantially free of polymorph A. The court found that such a change in stand would admittedly have a direct impact on patentability of either a compound of polymorphs A and B or of polymorph B free of polymorph A and that a full disclosure of these aspects would have had an impact on the patentability of the compound of polymorph A and B. It was, therefore, found by the Court that when Cipla questioned the validity of the 774 patent on the above ground, it did raise more than a credible challenge.

### ***No prima facie case***

Having found Roche guilty of not fully disclosing the facts, the Division Bench pointed out that if these facts were fully disclosed in the plaint and the entire specification of the 774 patent along with the x-ray diffraction data

of Tarceva were filed along with the plaint, it was possible that Roche might have had difficulty in showing that the patent held by it covered Tarceva as well. It was, therefore, held by the court that to the extent that Cipla had raised a serious doubt whether Roche in fact held a patent for the product sold in the tablet form as Tarceva, Roche must be held not to have been able to cross the first hurdle of showing that they had a prima facie case in their favour for grant of an order restraining Cipla from marketing Erlocip. It is significant to state here that the pending application for the compound containing polymorph B was rejected by the Controller after the order was reserved by the Division Bench.

### ***Credible challenge to validity of patent***

It was further held by the court that unless the enhanced efficacy as mandated by Section 3(d) of the Act was demonstrated, a patent could not have been granted. Cipla had been able to show that the order of the Controller of Patents was arguably deficient on this aspect and hence the court found that Cipla must, therefore, be taken to have raised a credible challenge to the validity of the patent.

### ***Public interest***

On the issue of public interest and pricing, Roche argued that if a patentee's rights were not respected, then it would be contrary to the public interest of encouraging further research. Further, Roche argued that since the Act provided for grant of compulsory license in the event of a patented product not being made available at a reasonable price, the court could not apply such principles at an anterior interlocutory stage. Roche claimed that it should be allowed to exploit the benefits of its research in which it invested considerable sums. According to Roche, public interest in low cost general drugs had to be balanced by the public interest in the protection of patent rights. The need to encourage scientific research in inventing the drug outweighed the public interest in obtaining a low cost generic drug, argued Roche.

The Division Bench found it unable to accept Roche's aforesaid arguments and observed that the amendment to the Act in 2005 introduced section 83(e) which stated that among the general principles applicable to working of patented inventions, regard shall be had "that patents granted do not in any way prohibit Central Government in taking measures to promote public

health”. Further, under Section 84 among the grounds on which a person could seek a compulsory license on a patent was that the “patented invention is not available to the public at reasonably affordable price”. The element of public interest was, therefore, not alien to the scheme of the Act.

The Division Bench, therefore, concurred with the findings of the Single Judge and held that Cipla had been able to demonstrate prima facie that Roche did not hold a patent yet for the drug Traceva, which was the polymorph B form of the compound; further Cipla had raised a credible challenge to the validity of the patent of Roche and in such circumstances, the public interest in greater public access to a life saving drug would have to outweigh the public interest in granting an injunction to Roche. While affirming the Single Judge’s findings in this behalf, the Division Bench referred to the ratio of the UK High Court’s seminal judgement in Roussel Uclaf and, in particular, the following observation:

*“Finally, therefore, I come to the interesting and novel point as to whether the court ought ever, and in particular, in this case to exercise its discretion to grant an injunction the effect of which will be, temporarily at any rate, to deprive members of the public of the benefit of a ‘life saving drug which may be prescribed’ for otherwise fatal heart diseases... I think this must be a question for decision in the particular circumstances of each case, though I feel that the onus in such cases must be very heavily on the plaintiffs that there is little, if any, likelihood of the public being injured by their inability to obtain the drug in question when necessary. A life-saving drug is in an exceptional position. There are often cases where a number of drugs exist alongside each other and are in general all equally efficacious for a particular ailment or disease. If the evidence shows it to be the fact there may and well be cases where it would make little, if any, difference to the public, apart from satisfying personal preference, whether a particular drug was no longer available or not, then in such a case it may well be proper to grant an injunction. At the other end of the scale, however, there is the unique life-saving drug where, in my judgement, it is at least very doubtful if the court in its discretion ever ought to grant an injunction and I cannot at present think of any circumstances where it should.”*