There are talks about unleashing an ‘Evergreen Revolution’ in the country to provide for increasing food demands. But what does ‘Ever Greening’ mean in the context of patents and especially with regard to the pharma industry?

Well, a company manufactures a product for which it secures a patent. Shortly before the expiration of that patent, the company files a new patent that revises or extends the term of protection. This is what ever greening is all about. Ever greening is a method by which technology producers keep their products updated, with the intent of maintaining patent protection for longer periods of time than would normally be permissible under the law. It refers to increasing the life of the patent or the patent term beyond 20 years to reap the benefits for a much longer period of time.

Drug patent ever greening is the single most important strategy that multinational pharmaceutical companies have been using. One form of ever greening occurs when the original manufacturer “stockpiles” patent protection by obtaining separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolized by the patient.

The ultimate consequence could be that the generic equivalents of the drug would be prohibited from entering the market so the price of the drug of the Innovator Company will be higher even after the patent expiry in absence of competition from generic drug makers.

The ever-greening process has caused some controversy in the pharmaceutical industry. Ever greening may be used by manufacturers of a particular drug to restrict or prevent competition from manufacturers of generic equivalents to that drug. The process of ever greening may involve specific aspects of patent law and international trade law. The main arguments in favour of governments regulating against ever greening are that rapid entry of multiple generic competitors after patent expiry is likely to lower prices and facilitate competition, and that eventual loss of monopoly was part of the trade-off for the initial award of patent (or intellectual monopoly privilege) protection in the first place.


Section 3(d) 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.”

Section 3(d) of the Indian Patents Act, 1970 prevents “Ever greening” of a drug. It is clear that unless the enhanced efficacy as mandated by Section 3(d) of the Patent Act was demonstrated, a patent could not
### Facts of the Case

OSI jointly owns a patent with Pfizer Products Inc. in respect of a small drug molecule medically termed as a "Human Epidermal Growth Factor Type-1/Epidermal Growth Factor Receptor" (HER/EGFR) inhibitor, popularly known as Erlotinib. It is claimed that the said drug marked a major breakthrough and innovation in the treatment of cancer.

Erlotinib is administered in the form of a Tablet and sold under the trademark name ‘Tarceva’, which is registered in the name of Roche. It is claimed that Erlotinib and its formulation Tarceva have been approved by the United States (U.S.) Food & Drug Administration (FDA) in the year 2004 and thereafter by the European Union (EU) in the year 2005.

On 13 March 1996, OSI along with Pfizer Products Inc. made an application to the Controller General of Patents, Trademarks and Designs, New Delhi for grant of a patent in respect of Erlotinib. The Controller General of Patents, New Delhi granted the said applicants a certificate bearing Patent No.196774 dated 23 February 2007, which was subsequently recorded in the Register of Patents on 6 July 2007.

The issue of contention originated when certain media reports in January 2008 alleged Cipla to have announced in the print and electronic media its plan to launch a generic version of Tarceva (Erlotinib) in India under the name ‘Erlocip’. The plaintiffs stated that from such news report they learnt for the first time of Cipla’s plans to infringe and violate the patent owner’s rights. They claimed that the drug Tarceva (Erlotinib) had been developed after a long sustained research and after incurring enormous expenditure *inter alia* on the tests, which are mandatorily conducted for its efficacy and safety.

It was alleged that the said innovation was duly protected under law and that no person except those legally authorized to exercise legal rights associated with the aforementioned patented drug could be allowed or permitted to simulate, recreate it in any manner or in any other name. It was alleged that the defendant had no right to opt to manufacture, sell or offer to sell any version of the drug Tarceva (Erlotinib) and that such action of the defendant, as announced by it, would be in blatant violation of the legal rights of the plaintiffs.

| Plaintiff 1 | F. Hoffman-La Roche Ltd (‘Roche’) |
| Plaintiff 2 | OSI |
| Defendant | Cipla Ltd (manufactured the drug ‘Erlocip’) |
| Patent Owner | OSI + Pfizer (Patent drug Erlotinib under trade name Tarceva) |
| Right of manufacture, sell, import given to | Roche |
| Name of Patented Drug | Erlotinib (marketed under the name Tarceva) |
| Plaintiff contested against the drug | ‘Erlocip’ (alleged generic version of Erlotinib) made by Cipla |
| Principle laid down by Hon’ble Court | Public access to a life saving drug would have to outweigh the public interest in granting an injunction to Patentee against suit of infringing rights |

Efforts should be made to make it accessible to the public at affordable price despite its commercial exploitation.

Roche made claims before the Single Judge in Hon’ble High Court, Delhi to restrain Cipla from manufacturing the said drugs, so that their business of drugs would not be affected. They made the claim that 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. Q Cipla, the Defendant then made the argument before the Single Judge that 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.

Cipla gave the argument before the Court that the 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. Roche had not proved that there was “any improved efficacy of the said drug”.

Cipla further argued that 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.
Cipla also defended on the following grounds:

- There was no data filed by Roche to demonstrate that the claimed compound ‘Erlotinib Hydrochloride’ in 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 patent granted subsequently clearly defeated the inventive step of the alleged invention. The 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.

Order passed by Single Judge
The Hon'ble court rejected the application for interim injunction prayer of Roche for restraining Cipla for manufacturing the said drugs, on 19 March 2008. It is relevant to state here that the interim injunction is an application made before a court to restrain others from doing a particular thing with immediate effect. 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 that irreparable injury would be caused to the public if the injunction was granted as the public would be deprived of Cipla’s products.

The Court further laid down that: “The plaintiff is not entitled to claim an ad-interim injunction, in the terms sought. However, this Court is not unmindful of the fact that if no equitable balancing order protecting its interest is made at this stage, there is a likelihood of the plaintiff being prejudiced at the final stage.”

Appeal Proceedings
Aggrieved by the order of Hon’ble Court, Roche went in appeal before the Division Bench of the High Court of Delhi. 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 (at first sight) case for grant of injunction, was that the specification of the patent showed that it was in respect of Erlotinib Hydrochloride Polymorphs A and B which was on their own showing an unstable form and which could not be administered as such. Cipla contended that the case of Roche itself was that it was Polymorph B that was the more stable form of the compound and 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 that was marketed by Roche was still pending before the patent office, a fact that was suppressed by Roche in the application for the suit patent as well as the suit.

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Polymorph
A specific crystalline form of a compound is that which can crystallize in different forms. Polymorphs have the same composition, different chemical structures. For example, Diamond is a polymorph of graphite (both are allotropes of carbon). Both contain carbon atoms, but they have extremely different properties because of the condition in which they are formed. Diamond is obtained after applying extreme pressures and temperature, which gives it a compact structure. On the other hand, graphite forms under comparatively lower pressures. The difference in conditions makes diamond much harder than graphite.
purify the B polymorph so as to get to the claimed compound for acceptable efficacy, and, therefore, the patent granted subsequently clearly defeated the inventive step of the alleged invention.

Cipla purchased a sample of 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 patent as it was claimed that the patented drug was a mixture of polymorph A & B.

Roche argued before the court that if a patentee’s rights were not respected, then it would be contrary to the public interest of encouraging further research. Roche claimed that it should be allowed to exploit the benefits of its research in which it invested considerable sums. Roche argued before the court that if a patentee’s rights were not respected, then it would be contrary to the public interest of encouraging further research. Roche claimed that it should be allowed to exploit the benefits of its research in which it invested considerable sums.

Principles laid down

Hon’ble Court held that public access to a life saving drug would have to outweigh the public interest in granting an injunction to Patentee against suit of infringing rights. Patent Act-1970 has been amended in 2005 with the introduction of 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".

Cipla while appealing before the Court had been able to demonstrate prima facie (at first sight) that Roche did not hold a patent yet for the drug Tarceva, which was the polymorph B form of the compound.

The Division Bench of the Hon’ble High Court, Delhi did not find merit in any of the submissions made on behalf of the appellant, Roche. The appeal was, therefore, dismissed with costs quantified at Rs. 5 lakh to be paid by the appellants/plaintiffs to the defendant within a period of four weeks.

The Roche versus Cipla case clearly depicts that, while researching for new drugs efforts should not only be concentrated on garnering profits but also fulfilling the needs of the public. If an innovation benefits a large number of people, efforts should be made to make it accessible to the public at affordable price rather than merely commercial exploitation.

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