IN THE HIGH COURT OF DELHI

DATED: 19.03.2008

CORAM

HON'BLE MR. JUSTICE S. RAVINDRA BHAT

IA 642/2008

F. Hoffmann-La Roche Ltd. And Anr. ... Plaintiffs

Vs.

Cipla Limited ... Defendant

JUDGMENT

S. Ravindra Bhat, J.

This order disposes of IA 642/2008, an application seeking ad-interim injunction, restraining the defendant from manufacturing, offering for sale, selling and exporting the drug Erlotinib, for which the plaintiff holds a patent. Emergent notice was issued, and the parties filed their pleadings as well as documents in support of their contentions, in the suit and the interlocutory proceedings. The application was heard finally for disposal.

I The suit

1. The Plaintiffs in this suit seek permanent injunction restraining infringement of their patent rights in the drug Erlotinib, rendition of accounts, damages and delivery up of the infringing goods.

2. The first Plaintiff is a company organized and existing under the laws of Switzerland and has its principal office at Grenzacherstrasse, 124 CH 4070, Basel Switzerland. The second Plaintiff is a company organized and incorporated under the laws of the United States with its registered office at 41, Pinelawn Road, Melville, New York 11747, USA. It 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 this drug marked a major breakthrough and innovation in the treatment of cancer; it is used to destroy some types of cancer cells while causing little harm to normal human cells. This drug is administered in the form of a tablet. The tablet formulation of Erlotinib is sold by the plaintiff under the trademark and name of 'Tarceva', which is registered in the name of the first plaintiff. It is averred that the drug Erlotinib and its formulation 'Tarceva' has been approved by the U.S. Food and Drug Administration in the year 2004 and thereafter by the European Union in the year 2005.

3. The second Plaintiff, along with M/s. Pfizer Products, Inc had applied for grant of a patent in respect of Erlotinib and its process by application No. 537/Del/1996 on 13.3.1996. The Controller General of Patents, Trademarks and Designs, New Delhi granted a certificate bearing Patent No. 196774 dated 23.02.2007, which was recorded in the Register of Patents on 06.07.2007. The molecular name of patent is 'A Novel [6,7-BIS(2-Methoxyethoxy) Quinazolin-4-YL] (3-Ethynylphenyl) Amine Hydrochloride'. The drug as well as the process of its manufacture is patented according to provisions of the Patent Act, 1970 (hereafter 'the Act'). The Central Drug Standard Control Organisation, Directorate General of Health Services, Central Government registered Tarceva, by Registration certificate dated 23.12.2005 in the name of the first Plaintiff. It is alleged that on 8.1.2001, under Section 68 of the Act, 1970 the Plaintiffs had entered into a Development Collaboration and Licensing Agreement, through which the first Plaintiff has a license to use, sell and offer for sale, ' the licensed products including the drug Erlotinib marketed as Tarceva. It is also submitted that the first plaintiff is further licensed and authorized to cause enforcement of any intellectual property rights for any of their products. The first Plaintiff is actively engaged in the manufacture, marketing and sale of the innovative drug

Tarceva in various countries including India and it introduced Tarceva in India sometime in April 2006.

4. The Defendant, CIPLA, is the second biggest pharmaceutical company in India. It is incorporated under the Indian Companies Act, 1956; it has its registered office at Mumbai. In December 2007 and January 2008, various news reports appeared in the print as well as the electronic media about the defendant's plans to launch a generic version of Erlotinib in India and also for exporting it to various countries. One such report appeared on 11.1.2008 in an English daily 'Mint' published by the Hindustan Times Group. The Plaintiffs claim their knowledge of the Defendant's plans to infringe their rights in the patent, from such reports. They have filed the present action seeking permanent injunction and damages.

5. It is averred by the Plaintiffs that Erlotinib was developed after long, sustained and substantial research, and after incurring enormous expenditure for the tests, mandatorily conducted to establish its efficacy and safety. It is submitted that this innovation is duly protected under the provisions of law and no person except those authorized to exercise the legal rights associated with the patented drug can be allowed or permitted to copy/simulate and/or re-create it in any manner or in any other name. They allege that the Defendant is following an illegal course to offer a generic version of the patented drug; firstly, in an unlawful manner by infringing the legal rights of the plaintiffs, and secondly, in a manner that may pose a serious hazard to the lives of the patients. They submit that they would suffer serious and irretrievable prejudice in case the Defendant is not restrained as prayed for. They further claim that the actions of the Defendant may cause a serious and grave hazard to the lives of the cancer patients.

6. The plaintiffs rely on a copy of the license issued by the Directorate General of Health Services, Central Government registering Tarceva; they also rely on a copy of the patent certificate, and the order if its grant, dated 6-7- 2007. The Controller of Patents had, by his order, rejected a pre-grant opposition to the

plaintiff's patent application. The plaintiff also relies upon the documents permitting it to import the drug into India, in support of its claim about the drug's presence in the Indian market. It has relied on the press reports, mentioned in the plaint, to allege that the defendant is likely to indulge in infringement of its (the Plaintiff's) products. The plaintiffs, through additional documents, filed after the filing of the suit, produced a copy of the claim; they also averred, in an additional affidavit that the sales of Tarceva in India were to the tune of Rs. 13.2 crores.

II TheWritten Statement and Counter-claim

7. In its written statement, the Defendant alleges that it applied for the drug approval for its Erlotinib tablet in May 2007, which was granted in October 2007. It also submitted that approval from the Government of Goa was received, for manufacturing of the said tablet, in various pack sizes of 30, 60, 100, 500, 1000. Further, the Defendant claim to have been marketing and selling the product since December, 2007 under the brand 'Erlocip'. It alleges that the Plaintiffs had not filed the complete patent specification before this Court, without which the latter could not have filed a suit for infringement. It also alleged that the Patent specification being a public document under the Act, the Plaintiffs cannot claim confidentiality over them and will have to produce the same. Consequently, the specification was brought on record by the Plaintiffs.

8. The Defendant also contends that under the Act only a Patentee or a person deriving the title in the patent can sue for infringement; the first Plaintiff, who has not submitted any document that establishes its right in the present patent, cannot therefore sue for infringement. The Defendant submits that patent is a new one and as such no presumption of validity must be attached to it. It submits that under Section 11A, normally all patents, date back to the date of application after they are granted. However, in the case of patent applications filed under Section 5(2) the rights of a patentee accrue only from the date of grant of patent by virtue of the second proviso to Section 11A(7). Thus, the right under the

alleged patent accrues from date of grant and would thus be a 'new patent'. It is further submitted that in terms of Section 13(4) of the Act, there is no presumption of validity of patents. The defendant submits that the Legislature has thought it fit to permit scrutiny of the patent at several different stages. Examination/ opposition at the patent office are just the first stage. The patent is subject to scrutiny at several higher levels, unlike in the case of trademarks. The Patent Act, provides that even after a patent is granted, post-grant opposition can be filed under Section 25(2) for a period of one year. This is obviously because, in relation to patents that are recent, a higher scrutiny is necessary. Thereafter, an appeal lies under Section 117A to the intellectual Property Appellate Board. Parallel revocation proceedings are also maintainable either before the Appellate Board or before a court in which a suit for infringement of the patent is filed. Moreover, they submit that a patent, which is recent in nature and is yet to undergo the scrutiny of time, no injunction would be granted on alleged infringement. Therefore, the patent under Section 11A being barely six months old, no prima facie presumption of validity can be attributed to it.

9. The Defendant, relying on a joint reading of Sections 107 and 64, alleges about its entitlement to use the grounds mentioned in Section 64 in defense against an action of infringement. It has consequently filed a counter claim for the revocation of the patent in question, where it seeks to establish that patent is invalid.

10. The defendant firstly, contends that the plaintiff's patent claim lacks an inventive step. It is alleged that the patent is liable to be revoked as Erlotinib, being a Quinazolin derivative, only seeks to improve from the existing prior Article It would be obvious for a person skilled in the art that quinazolin compounds are known to inhibit growth and proliferation of mammalian cells and have been used in cancer treatment. Various quinazolin derivatives are available in the market for treatment of different types of cancer. The patented compound of the Plaintiffs is a quinazolin derivative used for the treatment of

cancer therefore, a derivative of a known compound and hence not patentable under Section 3(d) of the Act.

11. It is next contended that the patent does not reveal any obvious inventive step. In support, the Defendant avers about existence of at least three European patents, which date back to 1993 that disclose quinazolin derivatives. One such patent discloses the exact Chemical structure contained in the Plaintiffs' patent except for one substitution, which is obvious to any person skilled in the Article Apart from this, the defendant alleges that the plaintiff has miserably failed in proving that there is any improved efficacy of the said drug and that no tables or comparative data are provided in support of such claim. Drawing from the summary of the invention in the patent specifications of the plaintiff, the Defendant submits that the Plaintiffs have admitted that the Erlotinib was a quinazolin derivate. It is alleged that in the absence of proven enhancement in efficacy in terms of Section 3(d) no patent can even be considered, let alone granted. The defendant alleges that Erlotinib is just a derivative from Gefitinib of Astra Zeneca for which patent was refused in India, on the ground that the said product was already in prior use and was in the public domain. Under such circumstances, the Defendant submits, the patent office ought not to have granted a patent for Erlotinib. It alleges that the Plaintiffs' attempt to protect Erlotinib (which is nothing but a derivative of Gefitinib), establishes that the plaintiff is indulging in evergreening. Evergreening, it is submitted is contrary to public policy, against the statutory language employed in Section 3(d) of the Act and in the context of the pharmaceutical industry against national interests. The defendant places reliance in this regard on the ruling of the Madras High Court in Novartis v. Union of India , where the Court extensively relied on legislative debates in this regard.

12. The Defendant, in the counter claim, relied on the following grounds for the revocation of the plaintiff's patent;

a) that the invention, so far as claimed in any claim of the complete specification, was claimed in a valid claim of earlier priority date contained in the complete specification of another patent granted in India;

b) that the subject of any claim of the complete specification is not an invention within the meaning of this Act;

c) that the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known or publicly used in India before the priority date of the claim or to what was published in India or elsewhere in any of the documents referred to in Section 13;

d) that the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step, having regard to what was publicly known or publicly used in India or what was published in India or elsewhere before the priority date of the claim;

e) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of that art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

f) that the scope of any claim of the complete specification is not sufficiently and clearly defined or that any claim of the complete specification is not fairly based on the matter disclosed in the specification;

g) that the patent was obtained on a false suggestion or representation;

h) that the subject of any claim of the complete specification is not patentable under this Act;

i) that the applicant for the patent has failed to disclose to the Controller the information required by Section 8 or has furnished information which in any material particular was false to his knowledge;

j) the drug was known or is at best a pre-1995 derivative of an invention for which no product patent can be granted in India as it does not have any added efficacy.

13. The Defendant also adverted to the alleged non-working of the patent. It is averred that the working of a recent patent is an absolute precondition for grant of injunction. In the present case the plaintiff does not manufacture the product in India. Though it applied for patent in 1996, it got an approval for importing and selling the drug only in December 2005. Even now, the product, due to its high pricing, is not easily available on a commercial scale in India. This is obvious, according to the defendant, from the fact that no sales figures or even a single invoice for the product specifically for India have been given in the plaint or the attached documents. It is alleged that the law at that time in India permitted the plaintiff to apply for Exclusive Marketing Rights (EMR) for selling the product in India, yet, it never chose to obtain an EMR, which clearly establishes that the Patentee was not in a position to market or sell the product. Even the US FDA approval was obtained in 2004 that establishes that the Product and the patent are new and to be treated as such. It is new patent, less than 6 years old and not commercially worked in India thus dis- entitled to exclusive protection. Thus the plaintiff is not entitled to an injunction.

14. It is alleged that apart from the defendant, it is in the interest of the patients that no injunction should be granted. The plaintiff's capsule costs Rs. 4,800/- per tablet and the equivalent tablet of the defendant costs Rs. 1,600/-. Thus, a month's dosage for a patient undergoing treatment for cancer is Rs. 1.4 lakh whereas the equivalent cost of the defendant would be Rs. 46,000/-. It is alleged that in the area of life saving drugs, it in the public interest of the general public and patients suffering from diseases like cancer that medicines are made

available at cheap and affordable prices so long as the defendant is not a 'fly-by-night' operator. In such cases, an injunction ought not to be granted due to the overwhelming interest of society.

III Submissions of the Plaintiff

15. Dr. Abhishek Manu Singhvi, leaned counsel for the Plaintiffs submitted that the materials clearly justify the plaintiff's entitlement for interim relief. The relied on the copy of the Controller of Patent's order dated 04.07.2007, the FDA approval, magazines to show the effectiveness of Tarceva, and the other approvals secured by the Plaintiffs, to submit that there is a strong prima facie case. He drew the attention of the Court to the fact that a patent under the Act is granted after scrutiny at three levels; first, under Sections 11A, 12 and 14, then at the stage of pre-grant opposition under Section 25(1) and finally, under Section 43 when the patent is granted subject to satisfaction of the two pre-conditions. Given that in the present case the patent has been granted after elaborate technical verification, it cannot be summarily and certainly not at the stage of arguments on interim injunction be held as invalid. Further, it would not be appropriate that the remedy of injunction prescribed under Section 108 of the Act is denied to the Plaintiff merely because the Defendant as raised a defense of invalidity of the patent.

16. It is urged that Erlotinib is not a derivative of a known substance. Counsel argued that the standard imposed in amended Section 3(d) is not country specific and that the explanation to it is merely declaratory about the required inventive step necessary for patentability of any product. In any event, relying on the medical literature he submits that Erlotinib satisfies the test of enhanced efficacy. Moreover, the question of non-patentability under Section 3(d) specifically raised by NATCO at the stage pre-grant opposition, based on documents now relied by the Defendant, was negatived by the Assistant Controller General of Patents in his order dated 4th July 2007. Counsel contended that the Defendant has not shown that there is any similarity between Gefitinib and Erlotinib, and

the Assistant Controller General of Patents has dealt with the plea that both are derivatives of Quinazolin.

17. Without prejudice to his other pleas, he submitted that Erlotinib was not the derivative of any compound. That the name Quinazolin Derivative is a term for a class of compounds and it is not a derivative in terms Section 3(d). The Plaintiffs patent is for a new compound, and has an ethynyl group instead of the methyl group. He submits that none of the prior art, indicated by the Defendant discloses the presence of an ethynyl group particularly substituted at metha position of Phenyl ring. Therefore, this group and its position make the Plaintiff's compound inventive over the prior art documents. In the absence of a prior art teaching of metha substitution of the phenyl moiety by an alkynyl such as the ethynyl group, a person skilled in the art would not arrive at the invention in an obvious manner. It was urged that the Defendant's position about availability of post grant opposition pointing to dilution of prior stages including scrutiny and pre-grant or their being irrelevant is erroneous. He submitted that post grant opposition does not efface the validity of scrutiny.

18. It was next contended that there is no distinction between an 'Old' patent and a 'New' patent under the provisions of the Act. In fact, the kind of opposition available under the Act is different from what existed earlier. Previously, there was no post-grant opposition. The only a provision of challenge by a third party was a pre-grant challenge under Section 25(1) as it then stood. Therefore, the Courts had evolved the rule of caution as the patent had not faced any challenge at the hands of the third parties. There is however a radical shift, due to incorporation of Section 25(2) where a third party is granted the right to challenge the patent after its grant. The grounds of challenge under Section 25(1) are identical to Section 25(2). In fact, Section 25(1) is broader than 25(2) as the latter is available only to a 'person aggrieved'. The ground that the patent is new is hardly relevant; it has to be afforded protection, through an appropriate injunction in an action for infringement, wherever the plaintiff can establish its case. In this context, learned Counsel also argued that the nature of changes

brought in by amendment in 2005, affording multiple challenges shows that the previous rule, evolved by courts ' one of caution, ungrounded on any principle, that is, about working of patents for 6 years, cannot now be applied while deciding whether to grant interim injunction, as it would seriously impinge on the period of patent itself.

19. It was contended that by virtue of Section 53, the term of a patent is reckoned from the date of the application. The provision in Section 11A is, therefore, inapplicable to the present case as clarified by its proviso. A patent holder will enforce his rights only after grant but he can claim for entire period after the date of publication. For mailbox applications alone the enforcements and claim of damages starts after the date of grant. This does not mean that Plaintiff's patent becomes valid for 20 years after the date of application. This period is counted from the date of application.

20. The patent in this case was granted after due application of mind. The application was made on 13.03.1996; the certificate was issued on 23.2.2007. The objector, NATCO filed its pre-grant opposition on 10.4.2007. The application was heard on 27.6.2007 and Order rejecting pre-grant opposition was made on 4.7.2007. The patent was recorded in register on 06.07.2007. This peculiar situation was because NATCO's objection was filed post grant but treated as pre 'grant opposition.

21. It is submitted that the two documents, EP 0566226 and EP 0635507 referred to in the counter claim of the Defendant were already cited in the pre- grant opposition proceedings as prior art and decided, by the Patent Office. On efficacy, it is urged that the plaintiffs' application was filed in 1996 when Section 3(d) and its Explanation did not exist. All literature discussed regarding efficacy were filed by the plaintiff in 2006 and 2007 prior to commencement of pre-grant opposition hearing. All materials regarding efficacy were available in all the 2007 hearings. Hence, the Defendant's contentions in this regard are irrelevant and misleading.

22. The Plaintiff contends that the plea that Erlotinib would be an isostere of known compounds is a speculation. A person skilled in the art knows that the smallest change in a molecule can have dramatic effects and can totally change the efficacy of a molecule. Many examples in the pharmaceutical industry show that a small change in an active molecule can lead to an inactive or toxic molecule. Thus, changing the smallest Chemical group or a molecule cannot be seen as obvious. The person skilled in the art a priori never considers that it would have been obvious to change a Chemical group for another. The Defendant's argument, the Plaintiff contends, is artificial and can only be the result of an ex post facto analysis. In the case of pharmaceutical products such 'reverse engineering' is employed with great effect. 'Inventive step' must be examined at the time of filing of the Tarceva patent. At that time and without the knowledge of Erlotinib, there was no motivation to replace the methyl group by a C=N group either in the general formula or in the specific formulae of EP 0566 226. The suggestion that that the Plaintiff used the Methyl prior art, progressed to the Cyano state (i.e. C=N) and then arrived at the Ethynyl stage, is pure speculation and false. The simple point is that prior art is Methyl and Gefitinib used the Methyl route. The defendant, contends the plaintiff, suggested the Cyano route in the Gefitinib patent. However, the plaintiffs have simply used the Ethynyl model and not the Methyl model. Indeed, all these arguments have already been taken into account in the pre grant opposition proceedings and the patent was granted nonetheless by the Indian patent office. The defendant does not bring any new prior art document or argument in this respect.

23. Dr. Singhvi contended that Erlotinib is patentable over the cited prior art under Section 3(d). It cannot be considered as derivative of known compounds under Section 3(d). Section 3(d) of the Act makes clear that 'a derivative of a known substance' does not include a new Chemical molecule, but includes only different forms of a known active substance. All the examples given of derivatives, i.e. salts, esters, polymorphs, particle size, mixture of isomers, etc., are variations where the active part of the therapeutic molecule remains the

same. This is clearly not the case here: Erlotinib is clearly not 'salts, esters, polymorphs, particle size, mixture of isomers, etc' of a known substance'. The defendant has not supported its allegation in this respect. Erlotinib is a novel compound, which fact has been acknowledged twice by the Indian patent office. It was also argued that Erlotinib is not a polymorph of a known compound. Counsel explained that in column paragraph 45, US6900221 discloses that the hydrochloride compound disclosed in the US Pat. No. 5,747,498 actually comprised a mixture of the polymorphs A and B, which, because of its partially reduced stability (i.e. from the polymorph A component) was not more preferred for tablet from the mesylsate salt form. The patent discloses Erlotinib which was a novel compound, i.e. a new Chemical entity.

24. Learned Counsel submitted that Erlotinib is not a salt, ester, polymorph or isomer any known compound. This statement was made in US 6900221 filed in 1999. This is well after the priority dated (30.03.1995) of the Tarceva patent in India US 6900221, it is not part of the prior art opposable to the Tarceva patent. The consequence is that US 6900221 cannot be used to examine the novelty or inventive step of the Tarceva patent. The hydrochloride Erlotinib made under the conditions disclosed in the US 5747498 actually comprised a mixture of the polymorphs A and B was found after the discovery of Erlotinib. And this fact was first disclosed upon the filing US 6900221 in 1999. This fact could not have been taken into account in 1995. Novelty and inventive step therefore, should be examined at the time of filing of the invention i.e. 1995 not 1999.

25. It was submitted that Erlotinib hydrochloride has the following structure: the Chemical name is [6,7-bis (2 methoxy 'ethoxy) quinazolin ' 4-yl]- (3-ethynyl-phenyl)-amine hydrochloride and common name is Erlotinib hydrochloride. This compound is clearly novel because its specific structure is not disclosed in the prior Article In other words, no prior art documents discloses this very specific structure. Erlotinib hydrochloride is not a salt, ester, polymorph or isomer of any compound known at the time the patent was filed. Prior to the Tarceva patent, erlotinib hydrochloride was unknown. Hence its polymorphs were also

unknown. Therefore, Defendant's argument that erlotinib hydrochloride is a polymorph of a known compound is unsound.

26. Learned Counsel argued that the US 6900221 was relied upon during the pre-grant opposition proceedings and properly dealt with as appears in the order of the Asst. Controller. He also submitted that patents for Erlotinib have been filed worldwide in about 80 countries and are so far granted in over 50 countries including India, USA, European countries, China and Japan. It is hence to be understood that over 50 countries in the world recognized the patentability of Erlotinib. No opposition was filed in Europe, further evidencing the patentability of Erlotinib. Further, to Plaintiffs knowledge, the patent is only currently challenged in India and nowhere else in the world. Also, FDA approval date for Tarceva is November 19, 2004 for lung cancer.

27. Dr. Singhvi submitted that the argument that Gefitinib, an existing drug, inspired Erlotinib and therefore the latter did not involve any inventive step is unfounded as they are composed of different compounds, different properties and Erlotinib is more efficacious. It is submitted in the context that Astra Zeneca, the owner of EP 566226, did not select the methyl compound as a drug candidate. Instead, it selected Gefitinib to proceed in further clinical trials to test its safety and efficacy for use in humans. Presumably, that meant that Gefitinib has better properties than the methyl compound, otherwise the methyl compound would have been selected as the drug candidate. Tarceva, on the other hand, has been shown to have much better properties than Gefitinib. Indeed, Tarceva is the first and only HER 1/ EGFR targeted therapy to demonstrate improved survival in a Phase III trial in second and third line setting of advanced NSCLS. Since Tarceva is better than Gefitinib, which in turn is better than the methyl compound, logically Tarceva must have better properties than the methyl compound as well. The ethynyl group is not a derivative of a methyl. Indeed, what may appear to be even minor changes in substituents between structurally similar compounds may result in significant differences in their suitability as a

drug for use in humans, as is overwhelmingly demonstrated in the clinical outcomes reported for Erlotinib.

28. It was therefore contended that the plaintiff had established that the claimed invention is novel, inventive and has industrial application. The claimed invention was never used in India or elsewhere in the world before date of patent. And therefore the requirement of Section 2(1)(j) and 2(1) was duly met by the patentee. It was further urged that the submission that the specification contains irrelevant and misleading information is unmerited. Although originally, an application was made for patent of 27 claims, during the examination proceedings, the Plaintiff restricted it to two claims and patent was granted with the two restricted claims that were fully supported by the original specification. Learned Counsel also submitted that the plaintiff did not deliberately withhold any material information by not disclosing of US Patent No. 6900 221. The Plaintiffs' patent was filed on 13th March 1996 whereas cited US Patent was filed on 9th November 2000. According to Section 59(1) of Patents Act no amendment of application for patent or complete specification can be allowed, the effect of which would be that the specification as amended would claim or describe a matter not in substance disclosed or shown in specification before the amendment. Therefore, the Plaintiff was not allowed to amend the specification of its patent claim, to include any subsequent invention.

29. Counsel for the plaintiff relied upon the decision in Telemecanique and Controls (I) Limited v. Schneider Electric Industries 2002 (24) PTC 632(Del) (DB) [hereafter referred to as Schneider], where it was held that a patent creates a statutory monopoly protecting the patentee against any unlicensed user of the patented device, and that once violation is established in case of a registered patent(subject to its being used), it cannot be contended that the patentee is not entitled to injunction and that a monopoly of the patent is the reward of the inventor. He also relied on the judgment reported as Hindustan Lever Ltd. v. Lalit Wadhwa 2007 (35) PTC 377. He also quoted from an older English

judgment, in Proctor v. Bayley 1889 (42) Ch 390, about the advisability of grant of temporary injunction, to secure interests of the patentee.

30. Dr. Singhvi next relied upon Dunlop Pneumatic Tyre Co. Ltd v. Neal 1899 (1) Ch. D. 807. In that decision it was held that the purchaser of a patented article can carry out repairs to it; however, he cannot manufacture a new article and claim that he had not infringed the patent because in the manufacture he had used an article derived from a patented article sold by its patentee. It was contended that the defendants cannot similarly claim, by process of 'reverse engineering' that their products were new and invented goods. They were clearly inspired by the plaintiff's products and after purchasing them, copied the main elements; their effort was an act of infringement, which had to be injuncted.

31. Learned Counsel relied heavily on the decision reported as American Cyanamid Co -v- Ethicon Ltd, 1975 (1) All. ER 504 to say what are the guiding principles which courts have to adopt in cases involving infringement of patent and copyright cases. Learned Counsel submitted, by placing reliance on the decision of the Supreme Court in Midas Hygiene Industries (P) Ltd v. Sudhir Bhatia , that in cases of infringement either of trade mark or of copyright, normally an injunction must follow. Mere delay in bringing action is not sufficient to defeat grant of injunction in such cases. The grant of injunction becomes necessary if it prima facie appears that the adoption of the mark was itself dishonest.

32. It was contended next by Dr. Singhvi that the amendments to the Act deleted Section 5 of the Act, which had specified that only methods or processes of manufacture are patentable for certain inventions, so as to allow product patent protection in all fields of technology including areas of foods, medicines and drugs. The compulsion for amendments to the Act was primarily to introduce product patents for all inventions as mandated by the TRIPS Agreement. Therefore, ifThis Court were to refuse granting injunction, even after a clear case of infringement and prima facie merits for relief were made out, the legislative

will, and the country's resolve to integrate with a global patent friendly regime, affording protection to inventions would be thwarted.

33. Dr. Singhvi submitted that the arguments sought to be raised, about comparative cost of the product, are dangerous. This would render Section 108, nugatory. The Defendant's argument that the Plaintiff's drug costs more and therefore balance of convenience would lie in refusing injunction is 'jingoistic'; it is also unacceptable in view of the country's signaling acceptance of the TRIPS mandated patent regime, through the new amendments to the Patent Act. The Plaintiff's drug, inclusive of the cost of research and development and clinical trials, is marketed at Rs. 3,200/- while the Defendant's drug is marketed at Rs. 1,600/- without these costs. It is also to be noted that plaintiff price for patented drug includes the import duty of 32% (i.e. approx 850/- which is included in Rs. 3200/-). To include the price as a criterion for denial of injunction would mean that any generic producer would successfully avoid the injunction by offering a lower price. Thus, Dr. Singhvi submitted that the lower price of an infringing drug is irrelevant, in an action for infringement of a pharmaceutical patent.

34. Learned Counsel submitted, in the context of balance of convenience, that the working of a patent only means 'accessibility' of the invention to its customers and its use in the territory. The drug is available in India and has been used since April 2006. No Indian law mandates that patents can be only worked thorough manufacture in the territory; it can equally be used through imports. An identical argument about non-working of patent in the context of import of the product, was repelled by the Division Bench in Schneider (supra).

IV Submissions of the Defendant

35. Mr. Arun Jaitley, learned senior counsel for the defendant contends that the patent was wrongly granted to the plaintiff and is liable to be revoked. He submitted that the test of Section 3(d) has not been satisfied as all documents of efficacy relied upon by plaintiff are post 2002 and it is not clear as to whether the drug dealt with in those publications is as per U.S. 5747498 or 6900221. It

was also submitted that the invention claimed in patent No. 196774 is obvious to persons skilled in the art and the patent lacks an inventive step.

36. According to counsel, two elements attaching to any patent can invalidate it, that is,

i) Obviousness and Lack of inventive step.

ii) Section 3(d) Under Section 3(d) of the Patent Act, the applicant for a patent for a derivative substance has to show significant differences in properties with regard to efficacy. In this case, he contends that:

> a) The patent specification of the plaintiff is silent on efficacy.
>
> b) There is no in-house data or statistics given to show efficacy of the patented product over the closet prior Article
>
> c) There is no material placed on record in relation to efficacy over the known drug Gefitinib which led to the filing of the specification.
>
> d) Lack of materials, on the record in relation to efficacy over the known drug Gefitinib which led to the filing of the specification.
>
> e) According to the plaintiff itself the test of efficacy has to be satisfied on the basis of the date of filing of the patent and no material of a later date can be entertained to prove efficacy.
>
> f) The materials relating to efficacy are three or publications in medical journals which are of 2004 There articles do not clarify as to whether the product being talked of is Polymorph B From or mixture a of A and B forms of Erlotinib. Normally, it is the duty of every patent applicant to show that the product is efficacious over the prior Article
>
> g) In the present case, another earlier product which is also a derivative for treating Cancer, namely, Gefitinib has been refused patent protection in India with the following reasons:
>
> Based on my finding under the ground of obviousness and lack of inventive step wherein I concluded that the claim of the applicant that the compound of the present invention are 4 to 16 times more potent than the prior art compounds, are not persuasive, I conclude that all the compounds claimed in the present invention do not significantly differ in efficacy compared to the prior art which

is the explicit requirement under Section 3(d) and therefore is not patentable under Section 3(d) of the Patent Act.

It is claimed that by this test Erlotinib also could not have been protected.

37. It was also submitted that all the publications relied upon by the plaintiff to prove efficacy were of dates in 2005 (The Oncologist of October, 2005; The New England Journal of 14th July 2005; the Journal of Clinical Oncology, 10th August 2005 and the Journal of Oncology dated 20th May 2007). These were all post 1996 and also publications subsequent to the second patent of the plaintiff in the US, and India for the Polymorph B Form made in the years 1999 and 2002 respectively. Mr. Jaitley submitted that efficacy was not established by the plaintiff, inter alia, because of the following reasons:

a) No data has been mentioned in the patent specification.

b) No comparative tables have been provided comparing the efficacy of the invention with the closest prior art i.e. EP 0566 226 A 1 in its patent application during prosecution or during opposition proceedings and not even during the present proceedings in this Court.

c) No data in the form of research done by the plaintiff has been placed on record.

d) All the articles and publications are post 2000 and thus there is no clarity as to whether the said research relates to original Form as claimed in US Patent No. 5747498 or Polymorph B from US Patent No. 6900221. Since the US FDA lists both the patents in orange book and the subsequent patent being of a better product as per the Plaintiffs itself, it has to be presumed that all the articles and publications relate to the subsequent product and not the suit patent.

38. The various patents filed by the Plaintiff in the U.S. and in India, it is contended, show that TARCEVA, marketed in India is the subject matter of US Patent No. 6900221. Learned Counsel submitted that the plaintiff's action is based on a recent patent; it is barely six months old and according to well settled law a patent cannot be presumed to be valid unless it is more than six years old. The patent is new one and also granted under peculiar and suspicious circumstances and thus no injunction ought to be granted as per the settled law.

He relied on the judgments reported as Franz Xaver Humer v. New Yash Engineers 2nd (1996) 2 Del 791, N.R.D. Corporation of India v. D.C.andG. Mills Co. AIR 1980 Delhi 132, Boots Pure Drug and Co. (India) v. May and Baker Ltd. 52 (Cal. W.N. 253) which was followed by the Madras High Court in Manicka Thevar v. Star Plough Works and the judgment ofThis Court in Standipack Pvt. Ltd. and Ors. v. Oswal Trading Co. Ltd. and Ors. .

39. Learned Counsel relied on the judgment reported as Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries and submitted that the proper way to construe a specification is not to read the claims first and then see what the full description of the invention is, but first to read the description of the invention, in order that the mind may be prepared for what it is, that the invention is to be claimed, for the patentee cannot claim more than he desires to patent. He next relied on the judgment of the Supreme Court in Monsanto Co. v. Coramandal Indag Products (P) Ltd. for the proposition that under Section 64(1)(d), a patent may be revoked on the ground that the subject of any claim of the complete specification is not an invention within the meaning of the Act. A patent can be revoked if the invention so far as claimed in any claim of the complete specification is not new, having regard to what was publicly known and publicly used in India before the date of the claim, and also if the invention so far as claimed in any claim of the complete specification is obvious or does not involve any inventive step having regard to what was publicly known or publicly used in India or what was published in India before the priority date of the claim. The court had then held that to satisfy the requirement of being publicly known as used in clauses (e) and (f) of Section 64(1), it is not necessary that it should be widely used to the knowledge of the consumer public. It is sufficient if it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or consumers.

40. It was next contended that the question of efficacy as well as inventiveness had to be seen in the context of comparative data; no such materials were

forthcoming, in support of the plaintiff's claim. Reliance was placed on the judgment of the Madras High Court in Novartis (supra). Similarly, reliance was placed on the judgment reported as Godrej Soaps Ltd. v. Hindustan Lever Ltd. PTC Suppl. (1) Cal 501.

41. Learned Counsel submitted that even if the plaintiff's assertions were to be assumed, though not admitted, the court cannot grant an injunction automatically and has to be further satisfied that the balance of convenience would be in its favor, for granting the relief. It was contended that apart from the Defendant, it is in the interest of cancer patients that no injunction be granted since the product is an anti-cancer, therefore a life saving drug. One of the Plaintiff's capsule costs Rs. 4,800/-and the equivalent tablet of the defendant costs Rs. 1,600/-. Thus, a one month dosage for a patient undergoing treatment for cancer is Rs. 1.4 lakh whereas the equivalent cost of the Defendant's tablets would be Rs. 46,000/-. It is urged that patients in India can ill-afford such high priced imported versions of the drug and the Plaintiffs also do not have the manufacturing facility to produce the said drug whereas the Defendant has a state of the arts international standard manufacturing facility. In the area of life-saving drugs, it is thus in the interest of the general public and patients suffering from diseases like cancer that medicines are made available at cheap and affordable prices so long as the defendant is not a fly- by-night operator. If the defendant is restrained from manufacturing and marketing their anti-cancer drug in the market it would cause great prejudice to public health and public interest and create a grave public health crisis with disastrous consequences. In such cases, where the balance of convenience is heavily tilted towards the defendant an injunction ought not to be granted due to the overwhelming interest of society. The Plaintiff justifies the huge price of Tarceva on the ground that it includes huge customs duties by the plaintiff. Counsel submits that Defendant also pays huge excise duties on the drugs manufactured by it and thus the price differential is extremely high despite the said duties paid by parties. In support of this contention, reliance is placed on the

judgment of the Bombay High Court, reported as Novartis AG and Anr. v. Mehar Pharma 2005 (30) PTC (Bom).

42. Learned Counsel submitted that the plaintiff's patent was wrongly granted and is liable to be revoked because of obviousness and lack of inventive step. The product for which patent had been granted has a molecular structure which is similar to one of the disclosed molecules in the European Patent 0566226. Counsel relied on the documents, and written note of submissions to submit, that

a) Claim 1 of the impugned patent claims is compound having a described formula. It is submitted that EP 0566226 A1 discloses a compound having the formula with a slight variation. This is coupled with the fact that the methyl substitute is in the third position. The defendant's argument is that the above substitution is obvious to a person skilled in the art; counsel submits that this has not been answered by the plaintiff and that the plaintiff merely argues that the said substitution is not contained in many documents relied upon by the defendant and hence the patent is not bad. This counsel submits, is a response to an anticipation argument, which is different from the objection of obviousness. It is the submission of the defendant that the patent therefore lacks inventive step and is obvious.

b) Counsel contends that there is non-disclosure of various patents filed by the plaintiff in the US and in India. The drug Tarceva in India is subject matter of US patent No. 6900221. The plaint is silent on the various patent applications which have been filed by the plaintiff for Erlotinib. The plaint ought to have disclosed the fact that a subsequent patent has been filed for the Polymorph B From being subject matter of US patent No. 6900221. The plaint is conspicuously also silent on the two further applications filed by the plaintiffs in India which include:

i) Application No. IN/PCT/2002/00507/DEL

ii) Application No. IN/PCT/2002/00497/DEL

43. According to the defendant, the mere statement that the product is Erlotinib has no meaning as such because Erlotinib as per the plaintiff itself in various documents has different forms. Therefore in the absence of the details of the product, a bald reference to Erlotinib is wholly insufficient. In US Patent No. 6900221, the plaintiff made a categorical statement that the suit patent is a mixture of Polymorph A and B with reduced stability which necessitated the filing of the subsequent patent for the Polymorph B from of Erlotinib being US Patent No. 6900221. The corresponding Indian application to this US Patent of the Polymorph B Form is still pending, according to the Defendant's counsel. The drug being sold by the plaintiffs in India is the Polymorph B Form of Erlotinib. Reliance in this regard is placed by the Defendant on an expert's affidavit.

44. Learned Counsel for the defendant submitted that the amendments to the Act brought into force in 2005, for the first time, ushered a regime whereby product patent is permissible in respect of pharmaceuticals and drugs. Parliament consciously enacted and added, to the pre-existing requirements of every claim, the disclosure of non-obviousness and the necessity of an inventive step significantly the list of what are not inventions, under Section 3(d), was also changed by stating that 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 are unpatentable. The explanation further amplified this intention; it excluded salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. Erlotinib is admittedly a quinazolin derivative and a polymorph. The Defendant has every right, therefore to seek its revocation, under Section 64, in defense.

Counsel contended that the inclusion of Section 3(d) and the explanation was with a specific objective to exclude monopolies in known compounds and life saving drugs, unless the substance differed significantly in properties with regard to efficacy. For this reason too, the Plaintiff cannot seek an ad-interim injunction.

45. Learned Counsel also urged that the nature of presumption that can be drawn in cases of patent infringement is limited. The court can ask the defendant in the case of infringement action involving process patent, to prove or disprove any fact, prescribed, under Section 104A. The absence of such condition in relation to product patents was a significant omission. This had to be viewed with the opening expression in Section 48 'subject to provisions of the Act' to mean that unlike in the case of trademarks and copyrights, the grant itself did not guarantee per se protection. The Act, after amendment, envisions scrutiny of the patent at five different stages such as before the Controller, a pre-grant opposition, post grant opposition; application for rectification to the Appellate Board and defense, under Section 107, read with Section 64, in an action for infringement.

V Analysis and Findings

A. Provisions of the Patent Act

46. Section 2 of the Patent Act is the definition clause; it inter alia, defines, inventions, inventive step, new invention, and patent, as follows:

> 2. (j) ``invention'` means a new product or process involving an inventive step and capable of industrial application;

(ja) ``inventive step'` means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;

(l) ``new invention'` means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete

specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art;

(m) ``patent'` means a patent for any invention granted under this Act;' Section 3 defines what are not inventions; it reads as follows:

> 3. WHAT ARE NOT INVENTIONS The following are not inventions within the meaning of this Act,-
>
> (a) an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
>
> (b) an invention the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
>
> (c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature;
>
> (d) 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. Explanation. - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to. efficacy;
>
> (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
>
> (f) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
>
> (h) a method of agriculture or horticulture;
>
> (i) any process for the medicinal, surgical, curative, prophylactic diagnostic therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.

(j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

(k) a mathematical or business method or a computer program per se or algorithms;

(l) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;

(m) a mere scheme or rule or method of performing mental act or method of playing game;

(n) a presentation of information;

(o) topography of integrated circuits;

(p) an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.

47. The application of anyone desirous of seeking patent has to contain specifications that are to conform to the requirements of Section 10. The claim should fully and particularly describe the invention and its operation or use and the method by which it is to be performed. It should also disclose the best method of performing the invention, which is known to the applicant and for which he is entitled to claim protection; and end with a claim or claims defining the scope of the invention for which protection is claimed.

48. The procedure for grant involves:

a) Publication of the application under Section 11A(3) subject to the terms of the Act and request for its examination under Section 11B;

b) Examination of the application by the Patent Office, under Section 12, including search for anticipation by previous application, under Section 13 and report of the patent examiner;

c) Various options with the Controller, under Sections 14 to 21.

d) Where an application for patent is published, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the grounds specified under Section 25(1)(a) to (k).

e) If the application is found to be acceptable and in order, the Controller can grant the patent, and enter it in the Register, under Section 43.

f) Within one year any person interested may give notice of opposition to the Controller in the prescribed manner about his opposition to the patent, under Section 25(2) on any of the grounds mentioned in clauses (a) to (k). In such event, the Controller has to constitute an Opposition Board, and give notice to the patentee. The Board will then examine the opposition, under Section 25(3). Under Section 25(4) the Controller shall order either to maintain or to amend or to revoke the patent, on the basis of the Board's recommendations.

49. Before the Appellate Board, or on a counter-claim in a suit for infringement of the patent, the High Court, a patent granted under the Act can be revoked on any ground enumerated in Section 64(1)(a) to (q). These grounds broadly coincide with the grounds of pre-grant opposition (by any person) and grounds for post grant opposition (by persons interested). Under Section 45(1), subject to the other provisions contained in the Act, every patent shall be dated as of the date on which the application for patent was filed. In terms of Section 11A(7), on and from the date of publication of the application for patent and until the date of its grant, the applicant has the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application. The first proviso however, prohibits the applicant from instituting any proceedings for infringement until the patent has been granted. The second proviso enacts, importantly that the rights of a patentee in respect of applications made under Sub-section (2) of Section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent.

50. Section 48(a) enacts inter alia, that subject to other provisions contained in the Act and the conditions specified in Section 47, a patent granted shall confer upon the patentee, where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India.

B. Nature of patent rights

51. The expression 'patent' connotes a right granted to anyone who invents or discovers a new and useful process, product, article or machine of manufacture, or composition of matter, or any new and useful improvement of any of those. It is not an affirmative right to practice or use the invention; it is a right to exclude others from making, using, importing, or selling patented invention, during its term. It is a property right, which the state grants to inventors in exchange with their covenant to share its details with the public. The precursor to the present Patent Act was an enactment of 1911, which had consolidated the pre-existing law.

52. It is not the object of this order to trace the changes to the Patent Act. However, some salient features, which have changed the regime, require to be noticed, for a proper understanding of the topic. India is a signatory to the agreement, in 1994 establishing the World Trade Organisation (WTO). The agreement on Trade Related Intellectual Property Rights (TRIPS) is a part of the WTO that India had ratified. In terms of these international regimes, the Act had to be amended, once the transition period of 10 years for developing countries expired on 31st December 2004, in terms of the TRIPS agreement, so as to extend product patent protection for inventions in the fields of food, Chemicals and pharmaceuticals. The Patent (Third) Amendment also provided for deletion of provisions relating to Exclusive Marketing Rights (which became redundant) and sought to streamline the system by having both pre-grant and post-grant opposition to patents. The amendment came into force on 1-1-2005.

53. The amendment, apart from enacting multiple challenge layers, to question grant of patents, also changed the definition of invention. Previously, Section 2(j) defined invention as any new and useful art, process, method or manner of manufacture; machine, apparatus or other article; and substance produced by manufacture. Now, 'invention' is defined as a new product or process involving an inventive step and capable of industrial application. More crucially, an inventive step was, by the amendment of 2002, defined as a step that makes the invention not obvious to a person skilled in the Article By further amendment, in

2005, 'inventive step' has now been defined to mean 'a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the Article '

54. Thus, an invention, in order to be patentable, should

a) involve an inventive step capable of industrial application;

b) which should involve technical advance as compared to the existing knowledge, or having economic significance or both; and

c) be not obvious to a person skilled in the Article

55. Section 3 outlines various situations where an invention (properly so called) can yet be not patentable. Section 3(d), as existing before 2005, after the previous amendment of 2002, read as follows:

> (d) the mere discovery of a new property or new use for a known substance or of a 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), and its explanation, (as amended with effect from 1-1-2005), now prescribe a class of discovery which cannot be subject matter of patent; it reads as follows:
>
> (d) 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. Explanation. - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to. efficacy;

The change, in 2005, is not without significance; it has introduced the concept of need for the discovery of a new form of a known substance (or a derivative,

which is deemed to be a substance) to differ significantly in properties with regard to the known efficacy.

56. The amended explanation was considered by a judgment of the Division Bench of the Madras High Court, in Novartis AG v. Union of India 2007 (4) MLJ 1153. The court held that:

> in sum and substance what the amended section with the Explanation prescribes is the test to decide whether the discovery is an invention or not is that the Patent applicant should show the discovery has resulted in the enhancement of the known efficacy of that substance and if the discovery is nothing other than the derivative of a known substance, then, it must be shown that the properties in the derivatives differ significantly with regard to efficacy. As we stated earlier, due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the discovery of a new form a of known substance had resulted in the enhancement of the known efficacy of the original substance and the derivative so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy.

57. It may be gathered from the above discussion that the test of patentability has become more precise and specific, with inclusion of concepts such as 'non-obviousness' of a process or substance, to a person skilled in the Article These concepts were not new; in the field of patent law, the test of obviousness had been evolved, and existed in the United States and was incorporated in 1952 into the enactment. Apart from this shift in the requirement of inventive ingenuity to entitle a patent applicant for a grant, the Indian Parliament also added to the list of what cannot be patented, the 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, unless it results in efficacy of use of the substance (Section 3(d)). The Explanation says that esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to the known efficacy.

58. In the absence of any legislative history, and the two amendments to the Patents Act, it could possibly have been argued that the essence of patentability, in pharmaceuticals and Chemicals, is inventive ingenuity, novelty and existence of industrial application or economic significance of the new product or process. However, the background of the amendments and the two stage change (2002 and 2005) brought about to the Act cannot be overlooked. A sound canon of statutory interpretation is that all provisions of a statute are to be given effect to; a statute is to be construed as a whole and that no words in a statute are presumed to be superfluous; also the court should avoid a construction which reduces any provision a dead letter. (Ref. Tribhuwan Prakash Nayyar v. Union of India ; East India Hotels Ltd. v. Union of India AIR 2001 SC 231; Mohammed Hussain Khan v. Mohd. Shafi). In view of the above discussion, and the settled position regarding statutory interpretation, it is not possible forThis Court to accept the Plaintiff's contention that Section 3(d) and its explanation are merely clarificatory of the pre-existing law. The Parliament consciously enacted the standard of non- obviousness as a condition for patentability; it also excluded some matter, i.e., derivatives of substances which are known to exist, unless they differ in properties, significantly, in the known efficacy. Thus, it has to be concluded that the test of non-obviousness of an invention and discovery of existence of significant enhancement in the known efficacy of a substance are pre-requisites of patentability. In other words, even if non-obviousness of an invention in the pharmaceutical or Chemical industry are established, the applicant should also prove that if the invention claimed is the derivative of a known substance, it does not fall within the excepted category, in the Explanation to Section 3(d) as it comprehends a discovery of significant enhancement in known efficacy of such known substance.

C. The cancer condition

59. The human body has a complex system of signaling between cells; the duplication of genes is a normal part of the process.'Proteins called growth factors signal other cells to initiate replication, towards beneficial duplication or

repairs in the cells.' Malfunctions in such growth factors are a part of cancer, as growth factors prompt excessive duplication.' A separate type of gene called a tumor suppressor gene regulates and restricts growth, sending signals to stop duplication or initiate apoptosis, an orderly system of'cell death.'A model of cancer suggests that it is a product of abnormal growth factors prompting duplication of cells and the failure of tumor suppressor genes to properly regulate them.'The Epidermal Growth Factor (EGF) plays a role in normal human development helping to repair damaged tissue.'EGF is expressed in many tumors. 'To initiate cell reproduction, a growth factor links with an associated receptor, like a lock and key.' EGF links with EGFR, the epidermal growth factor receptor.' According to recent research, the receptor rather than the growth factor itself has become the target of new drugs."

60. The receptor'has two basic p Articles Apparently, its activity results in what is termed as the tyrosine kinase (an enzyme that can transfer a phosphate group from ATP to a tyrosine residue in a protein) activity of phosphorylated EGFR in cancer cells, which results in the phosphorylation (addition of a phosphate (PO4) group to a protein molecule or a small molecule) of downstream proteins. These incite cell proliferation, invasion, metastasis (spread of cancer) and inhibition of apoptosis (a form of programmed cell death).'Cancer drugs, it is said work in two basic ways. They try to prevent binding at the ligand-binding domain,'or prevent autophosphorylation in the tyrosine kinase.' The existence of two separate functions means that drugs may later be combined.' Cells both give and receive signals.' A particular growth factor is involved both by receiving abnormal signals from other cells and giving them.'

VI Principles applicable in the case of interlocutory claims for injunction in patent infringement cases and their application to facts of this case.

61. The Plaintiff, as well as the Defendant, relied upon the celebrated English decision reported as American Cyanamid Co v. Ethicon Ltd 1975 (1) All. ER 504 to say what are the guiding principles which courts have to adopt in cases

involving infringement of patent and copyright cases. The Court had in that case enumerated the salient considerations which weigh with a court while granting or refusing interim injunction, in actions complaining infringement of patents; it was held as follows:

> As to that, the governing principle is that the court should first consider whether, if the plaintiff were to succeed at the trial in establishing his right to a permanent injunction, he would be adequately compensated by an award of damages for the the loss he would have sustained as a result of the defendant's continuing to do what was sought to be en joined between the time of the application and the time of the trial. If damages in the measure recoverable at common law would be adequate remedy and the defendant would be in a financial position to pay them, no interlocutory injunction should normally be granted, however strong the plaintiff's claim appeared to be at that stage.
>
> If, on the other hand, damages would not provide an adequate remedy for the plaintiff in the event of his succeeding at the trial, the court should then consider whether, on the contrary hypothesis that the defendant were to succeed at the trial in establishing his right to do that which was sought to be enjoined, he would be adequately compensated under the plaintiff's undertaking as to damages for the loss he would have sustained by being prevented from doing so between the time of the application and the time of the trial. If damages in the measure recoverable under such an undertaking would be an adequate remedy and the plaintiff would be in a financial position to pay them, there would be no reason upon this ground to refuse an interlocutory injunction.
>
> It is where there is doubt as to the adequacy of the respective remedies in damages available to either party or to both, that the question of balance of convenience arises. It would be unwise to attempt even to list all the various matters that may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them. These will vary from case to case.
>
> Where other factors appear to be evenly balanced it is a counsel of prudence to take such measures as are calculated to preserve the status quo. If the defendant is enjoined temporarily from doing something that he has not done before, the only effect of the interlocutory injunction in the event of his succeeding at the trial is to postpone the date at which he is able to embark upon a course of action which he has not previously found it necessary to undertake; whereas to interrupt him in the conduct of an established enterprise would cause much

greater inconvenience to him since he would have to start again to establish it in the event of his succeeding at the trial.

Save in the simplest cases, the decision to grant or to refuse an interlocutory injunction will cause to whichever party is unsuccessful on the application some disadvantages which his ultimate success at the trial may show he ought to have been spared and the disadvantages may be such that the recovery of damages to which he would then be entitled either in the action or under the plaintiff's undertaking would not be sufficient to compensate him fully for all of them. The extent to which the disadvantages to each party would be incapable of being compensated in damages in the event of his succeeding at the trial is always a significant factor in assessing where the balance of convenience lies, and if the extent of the un-compensatable disadvantage to each party would not differ widely, it may not be improper to take into account in tipping the balance the relative strength of each party's case as revealed by the affidavit evidence adduced on the hearing of the application. This, however, should be done only where it is apparent upon the facts disclosed by evidence as to which there is no credible dispute that the strength of one party's case is disproportionate to that of the other party. The court is not justified in embarking upon anything resembling a trial of the action upon conflicting affidavits in order to evaluate the strength of either party's case.

The above formulation has been followed in several later decisions; the Supreme Court of India too has approved and applied those principles (See Ramdev Food Products Ltd v. Arvindbhai Rambhai Patel and Ors.).

62. In several judgments in India, including judgments ofThis Court , it has been consistently held that where the patent is of recent origin and its validity has not been tested, the courts should not grant injunctions where infringement is alleged; it has also been held that if the defendant alleges that the patent cannot be sustained, the injunction should be refused (See Manicka Thevar v. Star Ploro Works ; Ram Narain v. Ambassador Industries) Surendra Lal Mahendra v. Jain Galzers 1981 PTC 112; National Research and Development Corporation of India v. Delhi Cloth and General Mills AIR 1980 Del 132; Standipack Pvt. Ltd. and Ors. v. Oswal Trading Co. Ltd. and Ors. . This rule, or practice, which appears to have been consistently followed stems from the English decision in Smith v. Grigg Ld. (1924) 41 RPC 149(1).This Court has also indicated, in

National Research and Development Corporation's case (supra) that if the patent is not less than six years old, injunction should not be granted as a matter of course. The recent judgment ofThis Court in Bilcare 'vs-Amartara Pvt. Ltd. 2007 (34) PTC 419 (Del) has also commented that mere grant of a patent does not guarantee its validity; in case an opposition is filed by the defendant and that if the counter claim of the defendant is based on that opposition, there cannot be any presumption in favor of the validity of the patent. Recently, after the judgment was reserved in this case, the Delhi High Court, in M. Mitra Co. (Pvt) Ltd., v. Kesar Medicaments and Anr. (decided on 22.02.2008 in CS (OS) 2020/2006, reported as Manu/DE/0306/2008) the Court considered an application for ad-interim injunction in a suit alleging patent infringement. The patent was in respect of a device for detection of antibodies to HepatIT is C Virus in human serum and plasma. The patent was granted on 22.09.2006. The Court held (in para 51) that the order of grant of patent, or rejecting pre-grant opposition cannot itself give rise to a presumption of validity of the patent, and the Court would have to look into the merits of the case of the plaintiff as well as the defense put forth by the defendant. The court, in Para 102, held, after discussing the rival contentions, that it would be impermissible for the defendant to rely on different documents disclosing different features of the product, that the product of the patent is known. Such 'mosaicing' is not a valid defense. The decision rejected the defenses, and on prima facie determination of validity of the patent, granted interlocutory injunction. The court did not however, discuss whether the patented product or the infringing goods had any life saving or such like element; it was not concerned with the interpretation of Section 3(d). Crucially, the question of balance of convenience was considered as enuring in favor of the plaintiff, since a prima facie case was established, and the patent was for a limited period. The plaintiff's contention, in the above circumstances, that a mere showing of prima facie existence of merits, being sufficient to injunct the defendant, cannot be adopted as a general rule. The reliance on Midas Hygene, in the opinion ofThis Court is not apt, since that was a case concerning

trademark infringement; the Supreme Court expressly did not mention the approach concerning patent infringement. Similarly, the Division Bench ruling in Schneider affirmed the refusal by the Single Judge, who had noted that the defendant did not dispute the patent, or challenge it. The main argument, repelled by the affirming judgment of the Division Bench, was that non-manufacture of the product in India, and its import did not disentitle the plaintiff to injunction, if other factors were to be established. The correct approach, of appreciating all the factors, and not merely the prima facie merits, is too well established in regard to grant of temporary injunction; specifically in the field of patent infringement, this was re-stated by a Division Bench in Franz Zaver Huemer v. New Yash Engineers .

63. One must confess bafflement at the 'six-year' rule preventing courts in India from granting interim injunction. No provision of law or rule was brought to the notice of the court in support of this practice. The six-year rule appears to have crept in Manicka Thevar, and subsequently picked up in other judgments to be developed into a universal rule. The rule can be explained as one cautioning the courts that patent infringement actions stand on a slightly different footing, (from other cases) where the courts should not automatically grant injunction on prima facie satisfaction of infringement, since patents can be challenged, even in defense. It has to be seen as a rule of caution and prudence rather than a rigid, ritualistic formula of mathematical application. In the context of the amended Act, where no less than five layers of scrutiny are inbuilt, what can be said is that the courts should examine the claim for interlocutory injunction with some degree of circumspection, even while applying all the tests that normally have to be satisfied when granting (or refusing) such relief. This view accords with the trend in the United States, where in eBay v. MercExchange 547 US 388 (2006) the Supreme Court of United States rendered a significant judgment relevant in the present context. eBay was found to be infringing a patent held by MercExchange. The latter sought to enjoin eBay from using its product. Under the Federal Circuit rulings prevailing at the time, an injunction was granted

automatically once infringement was discerned. Courts used to refuse it in exceptional circumstances, holding that injury could be presumed if prima facie case was established. The Supreme Court in an appeal by eBay, (against which injunction was issued), however, held that courts should consider the traditional four- factor test for issuance of an injunction, (i.e existence of prima facie case, balance of convenience, irreparable injury and public interest) and should not issue injunctions automatically. Such an approach has been also favored by two decisions ofThis Court , i.e Franz Zaver Huemer and Standipack Pvt. Ltd. The Calcutta High Court too has endorsed this view, in Godrej Soaps Ltd.

64. What then is the correct approach where a defendant challenges the validity of a patent' Here too, decided cases provide valuable guidance. At the stage of considering an application for interlocutory injunction, the defendant has to show that its challenge is a genuine one and not vexatious or set up to merely play for time: (Ref TJ Smith and Nephew Ltd. v. 3M United Kingdom PLC (1983) RPC 92 and Quantel v. Shima Seiki 1990 (RPC) 436). An almost identical line of reasoning, i.e. existence of a substantial question, raised by the Defendant, during interlocutory proceedings, has been favored in the United State Courts, exemplified in the following extract of a recent judgment by Rader, J, speaking for the US Court of Appeals for the Federal Circuit in Erico International Corporation v. DOC's Marketing Corporation 2008 U.S. App. Lexis 3439 (19.2.2008) 'Validity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial.' Amazon.com, Inc., 239 F.3d at 1358. In other words, a defendant need not prove actual invalidity. On the contrary, a defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable. Thus, a showing of [11] a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity.Id.'

65. To summarize, on the issue of interlocutory injunctions:

(i) In patent infringement actions, the courts should follow the approach indicated in American Cyanamid, by applying all factors;

(ii) The courts should follow a rule of caution, and not always presume that patents are valid, especially if the defendant challenges it;

(iii) The standard applicable for a defendant challenging the patent is whether it is a genuine one, as opposed to a vexatious defense. Only in the case of the former will the court hold that the defendant has an arguable case.

66. The first aspect to be considered is whether the Plaintiff's case is arguable. In support, the Plaintiff relies heavily on the grant of patent, on 6- 7-2007; the order of the Controller's office, rejecting the pre-grant opposition on 4-7-2007, the Food and Drug Administration approval of the United States, the copy of an article on Tarceva, published by the Canadian Online Pharmacy; copy of the journal 'Oncologist'; copy of the New England Journal of Medicine; and copies of the Journal of Clinical Oncology. The Plaintiff also relies on the documents issued in its favor permitting import of the drug, Tarceva, into India. It avers, in an affidavit about its sales having been made since 2006, and such sales being to an extent of Rs. 13.2 crores. It has also produced a copy of the claim with complete specification.

67. The plaintiff in its application with complete specification for grant of the patent 'Quinazoline Derivatives Compounds and Composition Thereof' filed a total of 27 claims. These claims were later amended and 25 claims were dropped. The corrected version of the claim of the plaintiff stood as 'A novel [6,7-bis(2-methoxyethoxy) quinazolin-4-yl]-3-ethynylphenyl)amine hydrochloride and a process for preparing the same'. The request for examination of the claim was made on 16.8.2004 and the application was published on 11.3.2005. The first examination report was issued on 22.2.2006 and thereafter eleven objections were listed. The case was placed for examination on 23.2.2007. In the claim the plaintiff finally claimed as follows:

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

> d s (2-methoxyedthoxy)quinazolin-4-yl] (3-ethynylphenyl) amine hydrochloride compound of the formula A
>
> 2) A process for preparing the compound as claimed in claim 1, wherein: a) the stated compounds react in the presence of isopropanol and pyridine under an inert atmosphere of dry nitrogen and under conditions more specifically described; and b) the obtained product is isolated from the reaction mixture.

The summary of the invention which is a part of the body of the claim describes it interalia as directed to pharmaceutical compositions for treating a hyperproliferative disease in mammals which comprise a hyperproliferative disease treating amount of a compound of the Formula I and a pharmaceutically acceptable carrier. The summary of the invention also states that it is directed to 4-(substituted phenylamino) quinazoline derivative of a described formula and pharmaceutically acceptable salts and products thereof (page 2 of the claim)

68. During the hearing it was emphasized that the Plaintiffs' claimed compound has an 'ethynyl group' present at metha position of phenyleniol group at a specific position, namely, position 3- i.e. metha position. It was claimed that the prior art indicated by the compound in the pre grant hearing, nowhere discloses the presence of such ethynyl group particularly substituted at metha position of phenyl ring. On this basis the plaintiff claimed that there was no prior art teaching indicative the above substitution and its effects and that a person skilled in the art would not arrive at this invention in an obvious manner.

69. The office of the Controller of Patents found that sometimes the modification in the prior art technologies, which seem minor, can bring great revolutions in the world never otherwise predicted by the society of intellectuals. He concluded as follows:

> A substitution of Group alkynl at metha position of phenyl moiety of known basic compound (i.e. substitute phenyl aminoquinazolines derivative) has brought revolution in the treatment of NSCLC and Pancreatic Cancers and proved its efficacy as compared to the drugs available in the prior Article The Journal clinical oncology, Volume 25 No. 15, May 2007, volume 24, No. 24, August, 2006 may be referred to look into all the facts. The compound appears

to be much more effective as compared to the compounds for the similar purpose. None of the prior art citations therefore are able to establish any motivating factors to the persons skilled in the art by looking into the prior art and their appears no possibility of anticipation of such a great improvement in the properties of the invention and invented new derivative compounds. The same thing appears to the allegation of compounds about the structure of the new derivative compound. Such a structural similarity as deduced by far a compound having great medicine value may not be accepted to establish the new derivative as obvious.

I rely on the decision issued by.... Therefore, I hereby held that the product as claimed in claim I and the process as claimed in claim 2 both are innovative and non obvious. Moreover, the patent office of various advanced countries have examined this invention for novelty and inventions are found. Presence of inventiveness and novelty in the invention (sic). These countries have issued the patent on this invention. Form ' 3 filed in patent office discloses this fact.' As to whether the invention was in respect of a derivative that disclosed significant enhancement in efficacy, the patent office, in the said order observed as follows:

The opponent during the hearing raised the issue that the present compounds fall under Section 3(d) of the Indian Patents Act as the claimed compounds are obvious variants of prior art compounds and do not significantly differ in therapeutic efficacy over the compounds of prior Article This issue was not taken in their representation. The applicants submit that the providing of efficacy data at filing was not possible. However, the same has been given as and when asked by Controller. The data regarding survival rate increase has been significantly increased as indicated in the Journal the Oncologist, 5.2.2007. In view of the fact that the opponents have not substantiated and elaborated this ground of objection further once the invention has been found inventive the invention cannot be patentable under Section 3(d) of the Patents Act. Moreover, the opponents have not properly established this ground. Therefore ,I held that the invention cannot be held non-patentable under Section 3(d) of the Patents Act, 1970. (sic)

70. The Defendant alleges that the claim does not sufficiently describe the inventive step, a vital pre-condition for the grant of a valid patent. They have contrasted the order of grant with another order of the Patent Office declining grant in the case Gefitinib. They also seek comparison of the claim of the Plaintiffs' claim with its subsequent claim made in US Patent No. 6900221 to

submit that an exhaustive description of the prior art is absent. More crucially, it is contended in the defense that the Plaintiff underplayed and the patent office ignored, the presence of ethynyl substitution, suggested in a prior patent, that is, EP 0635507 of 1995. A copy of that European Patient has been produced. It is contended that the product for which the patent had been granted has a molecular structure similar to what is disclosed in EP 0566226. The Defendant has set out two structures of that patent in its counter claim and contended that the ethynyl substitute claimed by the Plaintiff is in the third position of a published compound of formula in respect of a known-compound. It is, therefore, argued that the substance is obvious to a person skilled in the Article The Defendant urges that this aspect is, left without any explanation by the plaintiff. The Plaintiff's position on this is that the substitution with the Ethynyl element is not contained in any document.

71. From the above discussion a few distinctive factors require to be prima facie considered byThis Court. Firstly, whether the Plaintiff's claim and the patent as granted, involves an inventive step; and, whether it satisfies the test of non-obviousness and further, whether the patent for Erlotinib even if it is a Quinazolin derivative can nevertheless be patentable as there is significant enhancement in known efficacy. Here, the factors which weigh in favor of the plaintiffs claim for prima facie merits or that it has an arguable case, are that it's claim received the patent office's examination at two levels i.e. before the grant of patent and during the pre-grant position; a series of medical and Oncological publications which credited Erlotinib with some degree of success in treatment of NSCLS. Some of the publications indicated that the patients had an increased potentiality of survival, of 6.7 months in the case of Erlotinib, as opposed to 4.7 months in the case of placebos. These were, however, after 2005. The drug has also been admittedly produced. There is no serious dispute in that regard; it can therefore be said to have industrial application.

72. In the above background what has to be considered is whether the Defendants have been able to outline a credible or arguable challenge to the

Plaintiff's patent. The Defendant's objections are principally twofold, that is, that the product was obvious to a person skilled in the prior art and that since Erlotinib is a derivative of a known compound, the Plaintiff had to necessarily establish a significant enhancement in its known efficacy for its claims under Section 3(d).

73. In the United Kingdom, the Court of Appeal in, Windsurfing International Inc. v. Tabur Marine (GB) Ltd. [1985] RPC 59, required the following steps to be taken into account while determining patentability:

> 1. Identifying the inventive concept embodied in the patent;
>
> 2. Imputing to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;
>
> 3. Identifying the differences if any between the matter cited and the alleged invention; and
>
> 4. Deciding whether those differences, viewed without any knowledge of the alleged invention, constituted steps that would have been obvious to the skilled man or whether they required any degree of invention.

74. The U.S. Supreme Court in Grahametal. v. John Deere Co. of Kansas City et al. 383 U.S. 1 (1966) held that obviousness should be determined by looking at 1.the scope and content of the prior art; 2.the level of ordinary skill in the prior art; 3.the differences between the claimed invention and the prior art; and 4.objective evidence of non-obviousness. In addition, the Court outlined factors that show ``objective evidence of non- obviousness'`. They are:

> 1. commercial success;
>
> 2. long-felt but unsolved needs; and
>
> 3. failure of others.

75. There is a certain amount of elusiveness in what is obvious (or not obvious, depending on what one is looking at). Obviousness, as a concept, said Justice Learned Hand, was 'as fugitive, impalpable, wayward and vague a phantom as exists in the whole paraphernalia of legal concepts.' Courts in England have also

recognized the danger in too liberal an approach to obviousness, on the one hand, and too strict an approach on the other. Pumfrey J in Glaxo Group Ltd's Patent [2004] RPC 843 observed as follows:

> ``Both the Scylla of considering nothing obvious except that to which the skilled man is driven and the Charybdis of considering every invention obvious that can be decomposed into a sequence of obvious steps must be avoided. The former is unfair to industry because it stifles natural development. The latter is unfair to inventors and not countenanced by English patent law.`

76. The United States Supreme Court recently re-visited, in KSR International Co v. Teleflex 550 US 1,(2007), the test of obviousness. The US Supreme Court dealt with the test of obviousness being followed in a series of decisions consistently for the past two decades or so and popularly known as 'TSM' i.e. Teaching Suggestion and Motivation. The court held that such a test was restrictive, and emphasized the need to make an expansive and searching scrutiny as to whether the claim (for which patent is claimed or granted, or where infringement is complained) suffers from obviousness, in the following terms:

> The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations and it often may be the case that market demand rather than scientific literature will drive design trends. Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may in the case of patents combining previously known elements deprive prior inventions of their value or utility.' A hint of this TSM method appears to have crept in the examination of the plaintiff's claim, in the Controller's order, particularly at page 22, where he appears to have proceeded to rule out any motivational factors to the persons skilled in the art- by looking into the prior art for finding out or predicting the improvement in the properties of the quinazolin derivative compound. The plaintiff too appears to be emphasizing this since its argument is that the prior art does not contain description of a similar compound. The Controller's order,

besides not examining the objection about obviousness, as presented, appears to have mixed up the aspect of efficacy, a vital component required to be satisfied after the 2005 amendment; it has noted that documents about efficacy of the drug were not available as on the date of the application, but made available whenever required. In the facts of this case, the plaintiff also had to establish that the product is one differing significantly in properties with regard to efficacy. This was necessary since the compound is a derivative, and deemed to be part of a known compound. Though the defendants made a strong argument about the non application of mind by the Controller, since the patent certificate was issued on 23-2-2007, yet, the pre-grant order was made on 4-7- 2007 (also imputing that the pre-grant application was not maintainable) however, the court will not go into that aspect at this stage.

77. One cannot lose sight of the fact that the court at this stage is not making a detailed, in depth scrutiny of the merits of the patent. The endeavor here is only to consider, since the plaintiff has an arguable case, whether the Defendant has raised an arguable case or has it has made a palpably unfounded claim. The test of obviousness cannot be that the material or formula was published, but that having regard to the existing state of prior art or the published material, was it possible to a normal but unimaginative person skilled in the art to discern the step on the basis of the general common knowledge of the art at the priority date. The other deciding factor is whether the differences between the prior art would, without knowledge of the alleged invention, constitute steps which could have been obvious to the skilled man or whether they required any degree of invention. If this is the correct way, the Patent office order appears to have accepted non-obviousness readily, in the context of the plaintiff's submission that no prior art publication contained the structure of the compounds and the steps claimed by it. The inventive step should be such as could not have been discernable to the unimaginative person skilled in the art and not something which was published in the prior Article As extracted from the claim itself, the plaintiff had stated that the product is directed to 4-(substituted phenylamino) quinazoline derivative. The inventive step claimed is the methyl substitute is in the third position. The defendant's argument is that the above substitution is obvious to a person skilled in the art; and that this has not been answered by the

plaintiff, who merely argues that the said substitution is not contained in documents relied upon by the defendant and hence the patent is not bad. There is something to be said in the argument that this is a response to an anticipation argument, which is different from the objection of obviousness. There is also some merit in the plea that comparative data regarding efficacy of the plaintiff's drug, with existing drugs, was not independently shown at the time of examination of the claim, to establish difference, significantly in regard to its efficacy from the known substance or derivative. One contention of the plaintiff, that the defendant's goods are inferior, being unpatented, is irrelevant; it has received the drug license for sale in India. Likewise, the argument that the plaintiff's products have been patented in several countries, and have remained unchallenged, the present action being the exception, is not of much consequence. The patent regimes of each country differ; crucially, the municipal laws of the respective legal systems would determine the timing and scope of challenge.

78. On a conspectus of all the factors, the defendant's contention does not appear implausible. This is not to say that there is merit in its contentions; it is, not also meant to be reflective of the strength of such contentions. Any comment by the court, in that regard would be unfair to the plaintiff. The court should refrain from conducting a mini trial as to the strength of the parties, at the interlocutory stage. All that can be therefore said is that the plaintiff's case though arguable and though disclosing prima facie merit, has to answer a credible challenge to the patent, raised by the defendant.

79. The application of the American Cyanamid principles would then, at this stage, mean that the court should, in such cases, proceed to decide on the question of balance of convenience. This is necessary because the plaintiff has made out an arguable case; at the same time, the defendant's challenge is genuine. Even otherwise the aspect of balance of convenience should be gone into, if the plaintiff has a case on the merits. The House of Lords had with remarkable prescience refrained from attempting to list all the various matters

which need to be taken into consideration and deciding where the balance of convenience lies, let alone to suggest the relative weight to them; those factors would vary from case to case. While considering the issue of balance of convenienceThis Court has to consider the following factors:

> I) The extent to which disadvantages to each party would be incapable of being compensated in damages in the event of his succeeding at the trial;
>
> ii) The nature of the product and its use
>
> iii) The timing of the action
>
> iv) If the balance is approximately equal, the court may consider the relative strength of each party's case only where it is apparent by undisputed evidence that the strength of one party's case is disproportionate to that of the other party.

80. It would now be relevant to consider the various factual aspects other than the patent claims of the plaintiff. It is asserted on its behalf that the drug has been made available since the year 2006 by it and has till date recorded sales worth Rs. 13.2 crores. The plaintiff does not have a manufacturing facility in India; it imports Tarceva. It is unclear -- since no claim in that regard has been made, as to the marketing arrangements of the plaintiff for its product or its advertisement and other incidental expenses for Tarceva. The plaintiff asserts that one of its tablet costs Rs. 3200/- and that the effective treatment with the drug involves its use for two months, the patient taking the tablet once a day. The Defendant contests this and has produced packaging of the plaintiff and copies of bills disclosing the particulars of Tarceva, as costing Rs. 48,000/- per strip of 10 tablets. It has also produced bills from three pharmacists in different cities i.e. Chennai, Ahmedabad and Mumbai showing that the maximum retail price of its product Erlocip is Rs. 1600/- per tablet. The defendant has also produced a copy of the Central Government Standard Drug Control Organization permission in Form 46 under the Trade and Cosmetics Act, dated 19.10.2007 permitting it to manufacturing Erlocip for the treatment of non-small lung cancer.

81. As observed in a preceding part of this judgment the consistent trend of courts in deciding applications seeking interim injunction, involving claims for infringement of patents have been to be proceed with caution. As noticed earlier, this is more a rule of prudence than one of principle. Thus, unlike in cases involving infringement of other products, the Courts have to tread with care whether pharmaceutical products and more specifically life saving drugs are involved. In such cases, the balancing would have to factor in imponderables such as the likelihood of injury to unknown parties and the potentialities of risk of denial of remedies.

82. In a luminous decision, reported as Roussel Uclaf v. G.D. Sarle and Company Ltd. 1977 FSR 25, the Court of Appeal observed that even a limited injunction ensuring that a patient already on the drug in question should be continued to be supplied, as a condition for interlocutory restraint of the defendant, could prove inadequate. The court further said that such a limitation cannot deal with the issue where members of the public, whether they are already patients on the drug or not, should be deprived of the benefit of it. The court went on to observe that in such cases the onus must be on the plaintiffs to show 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 that there may 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 judgment, 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. There are infinite variations between these two limits.'

83. The above approach is not alien to Courts in our country. Although the Bombay High Court did not notice the decision in Uclaf, yet in Novartis AG (Supra) the Court held, in that case that if interim injunction were granted to the plaintiff, the manufacturing network of the defendant so far as drug is concerned would be dismantled and if due to any problem the plaintiffs could not make available the drug in required quantity in India it would be disastrous for patients. The aspect of price difference between the product of the plaintiff and defendants also influenced the Court.This Court too, in Franz Zaver Heumer voiced identical concerns in the following terms:

> 37. Balance of convenience has also an important role to play. Stultification of defendants' investment, loss of employment, public interest in the product (such a life saving drug), product quality coupled with price, or the defendant being smaller in size, may go against the plaintiff.

84. The plaintiff's counsel had at some stage argued eloquently about the country's entry into the TRIPS regime and its commitment to integrate with the global patent regime. He discounted the price differential between the plaintiffs Tarceva and the defendant's product Erlotinib as being 'dangerous' and 'jingoistic'. As noticed with reference to the two judgments cited above, price differential in the case of a life saving drug -- or even a life improving drug in the case of a life threatening situation, is an important and critical factor which cannot be ignored by the court. The materials before the Court in the form of documents undoubtedly show that the plaintiff does not have any manufacturing unit in India, for producing Tarceva. The defendant, on the other hand, manufactures and markets it. The plaintiff has not - apart from blandly asserting in its affidavit about the volume of sales being Rs. 13.2 crores - disclosed by any independent, objective material about its sales. Even if, its assertions are accepted, roughly 1000 patients have perhaps benefited from its drug on a rough conclusion so far. This is on the basis that the cost of the monthly doses being Rs. 1.28 lakhs; the course of treatment involving two months as against the total sale figure claimed as to be 13.2 crores. The defendant's product Erlotinib, on the

other hand, is marketed at a third of the cost of Tarceva; it costs Rs. 1600/- per tablet.

85. Undoubtedly, India entered into the TRIPS regime, and amended her laws to fulfilll her international obligations, yet the court has to proceed and apply the laws of this country, which oblige it to weigh all relevant factors. In this background the Court cannot be unmindful of the right of the general public to access life saving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted. Such injuries to third parties are un-compensatable. Another way of viewing it is that if the injunction in the case of a life saving drug were to be granted, the Court would in effect be stifling Article 21 so far as those would have or could have access to Erloticip are concerned. It is precisely this consideration that was emphasized as a relevant and significant factor in American Cyanamid and Roussel Uclaf. Even the United States Supreme Court was not unmindful of such considerations when recently it disavowed the liberal practice, of granting injunctions, and underlining the necessity of weighing relevant factors, including public interest, in eBay (Supra). In another decision, Cordis Corporation v. Boston Scientific Corporation 2004 US App. LEXIS 11557, the US Court of Appeals for Federal Circuit affirmed the refusal to enjoin the defendant, in a patent infringement action where the product was a drug-eluting stent. The court held that such injunction would inhibit a broad choice of availability of such stents. The court compared the public interest in protection of the patentee's right with the broader public interest in availability of the product, and held:

> While crediting the validity of this point,This Court also acknowledges that it cannot control in every case, without obliterating the public interest component of the preliminary injunction inquiry. Thus, for good reason, the courts have refused to permanently enjoin activities that would injure the public health.

86. The last and also significant factor that has to be examined is the question of irreparable hardship. Strangely, the plaintiff did not even address the court on this issue - presumably on its assumption that an injunction would follow once a prima facie case was established. As discussed earlier, in the section concerning balance of convenience, irreparable hardship is a separate distinct head which the Court of necessity has to examine and be satisfied about, while considering interlocutory applications for injunction. The crucial aspect here is whether refusal of injunction would cause such irreparable hardship to the plaintiff as cannot be later compensated in mandatory terms. The suit itself contains the averment that the defendant is a pharmaceutical giant in India. The plaintiff too claims to be holding a large number of patents for a wide variety of drugs, particularly life saving drugs. Neither party has produced any evidence as to the number of patients suffering from small cell lung cancer. Yet in one of the Newspaper articles produced by the plaintiff, states that about 90,000 men and 79,000 women in India suffer annually from lung cancer. The National Cancer Registry Report released by the Indian Medical Council in 2007 states that every hour 50 persons are diagnosed of cancer in the country. The same report states that 24% of all cancer incidents, are in relation to lung cancer. The figures of those suffering from the ailment that Tarceva and Erlocip seek to alleviate therefore, are significant. There is no empirical material, or statistical method by which the Court can deduce the numbers of such patients who would be using the plaintiff's product if injunction is refused; on the other hand, it is plain that a large number of them would be deprived of access to a life saving drug if injunction is granted. Therefore, this Court is of the opinion that as between the two competing public interests, that is, the public interest in granting an injunction to affirm a patent during the pendency of an infringement action, as opposed to the public interest in access for the people to a life saving drug, the balance has to be tilted in favor of the latter. The damage or injury that would occur to the plaintiff in such case is capable of assessment in monetary terms. However, the injury to the public which would be deprived of the defendant's

product, which may lead to shortening of lives of several unknown persons, who are not parties to the suit, and which damage cannot be restituted in monetary terms, is not only uncompensatable, it is irreparable. Thus, irreparable injury would be caused if the injunction sought for is granted.

87. The result of the above discussion is 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. Therefore, the defendant is hereby directed to:

> i) Furnish an undertaking toThis Court , within two weeks, to pay damages in the event of the suit being decreed. A director or other person, on behalf of the Defendant duly authorized by a specific resolution of its Board of Directors, shall execute the undertaking. The undertaking shall also include a stipulation that it would continue to bind the Defendant, regardless of its change in composition.
>
> ii) Towards effectuating direction (i) above, maintain faithful accounts of its sale of the product Erlocip and file quarterly accounts inThis Court , supported by the affidavit of one of its Directors, affirming about the veracity of the same;
>
> iii) File an annual statement of the sales figures, of Erlocip, duly authenticated by its chartered accountants, on the basis of its records, including the Sales tax and Excise returns.

88. IA 642/2008 is accordingly dismissed, subject to the directions in the preceding paragraph. Order dusty in addition.