IN THE HIGH COURT OF DELHI AT NEW DELHI

FAO (OS) 188/2008

Date of decision: April 24th 2009

F.HOFFMANN-LA ROCHE LTD. & ANR ..... Appellants

Through Dr. A.M. Singhvi, Senior Advocate, Mr. Parag. P. Tripathi, Senior Advocate with Mr. Raman Kapur, Mr. Manish Kumar, Mr. Jayant Mehta, Mr. Aditya Kant, Mr. Amit Kumar, Mr. Amey Nargolkar, & Ms. Arti Gupta, Advocates for appellant No. 1.

Mr. A.S. Chandhiok, Senior Advocate, Mr. Jayant Nath, Senior Advocate with Mr. Raman Kapur, Mr. Manish Kumar, Mr. Jayant Mehta, Mr. Aditya Kant & Mr. Amit Kumar, Advocates for appellant No. 2.

versus

CIPLA LTD. ..... Respondent

Through Mr. Arun Jaitley, Senior Advocate with Mr. S. Majumdar, Ms. Prathiba M. Singh, Ms. Bitika Sharma, Mr. Saurabh Mishra & Ms. Saya Chowdhary, Advocates.

CORAM:
HON'BLE THE CHIEF JUSTICE
HON'BLE DR. JUSTICE S.MURALIDHAR

1. Whether Reporters of local papers may be allowed to see the judgment? Yes
2. To be referred to the Reporter or not? Yes
3. Whether the judgment should be reported in Digest? Yes

JUDGMENT
24.04.2009

Dr. S. Muralidhar, J.

1. This appeal by the Plaintiffs F. Hoffmann-La Roche Ltd. (`Roche') and OSI Pharmaceuticals Inc. (`OSI') is directed against the judgment dated 19th March, 2008 passed by the learned Single Judge of this Court dismissing I.A. No. 642/2008 filed by them in their suit CS (OS) No.89/2008, thereby

declining their prayer for grant of an interim injunction to restrain the Defendant/Respondent Cipla Limited from manufacturing, offering for sale, selling and exporting the drug *Erlotinib*, for which the plaintiff No. 2 claimed to hold a patent jointly with Pfizer Products Inc. The impugned judgment nevertheless put the defendant to terms including furnishing an undertaking to pay damages to the plaintiffs in the event of the suit being decreed, to maintain accounts of the sale of its product *Erlocip*, file in the court quarterly accounts along with the affidavit of one of its directors, and to file in the court annual statement of the sales of *Erlocip* duly authenticated by its chartered accountants on the basis of its records, including the sales tax and excise returns.

2. For convenience, the appellants are referred to as the plaintiffs and the respondent as the defendant.

Case of the Plaintiffs

3. In the plaint in the suit CS (OS) No.89 of 2008 it is stated that plaintiff No.2 OSI jointly owns a patent with Pfizer Products Inc. in respect of a small drug molecule medically termed as a "Human Epidermal Growth Factor Type-1/Epidermal Growth Factor Receptor" (HER/EGFR) inhibitor, popularly known as *Erlotinib*. It is claimed that the said drug marked a major breakthrough and innovation in the treatment of cancer. According to the plaintiffs the various tests conducted on *Erlotinib* have shown a marked increase in the survival benefit in the patients suffering from advanced or metastatic non small cell lung cancer (NSCLC). The metastatic NSCLC is

most prevalent form of this cancer.

4. The plaintiffs state that *Erlotinib* is administered in the form of a Tablet and sold under the trademark and name of 'Tarceva', which is registered in the name of plaintiff No.1 Roche. It is claimed that *Erlotinib* and its formulation 'Tarceva' have been approved by the United States (U.S.) Food & Drug Administration (FDA) in the year 2004 and thereafter by the European Union (EU) in the year 2005. On 13th March, 1996 OSI along with Pfizer Products Inc. made an application to the Controller General of Patents, Trademarks and Designs, New Delhi for grant of a patent in respect of *Erlotinib*. The Controller General of Patents, New Delhi granted the said applicants a certificate bearing Patent No.196774 dated 23rd February, 2007 which was subsequently recorded in the Register of Patents on 6th July, 2007. It is submitted that in terms of the amendments to the Patents Act, 1970 ('Act') in 2005, the product *Erlotinib* as well as the process of its manufacture stand patented and are entitled to protection as such. The plaintiffs' product *Erlotinib* Hydrochloride Tablets (Tarceva) was registered by the Central Drug Standard Control Organisation, Directorate General of Health Services, Government of India under Registration Certificate dated 23rd December 2005 in the name of plaintiff No.1 Roche.

5. On 8th January, 2001, plaintiff No.2 OSI and plaintiff No.1 Roche entered into a development collaboration and licensing agreement whereby Roche was granted licence to use and sell and offer for sale the licenced products of the former including *Erlotinib*. Roche was further licenced and authorized to cause enforcement of any infringement of property rights of any of the products of

plaintiff No.2 OSI. It is claimed that Roche introduced Tarceva in India some time in April 2006. The announcement regarding the launch of Tarceva by the subsidiary of the Roche Group in India was given wide publicity by the media inter alia in view of its importance in cancer treatment.

6. The defendant Cipla Limited (`Cipla'), a company incorporated under the Companies Act 1956 and having its registered office at Mumbai, is alleged to have announced in the print and electronic media its plan to launch a generic version of Tarceva (*Erlotinib*) in India. One such news item appeared on 11th January, 2008 in an English daily 'Mint' having wide circulation in New Delhi, Mumbai and Bangalore. The plaintiffs state that from such news report they learnt for the first time of Cipla's plans to infringe and violate the plaintiffs' rights. According to the plaintiffs the drug Tarceva (*Erlotinib*) has been developed after a long sustained research and after incurring enormous expenditure inter alia on the tests which are mandatorily conducted for its efficacy and safety. It was alleged that the said innovation was duly protected under law and that no person except those legally authorized to exercise legal rights associated with the aforementioned patented drug could be allowed or permitted to simulate, re-create it in any manner or in any other name. It was alleged that the defendant had no right to opt to manufacture, sell or offer to sell any version of the drug Tarceva (*Erlotinib*) and that such action of the defendant, as announced by it, would be in blatant violation of the legal rights of the plaintiffs.

7. In para 20 of the plaint it was asserted that the plaintiffs were under imminent threat of violation of their patent rights inter alia at New Delhi. It

was further asserted that "the application for the patent of the drug and process of manufacture of Tarceva (*Erlotinib*) was made and the patent was granted at New Delhi". It was argued that, therefore, this Court has territorial jurisdiction to adjudicate the suit. The suit was valued at Rs. 20 lakhs and for the relief of damages, it was tentatively valued at Rs.1 crore.

8. The suit was filed on 15th January, 2008. Along with the suit the plaintiffs filed an application under Order XXXIX Rule 1 Code of Civil Procedure 1908 (CPC), I.A. No. 642/2008, seeking ad-interim injunction restraining the defendant from infringing the plaintiffs patent in respect of Tarceva (*Erlotinib*).The two important points to be noted at this stage are that the plaintiffs asserted in the plaint that plaintiff No.2 was granted a patent for Tarceva (*Erlotinib*) jointly with Pfizer Products Inc. It was stated that the certificate bearing patent No. 196774 dated 23rd February, 2007 recorded in the Register of Patents on 6th July, 2007 pertained to Erlotinib Hydrochloride which was marketed as Tarceva. Secondly, in the plaint no details of the specification of the aforementioned patent or the x-ray diffraction of the product (tablet) Tarceva or the defendant's *Erlocip* was indicated.

Plea of the defendant in its written statement to the injunction application

9. The suit was listed before the learned Single Judge on 15th January, 2008, on which date the defendant appeared. The case was thereafter listed on 18th January, 2008 for the hearing of the application I.A. No. 642/2008 filed by the plaintiffs seeking ad-interim injunction. The defendant filed an application on 18th January, 2008 for a direction to the plaintiffs to disclose the patent specification. At the hearing on 18th January, 2008, the counsel for the

plaintiffs handed over to the counsel for the defendant the patent specification.

10. On 21st January, 2008, the defendant filed its written statement to the injunction application along with documents. It was stated that the complete specification which ought to have been disclosed in the plaint was supplied by the plaintiffs only at the hearing of the injunction application. The defendant claimed that it had applied for drug approval for the *Erlotinib* tablet in May 2007 and the approval was granted in October, 2007. As on December, 2007 it had received approval from the Government of Goa for manufacturing the said tablet in various pack sizes of 30,60,100,500 and 1000 tablets. The defendant had launched the product under the mark *Erlocip* and the said tablet was used for treatment of lung cancer.

11. It was pointed in the written statement that in terms of the second proviso to Section 11-A(7) of the Patents Act 1970, introduced by the Patents (Amendment) Act, 2005 (effective from 1st January, 2005), in case of patent applications filed under Section 5 (2) [which concerns a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug] the rights of a patentee accrue only from the date of the grant of the patent. It was also pointed out that although a certificate was issued to the plaintiffs by the Controller General of Patents bearing Patent No.196774 dated 23rd February 2007, the pre-grant opposition was disposed of only on 4th July 2007. Therefore the patent could not have been granted with effect from 23rd February 2007. It was submitted that the patent certificate was accordingly incorrect and the proceedings in the suit ought to be stayed till the correct authenticated certificate was produced. It was claimed that the patent

could not be presumed to be valid unless it was more than six years old and since the patent was a new one patent and "granted under peculiar and suspicious circumstances" no injunction ought to be granted.

12. It was mentioned in para 15 that the defendant had also filed a counter claim along with written statement praying for the revocation of the patent granted to the plaintiff. The grounds for revocation raised in the counter-claim were asked to be treated as part of the written statement.

13. In para 16 of the written statement it was specifically averred that the plaintiffs' patent "for which the complete specification is yet to be disclosed for the drug *Erlotinib*" was "completely invalid". A reference was made to Section 3(d) of the Act and it was submitted that *Erlotinib* is a derivative of a known patent "Quinazoline". It was stated that there were at least three EU patents dating back to 1993 which disclosed the Quinazoline derivative. One of the said patents disclosed the exact chemical structure as found in the plaintiff's patent except for one substitution which is "obvious to any person skilled in the art". Further, the plaintiff had failed to prove that there was "any improved efficacy of the said drug". No figures or data had been provided in support of such claim. It was claimed that there was no invention or inventive step in the patent. The patent compound would be obvious to a person skilled in the art to arrive at. It was specifically averred that "the alleged patented product is nothing but a derivative from Gefitinib of Astrazeneca for which a patent was refused in India".

14. It was averred in the written statement that one of the pre-conditions for recently granted patent claim to be protected was that it ought to be "worked fully and commercially". It was pointed that the plaintiff got approval for importing and selling *Erlotinib* only in December 2005 and even as on date the product was neither easily available nor affordable due to its high pricing. No sales figures for the product for India had been given in the plaint in the attached documents and not even one invoice had been filed by the plaintiff. The plaintiff never chose to obtain exclusive marketing rights (EMRs) during the time that the law in India permitted it.

15. The written statement specifically pleaded public interest. It was pointed out that each tablet of the plaintiffs' drug Tarceva costs Rs.4,800/- whereas each tablet the defendant's *Erlocip* costs Rs.1,600/-. Thus, a one month dosage of Tarceva for a patient undergoing treatment for cancer would cost Rs.1.4 lakh whereas the equivalent dosage of *Erlocip* would cost Rs.46,000/-. It was pointed out that in the context of life saving drugs, it was in the public interest that the drug should be made available at cheap and affordable prices.

16. Along with the written statement, the defendant filed copies of the European Patent "Publication No.0566 226 A1" (hereinafter EP'226) which was an application of Astrazeneca Limited in the EU for grant of patent in respect of 'Gefitinib'. Among the other documents filed by the defendant was the decision dated 30th August, 2007 of the Controller of Patents in India rejecting the application by Astrazeneca UK Limited for grant of patent in respect of Gefitinib. In the said application Astrazeneca UK Limited had cited EP'226 as the prior art and claimed that Gefitinib involved an inventive step

with respect to that prior art and with enhanced efficacy. The Patents Controller concluded that Gefitinib was "obvious and does not involve an inventive step over the prior art EP '226. It was therefore held to be not an invention within the meaning of section 2(1)(j) of the Patents Act, 1970 and no patentable invention within the meaning of section 3(d) of the Patents Act, 1970. In its written statement to the injunction application the defendant also placed on record the documents pertaining to US Patent No.6900221 (hereafter U.S.'221) filed by OSI in the US for Polymorph-B. The said application was filed on 9th November, 2000 and was granted on 31st May, 2005.

Defendant's counter-claim

17. In the counter-claim filed by the defendant it was contended that under Section 2 (1) (ta) of the Patents Act 1970, inserted by the 2005 amendment, the expression 'pharmaceutical substance' has been defined to mean "any new entity involving one or more inventive steps" and under Section 2 (1) (l) a "new invention" was defined as an invention "which has not been anticipated by publication in any document used in the country or elsewhere in the world before the date of filing a patent application with complete specification." It was contended that the suit patent therefore needed a special scrutiny as to the question of validity in the light of the above provisions which were specific to inventions in the field of pharmaceuticals.

18. In para 3.6 of the counterclaim it was contended by the defendant that the plaintiff "had failed to provide any evidence that the compound of claim 1 of the impugned patent possesses significantly enhanced activity over the closest

compound of the prior art." In para 3.7 it was averred that the plaintiffs had not provided the relevant data that was required to demonstrate that the claimed compound had a higher therapeutic efficacy. In para 3.8 a reference was made to U.S.'221 which clearly stated that the compound Erlotinib Hydrochoride was a mixture of two polymorphs A&B and that one needed to separate and purify the B polymorph so as to get to the claimed compound for acceptable efficacy. It was stated that subsequent patent clearly defeated the inventive step of the alleged invention.

19. In para 4 of the counter claim it was averred that the suit patent, i.e., Patent No.196774 [corresponding to US Patent No.5747498 – hereafter U.S.'498] had been obtained by the plaintiffs by suppression of material information. It was stated in para 4.2 as under:

> "It is stated that the patentee knew very well that if it discloses the truth that the claimed product is in the form of a polymorph then the patent application would have been rejected at the outset because there is nothing to show that the product has enhanced therapeutic effect. Therefore by suppression of material facts the patentee has managed to obtain the impugned patent by by-passing the provisions of Section 3(d)."

20. In para 5.2 of the counter claim the defendant pointed out as under:

> "The present impugned patent fails to disclose that the compound of claim 1 of the impugned patent is actually a mixture of polymorphs, which is useless for pharmaceutical use. The patentee has intently and capriciously withheld material information that is important for practicing the alleged invention disclosed

in the impugned patent. Therefore, the defendant states that the specification of the impugned patent does not sufficiently describe the invention, particularly with regard to compound of claim 1 of the impugned patent. The impugned patent is therefore liable to be rejected on this ground alone."

Defendant's application under O VII R 11 CPC seeking dismissal of the Suit

21. On 30th January, 2008 the defendant filed an application I.A. No.1272/2008 before the learned Single Judge seeking dismissal of the suit. The thrust of this application was that the defendant had discovered that the plaintiffs had made two further applications for grant of patent in respect of the same chemical compound for a different crystal form which was termed by the plaintiffs as B-polymorph. The first application was filed on 14th May, 2002 and published first on May 20, 2005 and thereafter re-published on 23rd February, 2007. In the said application priority was claimed over three US applications one of which was U.S.'221. The second application which was filed on May 13, 2002 and published on 20th May, 2005 claimed priority over three US applications one of which was U.S.'221. It was pointed that the suit patent had claimed priority over U.S.'498 published on 5th May, 1998. A reference was made to the statements made by the plaintiffs in U.S.'221 which showed that the Indian patent No.196774 was in relation to the hydrochloride compound in the form of mixture of polymorphs A and B which was known to the plaintiffs way back in the year 2000 since this corresponded to U.S.'498 which was granted in 1998 itself. However, this fact was never stated in the application made before the Patent Controller. Since the admitted position of the plaintiffs was that patent No.196774 was not a preferred form for manufacture of tablets, the

defendant was curious to know how the plaintiffs were still importing and selling tablets of the said Hydrochloride compound under the brand "Tarceva". It sought to determine the actual crystalline structure of the tablets and accordingly purchased some manufactured in August 2006 from the local market. The x-ray diffraction data of Tarceva sold in India showed that it was "B-Polymorph of the Hydrochloride". This was confirmed by the defendant's expert Mr. Manish G. Gangrade who performed the technical evaluation. On an analysis of the X-ray diffraction pattern he came to the follwoing conclusion: "Tarceva tablets are wholly B polymorph of the hydrocholoride salt of N-(3-ethynylphenyl)-6, 7 bis(2-methoxyethoxy)-4-quinazolinamine. I further say that the X-ray powder diffraction of Tarceva clearly goes to show that it is not A polymorph or a mixture of A and B polymorph but is wholly B polymorph of the said compound."

22. It was stated in paras 12, 14 and 15 of the application as under:

> "12. The plaintiff in its various pleadings has claimed that the patented drug has been sold by it in India since April, 2006, meaning thereby the drug which is sold in India is the drug for which the patent has already been granted, i.e., Patent No.196774. However, an analysis of the drug which is sold in India and the patent which is registered as also the patent which is pending in India reveals that the case of the plaintiff is completely false. The drug sold by the plaintiff in India appears to relate to the said pending patent applications and not the granted patent No.196774.
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> ……
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> 14. It is, thus, obvious that the plaintiff has come to this Hon'ble Court with a completely false and

incorrect case. The plaintiff has deliberately failed to file the patent specification in the first place by claiming confidentiality. When the defendant showed that as per the statute a patent specification is a public document the plaintiff was forced to reveal the same. Now it has come to light that the drug which is marketed by the plaintiff is not at all the product for which the alleged patent has been obtained. The patent application for the drug which is marketed by the plaintiff is still pending in the patent office. The plaintiff has also suppressed the fact that it has made two further Patent Applications for the same compound, i.e. hydrochloride salt of N(3 ethynylphenyl)-6, 7-bis (2-methoxyethoxy)-4 quinazolinamine in B-Polymorph form. The defendant has already filed pre-grant oppositions against the said patent applications. Copy of the said pre-grant oppositions for patent application No. IN/PCT/2002/00507 and Patent application No.IN/PCL2002/00497 are annexed as Annexure E-6 and Annexure E-7. For ready reference the defendant is annexing herewith copies of the US Patent Nos. 5747498 and 6900221 downloaded from the USPTO. The said patent no. 5747498 corresponds to Indian Patent No.196774 which is the alleged equivalent of the patent which is subject matter of the present suit, while US Patent No.6900221 corresponds to the two aforesaid applications against which the opposition is filed by the defendant. The patent specification of Patent application No.IN/PCT/2002/00507 is annexed as annexure E-8 and the patent specification of Patent application No. IN/PCT/2002/00497 is annexed as Annexure E-9.

15. It is, thus, submitted that the entire case of the plaintiff is based on a false premise. The plaintiff is

> obviously not marketing the drug which is allegedly covered by the patent which is already granted. The drug which is being marketed is a drug which is related to the subsequent patent applications in India which are pending. These facts ought to have been disclosed by the plaintiff **before this Hon'ble Court**. The plaintiff has deliberately claimed in its pleadings that the sales of the patented drug are approx Rs.13.91 crores when it was well aware that the drug which is being manufactured and marketed by it is still pending for patent protection. Therefore, there has been no sale of the product form patented under No.196774." (emphasis supplied)

23. However, while notice was directed to issue in the application on 31st January 2008, on that very date the arguments in the injunction application I.A. No.642/2008 were concluded before the learned Single Judge and orders reserved. Thus in the impugned judgment the learned Single Judge did not advert to I.A. No.1272/2008 although a reference was made in the passing to the facts concerning polymorph-B.

Summary of conclusions of the learned Single Judge

24. The summary of the conclusions arrived at by the learned Single Judge in the impugned judgment dated 19th March, 2008 are as under:

(i) Section 3(d) of the Patents Act, 1970 was not merely clarificatory of the pre-existing law as contended by the plaintiffs. The Parliament consciously enacted a standard of known obviousness as a pre-condition of patentability; it also excluded the derivatives of known substances unless they differed significantly in properties with regard to efficacy.

(ii) In patent infringement actions the court should not presume that a patent is valid especially if the defendant challenges it; the test to be applied in such event is to find out if the challenge by the defendant is genuine as opposed to a vexatious one and further that the defendant has "an arguable case".

(iii) In the instant case although the plaintiffs' case was arguable and disclosed prima facie merit, it had to answer the "credible challenge" raised by the defendant to the validity of the patent.

(iv) The order dated 4th July 2007 of the Controller of Patents appeared to have readily accepted the contention of the plaintiffs that the inventive step claimed was not obvious to the unimaginative person skilled in the art and that the substitution of methyl for ethynyl in the third position was not contained in the documents submitted by the defendant. The Controller of Patents failed to appreciate that this was the plaintiffs' response to the anticipation argument and was different from the defendant's objection on the ground of obviousness.

(v) There was merit in the plea of the defendant that comparative data regarding efficacy of the plaintiffs' drug, with existing drugs, was not independently shown at the time of examination of the claim by the Controller of Patents to establish that the product differed significantly in regard to its efficacy from the known substance or derivative.

(vi) The court cannot be unmindful of the general access to life saving products and the possibility that such access would be denied if injunction was granted. If the Court was of the opinion that the public interest in granting an injunction in favour of the plaintiff during the pendency of an infringement action is outweighed by the public interest of ensuring easy and affordable access to a life saving drug, the balance should tilt in favour of the latter. In the instant case irreparable injury would be caused to the public if the injunction was granted as they would be deprived of the defendant's product. Several unknown persons who are not parties to the suit and who would be deprived of the life saving drug

would not be able to be restituted in monetary terms for the damage that would be caused to them if the injunction were granted.

(vii) The injunction was accordingly refused subject to conditions already adverted to in the earlier paragraphs.

25. This court while admitting the appeal by an order dated 22nd April 2008 did not stay the operation of the impugned judgment. However, it restrained the defendant from exporting *Erlocip* to countries where the appellants have a registered patent during the pendency of the appeal.

26. At the request of the parties, the appeal was taken up for expeditious final hearing. Mr. Parag Tripathi and Dr. A.M. Singhvi, learned Senior Advocates appeared for the plaintiffs and Mr. Arun Jaitley, learned Senior Advocate and Ms. Pratibha Singh, learned Advocate appeared for the defendant.

Plaintiffs' subsequent application for grant of patent in respect of Polymorph B

27. In this appeal, one of the significant issues posed by the defendant, which has a bearing on whether the plaintiffs have made out a prima facie case for grant of injunction, is that the specification for the suit patent (i.e. patent No.196774 corresponding to U.S.'498) showed that it was in respect of Erlotinib Hydrchloride Polymorphs A+B which was on their own showing an unstable form which could not be administered as such. It was contended that the case of the plaintiffs themselves was that it was Polymorph B which was the more stable form of the compound which could be administered in the tablet form. The x-ray diffraction pattern of the tablet Tarceva showed that it

corresponded to Polymorph B for which the plaintiffs did not yet hold a patent. Their application for the grant of patent for Polymorph B was pending consideration. It was submitted that therefore not even a prima facie case was made out by the plaintiffs since they were seeking an injunction against the defendant in respect of a drug for which they did not yet hold a patent. Moreover, this fact had been suppressed by the plaintiffs both before the Controller of Patents as well as in the suit. On this sole ground injunction ought to have been refused.

28. It was pointed out by learned Senior Counsel for the defendant that the plaintiffs had been changing their stand in regard to polymorph B in the pending application before the Controller of Patents and during the hearing of the present appeal. Clearly the plaintiff s were trying to mislead both this court as well as Controller of Patents to the effect that Polymorph B was subsumed in Polymorphs A and B. In fact it was initially contended before the Patents Controller that the closest prior art i.e. U.S.'498 did not teach a compound of Polymorph B free of Polymorph A whereas in the subsequent letter dated 18th August 2008 the plaintiffs sought to contend that the earlier compound (polymorphs A and B) included all known and unknown polymorphs. If in fact Tarceva corresponded to polymorphs A and B, there was no need for the plaintiffs to have applied for a separate patent in respect of polymorph B. In any event polymorph B also could not be granted a patent since it was not patentable under Section 3 (d) and further the plaintiffs failed to demonstrate any enhanced efficacy over the known closest prior art polymorphs A and B. It is pointed out that in the published literature pertaining to the history of Roche, which was placed on record by the plaintiffs themselves, it was claimed that

Tarceva was invented only in 2004. Clearly therefore Polymorph B form of Erlotinib Hydrochloride (which was the tablet form of Erlotinib Hydrochloride and marketed as Tarceva) was not known to the plaintiffs at the time they applied for a patent for Erlotinib Hydrochloride as a combination of Polymorphs A and B. Therefore Polymorph B could not be said to be subsumed in the compound of a combination of Polymorphs A and B.

29. The response of the plaintiffs to this contention was that the fact that they had applied for a separate patent in respect of Polymorph B would make no difference to the claim based on the granted patent in respect of Polymorphs A and B. This was because Polymorph B was subsumed in the compound which was a mixture of polymorphs A and B. As regards non-mention of the above facts before the learned Single Judge it is submitted that the application for Polymorph B was independent of the patent validly granted to the plaintiffs in respect of Polymorphs A and B. Inasmuch as even the defendant had in the written statement proceeded on the footing that the plaintiffs held a patent for Tarceva, and had therefore raised a challenge to the validity of the said patent, the Learned Single Judge was justified in not adverting to the contentions raised in the counter-claim and the I.A.1272 of 2008 while deciding the injunction application. It is further submitted that since the counter-claim and the I.A.1272 of 2008 were pending consideration before the learned Single Judge, this Court should not in deciding this appeal advert to the contentions raised therein.

30. Since this is an issue that did not arise for consideration before the learned Single Judge, and has been specifically raised in the appeal, this Court

proposes to deal with it first. It must be noted at the outset that by the time the learned single Judge took up for consideration I.A. No. 642/2008 filed by the plaintiff seeking the ad interim injunction, the defendant had already filed I.A. No. 1272 of 2008 under Order 7 Rule 11 CPC. It had also filed a counter claim. In both these documents the defendant raised the plea that the suit patent pertained to Polymorph A + B whereas Tarceva was Polymorph B. The detailed sequence of the proceedings before the learned Single Judge have already been adverted to earlier in this judgment. The contents of the counter-claim and the IA 1272 of 2008 have also been set out in some detail and therefore need not be repeated. The fact remains that while the above fact concerning Polymorph B was noticed by the learned single Judge in the passing in para 43 of the impugned judgment, the learned Single Judge had no occasion to consider whether this was a relevant factor for determining if the plaintiffs had made out a prima facie case for grant of injunction in their favour.

31. This Court does not find merit in the contention of the plaintiffs that since the counter-claim and I.A. 1272 of 2008 are pending before the learned Single Judge, and in any event the contents thereof have not been discussed in the impugned judgment of the learned Single Judge, this Court should not make any observation in that regard which might prejudice the case of the plaintiffs. The position is that the entire record of the case before the learned single Judge before this Court. It contains both the counter claim as well as I.A. No. 1272 of 2008. While this Court is not deciding either the counter-claim or the I.A. 1272 of 2008, it is not possible to accept the plea of the plaintiffs that the contents thereof are not relevant for deciding whether the plaintiffs had made

out a prima facie case before the learned single Judge for grant of injunction in their favour.

32. To recapitulate the contention of the defendant is that the plaintiffs suppressed the fact of their having filed a separate application for Polymorph B both before the Controller of Patents as well as the learned Single Judge. The effect of the pendency of the latter application of the plaintiffs for Polymorph B on the grant of patent in their favour in respect of Polymorphs A and B has to be examined.

33. The plaintiffs own case before the Controller of Patents in their 'clarificatory' letter dated 18th August 2008 is that while in the U.S.A "it is perfectly possible and routinely done to patent incremental inventions e.g. Polymorph B of the main compound in addition to the main/dominating/umbrella compound", in India this is possible only subject to the conditions specified in Section 3 (d) of the Patents Act 1970. In other words Section 3 (d) read with its Explanation is, in the context of pharmaceutical products, an anti-evergreening provision. In the subsequent application for Polymorph B, the plaintiffs asserted that "polymorph B is claimed to be **thermodynamically more stable and it helps in providing improved oral dosage in solid form**." Although the plaintiffs were quick to add that this did not mean that the umbrella compound and all possible polymorphs thereof whether singly or in mixtures "were not useful and could not be used in solid oral dosage form", it does not answer a fundamental question that arises and which is this. Had the Controller of Patents while examining the plaintiffs' claim in respect of the compound which was a

mixture of Polymorphs A and B been informed or was cognizant of the fact that there was another application pending in respect of Polymorph B in which the above statement was made by the plaintiffs, would he have not had to account for it while deciding the question whether the compound, as a combination of Polymorphs A and B, was demonstrated as showing enhanced efficacy over the closest prior art? From the plaintiffs' own showing it would not have been possible for the Controller of Patents to have granted a patent in their favour both in respect of Polymorphs A and B as well as Polymorph B. If the compound which was a combination of Polymorphs A and B was an inventive step over its closest prior art (EP'226) then clearly Polymorph B was only a different crystal form thereof and would fail the tests of novelty and obviousness. However the patentability tests do not stop there. Section 3 (d) requires the demonstration of enhanced efficacy of the product. Although it was urged by the plaintiffs that stability of a product is not the same thing as its efficacy, it would have to be demonstrated by the Plaintiffs, particularly in light of their statements in the application for grant of a patent in respect of Polymorph B (and their statements in the corresponding patent U.S.'221) that a compound of Polymorphs A and B (and not A alone or B alone) could be orally administered as a drug. It is hard to imagine that the therapeutic efficacy of a pharmaceutical product could be tested without it even being able to be administered to a sample population.

34. This brings us to another significant issue. Should not an applicant for a patent of a pharmaceutical product be bound to disclose the details of all other applications made by the applicant for grant of patent of derivatives or forms of such product? For instance, in the instant case the application for grant of

patent for Polymorphs A and B (the suit patent) was considered by the Controller of Patents in February 2007 and a certificate No. 196774 dated 23rd February 2007 was issued by him. The pre-grant opposition to the suit patent was considered thereafter and rejected by the order dated 6th July 2007. By this time the plaintiffs had already filed two applications, on 13th and 14th May 2002, for grant of patent in respect of Polymorph B of the compound of Polymorphs A and B. In these applications a reference was made to both U.S.'498 and U.S'221 which were for Polymorphs A and B and Polymorph B alone respectively.

35. At this stage it may be useful to refer to the U.S'221 which was granted to the plaintiffs for Polymorph B. The title begins with the words "***Stable Polymorph*** on N-(3-Ethnylphenyl)-6, 7-Bis (2 Methoxyethoxy)-4-Quinazolinamine Hydrochloride, Methods of Production, and Pharmaceutical Uses thereof." In the said document a reference is made to the earlier US Patent No.5747498 issued on May 5, 1998 (which corresponds to Erlotinib Hydrocloride a combination of Polymorphs A&B). A reference was made to the mesylate form of the compound which is easily deliverable according to parenteral methods of administration. By contrast, the hydrochloride compound was stated to be "preferred with respect to solid administration such as with tablets and oral administration". The 'Summary' of the invention stated that the "present invention relates to polymorphs, and methods for the selective production of polymorphs of N-(3-Ethnylphenyl)-6,7-Bis(2Methoxyethoxy)-4-Quinazolinamine Hydrochloride, particularly in the stable polymorph form". It was further disclosed in the said application as under:

> "Stability of the hydrochloride compound is of concern for its use in the treatment of patients since variations will affect effective

dosage level and administration. It has been discovered that the hydrochloride of N-(3-ethynylphenyl)-6.7 bis(2-methoxyethoxy)-4-quinazoliamine exists in two polymorph states, polymorph A and B. This contrasts with the mesylate compounds which exist in three polymorph states (mesylate polymorphs A, B and C). Polymorph B of the hydrochloride was found to be the thermodynamically most stable and desirable form and the present invention comprises the polymorph B compound in the substantially pure polymorphic B form and pharmaceutical compositions of the substantially pure form of polymorph B, particularly in tablet form and a method of the selective production of the compound.

The hydrochloride compound disclosed in the U.S. Pat. No. 5,747,498 actually comprises 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 form than the mesylate salt forms."

36. In the subsequent Polymorph B patent specification the plaintiff admitted that "the Hydrocholoride compound disclosed in the US patent no. 5747498 actually comprised a mixture of Polymorphs A and B, which, because of its partially reduced stability (i.e from the Polymorph A component) was not more preferred for tablet form than the mesylate salt forms." It was further stated that "Polymorph B of the Hydrochloride was found to be the thermodynamically most stable and desirable form and the present invention comprises the Polymorph B compound in the substantially pure Polymorphic B form and pharmaceutical compositions of the substantially pure form of Polymorph B, particularly in tablet form and a method of the selective production of the compound."

37. Had the Controller of Patents been cognizant of this fact when he considered the application for the grant of the suit patent, he would have had to address the issue whether it was the combination of Polymorphs A and B or Polymorph B alone which satisfied all the patentability tests vis-a-vis Section 3 (d). He would have asked to examine in some detail what was in fact claimed and stated in U.S.'498 and U.S.'221. It may be noted that the application for U.S.'498 was made on 28th May 1996 and granted on 5th May 1998. The application for U.S.'221 was made on 9th November 2000 and granted on 31st May 2005. So by the time Patent No. 196774 was granted on 23rd February 2007 to the plaintiffs, the facts concerning U.S.'498 and U.S.'221 were already known to the plaintiffs. The failure by the plaintiffs to bring the above facts to the notice of the Controller of Patents at the time of consideration of their application for patent for the compound of a combination of Polymorphs A and B was not consistent with the requirement of a full disclosure. The plaintiffs cannot be heard to say that after all the applications for grant of patent in respect of Polymorph B were pending before the Controller of Patents and he should have known that fact any way. It is perfectly possible that the Controller of Patents might not know, unless his attention is drawn to the fact, of other pending applications concerning the derivatives and forms of the product in question. It is also possible that the pre-grant opposer is not aware of them. Certainly the applicant would, as in this case, know how many more applications it has filed which are pending consideration. It would know what statements it made in the corresponding patents granted to it elsewhere. This would be relevant not only for the tests of novelty and obviousness but of efficacy as well.

38. There is more to the effect of non-disclosure by the plaintiffs to the Controller of Patents of the fact of their pending applications for Polymorph B when their application for the product being a combination of Polymorphs A and B was being considered. This Court notices that the plaintiffs have in their reply to the pre-grant opposition of the defendant to their application for grant of patent in respect of Polymorph B, and later in their letter dated 18th August 2008 addressed to the Controller of Patents, acknowledged their contradictory stands. The plaintiffs' stand initially was that U.S.'498 (which corresponded to Indian Patent No. 196774) "does not contain an unambiguous disclosure of Polymorph B free of Polymorph A." In para 9.4 of their reply to the opposition of the defendant the plaintiffs stated: "There is no indication in the US'498 that there are different polymorphs of hydrochloride salt." In para 10.2 of the reply to the opposition it was stated that the Polymorph forms were not deemed to be within the prior art; that the US '498 (suit patent) was silent on the Polymorphs and so was the suit patent which was granted in 2007. It was further contended in para 10.3 that the inventors unexpectedly discovered in an around 1999 that Polymorph B had superior stability properties that made it particularly suited for solid oral dosage forms. It was contended in para 11.3 "the stable Polymorph B had been successfully used in human clinical trials before the examination of the application of the impugned patent and much prior to the filing of the suit." Even in the US the stand of the plaintiff while prosecuting its Polymorph B patent was that although the lung cancer was mentioned in '498 patent, NSCLC was not. The stand of the plaintiff, therefore, appears to be that Polymorph A + B of Erlotinib Hydrochloride covered under the US '498 deals with lung cancer and not with NSCLC. However, in their 'clarificatory' letter dated 18th August 2008 the plaintiffs did a 'flip-flop' and

contended that U.S.'498 "is for the main compound erlotinib hydrochloride which includes all possible polymorphs of main compound known and unknown." Also, they sought to contend that what they were claiming was a 'selection invention' limited only to Polymorph B which is substantially free of Polymorph A. While this Court is not called upon to comment on whether this flip flop is permissible or tenable, it is plain that the change in stand would admittedly have a direct impact on the question of patentability of either a compound of Polymorphs A and B or of Polymorph B free of Polymorph A. This made the full disclosure by the plaintiffs of all the facts pertaining not only to the 'umbrella' compound but the crystal or other forms of the product to the Controller of Patents imperative. It can be said with some certainty that such disclosure would have impacted the decision on the patentability of compound of Polymorphs A and B. When the defendant therefore questioned the validity of Patent No.196774 on the above ground, it did raise a more than credible challenge.

39. The effect of non-disclosure of the above facts by the plaintiffs in their plaint in the suit will be considered next. Admittedly the plaintiffs did not disclose the above facts even while they asserted that Patent No.196774 covered the product being marketed by them as Tarceva. The plaintiffs should have been candid and disclosed to the Court that they had filed separate applications for Polymorph B. They may have taken the plea, as they did repeatedly before this Court, that the subsequent application for Polymorph B was out of abundant caution and that Polymorph B was subsumed in the compound which was a combination of Polymorphs A and B. However, this was not done and this Court has had no valid explanation offered by the

plaintiffs for this non-disclosure. Also, it may be recalled that the plaintiffs also did not disclose the complete specification of the product till the defendant filed an application seeking the information. There could well be a situation where the plaintiffs were pressing for an ex parte ad interim injunction. The effect of the failure to disclose the complete specification of the product and the facts concerning the pending applications for Polymorph B would be that the learned Single Judge would not have the occasion to consider if in fact the suit patent covered Tarceva. This, in the considered view of this Court, is sufficient ground to hold that the plaintiffs in fact failed to demonstrate before the learned Single Judge and even before this Court that notwithstanding the pending applications in respect of Polymorph B which wholly corresponded to the tablet Tarceva, they had a prima facie case.

40. This Court holds that in an application seeking ad interim injunction in a suit for infringement of patent, it would be incumbent on the plaintiffs to make a full disclosure of the complete specification of the product whose patent is claimed to have been infringed. The plaintiffs will also have to disclose to Court the x-ray diffraction data of the product, particularly if it is a pharmaceutical drug. The plaintiffs have to make an unequivocal disclosure that the patent they hold covers the drug in question; whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent and the effect of such applications on the suit patent. Short of the above details, the Court being approached for the grant of an ad interim relief will be unable to form a view on whether the plaintiff has made out a prima facie case. Otherwise it would be a case of suppression of material facts that would have a

bearing on the question.

41. Reverting to the case on hand, what is significant is that when the plaintiffs filed their suit in this Court they was fully aware of the fact that Polymorph B was the more stable form of Erlotinib Hydrochloride. For marketing it in the tablet form, it was Polymorph B, which would be relevant. The plaintiffs knew that a separate application for grant of patent for Polymorph B had been made and obtained in the USA. They knew that in the USA while being granted that patent (which although an exercise in evergreening is stated to be permissible there), it was claimed that the closest prior art U.S.'498 was for treatment of lung cancer in general not NSCLC in particular. The enhanced efficacy was sought to be thus justified. In short their case was that on its own strength Polymorph B of Erlotinib Hydrochloride deserved an exclusive patent on the ground of inventiveness and enhanced efficacy, non-obviousness and non-teaching by any prior art. Clearly the applications made by the plaintiff before the Controller of Patents for grant of patent in respect of Polymorph B was on the same lines. It is indeed in intriguing why the plaintiffs did not chose to be candid with this Court in making a full disclosure of all the above facts in its plaint. There can be no manner of doubt that had these facts fully disclosed in the plaint and the entire specification of the patent held by the plaintiff together with X-ray diffraction data of Tarceva and Erlocip filed along with the plaint, it is possible that the plaintiff may have had difficulty in showing that the patent held by it (No.196774) covered Tarceva as well. In other words, the Court would have had to first be convinced that the plaintiffs held a patent for the product which was marketed as Tarceva and further that the product of the defendant had a x-ray diffraction data which matched Tarceva as well as the

compound which was a combination of Polymorphs A and B and not Polymorph B alone.

42. The case of the defendant is founded on the proviso to Section 11 A (7) of the Patents Act 1970 which states: "Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted." An off shoot of this argument is that the plaintiffs are admittedly not commercially exploiting the patent granted in their favour for a compound which is a mixture of Polymorphs A and B, since the tablet form corresponds to Polymorph B of the said compound Erlotinib Hydrochloride. In ***Franz Xaver Huemer v. New Yash Engineers AIR 2000 Del 23*** a Division Bench of this Court held that the patent of a product which is not being commercially utilized cannot be enforced. The defendant must be held as having been able to demonstrate prima facie that the plaintiffs are not entitled to enforce Patent No.196774 as such.

43. Therefore, this Court holds that to the extent that the defendant has raised a serious doubt whether the plaintiffs in fact hold a patent for the product sold in the tablet form as Tarceva, the plaintiffs must be held not to have been able to cross the first hurdle of showing that they have a prima facie case in their favour for grant of an order restraining the defendant from marketing Erlocip.

The effect of the order dated 15th December 2008 of the Controller of Patents

44. After the orders were reserved in the present appeal, the application filed by the plaintiff for grant of patent in respect of Polymorph B was rejected by the Controller of Patents by an order dated 15th December 2008. The said

order has been placed on record along with CM No. 219/2009 filed by the plaintiff in the present appeal. A perusal of the said order shows that the rejection was on the ground that the applicant had failed to provide comparative data compared to prior art U.S.'498 to show any enhancement in the therapeutic efficacy of the polymorph B. Even for the stability and bioavailability they claimed, no data was provided vis-à-vis the prior art U.S.'498 compound. It was further held: "A mere difference in physical property is a well known conventional variation of the same pure substance not showing an unobvious properties. Therefore, the changes alleged by the applicant is in the physical properties and not in the therapeutic efficacy. I therefore conclude that claim 1 and 2 are not patentable under Section 3 (d) of the Patent (Amendment) Act." Claim 6 of the plaintiffs in relation to composition comprising polymorph B form of Erlotinib was also struck down. The process claims of the plaintiffs in relation to Polymorph B have been set down for hearing.

45. It is sought to be contended by the plaintiffs that since their application for a patent in respect of the product Polymorph B form of *Erlotinib* stands rejected, the said order "sets at rest the argument of the respondent regarding the Polymorph B application prejudicing and invalidating the present suit or the claim of the appellants for an interlocutory injunction." It was submitted that since the application has been rejected on the ground of non-patentability in terms of Section 3 (d), the Controller of Patents had by implication accepted the argument that Polymorph B was subsumed in Polymorphs A and B. However, in the reply to the application it has been contended by the defendant that this is a misreading of the order dated 15th December 2008 of the

Controller of Patents. It is pointed that the plaintiff's application for Polymorph B was rejected on the ground of failure by them to demonstrate enhanced therapeutic efficacy over the closest prior art, U.S.'498. The plaintiffs filed a separate application for Polymorph B since they claimed that it was only during further studies and research on Erlotinib Hydrochloride that they found that it was Polymorph B which could be made into a tablet form and not the Erlotinib Hydrchloride prepared according to Example 20 of the suit patent. It is submitted that after the rejection of their application for a patent for Polymorph B, the plaintiffs cannot be expected to be in a better position against the defendant than when the said application was pending.

46. This Court is not aware with the plaintiffs wish to further pursue its application for grant of patent in respect of Polymorph B by challenging the order dated 15th December 2008 passed by the Controller of Patents. This Court therefore refrains from commenting on the said order. Whatever be the outcome in the said proceedings, the fact remains that when the Controller of Patents passed the order dated 6th July 2007 negativing the pre-grant opposition to Patent No.196774, none of the facts pertaining to the separate applications for Polymorph B were accounted for. Those facts did have a bearing on the issue of patentability of the compound which was a combination of Polymorphs A and B. The order dated 15th December 2008 also makes no change to the position as regards the failure of the plaintiffs to make out a prima facie case before the learned Single Judge.

47. The learned Single Judge proceeded on the footing that the plaintiff in fact had a valid patent in its favour for the product Tarceva and proceeded to

examine whether despite the plaintiffs holding such patent, it can be denied injunction. However, in view of the above decision of this Court the case has attained a different complexion. This Court finds that the plaintiffs ought to have been refused injunction for their failure to make out a prima facie case.

48. This court nevertheless proposes to consider the points raised in the appeal independent of the finding on the issue of maintainability since extensive arguments have been addressed on this aspect.

Principles that should govern while considering an application for grant of an injunction in a suit for infringement of a patent

49. The submission of the appellant is that once the plaintiff has been able to show that it has a prima facie case, injunction should automatically follow. Since the plaintiffs hold a valid patent in respect of Erlotinib Hydrochloride (polymorphs A&B), which was not shown by the defendant to have been obtained by fraud, the plaintiff had made out a prima facie case of infringement and an injunction should automatically follow. It is submitted that that the patent granted to the plaintiffs in the instant case has undergone multiple level scrutiny and examination in terms of the procedures outlined under the Patents Act, 1970 as amended in 2005. The publication of the application under Section 11(A)(7), the request for examination by the application under Section 11(B) (i.e. the examination by any third party interested), overall examination by an expert technically qualified as examiner under Section 12, the consideration of the examiner's report by the Controller under Section 14, the disposal of the pre-grant opposition to the plaintiff's application for grant of patent by any person in terms of Section 25(1), a full blown post grant opposition under Section 25(2) and the final grant of patent upon an overall

holistic view under Section 43. It is submitted that the grant of a patent after following the procedure involving multi-layered scrutiny must be given considerable weight. Unless the defendant is able to discharge the heavy burden of showing that it has a stronger prima facie case than the plaintiff, it should not be permitted to defeat the right of the plaintiff to an injunction against infringement by casually raising a challenge to the validity of such patent. Reliance is placed on the judgment in ***American Cyanamid Company v. Ethicon Ltd***. ***(1975) 1 All. E.R. 504***, ***Raj Prakash v. Mangat Ram Choudhary AIR 1978 Delhi 1***, ***Proctor v. Bayley 1889 (XLII) Ch. 390***, ***Telemecanique Controls v. Schnider 94 (2001) DLT 865***, ***Hindustan Lever v. Lalit Wadhwa 2007 (35) PTC 377***, ***Midas Hygiene Industries (P) Ltd. v. Sudhir Bhatia (2004) 3 SCC 90***, ***Laxmi Patel v. Chetan Bhat Shah JT 2001 (10) SC 285***.

50. The judgment of the learned single Judge has been assailed as proceeding on incorrect principles. A separate note has been filed by the plaintiff indicating what according to it are errors in judgment. It sought to be contended that even after finding that there was a prima facie case made out by the plaintiff, the learned single Judge split it into a two-stage test by first determining whether the plaintiff had a prima facie case and thereafter whether there was a prima facie case made out by the defendant. It is submitted that there is no precedent indicated by the learned single Judge for adopting this course. The judgment is criticized for using a multitude of phrases in deciding this issue. At one place the impugned judgment holds that the case of the defendant "is not implausible", at another place it is stated that defendant has "a credible or arguable challenge to the plaintiff's patent" and at another place

that the defendant has not made "a palpably unfounded claim".

51. It is contended on behalf of the defendant that under the Patents Act, 1970, as contrasted with the Trade Marks 1999, there is no presumption of validity of a patent. This is evident from reading of Section 13(4) as well as Sections 64 and 107 of the Act. It is possible to raise multiple challenges to validity of patent at various stages. It could be at the pre-grant and post-grant stages before the Controller of Patents. Thereafter before the Appellate Board or in a suit for infringement the defendant could question the validity of a patent on the grounds set out in Section 64. The patent in the instant case was, therefore, vulnerable to challenge notwithstanding it surviving the challenge at the pre-grant stage. The object behind this was to ensure that known inventions are not granted patents and that the patent is used for the public benefit.

52. The above submissions have been considered. It must be clarified that this Court has held already that the Plaintiffs have failed to make out a prima facie case. The above submissions of the plaintiffs are therefore being dealt with assuming, as the learned Single Judge did, that the Plaintiffs have made out a prima facie case. Given the scheme of Patents Act it appears to this Court that it does contemplate multiple challenges to the validity of a patent. Unlike Section 31 of the Trade Marks Act which raises a prima facie presumption of validity, Section 13(4) of the Patents Act 1970 specifically states that the investigations under Section 12 "shall not be deemed in any way to warrant the validity of any patent." Section 48 of the Act also is in the form of a negative right preventing third parties, not having the consent of the patent holder, from making, selling or importing the said product or using the patented process for

using or offering for sell the product obtained directly by such process. It is also made subject to the other provisions of the Act. This is very different from the scheme of the Trade Marks Act as contained in Section 28 thereof. Section 3(d) itself raises several barriers to the grant of a patent particularly in the context of pharmaceutical products. It proceeds on the footing inventions are essentially for public benefit and that non-inventions should not pass off as inventions. The purpose of the legal regime in the area is to ensure that the inventions should benefit the public at large. The mere registration of the patent does not guarantee its resistance to subsequent challenges. The challenge can be in the form of a counter claim in a suit on the grounds set out in Section 64. Under Sections 92 and 92 A the Central Government can step at any time by invoking the provision for compulsory licencing by way of notification. Therefore, the fact that there is a mechanism to control the monopoly of a patent holder (Section 84 and Section 92) and to control prices (by means of the drug price control order) will not protect an invalid grant of patent.

53. The plea of the plaintiff that since there is a multi-layered, multi-level examination of the opposition to the grant of patent it should accorded the highest weightage, is not entirely correct. The contention that there is a heavy burden on the defendant to discharge since it has to establish that it has a stronger prima facie case of the plaintiff is contra indicated of the decisions in the context of Section 13(4). Reference may be made to the decisions in ***Biswanath Prasad Radhey Shyam v. M/s Hindustan Metal Industries AIR 1982 SC 1444***, ***Standipack Pvt. Ltd. v. Oswal Trading Co. Ltd. AIR 2000 Del 23***, ***Bilcare Ltd. v. Amartara Pvt. Ltd. 2007 (34) PTC 419(Del)***, ***Surendra Lal***

Mahendra v. Jain Glazers (1979) 11 SCC 511. In ***BeechamGroup Ltd. v. Bristol Laboratories Pty Ltd. (1967-68) 118 CLR 618*** and ***Australian Broadcasting Corporation v. O'Neill (2006)229 ALR 457*** it was held that the defendant alleging invalidity bears the onus of establishing that there is "a serious question" to be tried on that issue. In ***Hexal Australai Pty Ltd. v. Roche Therapeutics Inc. 66 IPR 325*** it was held that where the validity of a patent is raised in interlocutory proceedings, "the onus lies on the party asserting invalidity to show that want of validity is a triable question." In ***Abbot Laboratories v. Andrx Pharmaceuticals Inc. (decision dated 22nd June 2006 of the U.S.Court of Appeals for the Federal Circuit 05-1433)*** the Court of Appeals followed its earlier ruling in ***Helifix Ltd. v. Blok-Lok Ltd. 208 F.3d 1339*** where it was held (at 1359): "In resisting a preliminary injunction, however, one need not make out a case of actual invalidity. **Vulnerability** is the issue at the preliminary injunction stage, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself." (emphasis supplied) In ***Erico Int'll Corprn v. Vutec Corprn (U.S.Court of Appeals for the Federal Circuit, 2007-1168)*** it was held that the "defendant must put forth a substantial question of invalidity to show that the claims at issue are vulnerable."

54. In the present case, the grant of a patent to the plaintiffs for Erlotinib Hydrochloride as a mixture of Polymorphs A and B will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. The use by the learned Single Judge of the expressions "strong credible challenge",

"arguable case" or that the defendants claim being not unfounded, cannot be termed as vague and inconsistent since they convey the same meaning in the context of the strength of the defendant's challenge.

55. The question before this Court is when can it be said that the defendant has raised a credible challenge to the validity of a patent held by the plaintiff in an infringement action? During the course of the argument it was suggested by counsel that the challenge had to be both strong and credible. Also, the defendant resisting the grant of injunction by challenging the validity of the patent is at this stage required to show that the patent is "vulnerable" and that the challenge raises a "serious substantial question" and a triable issue. Without indulging in an exercise in semantics, the Court when faced with a prayer for grant of injunction and a corresponding plea of the defendant challenging the validity of the patent itself, must enquire whether the defendant has raised a credible challenge. In other words, that would in the context of pharmaceutical products, invite scrutiny of the order granting patent in the light of Section 3(d) and the grounds set out in Section 64 of the Patents Act 1970. At this stage of course the Court is not expected to examine the challenge in any great detail and arrive at a definite finding on the question of validity. That will have to await the trial. At the present stage of considering the grant of an interim injunction, the defendant has to show that the patent that has been granted is vulnerable to challenge. Consequently, this Court rejects the contentions of the plaintiffs on this issue and affirms the impugned judgment of the learned Single Judge.

Defendant's challenge to the validity of the patent

56. The next question is whether the defendants have in fact been able to

demonstrate that there exist serious triable issues concerning the validity of Patent No.196774 granted to the plaintiffs.

57. The plaintiffs submit that apart from merely challenging the validity of the patent granted in their favour, the defendant had not produced any material to demonstrate that the compound for which the patent was granted was not a novel invention with proved enhanced efficacy over the closest prior art. Since the plaintiffs had demonstrated successfully before the Controller of Patents that their compound was an inventive step over the closest prior art, the burden lay on the defendant to show that the inventive step was obvious to a person having ordinary skill in the art. Contrary to the claim of the defendant, Erlotinib Hydrocholoride could not be anticipated with reference to the closest prior art EP'226. Methyl and ethynyl groups are different and the substitution of ethynyl with methyl in the theta position could not have been anticipated even by a person skilled in the art with reference to the EP'226 patent.

58. On the other hand it is contended by the defendant that Section 3(d) of the Act introduced in 2005 has made dramatic changes to the patent law regime, particularly, in the context of drugs and medicines. Unless the drug or compound is proved to be of enhanced efficacy and is an inventive step, the patent is not granted. Where the compound is a new form of a known substance (evergreening), unless it is shown to demonstrate enhanced efficacy, the mere discovery of a new property or a new use would not entitle the applicant for the grant of a patent. The derivatives of the known substances would also be considered as the same substances unless they differ significantly in properties with regard to the efficacy.

59. It is further submitted by the defendant that a perusal of the order dated 4th July 2007 of the Controller of Patents shows that the Controller confused the concepts of inventive step, anticipation and obviousness. Even as regards the question of efficacy the plaintiffs failed to produce relevant data. The journals referred to in the order of the Controller pertained to results of the research conducted by or sponsored by OSI itself. Such studies could not, therefore, have inspired credibility as regards the proof of enhanced efficacy of the product over the closest prior art. Irrespective of the above submissions, the defendant submits that the product claimed to be a combination of polymorphs A and B was clearly anticipated by the closest prior art, EP'226. It was also anticipated in the earlier patents granted by the EU. It is submitted that the claimed invention was neither novel nor an inventive step over the closest prior art.

60. The above submissions have been considered. It is not possible to accept the contention of the plaintiffs that the Section 3(d) does not bring any significant change to the Patents Act. Not only has the substantive portion of Section 3(d) indicated a change in 2005 but the Explanation which has been added appears to particularly target pharmaceutical products. It discourages evergreening and prevents such derivative or other forms of the already patented product being granted patent unless the derivatives or other forms "differ significantly in properties in regard to efficacy." The plaintiffs contest the argument that Erlotinib Hydrochloride is a derivative of a known substance EP'226. However, it appears that the closest prior art does teach the compound for which patent has been granted to the plaintiffs. Therefore, unless the enhanced efficacy as mandated by Section 3(d) was demonstrated, patent

could not have been granted. The defendant has been able to show that order of the Controller of Patents was arguably deficient on this aspect. The defendant therefore must be taken to have raised a credible challenge to the validity of the patent.

61. Elaborate arguments have been addressed on whether Erlotinib Hydrochloride was only a modified form of Gefitinib. The order of the Patent Controller refers to EP '226 which was relied upon by the defendant to suggest that the molecule structure of the suit patent was similar to those disclosed in the aforementioned patent. In other words, it was contended by the defendant that the substitution of Methyl with Ethynyl would be obvious to a person skilled in the art when the closest prior art is taken to be Gefitinib which was claimed in EP '226. It is sought to be contended by the plaintiffs on the other hand that Erlotnib Hydrochloride was a derivative of another disclosed compound / structure (Example 51) and not Gefitinib. It is submitted that the defendant should not be permitted by a device of reverse engineering to claim that the substitution of Methyl by Ethynyl was obvious.

62. In ***Pfizer v. Apotex (U.S.Court of Appeal, 2006-1261)***, it was held that for the test of obviousness only a reasonable expectation of success and not a guarantee is needed. In ***Aventis v. Lupin (U.S.Court of Appeal, 2006-1530)*** it was held that "where the prior art gives the reason or motivation to make the claimed compositions, creates a prima facie case of obviousness."

63. According to the defendant with reference to the patent held by the plaintiff for Erlotinib Hydrochloride as a combination of Polymorphs A and B, the

closest prior art is a molecule structure disclosed in EP '226 which was the patent granted to Zeneca Limited. The Patent Controller ought to have examined EP '226 when examining the claim of the plaintiff. According to the defendant the closest prior art EP '226 patent disclosed a molecule structure in a Quinazoline derivative with Methyl group at the third position. It is stated that such substitution is obvious to persons skilled in the art and that persons wishing to obtain further compounds having anti-cancer properties would have been easily motivated to substitute methyl with the specifically disclosed ethynyl group. It is stated that methyl and ethynyl are normally used interchangeably in chemical arts because they share common attributes.

64. The plaintiffs on the other hand have elaborately argued on the "teaching, suggestion and the motivation to try" (TSM) test and submitted that the inventive step in the patent granted to it is in providing a compound which shows improved efficacy in its treatment of various cancers. The state of art on the priority date of the patent was Gefitinib. The inventive step in the patent goes beyond the state of art as demonstrated by the published articles in the journals. It was argued that FDA and the Drug Regulator of the concerned European agency directed withdrawal of the alleged prior art Gefitinib. In fact even Astrazeneca agreed to the same. It also did not object, in any region of the world, to the plaintiff being granted patent for Erlotinib Hydrochloride. It is urged that the obvious inference was that Erlotinib Hydrochloride was far better in enhanced efficacy than Gefitinib. It is therefore urged that a person of ordinary skill in the art would find no motivation at all to replace the methyl group at position 3 by an ethynyl group. It is further argued that even if a person of ordinary skill attempted to modify Example 51 of EP '226, the

motivation would be to modify 6 or 7 positions not the third position. Even if such person was motivated to change the substitution in the third position the choice would be a halogen such a chlorine and fluorine and not ethynyl.

65. In the view of this Court, a bare perusal of the order of the Patent Controller would indicate that neither of the above arguments has been considered, and in any event not in the detailed manner in which they have been advanced before this Court. It is perfectly possible that the Controller had no occasion to consider such argument as it was not raised before him. That is perhaps the very purpose of the legislature permitting a challenge by a defendant to the validity of a patent in answer to an infringement suit, even if such defendant had not earlier raised an opposition either at pre-grant or the post-grant stages. Therefore a patent which survives the pre-grant and post-grant challenges can still be made vulnerable on grounds different from the ones raised at those stages. The fact that the challenge is on grounds not urged at those stages, would lend credibility to the challenge. If the challenge is on the same grounds considered and rejected by the Controller of Patents, then of course, the burden on the defendant to demonstrate credibility of the challenge would be considerably higher degree.

66. There are other factors pointed out by the defendant to render the patent vulnerable to challenge. It is submitted that the Controller of Patents has confused the tests of inventiveness with obviousness. For instance it is observed by the Controller that "sometimes the modification in the prior art technologies which appear to be minor may bring great revolutions in the world which could never be predicted by the society of intellectuals ……."

This, it is pointed out, is really about 'anticipation' and not 'obviousness'. It was not enough for the plaintiffs to show that the defendant was unable to 'anticipate' the product in question by starting from the closest prior art EP'226. The plaintiffs had still to show that it would not have been obvious to the person having ordinary skill in the art. Reliance is placed on the decisions in ***Shire Biochem v. Ministry of Health 2008 FC 538*** to underscore the difference between novelty and obviousness. The difference between anticipation and obviousness is brought out in the decisions ***Synthon BV v. Smith Kline Beecham [2005] UK HL 59*** and ***KSR International Company v. Teleflex 550 US 1 (2007)***.

67. The decision in ***KSR International*** makes a conscious departure from the rigidity in the application of the TSM test applied to determine if the invention in question is patentable. It was observed therein (550 US 1 at 15): "The obviousness analysis cannot be confined to 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..... 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."

68. The criticism by the defendant of the order of the Controller of Patents is, in the view of this Court, not without merit. The Controller failed to appreciate that the patent was claimed specifically on Example 20 and therefore stood on a footing different from that granted to the plaintiffs in other countries. The

point about the credibility of the articles published in the journals being the product of researched sponsored by Plaintiff No.2 OSI was not even noticed by the Controller of Patents. The entire discussion on the aspect of enhanced efficacy in the order of the Controller is limited to a mention of these articles. Also, in the order dated 4th July 2007 of the Controller of Patents there is an incomplete sentence when there is a reference to the decided cases. The anomaly of the pre-grant opposition being disposed of only on 4th July 2007 whereas the patent certificate is of 23rd February 2007 remains unexplained. If it was indeed a pre-grant opposition that was being rejected, it is conceivable that the certificate would pre-date it.

69. Elaborate arguments were addressed on the question of balance of convenience on the ground that the judgment of the House of Lords in ***American Cyanamid*** requires such factor to be considered once it is shown that the damages would not provide an adequate remedy to the plaintiff in the event of it succeeding at the trial. In the considered view of this Court, this aspect need not be examined in the present case for more than one reason. First, the plaintiffs have, for the reasons discussed earlier, failed to make out a prima facie case in their favour. Even if it is assumed that they have, in view of the fact that the defendant has raised a credible challenge that renders the patent's validity vulnerable, the question of balance of convenience does not arise because clearly the Court will not, at the interlocutory stage without the case going to trial, come to the aid of a holder of a patent of doubtful validity seeking to enforce such patent.

70. One submission of Dr. Singhvi that needs to be dealt with at this stage is

whether the statements made by an applicant for a patent in the applications made by such applicant in other countries would be permitted to be looked into by the Controller of Patents while examining such application. Reference was made to the decision in *T.I. Group Automotive System v. V.D. North America 375 F 3d 1126* and the decision dated 2nd August 2006 of the Court of Appeals in *Pfizer v. Ranbaxy (06-1179).* This Court is unable to accept the above submission. A perusal of the definition of "new invention" in Section 2(1) (l) indicates that the invention or technicality for which a patent is sought should not have been anticipated "by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete subscriptions, i.e,, the subject matter is not filed in public domain so that it does not form part of the state of the art". The phrase "public domain" and "state of the art" have therefore to admit of a wide scope given the legislative intent in introducing the above definition by the Amendment Act, 2005. It appears that this was introduced in acknowledgement of the fact that a claim by an applicant for a patent anywhere in the world and the statements made therein would be relevant for the authority in India determining whether the invention claimed is indeed a new invention. With the easy availability of information on the internet, it is possible for the patents authorities in this country to ascertain what in fact is the closest prior art and which is a known substance. A statement made by the applicant while prosecuting a patent application in any country would certainly be a relevant material to be considered. The decisions cited by learned counsel are not relevant in this context as the law in this country is governed by the Patents Act 1970 which requires the applicant to make a full disclosure as noticed hereinbefore.

71. The discussion on this aspect is concluded by concurring with the learned Single Judge that, assuming that the plaintiffs held a patent for the product which was the subject matter of the suit for infringement, the defendant has raised a credible challenge to the validity of the patent by raising a serious triable and substantial question that renders it vulnerable to challenge.

Public Interest

72. That brings us to the last submission of the plaintiffs which is that the learned Single Judge had applied principles not known to law in refusing injunction. The issues of public interest and pricing were not germane or relevant in the context of patent law. Public interest on the other hand required protecting a validly granted patent. The question of availability of the drug at affordable price was provided for in the Patents Act, 1970 by way of provisions for compulsory licencing. Since the legislative intent was to grant a monopoly to the patent holder for at least the first three years after the grant of patent to enable it to recover the enormous costs incurred in research and development of the product, the court should not override such legislative intent on the basis of untested principles. The argument of the plaintiff is that if the rights of a patentee are not respected then it would be contrary to the public interest of encouraging further research. Further it would discourage the requirement of disclosure which inheres in patent regime thereby creating a situation where opportunity of further innovation based on fundamental research on an existing patent product/process would be lost or unduly deferred.

73. An attack was also mounted on the impugned order of the learned single

Judge for linking up the issue of pricing with public interest. It is submitted since the Act provides for grant of compulsory licence in the event of the patented product not being made available at the reasonable price, it was not for the Court to apply such principles at an anterior interlocutory stage. The legislature has for good reasons granted a statutory monopoly to a patent, although for a limited period. The grant of such limited monopoly must therefore also be taken to be in the public interest. It is submitted that the patentee has the right to exploit the benefits of its research in which it has invested considerable sums. By contrast, a generic drug manufacturer has little or no research and development costs. Therefore as a rule the copier would always price its products lower than the inventor.

74. The plaintiffs contend that the provisions of the Essential Commodities Act, 1953 (ECA) will apply to pharmaceutical drugs as well. It is submitted that the Central Government can also take recourse to the device of a Drug Price Control Order (DPCO) framed under Section 3 ECA to fix the market sale price in respect of bulk drugs both for scheduled as well as non-scheduled formulations. It is accordingly submitted that the judgment of the US Supreme Court in ***E Bay v. MerExchange [547 US 338(2006)]*** has to be understood in the context of there being no provision under the American law either for granting any right to the Government to control the prices in the manner indicated, or a power under Section 47 of the Patents Act, 1970 to grant patents subject to conditions including use of the process by the government or even a pre-grant opposition akin to Section 25(1) of the Act. It is submitted that public interest in low cost general drugs has to be balanced by the public interest in protection of patent rights and that the need to encourage scientific

research in discovering the drug outweighs the public interest in obtaining a low cost generic drug. Reliance is placed on the judgment of the District Court of the US in ***Eisai Co. v. Teva Pharamaceuticals [dated 28.3.2008/Civ. No.05-5727 (HAA) (ES)]***, ***Payless Shoesource Inc. v. Reebok International Ltd. (998 F.2d 985)*** and ***Sanofi – Synthelabo v. Apotex (470 F.3d 1368)***.

75. The defendant on the other hand counters this submission by submitting that pricing would indeed be a relevant considerations in determining whether the grant of an injunction would adversely affect the easy availability of a life saving drug. Reliance is placed on the decisions in ***Novartis AG v. Mehar Pharma 2005 (30) PTC 160(Bom.)***,***Franz Xaver Huemer v. New Yash EngineersAIR 1997 Del 79*** and ***Russel Uclaf v. G.D.Searle (1977) Fleet Street Patent Law Reports 125***.

76. This court is unable to accept the submissions of the plaintiffs on this aspect. The amendment to the Patent Act 1970 in 2005 introduced Section 83(e) which states that among the general principles applicable to the working of patented inventions regard shall be had "that patents granted do not in any way prohibit Central Government in taking measures to promote public health" and under Section 83 (g) "that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public." Under Section 84 among the grounds on which a person can seek a compulsory licence on a patent is that "the patented invention is not available to the public at reasonably affordable price." The element of public interest is therefore not alien to the scheme of the Patents Act 1970.

77. The approach of the learned Single Judge was not inconsistent with the judicial decisions on this aspect. In ***Franz Xaver Heumer*** in the context of balance of convenience it was observed (AIR, p. 87):

> "33. 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."

78. In *Novartis AG* the Bombay High Court was considering a case where the defendant challenged the grant in favour of the plaintiff of exclusive marketing rights (EMR) in respect of a drug Imatinib on the ground of lack of novelty. In refusing injunction to the plaintiff it was observed (PTC, pp.173-174)

> "28. A comparison of what is stated in the application submitted by plaintiffs in Canada for the patent in 1993 and the contents of paragraph 10, in my opinion, definitely raises a serious question as to whether the product in relation to which EMR has been granted is really a new product or not. In paragraph 8 of the plaint, the plaintiffs describe the invention as B crystalline form of Imatinib Mesylate. In paragraph 10, the plaintiffs admit that Imatinib Mesylate crystals were found to be in two forms - Alpha (a) and Beta (B). Alpha was needle shaped. Beta was found to be thermodynamically stable and was prepared for use in pharmaceutical preparations. Perusal of the application submitted by the plaintiffs in 1993 for patent in Canada shows that the plaintiffs have disclosed the compound as well as its salt. Beta crystals are clearly disclosed in the application. Therefore, in my opinion, apart from other challenges, this challenge can definitely be said to be serious insofar as the validity of EMR granted is concerned and if that be so, in terms of the law that appears to be

settled referred to above, the EMR being of recent origin, the plaintiffs would not be entitled to the temporary injunction sought. It is further to be seen here that in the present case, it cannot be said that even if the plaintiffs ultimately succeed, the loss or injury that may be caused to the plaintiffs is not incapable of being compensated in terms of money. Indeed, in the plaint, the plaintiffs have worked out loss suffered by them and have in fact sought a monetary decree in relation thereto. In my opinion, the aspect of balance of convenience has also to be answered in favour of the defendants, especially because the drug in relation to which EMR is granted is a anti-cancer drug, is a life saving drug and the plaintiffs do not manufacture the drug in India but import it from foreign country. The defendants have stated that the demand of capsules is over 30,00,000 per month. This does not appear to have been disputed by the plaintiffs. It is clear that the demand of this drug in India is very large, it is a life saving drug. The defendants manufacture the drug in India. The plaintiffs do not manufacture the drug in India. They state that they will import required quantity of the drug from a foreign country. Therefore, the plaintiffs will rely entirely on the international transport system for making the drug available in India in required quantity. In case interim injunction is granted in favour of the plaintiffs, the manufacturing and marketing network of the defendants so far as the drug is concerned would be dismantled. If due to any problem, the plaintiffs cannot make available the drug in required quantity in India, it obviously will be disastrous for the patients. This consequence is foreseeable, therefore in my opinion, the Court should not pass any interim order which may possibly lead to such a situation. In my opinion, the aspect of the difference in price of the product of the plaintiffs and the defendants also cannot be ignored, especially at the stage of considering the question whether the plaintiffs are entitled to any interim relief."

79. In ***Roussel Uclaf*** the plaintiffs were a company which held a licence under a patent which gave them exclusive rights to sell in the United Kingdom two drugs, an amide base and a phosphate salt, both giving rise to the same active ingredient in the body. The first defendants began to sell the phosphatic salt in July 1976 and the plaintiffs sought, inter alia, an interlocutory injunction to restrain the sale. The plaintiff's sale of the amide base represented 2.2 per cent of their total U.K. sales. They did not market the phosphate salt though they had plans to do so. In certain cases of heart disease the drugs could be life-saving and on other drugs were directly comparable. The High Court while refusing injunction dwelt on the aspect of the drug being a life saving one. It was noticed that there was no other drug available which was comparable with the drug in question and had the same effect. It was held this aspect and the fact that patients suffering from heart disease may easily be suspicious of a new drug and be adversely affected by having to change from one drug to another had to be "taken into account when considering the balance of convenience and whether in all the circumstances the discretion of the court should be exercised to grant an injunction." On the aspect of availability of a life saving drug it was held:

> "Finally, therefore, I come to the interesting and, I think novel point as to whether this court ought ever and, in particular, in this case to exercise its discretion to grant an injunction the effect of which will be, temporarily at any rate, to deprive members of the public of the benefit of a `life-saving drug which may be prescribed' for otherwise fatal heart diseases. In fairness to Mr. Aldous and the plaintiffs, I should say that it was made clear that if the proper conclusion was that this drug in question was unique they would not feel it right to contend that an injunction should be granted in such a case. It would, of course, be simple, subject to the practical difficulties of distribution, which could probably be

got over, to make a limited injunction ensuring that patients already on the drug in question continued to be supplied with it. I do not think, however, that such a limitation can deal with the real point, which is whether members of the public, whether they are already patients on the drug or not, should be deprived of the benefit of it. I think this must be a question for decision in the particular circumstances of each case, though I feel that the onus in such cases must be very heavily on the plaintiffs 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 variation between these two limits. The present case is very near to the unique end, because the soluble salt has at present no precise equivalent, the base not having, on the evidence, the same biological activity even though the active disopyramide once in the blood will have the same effect, other things being equal, in both cases. To add to this, there is uncontradicted evidence that heart patients are peculiarly sensitive to and fearful of changes in drugs and their regime."

80. Turning to the case on hand, there is no doubt that the product in question is a drug for cancer treatment at the terminal stages. It is the second line treatment after the first line of treatment by way of chemotherapy had proved

unsuccessful. It is expected to be directed of a particular form of non-small cell lung cancer. This drug is not readily available in India. The plaintiffs do not yet manufacture it in India. They import and sell the drug. Even if the price per tablet is taken to be Rs.3200 as claimed by the plaintiffs it is a drug which is expensive. It is clearly beyond the reach of many patients suffering from this dreaded form of cancer.

81. This Court is inclined to concur with the learned single Judge that in a country like India where question of general public access to life saving drugs assumes great significance, the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. Erlocip is the Indian equivalent produced by the defendant in India as a generic drug manufacturer. It is priced at Rs.1600 per tablet. Even if this does not make it inexpensive, the question of greater availability of such drug in the market assumes significance.

82. In the considered view of this Court, while it may be possible to distinguish the judgment of the US Supreme Court in ***E Bay*** as relating to a case of permanent and not temporary injunction, the traditional four factor test identified in the said judgment does assume relevance even at the stage of grant of an interim injunction. Given the nature of the drug, in the instant case, which admittedly is a life saving one, the fourth test identified in ***E Bay*** that the grant of an injunction should not result in the public interest being "disserved" would be relevant.

83. The judgments relied upon by the plaintiffs underscore the approach of

determining these questions on a case by case basis. Whether indeed the public interest in the availability of the drug to the public at large is outweighed by the need to encourage research in the invention, would obviously differ from case to case and depend on a host of factors. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect after an analysis of all the relevant factors.

84. Even while considering this aspect, the Court is conscious that the defendant has been able to demonstrate prima facie that the plaintiffs do not hold a patent yet for the drug Tarceva, which is the Polymorph B form of the substance for which they hold a patent. Secondly, the defendant has raised a credible challenge to the validity of the patent held by the plaintiffs. In such circumstances, the public interest in greater public access to a life saving drug will have to outweigh the public interest in granting an injunction to the patent holder.

Summary of conclusions

85. To summarise our conclusions:

(i) The failure by the plaintiffs to bring the facts concerning the filing of the subsequent applications for grant of a patent in respect of the Polypmorph B form of the compound to the notice of the Controller of Patents at the time of consideration of their application for patent for the compound of a combination of Polymorphs A and B was not consistent with the requirement of a full disclosure.

(ii) The change in the stand of the plaintiffs that the earlier patent U.S.'498 (in respect of a mixture of Polymorphs A and B) did not

disclose Polymorph B free of Polymorph A by stating that it covered all known and unknown forms of the compound, would admittedly have a direct impact on the question of patentability of either a compound of Polymorphs A and B or of Polymorph B free of Polymorph A. This made the full disclosure by the plaintiffs of all the facts pertaining not only to the 'umbrella' compound but the crystal or other forms of the product to the Controller of Patents imperative. Such disclosure would have impacted the decision on the patentability of compound of Polymorphs A and B. When the defendant therefore questioned the validity of Patent No.196774 on the above ground, it did raise a more than credible challenge.

(iii) In an application seeking ad interim injunction in a suit for infringement of patent, it would be incumbent on the plaintiffs to make a full disclosure of the complete specification of the product whose patent is claimed to have been infringed. The plaintiffs will also have to disclose to Court the x-ray diffraction data of the product, particularly if it is a pharmaceutical drug. The plaintiffs have to make an unequivocal disclosure that the patent they hold covers the drug in question; whether there are any other pending applications seeking the grant of patent in respect of any derivatives or forms of the product for which they already hold a patent and the effect of such applications on the suit patent.

(iv) The failure by the plaintiffs to disclose the complete specification of the product and the facts concerning the pending applications for Polymorph B led to the learned Single Judge not having the occasion to consider if in fact the suit patent covered Tarceva. Had these facts fully

disclosed in the plaint and the entire specification of the patent held by the plaintiff together with X-ray diffraction data of Tarceva and Erlocip filed along with the plaint, it is possible that the plaintiff may have had difficulty in showing that the patent held by it (No.196774) covered Tarceva as well.

(v) To the extent that the defendant has raised a serious doubt whether the plaintiffs in fact hold a patent for the product sold in the tablet form as Tarceva, the plaintiffs must be held not to have been able to cross the first hurdle of showing that they have a prima facie case in their favour for grant of an order restraining the defendant from marketing Erlocip. The plaintiffs therefore ought to have been refused injunction for their failure to make out a prima facie case.

(vi) Notwithstanding the above, assuming that the plaintiffs held a patent for the product which was the subject matter of the suit for infringement, the grant of such patent to the plaintiffs will not ipso facto entitle them to an interim injunction if the defendant is able to satisfy the court that there is a serious question to be tried as to the validity of the patent. In the present case, the defendant has raised a credible challenge to the validity of the patent by raising a serious triable and substantial question that renders it vulnerable to challenge.

(vii) The question of general public access in our country to life saving drugs assumes great significance and the adverse impact on such access which the grant of injunction in a case like the instant one is likely to have, would have to be accounted for. This Court finds no ground to differ with the reasoning or the conclusions arrived at by the learned Single Judge on this aspect.

(viii) The defendant has been able to demonstrate prima facie that the plaintiffs do not hold a patent yet for the drug Tarceva, which is the Polymorph B form of the substance for which they hold a patent. Secondly, the defendant has raised a credible challenge to the validity of the patent held by the plaintiffs. In such circumstances, the public interest in greater public access to a life saving drug will have to outweigh the public interest in granting an injunction to the plaintiffs.

86. For all the aforementioned reasons this Court does not find merit in any of the submissions made on behalf of the appellant. It is however made clear that this order will not influence the decision of the learned Single judge in the pending application IA No.1402 of 2008 and the counter-claim of the defendant in the aforementioned suit.

87. The appeal is dismissed with costs quantified at Rs.5 lakhs which will be paid by the appellants/plaintiffs to the defendant within a period of four weeks. The interim order stands vacated. The applications are disposed of accordingly.

S. MURALIDHAR, J.

CHIEF JUSTICE

APRIL 24, 2009
Rohtash/dk